



# Annual Activity Report 2020

## Annexes

DG Health and Food Safety (DG SANTE)

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## **ANNEX 1: Statements of the Director and the Deputy Directors-General**

### **Director in charge of risk management and internal control in Directorate A**

***“I declare that in accordance with the Commission’s communication on the internal control framework, I have reported my advice and recommendations on the overall state of internal control in the DG to the Director-General.***

***I hereby certify that the information provided in Section 2 of the present Annual Activity Report and in its annexes is, to the best of my knowledge, accurate and complete.”***

*(e-signed)*

*Matthew Hudson*

*Brussels, 29 March 2021*

### **Deputy Director-General for Health responsible for Directorates B and C**

***“In DG SANTE's 2020 Annual Activity Report, Section 1, I have reported to the Director-General on the achievements of the operational objectives in the policy area Public Health.***

***I hereby certify that the information provided in Section 1 of the present Annual Activity Report and in its related annexes is, to the best of my knowledge, accurate and complete.***

*(e-signed)*

*Pierre Delsaux*

*Brussels, 29 March 2021*

### **Deputy Director-General for Food Sustainability responsible for Directorates D to G**

***“In DG SANTE's 2020 Annual Activity Report, Section 1, I have reported to the Director-General on the achievements of the operational objectives in the policy area Food Sustainability.***

***I hereby certify that the information provided in Section 1 of the present Annual Activity Report and in its related annexes is, to the best of my knowledge, accurate and complete.***

*(e-signed)*

*Claire Bury*

*Brussels, 30 March 2021*

## ANNEX 2: Performance tables

General objective 1: A European Green Deal			
<b>Impact indicator: Pesticide risk<sup>1</sup></b>			
<b>Explanation:</b> This indicator shows changes in the potential risks from pesticide use for human health and the environment. The indicator is calculated by multiplying the quantities of active substances placed on the market in plant protection products by their hazard weighting. Index: 2015-2017 = 100			
<b>Source of the data:</b> Member States annually report data to Eurostat under <a href="#">Regulation (EC) No 1185/2009</a>			
Baseline (2015-2017)	Interim Milestone (2022)	Target (2024 <sup>2</sup> )	Latest known results (situation on 31/12/2020)
<b>100</b>	<b>80</b>	<b>70</b>	<b>92</b>
Specific objective 1.1: Ensuring food and feed safety			Related to spending programme(s): Single Market Programme
<b>Result indicator 1.1.A (Animal health): Increase of the officially free areas from certain zoonoses (Bovine Brucellosis, Bovine Tuberculosis, Sheep and Goat Brucellosis)</b>			
<b>Explanation:</b> Member States implement EU co-financed programmes aiming to reduce and eventually eliminate certain zoonoses from their territories (Bovine Brucellosis, Bovine Tuberculosis, Sheep and Goat Brucellosis). As control progresses more countries or parts thereof are declared officially free from these diseases. Increase of the overall officially – free areas reflects the progress achieved in the control of these diseases.			
<b>Source of data:</b> Grant Commission Decisions designating MS or regions thereof officially free from the above mentioned diseases			
Baseline (2019)	Interim Milestone (2022)	Target (2024)	Latest known results (situation on 31/12/2020)
EU countries (or parts thereof) free from the above diseases	<b>+15%</b>	<b>+25%</b>	<b>+7%</b>
<b>Result indicator: 1.1.B (Plant health): Number of phytosanitary programmes successfully implemented / total number of phytosanitary programmes approved</b>			
<b>Explanation:</b> Following the submission of technical and financial final reports by the Member States, the Commission carries out the evaluation and decides on the final payment of the eligible costs incurred for each previously approved programme (survey, eradication and containment). Programmes whose implementation is in line with the EU legislation and the terms agreed with the Commission are considered successful.			

<sup>1</sup> The indicator will be published in Eurobase with code sdg\_02\_51 once the 2020 edition of the EU SDG monitoring report is released

<sup>2</sup> Please see the indicator explanations in the DG SANTE Strategic Plan 2020-2024.

<b>Source of data:</b> Data can be procured using the Survey programs submitted by MS			
<b>Baseline</b> (2020)	<b>Interim Milestone</b> (2022)	<b>Target</b> (2024)	<b>Latest known results</b> (situation on 31/12/2020)
N/A <sup>3</sup>	80%	90%	87%
<b>Result indicator: 1.1.C (Official controls): Percentage of DG SANTE's recommendations following its audits that Member States (MS) have satisfactorily addressed with corrective action</b>			
<b>Explanation:</b> This is a dynamic rolling indicator and the objective is to demonstrate the impact of DG SANTE audits based on verified corrective actions taken by Member States in response to DG SANTE audit recommendations. The basis for the indicator is not static and therefore the objective is to increase the result level over the five year period through intensified systematic follow-up actions.			
The indicator for Year N is calculated based on the verified actions taken in respect of the sum of recommendations resulting from audits conducted in years N-4, N-3 and N-2.			
All recommendations remaining open at the end of Year N continue to be subject to monitoring by the Commission services to assess progress.			
<b>Source of data:</b> Commission internal (DG SANTE)			
<b>Baseline</b> (2020)	<b>Interim Milestone</b> (2022)	<b>Target</b> (2024)	<b>Latest known results</b> (situation on 31/12/2020)
48%: Based on sum of audits carried out in years 2016+2017+2018	75%: Based on sum of audits carried out in years 2018+2019+2020	80%: Based on sum of audits carried out in years 2020+2021+2022	62% Based on sum of audits carried out in years 2016+2017+2018
<b>Result indicator 1.1.D (Burden reduction): Proportion of proposed legislative revisions that include burden reduction measures</b>			
<b>Source of data:</b> DG SANTE			
<b>Baseline</b> (2020)	<b>Interim Milestone</b> (2022)	<b>Target</b> (2024 d)	<b>Latest known results</b> (situation on 31/12/2020)
N/A	Positive trend	Positive trend	...

<b>Main outputs in 2020:</b>			
<b>Output description</b>	<b>Indicator</b>	<b>Target</b>	<b>Latest known results</b> (situation on 31/12/2020)
<b>New policy initiatives</b>			

<sup>3</sup> This is a new Result Indicator and no Baseline is available at the time of drafting. As such, measurements will start in and a baseline will be established for 2020 (n) and included in the Management Plan for each following year (as of n+1). The Annual Activity Report for each following year (as of n+1) will report the trend based on data from the year before (n-1).

<b>Main outputs in 2020:</b>			
<b>Output description</b>	<b>Indicator</b>	<b>Target</b>	<b>Latest known results</b> (situation on 31/12/2020)
<b>Initiatives linked to regulatory simplification and burden reduction</b>			
Simplification of the financial management of veterinary programmes	Launch	In the course of 2020	Launched
<b>Evaluations and fitness checks</b>			
Evaluation of the food irradiation legislation (PLAN/2016/506)	Publication of SWD		SWD under preparation. Publication planned Q2 2021
<b>Public consultations</b>			
Open Public Consultation for the Evaluation of the food irradiation legislation	Publication		Published on 2 March 2020
<b>Enforcement actions</b>			
Collection of data on food irradiation 2019	Number of MS reporting	28/28	27/28
Report on food irradiation 2018-2019	Publication	Q4 2020	Collection of data delayed by COVID-19. Publication planned Q1 2021
Approval of control programmes and special guarantees for Salmonella	Number of control programmes evaluated / number of control programmes received	2/2	The implementing Regulation approving the revised control programmes of FI and SE is voted and should be adopted Q1 2021
INFR(2020)2283 regarding UK measures on <i>Xylella Fastidiosa</i> and <i>Ceratocystis Platani</i> contrary to Decision 2020/758, Regulation 2020/1201, and Regulation 2019/2072	Letter of formal notice sent on 30 October 2020		On-going
INFR(2016)4222 against Czechia regarding pre-notification obligation of the requirements regarding the official controls performed to ensure the verification of compliance with feed and food law, animal health and	Supplementary letter of formal notice sent on 2 July 2020		On-going

<b>Main outputs in 2020:</b>			
<b>Output description</b>	<b>Indicator</b>	<b>Target</b>	<b>Latest known results</b> <i>(situation on 31/12/2020)</i>
animal welfare rules			
INFR(2020)4041 against Romania regarding non-compliance with specific hygiene rules applicable to foodstuffs of animal origin	Letter of formal notice sent on 2 July 2020		On-going
INFR(2020)4042 against Bulgaria regarding non-compliance with the marketing requirements for natural mineral and spring waters.	Letter of formal notice sent on 2 July 2020		On-going
Commission Implementing Directive (EU) 2019/1813 of 29 October 2019 amending Implementing Directive 2014/96/EU on the requirements for the labelling, sealing and packaging of fruit plant propagating material and fruit plants intended for fruit production, falling within the scope of Council Directive 2008/90/EC as regards the colour of the label for certified categories of propagating material and fruit plants and the content of the supplier's document	8 letters of formal notice sent on 28 May 2020		All infringements closed since the Member States have notified their transposition measures.
Commission Implementing Directive (EU) 2019/1985 of 28 November 2019 amending Directives 2003/90/EC and 2003/91/EC setting out implementing measures for the purposes of Article 7 of Council Directive 2002/53/EC and Article 7 of Council Directive 2002/55/EC respectively, as regards the characteristics to be covered as a minimum by the	7 letters of formal notice sent on 20 July 2020		One infringement remains pending, the other Member States notified their transposition measures.

<b>Main outputs in 2020:</b>			
<b>Output description</b>	<b>Indicator</b>	<b>Target</b>	<b>Latest known results</b> (situation on 31/12/2020)
examination and the minimum conditions for examining certain varieties of agricultural plant species and vegetable species			
Commission Implementing Directive (EU) 2020/177 of 11 February 2020 amending Council Directives 66/401/EEC, 66/402/EEC, 68/193/EEC, 2002/55/EC, 2002/56/EC and 2002/57/EC, Commission Directives 93/49/EEC and 93/61/EEC and Implementing Directives 2014/21/EU and 2014/98/EU as regards pests of plants on seeds and other plant reproductive material	13 letters of formal notice sent on 20 July 2020		Two infringements remain pending, the other Member States notified their transposition measures.
Commission Implementing Directive (EU) 2019/990 of 17 June 2019 amending the list of genera and species in Article 2(1)(b) of Council Directive 2002/55/EC, in Annex II to Council Directive 2008/72/EC and in the Annex to Commission Directive 93/61/EEC	9 letters of formal notice sent on 20 July 2020		Only one infringement remains pending; the other Member States notified their transposition measures.
Commission Implementing Directive (EU) 2020/432 of 23 March 2020 amending Council Directive 2002/55/EC with regard to the definition of vegetables and the list of genera and species in Article 2(1)(b)	12 letters of formal notice sent on 20 July 2020		Two infringements remain pending, all other Member States notified their transposition measures.



<b>Main outputs in 2020:</b>			
<b>Output description</b>	<b>Indicator</b>	<b>Target</b>	<b>Latest known results</b> (situation on 31/12/2020)
<b>External communication actions</b>			
<b>Press and Media</b> Communicate on actions being taken by the EU especially during times of outbreaks	National print media coverage of EU's actions if/when outbreaks are reported	Media coverage by at least 10 EU countries	Media coverage by at least 15 countries <sup>4</sup>
<b>Social Media</b> Sustained tweets throughout the year on the various aspects of Food and feed safety	Increase engagement on twitter	Average a minimum of 100 engagements per tweet. (all engagements)	74 engagements per tweet <sup>5</sup>
	Increase the number of followers on the EU Food Safety account	Increase the number of followers by another 5000 followers (shared with other specific objectives)	+4.200 Followers
<b>Website</b> Update of related webpages	Increase in the number of visitors to the SANTE food and feed related webpages	5% increase (Baseline 2019 - 4,291,614 visits / 12,887,617 pageviews / 8,708,970 unique pageviews)	11,815,268 pageviews / 8,396,548 unique pageviews <sup>6</sup> , representing a slight decrease of about 8%
<b>Other important outputs</b>			
Support to the UKTF for the negotiations of a Trade and	Support Delivered		Delivered through 2020

<sup>4</sup> The coverage related to outbreaks of diseases such as African Swine Fever (ASF) in Germany and Belgium, Xylella Fastidiosa in Italy and sesame seed contamination in France.

<sup>5</sup> Apart from the end of May and late in the year there was, in 2020, a shortage of material for the Food Account due to the cancellation of most activities due to COVID 19. This resulted in the account being mainly used for retweets and rehashing of old material resulting in a lower engagement. As from September the account was used more proactively which resulted in the target being met in the last four months (111 average engagements / tweet).

<sup>6</sup> These figures refer to the statistics of the Food Safety website as a whole

<b>Main outputs in 2020:</b>			
<b>Output description</b>	<b>Indicator</b>	<b>Target</b>	<b>Latest known results</b> (situation on 31/12/2020)
Cooperation Agreement with the UK			
Report to the European Parliament and the Council on additional forms of expression and presentation of the nutrition declaration on food labels (PLAN/2017/923)	Adoption		Adopted COM(2020)207)
Commission notice on provisions related to the indication of the country of origin or place of provenance of food (PLAN/2018/4501)	Adoption		Adopted C(2020)428)
<b>Actions on animal and plant diseases under the current Common Financial Framework</b>			
2020 Eradication, surveillance and monitoring programmes:			
Bovine brucellosis	No. of MSs with a veterinary programme approved for EU cofinancing	3	3
Bovine tuberculosis	No. of MSs with a veterinary programme approved for EU cofinancing	6	6
Ovine/caprine brucellosis	No. of MSs with a veterinary programme approved for EU cofinancing	5	5
Bluetongue	No. of MSs with a veterinary programme approved for EU cofinancing	15	15
Swine diseases	No. of MSs with a veterinary programme approved for EU cofinancing	26	26

<b>Main outputs in 2020:</b>			
<b>Output description</b>	<b>Indicator</b>	<b>Target</b>	<b>Latest known results</b> (situation on 31/12/2020)
Avian influenza	No. of MSs with a veterinary programme approved for EU cofinancing	25	25
Transmissible Spongiform Encephalopathies (TSE), Bovine spongiform encephalopathy (BSE) and scrapie	No. of MSs with a veterinary programme approved for EU cofinancing	26	26
Rabies	No. of MSs with a veterinary programme approved for EU cofinancing	12	12
Salmonella in poultry	No. of MSs with a veterinary programme approved for EU cofinancing	23	25
Lumpy Skin Disease (LSD)	No. of MSs with a veterinary programme approved for EU cofinancing	3	3
Emergency measures	Adoption	In course of 2020	78
ASF and LSD strategies with thirds countries	No. of programmes which received co-financing	7 for ASF 4 for LSD	7 for ASF 4 for LSD
<b>Actions in view of the next Multiannual Financial Framework (MFF) – Single Market Programme (SMP)</b>			
Guidelines and standard operating procedures to manage the new SMP food and feed strand	Adoption	Q4 2020, following adoption of the SMP	Postponed to Q3 2021 following adoption of the SMP
<b>Animal health and animal diseases</b>			
Delegated Regulation on the approval of germinal product establishments and the	Adoption	Q4 2020	Adopted Regulation (EU) 2020/686, OJ L 174 of

<b>Main outputs in 2020:</b>			
<b>Output description</b>	<b>Indicator</b>	<b>Target</b>	<b>Latest known results</b> <i>(situation on 31/12/2020)</i>
traceability and animal health requirements for movements within the Union of germinal products of certain kept terrestrial animals (PLAN/2017/1290)			3.6.2020
Delegated Regulation on rules for surveillance, eradication programmes, and disease-free status for certain listed and emerging diseases (PLAN/2018/2573)	Adoption	Q4 2020	Adopted Regulation (EU) 2020/689, OJ L 174 of 3.6.2020
Delegated Regulation on rules for the prevention and control of certain listed diseases (PLAN/2018/2574)	Adoption	Q4 2020	Adopted Regulation (EU) 2020/687, OJ L 174 of 3.6.2020
Delegated Regulation on animal health requirements for movements within the Union of terrestrial animals and hatching eggs (PLAN/2018/2576)	Adoption	Q4 2020	Adopted Regulation (EU) 2020/688, OJ L 174 of 3.6.2020
Delegated Regulation on rules for entry into the Union, and the movement and handling after entry of consignments of certain animals, germinal products and products of animal (PLAN/2018/2575)	Adoption	Q4 2020	Adopted Regulation (EU) 2020/692, OJ L 174 of 3.6.2020
Delegated Regulation on animal health requirements for movements within the Union of aquatic animals and products from aquatic animals (PLAN/2018/2572)	Adoption	Q4 2020	Adopted Regulation (EU) 2020/990, OJ L 221 of 10.7.2020
Delegated Regulation on rules for aquaculture establishments and transporters of aquatic animals (PLAN/2018/2571)	Adoption	Q4 2020	Adopted Regulation (EU) 2020/691, OJ L 174 of 3.6.2020

<b>Main outputs in 2020:</b>			
<b>Output description</b>	<b>Indicator</b>	<b>Target</b>	<b>Latest known results</b> <i>(situation on 31/12/2020)</i>
Delegated Regulation on animal health requirements for the production, processing and distribution within the Union of products of animal origin (PLAN/2017/1342)	Adoption	Q4 2020	Adopted Regulation (EU) 2020/2154, OJ L 431 of 21.12.2020
Delegated Regulation on management, storage and replacement of stocks of the Union antigen, vaccine and diagnostic reagent banks and the biosecurity, biosafety and bio-containment requirements for the operation of those banks (PLAN/2019/5736)	Adoption	Q4 2020	Draft ready. Discussion in the Expert Group starts on 5.2.2021. Adoption scheduled in 2021
Delegated Regulation on rules for the use of veterinary medicinal products for the purpose of prevention and control of category A and B diseases in terrestrial animals (PLAN/2020/6817)	Adoption	Q4 2020	Draft under discussion in the Expert Group. Adoption scheduled to Q2 2021
Implementing Regulation on Identification and registration of terrestrial animals (except equidae) (SANTE/1123/2018)	Adoption	Q3 2020	Draft to be presented for a vote as point B at PAFF Committee on 15/1/2021. Vote by a written procedure. Adoption: Q1 2021
Implementing Regulation on the approval of germinal product establishments and the traceability of germinal products of bovine, porcine, ovine, caprine and equine animals (PLAN/2017/1291)	Adoption	Q3 2020	Adopted Regulation (EU) 2020/999, OJ L 221 of 10.7.2020
Implementing Regulation on Union notification, reporting, the computerised information system, eradication programmes and the disease-free status (PLAN/2018/2500)	Adoption	Q3 2020	Adopted Regulation (EU) 2020/2002, OJ L 412 of 8.12.2020

<b>Main outputs in 2020:</b>			
<b>Output description</b>	<b>Indicator</b>	<b>Target</b>	<b>Latest known results</b> (situation on 31/12/2020)
Implementing Regulation on the list of third countries for entry into the Union of animals and products (PLAN/2018/2509)	Adoption	Q3 2020	Voted by written procedure (positive vote). Document in translation. Adoption Q1 2021.
Implementing Regulation on rules for EU antigen, vaccine and diagnostic banks (PLAN/2019/5737)	Adoption	Q3 2020	Draft ready. Discussion in the Working Group to start in February 2021. Adoption scheduled in 2021
Commission decisions on handling evolving epidemiological situations	Adoption of emergency Decisions as necessary, according to the epidemiological situation	In course of 2020	Adopted in course of 2020.
Commission rules on safe imports, trade and related aspects	Adoption of Commission implementing rules.	In course of 2020	Adopted in course of 2020.
BTSF seminars and conferences	No. of seminars and conference held	160 (this target was set pre-COVID-19. All BTSF activities were suspended on 6.03.20 until at least 31.08.20)	Due to COVID 19 restrictions all BTSF activities were re arranged into virtual online trainings. Start of activities (seminars) on 19 January 2021.
<b>Plant health and diseases</b>			
Rules on plant passports (PLAN/2018/2520)	Adoption	Q2 2020	Adopted C(2020)8148
Establishment of format to report on plant health surveys (PLAN/2019/5738)	Adoption	Q3 2020	Adopted C(2020)5770
Derogation ash wood US (PLAN/2020/7075)	Adoption	Q2 2020	C(2020) 4548 (Ash wood US)
Derogation ash wood Canada (PLAN/2020/7075)	Adoption	Q2 2020	C(2020)4293 (ash wood Canada)
Recognition of the US visual inspections of maize seeds in the field (PLAN/2020/7080)	Adoption	Q4 2020	Withdrawn

<b>Main outputs in 2020:</b>			
<b>Output description</b>	<b>Indicator</b>	<b>Target</b>	<b>Latest known results</b> <i>(situation on 31/12/2020)</i>
Containment measures (PLAN/2020/7077)	Adoption	Q4 2020	Several measures have been discussed in PAFF, for adoption first half of 2021
Derogation import bonsai from Korea (prolongation) (PLAN/2020/7075)	Adoption	Q3 2020	Adoption on hold
Delegated act on Pathogen Zero Plant Health Surveys	Adoption	Q4 2020	To be adopted Q2 2021
Amendment Annexes Plant Health Regulation (PLAN 2020/7072)	Adoption	Q4 2020	First amendment adopted Q4 C(2020)8361
Implementing act on wood packaging material (PLAN/2020/7746)	Adoption	Q4 2020	Voted December 2020
Amendment of Implementing Regulation on frequency of controls at BCPs (AP fiche to be approved)	Adoption	Q4 2020	Adoption delayed due to other priorities
Delegated Regulation on controls at control points	Adoption	Q4 2020	Withdrawn
Amendment implementing Regulation on Plant Health official controls. Inclusion of post-import controls for dormant plants (PLAN/2019/5745)	Adoption	Q3 2020	Adopted Q2 2020 C(2020)4185
Adoption of decisions on high-risk plants dossiers	No. of decisions adopted	5	4 Regulations adopted C(2020)5675 and C(2020)5694; (C(2020) 5675 (Albizia), C(2020) 6583 (Acer)
Commission Decisions on emergency measures against some specific pests	Adoption according to (new) outbreak situations	In course of 2020	3 Regulations adopted C(2020) 5520 (Xylella) C(2020)4163 (kiwi canker) C(2020)5453 (ToBRFV)
Commission Decisions with specific import requirements for trade lines where there are too many import interceptions	Adoption according to import interception	In course of 2020	2 Regulations adopted C(2020)5642 (CBS Argentina) C(2020)6192 (Agrilus

<b>Main outputs in 2020:</b>			
<b>Output description</b>	<b>Indicator</b>	<b>Target</b>	<b>Latest known results</b> (situation on 31/12/2020)
	notifications from Member States		Ukraine)
Evaluation of co-financing requests of Member States eradication measures	No. of eradication measures that received co-financing	72	73
Review of the legislation on Xylella Fastidiosa (PLAN/2020/6876)	Adoption	Q3 2020	Adopted C(2020)5520
Preparatory work for IYPH events: 1. Ministerial Conference 2. Global Conference 3. IPPC Strategic Framework 2020-2030	Approved by the Council	Q1 2020	1. Postponed to 2022 2. Cancelled 3. International approval postponed to March 2021
Ministerial Declaration on International Plant Health	Approved by the Council	Q1 2020	Postponed to 2022 (tentative)
<b>Market access for safe substances</b>			
Commission Implementing Regulation (EU) amending the rules concerning the addition of vitamins & minerals to foods in view of the new Transparency Regulation (PLAN/2020/6422)	Adoption	Q3 2020	Not adopted. The transposition of the provision of the Transparency Regulation to the procedure outlined in Article 8 of Regulation (EC) No 1925/2006 raises some questions that need to be thought out well before the adoption.
Commission Regulation (EU) amending the rules concerning recycled plastic food contact materials in view of the "Transparency Regulation" (PLAN/2020/6413)	Adoption	Q3 2020	Following a further assessment it was not considered necessary to amend this regulation in view of the Transparency Regulation
Commission Implementing Regulation (EU) amending the rules for applications for food additives, enzymes & flavourings in view of the "Transparency Regulation	Adoption	Q3 2020	Adopted C(2020)8358 02/12/2020



<b>Main outputs in 2020:</b>			
<b>Output description</b>	<b>Indicator</b>	<b>Target</b>	<b>Latest known results</b> <i>(situation on 31/12/2020)</i>
(PLAN/2020/6415)			
Commission Implementing Regulation (EU) amending the rules concerning the re-evaluation of approved food additives in view of the “Transparency Regulation” (PLAN/2020/6414)	Adoption	Q3 2020	Adoption ongoing. Slight delays due to the translation
Commission Implementing Regulation (EU) amending administrative & scientific requirements for applications for novel foods in view of the “Transparency Regulation”(PLAN/2020/6416)(PLAN/2020/6416)	Adoption	Q3 2020	Adopted C(2020)8169 26/11/2020
Commission Implementing Regulation (EU) amending the administrative and scientific requirements for traditional foods in view of the “Transparency Regulation” (PLAN/2020/6417)	Adoption	Q3 2020	Adopted C(2020)8347 02/12/2020
Commission Regulation (EU) amending the rules concerning active and intelligent food contact materials in view of the “Transparency Regulation” (PLAN/2020/6419)	Adoption	Q3 2020	Following a further assessment it was not considered necessary to amend this regulation in view of the Transparency Regulation
Commission Implementing Regulation (EU) setting out the rules governing the renewal procedure for active substances in view of “Transparency Regulation” (PLAN/2020/6421)	Adoption	Q3 2020	Adopted C(2020)7982 20/11/2020
Implementing Regulation (EU) amending the rules concerning feed additives applications and assessment in view of the “Transparency Regulation”	Adoption	Q3 2020	Adopted C(2020)8171

<b>Main outputs in 2020:</b>			
<b>Output description</b>	<b>Indicator</b>	<b>Target</b>	<b>Latest known results</b> (situation on 31/12/2020)
(PLAN/2020/6420)			
Regulation establishing a list of intended uses of feed intended for particular nutritional purposes ("Dietetic feed") (2015/SANTE/111)	Adoption	Q1 2020	Adopted. C(2020)1183
Regulatory measures on contaminants in feed and food following EFSA opinions	Adoption	In course of 2020	4 acts adopted
Commission Implementing Regulation on the conditions governing imports of agricultural products originating in third countries following the accident at the Chernobyl nuclear power station (PLAN/2020/6576)	Adoption		Adopted C(2020)5226
Authorisations of health and nutrition claims, generic descriptors, vitamins and mineral substances etc.	Adoption	In course of 2020	No acts adopted
Commission Regulations prohibiting, restricting or banning the use of substances other than vitamins and minerals in food (Article 8 procedure)	Adoption	In course of 2020	No acts adopted
Authorisations of health claims made on foods and referring to children's development	Adoption	In course of 2020	No acts adopted
Authorisation of novel foods under the Regulation on Novel Foods	Adoption	Up to 25 in course of 2020	13 acts adopted
Authorisation of traditional foods from third countries under the Regulation on Novel Foods	Adoption	4 in course of 2020	2 acts adopted
Decisions on data protection under the Regulation on Novel	Adoption	Ongoing regular activity in 2020	5 acts adopted including data protection

<b>Main outputs in 2020:</b>			
<b>Output description</b>	<b>Indicator</b>	<b>Target</b>	<b>Latest known results</b> (situation on 31/12/2020)
Foods			
Authorisations for new substances and new uses of already authorised substances used as food additives or food flavourings	Adoption	Ongoing regular activity in 2020; adoption of approx. 13 acts amending the uses and use levels for food additives and flavourings.	10 acts adopted
Authorisations for new substances and new uses of already authorised substances used in food contact materials	Adoption	Ongoing regular activity in 2020, for an estimated 15 substances.	4 substances (one act)
Delegated act providing details for the application dossier for the authorisation of a veterinary medicine (PLAN/2018/4493)	Adoption	Q4 2020	In translation. Adoption in Q1 2021
Implementing act on the list of variations not requiring assessment (PLAN/2018/3968)	Adoption	Q4 2020	Adopted C(2021)17 08/01/2021
Implementing act on the necessary measures and practical arrangements for the Union database on veterinary medicinal products (PLAN/2018/3969)	Adoption	Q4 2020	Adopted C(2021)8 08/01/2021
Implementing act on the good distribution practice for veterinary medicinal products (PLAN/2018/3983)	Preparation	Q4 2020	In preparation
Implementing act on the good distribution practice for active substances (PLAN/2018/3965)	Preparation	Q4 2020	In preparation
Implementing act on the good pharmacovigilance practice and on the pharmacovigilance system master file (merged into one act) (PLAN/2018/3967 &	Preparation	Q4 2020	In preparation

<b>Main outputs in 2020:</b>			
<b>Output description</b>	<b>Indicator</b>	<b>Target</b>	<b>Latest known results</b> <i>(situation on 31/12/2020)</i>
PLAN/2018/3982)			
Implementing act on the content of the pharmacovigilance system master file (PLAN/2018/3982)	Preparation	Q4 2020	Initiative merged with PLAN/2018/3967
Implementing act on the common logo for online sales (PLAN/2018/3981)	Preparation	Q4 2020	In preparation, received positive opinion at Standing Committee of September. Logo to be registered in preparation.
Delegated act on the horse passport (PLAN/2020/6502)	Preparation	Q4 2020	In translation. Adoption Q1 2021.
Authorisations of GMO for food / feed and cultivation uses	Adoption	Ongoing regular activity in 2020	One act adopted
Approval/ non-approval, renewal/non-renewal of active substances for plant protection products	Adoption	Ongoing regular activity in 2020	20 acts adopted
Regulations establishing maximum residues levels (MRL) for pesticides	Adoption	Ongoing regular activity in 2020	10 acts adopted <sup>7</sup> (comprising 59 substances)
Development of cumulative risk assessment method for pesticides residues	Developed	Ongoing activity in 2020	EFSA action plan (with SANTE contribution) for the further development of the methodology for cumulative risk assessment of pesticides residues and subsequent implementation was prepared.
Regulation establishing a first list of non-acceptable co-formulants in plant protection products (PLAN/2017/1190)	Adoption	Q4 2020	Unanimous support in the Standing Committee on Plants, Animals, Food and Feed. New target for adoption after Parliament and Council scrutiny : early 2021.

<sup>7</sup> Two more acts (comprising 16 substances) were expected to be adopted in 2020, however the EP objected during the regulatory procedure with scrutiny, so that they could not be adopted in 2020.

<b>Main outputs in 2020:</b>			
<b>Output description</b>	<b>Indicator</b>	<b>Target</b>	<b>Latest known results</b> (situation on 31/12/2020)
Implementing Regulations renewing/non-renewing the approval of biocidal active substances	Adoption	Ongoing regular activity in 2020	No renewal/non-renewal Regulation adopted
Implementing Regulations for approval/non-approval of biocidal active substances included in the review programme	Adoption	Ongoing regular activity in 2020	3 approval Implementing Regulations (covering 6 active substance/product-type combinations) + 1 non-approval Implementing Decision
Implementing Regulations granting or amending Union authorisation of biocidal products	Adoption	Ongoing regular activity in 2020	8 Implementing Regulations granting a Union authorisation + 1 Implementing Decision not granting a Union authorisation
Commission Implementing Decisions allowing a Member State to authorise products consisting of in-situ generated nitrogen for the protection of cultural heritage	Adoption		7 acts adopted
Re-evaluations of authorisations, new authorisations, denial of authorisation, modifications of authorisations and renewal and non-renewal of authorisations of feed additives	Adoption	Ongoing regular activity in 2020	89 Implementing Regulations adopted, concerning a total of 109 feed additives.
Authorisations of veterinary medicinal products	Adoption	Ongoing regular activity in 2020	19 Decisions adopted
Setting of MRLs for substances used in veterinary medicinal products	Adoption	Ongoing regular activity in 2020	4 Decisions adopted
<b>Food Hygiene</b>			
Amendment of Regulation (EC) No 852/2004 as regards hygiene rules on food allergen management, redistribution of food and food safety culture (PLAN/2020/7085)	Adoption		Planned for Q1 2021

<b>Main outputs in 2020:</b>			
<b>Output description</b>	<b>Indicator</b>	<b>Target</b>	<b>Latest known results</b> <i>(situation on 31/12/2020)</i>
Amendment of Regulation (EC) No 853/2004 on specific hygiene requirements for food of animal origin (PLAN/2020/7701)	Adoption		Planned for Q2 2021
Commission Implementing Regulation on the lists of countries authorised for the entry into the European Union of certain animals and goods intended for human consumption (PLAN/2020/6819)	Adoption		Act voted in PAFF Committee on 10 December 2020, and currently being translated
Processing of authorisation requests for decontamination substances	Number of requests processed / Number requests received		The dossier submitted is now being evaluated by EFSA
<b>Control systems, including audits, and rapid alert systems</b>			
Amendment to Regulation (EU) 2015/1375 as regards sampling, the reference method for detection and import conditions related to Trichinella control (PLAN/2020/6818)	Adoption		Adopted
Amendment of Delegated Regulation (EU) 2019/624 as regards certification in case of slaughter at the holding of provenance (PLAN/2020/7683)	Adoption		Planned for Q2 2021
Amendment of Delegated Regulation (EU) 2019/625 as regards import conditions for farmed live snails intended for human consumption and of composite of products (PLAN/2020/8163)	Adoption		Adopted

<b>Main outputs in 2020:</b>			
<b>Output description</b>	<b>Indicator</b>	<b>Target</b>	<b>Latest known results</b> <i>(situation on 31/12/2020)</i>
Amendment of Implementing Regulation (EU) 2019/627 as regards uniform practical arrangements for the performance of official controls on products of animal origin (PLAN/2020/7684)	Adoption		Planned for Q2 2021
Exemptions from BCP checks (PLAN/2020/6654)	Adoption	Q4 2020	Adoption foreseen February 2021
Derogation from accreditation requirement regarding official laboratories (PLAN/2020/6653)	Adoption	Q4 2020	Delayed to Q2 2021 due to complex consultations
Amendment to Regulation (EU) 2019/2122 on personal imports (PLAN/2020/7563)	Adoption	Q4 2020	Delayed to Q1 2021 due to inclusion of Brexit-related issue
Temporary flexibility in official controls during COVID-19 (no AP reference, review tbc) [No DECIDE Ref – adopted as an urgency measure]	Adoption	Q2 2020	Adopted
Adoption of implementing acts on model official certificates (linked to the entry into application of the Animal Health Law):	Adoption	Q4 2020	Adopted
Model official certificates for animals and goods (PLAN/2020/7566)	Adoption	Q4 2020	Adopted
Model official certificates for certain categories of terrestrial animals and germinal products thereof (PLAN/2020/ 7565)	Adoption	Q4 2020	Adoption delayed to Q1 2021
Model official certificates for certain aquatic animals and products thereof (PLAN/2020/7564)	Adoption	Q4 2020	Adopted
European Reference Laboratories	Number of laboratories funded	44	44

<b>Main outputs in 2020:</b>			
<b>Output description</b>	<b>Indicator</b>	<b>Target</b>	<b>Latest known results</b> (situation on 31/12/2020)
European Reference Centres	Number of centres funded	3	3
Better Training for Safer Food	No. of training courses organised	160	Due to COVID 19 restrictions all BTSF activities were re arranged into virtual online trainings. Start of activities (seminars) on 19 January 2021.
Audits in the area of food safety and quality, animal health, animal welfare and plant health	Approx. 117 audits completed	In the course of 2020	97 audits and similar controls were carried out, of which 61 were done remotely due to COVID
Report from the Commission to the European Parliament on the overall operation of official controls performed in Member (PLAN/2020/7680)	Publication	Q3	Published on 24 November 2020
Staff Working Document accompanying the Report on the operation of official controls performed in Member States (2017-2018) (PLAN/2020/7681)	Publication	Q3	Published on 24 November 2020
Guidance document on multi-annual national control plans (MANCP) (PLAN/2019/5813)	Publication	Q2	Publication planned for January 2021 due to delay with translation
Guidance document on how to conduct audits by Member States (PLAN/2019/5814)	Publication	Q2	Publication planned for January 2021 due to delay with translation
Guidance document on how to fill in the standard model form for Member States Annual Reports (PLAN/2019/5815)	Publication	Q2	Publication planned for January 2021 due to delay with translation
Organisation of regular meetings of networks of Member State officials responsible for the multi-annual national control plans and national audits to facilitate exchanges of	Number of meetings held	5 plenary meetings; 4 subgroup meetings	Four meetings took place: - 3 of the MANCP Network (2 remotely) and - 1 of the NAS Network (remotely). Less than planned due to COVID pandemic.



<b>Main outputs in 2020:</b>			
<b>Output description</b>	<b>Indicator</b>	<b>Target</b>	<b>Latest known results</b> <i>(situation on 31/12/2020)</i>
experiences and the preparation of guidance to enhance official control systems			
Organisation of meetings with Member State experts in a number of areas such as animal welfare or the sustainable use of pesticides to discuss common problems and exchange best practices identified	Number of meetings held	1 meeting of the working group on the Sustainable Use Directive  1-2 meetings of the National Contact Point group on animal welfare	SUD WG meeting held (remotely) Nov. 2020  National Contact Point (NCP) group on animal welfare; meetings deferred to 2021 due to new work on coordinating information from NCP to ensure free movement of livestock vehicles between EU countries in view of COVID restriction
Assessment of planned facilities of Border Control Posts (BCPs)	Assessments carried out	Approx.30 per year, based on demand from the Member States	67 notifications were received in 2020 related to new or amendments to existing BCPs, (including inspection centres).  47 files received a favourable assessment. The results of 20 files were unfavourable or awaiting further information.  Due to the COVID 19 pandemic, only three BCPs were exceptionally visited.
Evaluation of Member States' and non-EU countries' residue monitoring plans (food of animal origin)	Number of evaluation carried out	27 Member States plans, plus the UK's;  up to 50% of non-EU country plans	27 MS Plans plus 5 UK Plans have been evaluated. 60% (55 TC) have been evaluated (several of them more than once, for a total of 74 country evaluations).

<b>Main outputs in 2020:</b>			
<b>Output description</b>	<b>Indicator</b>	<b>Target</b>	<b>Latest known results</b> (situation on 31/12/2020)
Management of lists of approved non-EU country establishments for the production of food of animal origin	Number of request managed	Approx. 500 requests equating to around 2000 modifications to the establishment list in TRACES	504 requests of which 454 requests were processed or in progress and 50 which did not proceed (incomplete, incorrect, duplicates or were for commodities that do not require listing).  The 454 requests resulted in 2363 establishment changes (additions, modifications and deletions).
Operation and further development of the notification system EUROPHYT for plant health interceptions, outbreaks and reporting on plant pests	Publication on Europhyt monthly and annual statistics and reports	In course of 2020	Europhyt Outbreaks annual report planned for Q3 of 2021, after development of IT statistical queries
Plant health surveys	Member States' survey results for harmful organisms presented to Standing Committee on PAFF	In course of 2020	Results of eight surveys were presented in 2020.
Computerised systems + IT (e.g. TRACES, ADNS, EUROPHYT)			
TRACES	No of active end-users	61000	61000
ADNS	No of active end-users	450	480
iRASFF	No of active user accounts	7211	8000
EUROPHYT (Interceptions and Outbreaks)	No of active end-users	1100	1100

<b>Specific objective 1.2:</b> <b>Ensuring sustainable food systems – the ‘Farm to Fork’ strategy</b>		Related to spending programme(s) Single Market Programme	
<b>Result indicator 1.2.A : Use of more hazardous pesticides</b>			
<b>Explanation:</b> This indicator shows changes in the quantities of pesticides, containing active substances categorised as candidates for substitution, as defined by Article 24 of Regulation (EC) No 1107/2009, which are sold each year. Member States are obliged to perform a comparative assessment when evaluating an application for authorisation for a pesticide containing an active substance approved as a candidate for substitution, and shall not authorize, or shall restrict the use of, the pesticide if certain criteria are satisfied.			
<b>Source of data:</b> Member States report data on pesticide sales annually to <a href="#">Eurostat</a> under <a href="#">Regulation (EC) No 1185/2009</a> .			
<b>Baseline</b> (2015-17) <sup>8</sup>	<b>Interim Milestone</b> (2022)	<b>Target</b> (2024)	<b>Latest known results</b> (situation on 31/12/2020)
<b>100</b>	<b>85 (15% decrease)</b>	<b>70 (30% decrease)</b>	<b>100<sup>9</sup></b>
<b>Result indicator 1.2.B : Sales of antimicrobials in farmed animals and aquaculture</b>			
<b>Explanation:</b> This indicator measures the average volume of overall sales of antimicrobials in Europe, expressed in milligrams of antimicrobial sold per animal population correction unit (mg/PCU). A population correction unit (‘PCU’) is applied as a proxy for the size of the animal population.			
<b>Source of data:</b> European Medicines Agency [European Surveillance of Veterinary Antimicrobial Consumption (ESVAC) Report]. Please note that the baseline is set based on data from 2017 (latest available ESVAC report) and that the interim milestone in 2022 and the target in 2024 will reflect data from 2020 and 2022, respectively			
<b>Baseline</b> (2020)	<b>Interim Milestone</b> (2022)	<b>Target</b> (2024)	<b>Latest known results</b> (situation on 31/12/2020)
<b>110 mg/PCU<sup>10</sup></b>	<b>95 mg/PCU</b>	<b>85 mg/PCU</b>	

<sup>8</sup> The baseline period was incorrectly given as 2020 in the DG SANTE Strategic Plan 2020-24.

<sup>9</sup> The latest data (June 2020) indicates there has been no change in the sales of the more hazardous pesticides compared with the baseline.

<sup>10</sup> Following the publication of the 2020 ESVAC report (with data from 2018), it was agreed with DG AGRI to consider the EU average value of 118,6 mg/PCU (which does not consider the data from the UK) as the new baseline for the purpose of the F2F target and for setting the recommendations to MSs in the context of the new CAP national strategic plans.

**Result indicator 1.2.C : Number of Member States that have put in place national food waste prevention strategies**

**Explanation:** The number of Member States that have put in place integrated food waste prevention strategies and roadmap/action plan to prevent food loss and waste, based on the “Target, Measure, Act” approach<sup>37</sup> and involving all key players. The development of such strategies by Member States is one of the key recommendations of the EU Platform on Food Losses and Food Waste (adopted in Dec 2019).

**Source of data:** DG SANTE will carry out a data collection exercise to assess implementation of national food loss and waste prevention programmes by Member States. Such an exercise could also support a possible initiative of the DE PCY to update EU/Member States developments/progress on the Council conclusions on food losses and waste (2016)

<b>Baseline</b> (2020)	<b>Interim Milestone</b> (2022)	<b>Target</b> (2024)	<b>Latest known results</b> (situation on 31/12/2020)
N/A	20	27	19 MS have developed national food waste prevention strategies (9) and/or have included specific measures as part of their national waste prevention programmes/strategies (10)

**Result indicator 1.2.D : Percentage of DG SANTE's recommendations following its audits on Animal Welfare that Member States have satisfactorily addressed with corrective action**

**Explanation:** The objective of this indicator is to evaluate the compliance of Member States with animal welfare legislation based on verified corrective actions taken by Member States in response to DG SANTE audit recommendations in the area of animal welfare. The indicator is based on all recommendations made to Member States in audit reports on animal welfare since 2010. The indicator represents the percentage of recommendations closed following verification of corrective actions taken by the Member States in response to these recommendations.

**Source of data:** Commission internal (DG SANTE)

<b>Baseline</b> (2020)	<b>Interim Milestone</b> (2022)	<b>Target</b> (2024)	<b>Latest known results</b> (situation on 31/12/2020)
81% (based on recommendations 2010-2019)	83% (based on recommendations 2010-2021)	85% (based on recommendations 2010-2023)	82% (based on recommendations 2010-2019)

<b>Result indicator 1.2.E (Burden reduction): Proportion of proposed legislative revisions that include burden reduction measures</b>			
<b>Source of data:</b> DG SANTE			
<b>Baseline</b> (2020)	<b>Interim Milestone</b> (2022)	<b>Target</b> (2024)	<b>Latest known results</b> (situation on 31/12/2020)
N/A	Positive trend	Positive trend	...

<b>Main outputs in 2020:</b>			
<b>Output description</b>	<b>Indicator</b>	<b>Target</b>	<b>Latest known results</b> (situation on 31/12/2020)
<b>New policy initiatives</b>			
Communication on the sustainability of food systems - 'Farm to Fork' Strategy (non-legislative)	Adoption	Q2 2020	Adopted in May 2020
Commission Communication replying to the European Citizen initiative 'Eat original'	Adoption (if validated before July 2020)	Q4 2020	The 'Eat Original' initiative did reach 1 million signatures and is still pending.
Proposal for a revision of the Sustainable Use Directive for pesticides (SUD) (PLAN/2020/6975)	Inception Impact Assessment published for feedback	29 May 2020	Combined Evaluation roadmap and Inception Impact Assessment published on 29 May 2020
Impact Assessment on food information to consumers: nutrient profiling (for Front-of-pack labelling and health claims); origin indication for certain products and date marking (PLAN/2020/8886)	Launch	Q4 2020	Inception Impact Assessment published in December 2020
Impact Assessment on Food Contact Material (PLAN/2020/7637)	Launch	Q4 2020	Inception Impact Assessment published in December 2020
Impact Assessment on ceramic Food Contact Material (PLAN/2018/4857)	Launch	Q4 2020	Process ongoing. Publication of the consultation strategy: Contract signed for a study supporting the IA signed in December 2020.

<b>Main outputs in 2020:</b>			
<b>Output description</b>	<b>Indicator</b>	<b>Target</b>	<b>Latest known results</b> <i>(situation on 31/12/2020)</i>
Impact Assessment on a Proposal for a revision of the Feed Additives Regulation (PLAN/2020/8500)	Launch	Q4 2020	Combined Evaluation Roadmap/Inception Impact Assessment published in December 2020.
<b>Initiatives linked to regulatory simplification and burden reduction</b>			
<b>Evaluations and fitness checks</b>			
Evaluation of the nutrition and health claims Regulation (2015/SANTE/595) Annex II of the CWP 2016	Publication of SWD	Q2 2020	Published on 20 May 2020
Evaluation of the Food Contact Material (FCM) legislation (PLAN/2016/436)	Continuation of the work	Ongoing in 2020	Study supporting the evaluation published in July 2020. Adoption of SWD on the evaluation planned for 2021
Evaluation of the feed additives legislation (PLAN/2017/988)	Publication of SWD	Q4 2020	Process ongoing as part of a combined evaluation /inception impact assessment. The SWD on the evaluation will be published together with the Impact Assessment SWD in Q4 2021
Evaluation of Regulations on plant protection products and pesticides residues (2016/SANTE/197) Annex II of the CWP 2016	Adoption/publication of Report to Parliament and Council and accompanying SWD	Q2 2020	Report to Council and EP on the evaluation of pesticides legislation was published on 20 May 2020 together with accompanying Staff Working Document COM(2020)208 final and SWD (2020) 87 final.
Evaluation of the EU Animal Welfare Strategy (2012-15)	Publication of SWD	Q4 2020	The SWD is expected to be published in Q1 2021.
FITNESS check of the animal welfare legislation	Signature of the contract for external study	Q4 2020	Contracting process ongoing
<b>Public consultations</b>			
Open Public Consultation for the	Publication		Published on 23 March

<b>Main outputs in 2020:</b>			
<b>Output description</b>	<b>Indicator</b>	<b>Target</b>	<b>Latest known results</b> (situation on 31/12/2020)
Evaluation of the EU Animal Welfare Strategy (2012-15)			2020
<b>Enforcement actions</b>			
<b>External communication actions</b>			
<p><b><u>Adoption of the Farm to Fork strategy</u></b></p> <p><b>Press material</b></p> <p>Media material produced for adoption. of Farm to Fork Strategy</p> <p>Technical briefing organised for journalists (both in Brussels and online)</p>	<p>Number of Online views, downloads of media material</p> <p>Number of media items mentioning Commsr Kyriakides</p> <p>Number of journalists attending technical briefings</p> <p>Geographical spread of news in various EU countries</p> <p>Number of published articles on farm to Fork in non Brussels bubble media</p>	<p>Minimum of 200 online views, downloads</p> <p>Minimum of 10</p> <p>Minimum of 100 journalists receiving information</p> <p>Media items in the 27 member states (as per media monitoring)</p> <p>Over 100 media articles generated, reaching 25% of EU citizens via traditional media (to be cross checked with</p>	<p>16.016 pageviews of the <a href="#">press release</a> and 10.927 downloads of the factsheet</p> <p>35 articles mentioned the Commissioner in the days following the launch of Farm to Fork at the end of May.</p> <p>A technical briefing was organized through DG AGRIs journalist network (where over 150 journalists attended)</p> <p>Media coverage by all 27 EU countries following the launch in May.</p> <p>170 media articles<sup>11</sup>,</p>

<sup>11</sup> 140 articles were published in non-Brussels media. leading up to, and following, the launch in May with some 30 subsequent analytical articles of the strategy published thereafter

<b>Main outputs in 2020:</b>			
<b>Output description</b>	<b>Indicator</b>	<b>Target</b>	<b>Latest known results</b> (situation on 31/12/2020)
<p><b>Social Media</b> Sustained tweets during adoption and as follow up. The hashtag #EUFarm2Fork monitored continuously Paid promotion of tweets</p> <p><b>Website</b> Update of Farm to Fork Page to include ongoing consultation as well as all F2F related documentation.</p> <p><b>F2F Events and fairs</b> Organisation of an event on Farm to Fork in October 2020. 650 persons invited (will be transformed into an online event if the COVID situation does not permit mass gatherings).</p>	across the EU	knowledge on F2F when EB on F2F is conducted later in the year)	<p>2020 - Average Engagement for tweets with Hashtag: 69</p> <p>2020: +4.200 Followers</p> <p>2020: 17,832 Pageviews, representing an increase by 100%</p> <p>NA (Not available)<sup>12</sup></p> <p>Over 95% described the event as useful in the survey sent to all participants</p>
	Increase engagement on twitter per tweet	Reach average target of 100 engagements per tweet (average of 10 tweets per day)	
	Increase the number of followers on the EU Food Safety account	To add 2500 followers (current level 27k)	
	Number of visitors to the site	Resulting in increase in web traffic on the farm to Fork page. by 100% (roughly exceeding 60000 views when compared to 2019 baseline)	
	Number of visitors to the site that have a positive view on the ongoing consultation process on F2F deliverables.	80% positive satisfaction rate when asked in survey)	
	Usefulness of event for attendees (survey amongst attendees)	85% useful or very useful as per survey during event (online)	
	Percentage of attendees having a more positive opinion of the EU's Farm to	85% positive or very positive when asked in survey during event (online)	

<sup>12</sup> Satisfaction rates are not available given that a survey was not carried out



<b>Main outputs in 2020:</b>			
<b>Output description</b>	<b>Indicator</b>	<b>Target</b>	<b>Latest known results</b> (situation on 31/12/2020)
Participation with a stand in international events on "farm to fork"	Fork Strategy as a result of the event (survey amongst attendees)	2500 persons across EU	85% appreciated the positive aspects of the strategy when asked in the survey
	Media reach of event including social and traditional	Retention of 2019 targets (For SIA: 140,000 visitors on the stand, 27,000 visitors engaged - For IGW: 200,000 visitors on the stand, 50,000 visitors engaged)	Over 9,500 participants were logged into the event on average on both days (high number is result of push to completely virtual event due to COVID crises)
	Number of visits to Salon de l'Agriculture (SIA) and Grüne Woche (IGW) -		Events cancelled due to COVID-19
<b>Other important outputs</b>			
Revamp of GFL expert group into GFL SFS expert group	Publication of revised terms of reference		Q4 2020
Code of conduct	Launch of the process at technical level		Launched in January 2021
Sustainable food systems framework	Signature of administrative arrangement with JRC		signed in December 2020
<a href="#">Eurobarometer</a> <sup>13</sup> "Making our food fit for the future" – Citizens' expectations	Completed		Published in December 2020
<b>Plant Protection Products and sustainable use thereof</b>			
Report to the Council and the European Parliament on the implementation of the Sustainable Use of pesticides Directive (SUD) (PLAN/2018/4570)	Adoption	20 May 2020	Published in May 2020

<sup>13</sup> Special Eurobarometer 505 (December 2020), [Making our food fit for the future – Citizens' expectations](#).

<b>Main outputs in 2020:</b>			
<b>Output description</b>	<b>Indicator</b>	<b>Target</b>	<b>Latest known results</b> <i>(situation on 31/12/2020)</i>
Indicators for the reduction of risk and use of chemical pesticides at the EU level (Harmonised risk indicators 1 and 2 as set by Article 15 of the Sustainable Use Directive, 2009/128/EC)	Publication	Q3 2020	Indicators published on 27 August 2020.
Adaptation of data requirements for microorganisms	Ongoing work	In course of 2020	Initial drafts to update the data requirements for application dossiers for micro-organisms and plant protection products containing them were presented to the Member States in December.
<b>Reduction in the use of antimicrobials in animals to contribute to fight AMR</b>			
Delegated act on the requirements for the collection of data on antimicrobial medicinal products used in animals (PLAN/2018/4495)	Preparation	Q4 2020	In translation. Adoption Q1 2021
Implementing act on the format for the collection of data on antimicrobials (PLAN/2018/3984)	Preparation	Q4 2020	In preparation
Delegated act on the detailed rules on exports from third countries to the EU (Art. 118) (PLAN/2018/4503)	Preparation	Q4 2020	In preparation
Delegated act to establish the criteria for designation in the EU of those antimicrobials to be reserved for human use (PLAN/2018/4510)	Preparation	Q4 2020	In preparation.
Implementing act on the list of antimicrobials reserved for human use (PLAN/2018/3966)	Preparation	Q4 2020	In preparation.
Implementing act on the list of antimicrobials that cannot be used outside the terms of their marketing authorisations, or	Preparation	Q4 2020	In preparation.

<b>Main outputs in 2020:</b>			
<b>Output description</b>	<b>Indicator</b>	<b>Target</b>	<b>Latest known results</b> (situation on 31/12/2020)
that can be used outside the terms of their marketing authorisations subject to certain conditions			
PAuthorisation of feed additives improving the gut health of the animals, thus reducing the need for treatment with antibiotics	Adoption of authorisations for gut flora stabilising feed additives	About 10 authorisations of this type of additives	12 authorisations adopted
'One Health' antimicrobial resistance (AMR) country visits	1 visit carried out	In course of 2020	None carried out (postponed due to COVID-19)
<b>Sustainable animal nutrition</b>			
Authorisation of feed additives contributing to a more sustainable animal nutrition, in particular reducing negative impacts on the environment	Adoption of authorisations/renewal of authorisations/modification of authorisations of feed additives consisting in particular of antioxidants, preservatives, hygiene condition enhancers, amino acids, enzymes and microorganisms	In course of 2020	More than 50 implementing regulations adopted
Revision of the Catalogue of feed materials to facilitate the safe usage of more sustainable feed materials (PLAN/2020/8800)	Preparation	Q3 2020	Work in progress. Adoption foreseen in Q3 2021
<b>Food loss and waste</b>			
Operational support services for the EU Platform on Food Losses and Food Waste	Operation of digital platform and user activity	Ongoing regular activity in 2020	Done

<b>Main outputs in 2020:</b>			
<b>Output description</b>	<b>Indicator</b>	<b>Target</b>	<b>Latest known results</b> <i>(situation on 31/12/2020)</i>
Meetings of the EU Platform on Food Losses and Food Waste	2 meetings held	Q2/Q4 2020	Done
Meetings of the sub-groups of the EU Platform on Food Losses and Food Waste	4 meetings held	Q2/Q4 2020	No meetings of the sub-groups have been held in 2020, only two webinars on food waste measurement for the MS Expert Group.
New digital resource centre, the EU Food Loss and Waste Prevention Hub	Website launched	Q4 2020	Authorisation from DIGIT and DG COMM obtained, website under development, to be launched in 2021.
Grant (European Food Banks Federation -FEBA)	Launched	Q4 2020	Grant agreement signed in 2020. New grant will be attributed in 2021 (procedure ongoing).
<b>Animal Welfare</b>			
Pilot project on the welfare of dairy cows	Signature of contract	Q4 2020	Foreseen delay to 2021
Pilot project on the welfare of laying hens	Signature of contract	Q4 2020	Foreseen delay to 2021
Study on animal welfare labelling	Signature of contract	Q4 2020	Foreseen delay to 2021
<b>Food Fraud</b>			
Food fraud audits	No. of audits carried out	2 pilot fact-finding visits	2 pilot fact-finding visits to AT and IE carried out in 2020
<b>Support to innovation (including novel food, plant reproductive material and innovative techniques)</b>			
<i>Implementation of the plant reproductive material marketing Directives</i>			
Revision of Regulation (EC) 637/2009 on variety denominations (PLAN/2018/3863)	Adoption	Q3 2020	Adopted Q1 2020 C(2020)649)
Updates on variety testing protocols	Adoption	Q4 2020	Voted in Committee Q4 2020, to be adopted Q1 2021
Temporary experiment on risk-based official field inspections for agricultural crops	Adoption	Q4 2020	To be adopted Q1 2021

<b>Main outputs in 2020:</b>			
<b>Output description</b>	<b>Indicator</b>	<b>Target</b>	<b>Latest known results</b> (situation on 31/12/2020)
(PLAN/2020/7070)			
Amendment of scientific names of several species in the cereals marketing Directive (PLAN/2020/7561)	Adoption	Q4 2020	Adopted Q3 2020; C(2020)4955
Amendment of the Annexes of Directives on marketing seed of agricultural crops, including requirements on BMT	Launch	Q4 2020	To be adopted Q1 2021
Regulation of the European Parliament and of the Council on extending the duration of Community Plant Variety Rights (PLAN/2020/8289)	Adoption	Q4 2020	Postponed due to ongoing discussions
<b>Implementation of the Organic Regulation</b>			
Delegated act on organic heterogeneous material (PLAN/2019/5552)	Adoption	Q4 2020	Adopted by COM Q2 2020 (COM(2020) 137); published 4Q 2020
Temporary experiment on organic varieties (PLAN/2020/7562)	Launch	Q4 2020	Adopted Q4 2020 C(2020) 6651
Article 241 TFEU study on NGT (PLAN/2020/6573)	Launch	Q4 2020	On-going (Publication target date: April 2021)
<b>Food Contact Materials</b>			
Authorisation of recycling processes for plastics used in food contact materials	Adoption	140 processes authorised in course of 2020	Preparatory work still ongoing. Adoption of authorisation decisions in Q3 2021

<b>Specific objective 1.3: International promotion of EU food safety standards</b>	Related to spending programme(s) Single Market Programme
<b>Result indicator 1.3.A: Percentage of DG SANTE's audit recommendations that third countries have satisfactorily addressed with corrective action</b>	
<b>Explanation:</b> This is a dynamic rolling indicator and the objective is to demonstrate the impact of DG SANTE audits based on verified corrective actions taken by third countries in response to DG SANTE audit recommendations. The basis for the indicator is not static and therefore the objective is to increase the percentage over the five year period through administrative and audit follow-up. The indicator for Year N is calculated based on the verified actions taken in respect of the sum of recommendations resulting from audits conducted in years N-4, N-3 and N-2. All recommendations	

remaining open at the end of Year N continue to be subject to monitoring by the Commission services to assess progress			
<b>Source of data:</b> Commission internal (DG SANTE)			
<b>Baseline</b> (2019)	<b>Interim Milestone</b> (2022)	<b>Target</b> (2024)	<b>Latest known results</b> (situation on 31/12/2020)
67%: Based on sum of audits carried out in years 2015+2016+2017	70%: Based on sum of audits carried out in years 2018+2019+2020	75%: Based on sum of audits carried out in years 2020+2021+2022	64%: Based on sum of audits carried out in years 2016, 2017 and 2018

<b>Main outputs in 2020:</b>			
<b>Output description</b>	<b>Indicator</b>	<b>Target</b>	<b>Latest known results</b> (situation on 31/12/2020)
<b>New policy initiatives</b>			
<b>Initiatives linked to regulatory simplification and burden reduction</b>			
<b>Evaluations and fitness checks</b>			
<b>Public consultations</b>			
<b>Enforcement actions</b>			
<b>External communication actions</b>			
<b>Website</b> Update of webpages related to the international work of DG SANTE  (see also indicator under objective 1.2 Participation with a stand in international events on Farm to Fork)	Number of visitors to the related webpages (International Affairs web section)	5% increase in the number of visitors to the related websections (Baseline 2019: 178,235 page views)	2020: 175,486 pageviews, representing a decrease of 1.6%  No international event held in 2020
<b>Other important outputs</b>			
<b>Multilateral SPS relations</b>			
Common positions coordinated with EU Member States to promote the alignment of existing and planned EU legislation and initiatives with Codex standards	Delivered	In course of 2020	36

<b>Main outputs in 2020:</b>			
<b>Output description</b>	<b>Indicator</b>	<b>Target</b>	<b>Latest known results</b> (situation on 31/12/2020)
Coordinated EU position for the OIE aquatic and terrestrial Code and Manual	Delivered	In course of 2020	0 Due to COVID-19, in 2020 there was no OIE General Session. There were however 15 Coordinated EU positions on the approval of the Proposal for an Adapted Procedure for the adoption of OIE resolutions in the wake of the Covid-19 pandemic and on the voting of certain administrative and technical resolutions)
Coordinated EU Statements for the World Organisation for Animal Health (OIE) General Assembly	Delivered	In course of 2020	0 Due to COVID-19, in 2020 there was no OIE General Session)
Coordinated EU positions in documents and guidelines of the International Union for the Protection of New Varieties of Plants (UPOV)	Delivered	In course of 2020	60
Coordinated EU positions in the resolutions of the Governing Body of the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA)	Delivered	In course of 2020	No meetings, due to the pandemic
Coordinated EU positions in the World Trade Organisation SPS	Delivered	In course of 2020	22
Coordinated EU position regarding synthetic biology and gene drives for the preparation of the Conference of the Parties of the Convention on Biological Diversity	Delivered	In course of 2020	Delivered
Contribution to the preparation of the intersessional activities under the Convention on Biological Diversity (CBD) and the Cartagena Protocol on	Delivered	In course of 2020	Delivered

<b>Main outputs in 2020:</b>			
<b>Output description</b>	<b>Indicator</b>	<b>Target</b>	<b>Latest known results</b> (situation on 31/12/2020)
Biosafety			
<b>SPS Bilateral relations</b>			
Bilateral trade negotiations (SPS Chapter)	Negotiate comprehensive SPS Chapter that includes all the necessary tools to ensure safe and secure trade and facilitate the access of EU products to non-EU markets.	Balanced SPS Chapter within the ongoing FTA agreements	In process  Negotiations with the UK held from February to December 2020.
Negotiate with non-EU countries harmonised export conditions that ensure the cohesion of the EU as regards exports (EU single entity) by ensuring that the same conditions are applied to all the EU territory having the same sanitary or phytosanitary level	Negotiate harmonised export certificates for EU products	In course of 2020	In process
Coordinate EU position in negotiations of Agreements with non-EU countries	Delivered	In course of 2020	Delivered for SPSC EU-Korea (November 2020) and EU-Singapore (November 2020)
Coordinate EU position on the management of the SPS Committees of the Agreements in force	Delivered	In course of 2020	Delivered for Agreements EU-Central America and EU-Colombia, Ecuador and Peru
Commission Decision amending Decision 2011/163/EU, recognising the residues monitoring plans of non-EU countries (PLAN/2020/6857)	Ongoing	Q4 2020	In process
EU-China Memorandum of understanding on animal health (ISC/2020/01685)	Revision	Q4 2020	Text accepted at technical level.
EU- Australia mutual equivalence recognition for beef/pork		Q4 2020	In process



<b>Main outputs in 2020:</b>			
<b>Output description</b>	<b>Indicator</b>	<b>Target</b>	<b>Latest known results</b> <i>(situation on 31/12/2020)</i>
EU-US shellfish equivalence: Implementing Decisions allowing trade of bivalve molluscs between EU and US (PLAN/2018/3849)	Adoption	Q4 2020	Adopted (Commission Implementing Regulation (EU) 2020/1641)
EU-US Administrative Arrangement on Shellfish	Conclusion	Q4 2020	Finalised (Ares(2020)4051355)
Meetings of the EU-US Animal Health Technical Working Group and Plant Health Technical Working Group: Facilitate trade and better cooperation on animal, plant health and food safety issues with the US	3 meetings held	Q4 2020	2 meetings held:  Animal Health Technical Working Group in March 2020 and October 2020
Meetings of the EU-Japan Animal Health Technical Working Group: Facilitate trade and better cooperation on animal health issues with Japan (regionalisation)	1 face-to-face meeting held	Q4 2020	Held on 9-10 November 2020 (video conference)
Finalisation of the EU-China regionalisation project, launching and development of road map activities	Project finalised	Q3 2020	Project finalised and launched. Working Groups activities to come.

<b>General objective 2 : Promoting our European way of life</b>			
<b>Impact indicator:</b> Healthy life years at birth			
<b>Explanation:</b> Number of years in absolute value that a person is expected to continue to live in a healthy condition			
<b>Source of the data:</b> Eurostat (Eurostat data code: [hlth_hlye])			
<b>Baseline</b> (2018)	<b>Interim Milestone</b> <sup>14</sup> (2022)	<b>Target</b> (2024)	<b>Latest known results</b> (2018)
Males: 63.7 years Females: 64.2 years Total: 64.0 years	Increase	Increase	(2019 statistics are not yet available)
<b>Specific objective 2.1: Diminishing the impact of cancer in Europe</b>			
			Related to spending programmes EU4Health, Health Programme
<b>Result indicator 2.1.A:</b> Age-standardised five-year net survival of cervical, breast and colorectal cancer			
<b>Explanation:</b> Cervical, breast and colorectal cancer survival is one of the key measures of the effectiveness of health care systems in cancer care, reflecting both efficiency in early detection and the effectiveness of treatment.			
<b>Source of data:</b> EUROCORE (Joint Research Centre) and CONCORD Programme, London School of Hygiene and Tropical Medicine			
<b>Baseline</b> (2014)	<b>Interim Milestone</b> (2022)	<b>Target</b> (2024)	<b>Latest known results</b> (2020)
<b>Cervical cancer:</b> 63% (EU average) <b>Breast cancer:</b> 83% (EU average) <b>Colorectal cancer:</b> 59% (EU average)	Increase  Increase  Increase	Increase, with at least 2/3 of Member States above baseline	European Network of cancer Registries (ENCR) and JRC call for data protocol is ready to launched early in 2021 (February-March) as data protection issues still need to be fixed..

<sup>14</sup> In case of short- or medium-term objectives (all targets are set to be achieved in less than 3 years) the milestones column should be deleted from the table.

			Therefore data as of 2020 will be available as planned in 2022 (Interim milestone)
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**Result indicator 2.1.B:** Ratio of Cancer Registries (CRs) and number of Member States (MSs) reporting information on cervical, breast, and colorectal cancer stage at diagnosis

**Explanation:** Information on cervical, breast and colorectal cancer stage at diagnosis is an essential information item collected by Cancer Registries (CRs) to estimate stage-specific survival, and to evaluate population based screening performance. It has been recognized that cancer stage at diagnosis is an essential information to be collected by all European Cancer Registries.

**Source of data:** European Cancer Information System (ECIS - Joint Research Centre) and EURO CARE

Baseline (2015)	Interim Milestone (2022)	Target (2024)	Latest known results (2020)
CRs reporting cervical cancer stage at diagnosis: 51% CRs reporting breast cancer stage at diagnosis: 53% CRs reporting colorectal cancer stage at diagnosis: 52% Number of MS reporting cervical cancer stage at diagnosis: 20 Number of MS reporting breast cancer stage at diagnosis: 20 Number of MS reporting colorectal cancer stage at diagnosis: 20	Increase in all ...	Increase, at least 2/3 of Cancer Registries above baseline.  All Member States reporting the information on cancer stage	European Network of cancer Registries (ENCR) and JRC call for data protocol is ready to be launched early in 2021 (February-March) as data protection issues still need to be fixed.. Therefore data as of 2020 will be available as planned in 2022 (Interim milestone)

**Result indicator 2.1.C:** Smoking prevalence

**Explanation:** This indicator is part of the EU Sustainable Development Goal Indicator set and measures the percentage of the population aged 15 years and over who report that they currently smoke boxed cigarettes, cigars, cigarillos or a pipe. It does not include the use of other tobacco products such as electronic cigarettes and snuff.

**Source of data:** Collected through [a Eurobarometer survey](#) and are based on self-reported use during face-to-face interviews in people's homes.

Baseline (2010)	Interim Milestone (2021)	Target (2024)	Latest known results (2020)
<b>29%</b>	<b>25%</b> <sup>15</sup>	<b>21%</b> <sup>16</sup>	<b>23%</b> <sup>17</sup>

<sup>15</sup> Estimated prevalence reduction as a result of the Tobacco Products Directive.

<b>Main outputs in 2020:</b>			
<b>Output description</b>	<b>Indicator</b>	<b>Target</b>	<b>Latest known results</b> (situation on 31/12/2020)
<b>New policy initiatives</b>			
Europe's Beating Cancer Plan (PLAN/2020/6485)	Adoption	Q4 2020	Adoption planned for 03/02/2021
Audit guidelines for the track and trace system for tobacco products	Launched	Q2 2020	Adopted and published in May 2020
<b>Public consultations</b>			
Public consultation on Cancer Plan	Completed	Q2 2020	Completed
<b>Enforcement actions</b>			
INFR(2016)0545 regarding non-communication of Luxembourg measures to implement the Tobacco Products Directive 2014/40/EU in its national law	Reasoned opinion sent on 9 December 2016		Closed
<b>External communication actions</b>			
The Cancer plan is a key communication priority for 2020			
Preparation of Press material	Number of online views, downloads of media material	Minimum of 200 online views, downloads	Not Available (NA) <sup>18</sup>
	Number of media items mentioning Commsr Kyriakides	Minimum of 10 articles	At least 90 media items mentioned the Commissioner <sup>19</sup>

<sup>16</sup> This target is based on the international processes, most notably the SGD goals and the WHO (and FCTC) global targets for NCDs. This corresponds to a 30% reduction in smoking prevalence by 2025 against a baseline in 2010. The 2024 target has been calculated on that basis.

<sup>17</sup> EU27 and the UK.

<sup>18</sup> There were technical issues with this corporate press material and, therefore, the statistics are either irrelevant or inexistent.

<b>Main outputs in 2020:</b>			
<b>Output description</b>	<b>Indicator</b>	<b>Target</b>	<b>Latest known results</b> <i>(situation on 31/12/2020)</i>
	Geographical spread of news in various EU countries	Media items in the 27 member states (as per media monitoring)	Media coverage by at least 20 EU countries after February's launch event
Production of video showing the benefit of the EU Cancer Plan for citizens	Number of views, embeds and downloads	Minimum 10,000	Video postponed to 2021
Promotion on social media, through both owned and paid content. The hashtag #EUCancerPlan monitored continuously	Number of engagements per tweet	Average a hundred engagements per tweet	2020: 128 engagements per Tweet with the Hashtag #EUCancerPlan
The dedicated web section on europa.eu as well as the policy page are regularly updated.	Number of page views	Increase page views by 10% Baseline 2019: 2,233 page views	2020: 19,835 pageviews, representing an increase by 788%
<b>Other important outputs</b>			
Meetings with Member States on the implementation of the Tobacco Products Directive and its implementing rules	Organised	Q4 2020	Total of 8 meetings held: 2 Expert Groups on Tobacco Policy 1 Subgroup on Tobacco Ingredients 5 Subgroups on Traceability and Security Features
Perception study of different tobacco products (for TPD implementation report)	Completed	Q2 2020	Finished in August 2020.
Advertising and smoke-free monitoring study	Launched	Q2 2020	Launched in June 2020.

<sup>19</sup> The Commissioner's mentions in media items were concentrated in February, most of which following the launch event on 4 February

<b>Main outputs in 2020:</b>			
<b>Output description</b>	<b>Indicator</b>	<b>Target</b>	<b>Latest known results</b> <i>(situation on 31/12/2020)</i>
First draft of Article 28 TPD implementation report	Completed	Q4 2020	First draft prepared in time for meeting the publication deadline of May 2021
Compliance checks of TPD	On-going	Q4 2020	The first stage of compliance assessment (transposition checks) concluded with the closure of last infringement case in April 2020. Final conformity checks (second stage) completed for 13 Member States, followed by bilateral structural dialogues. Member State conformity checks are an ongoing process and closure depends on changes in national legislation to comply with the Directive.
Eurobarometer on smoking prevalence	On-going	Q4 2020	EB survey conducted in August-September 2020; Draft report received in December 2020.

<b>Specific objective 2.2: Patients' access to safe, innovative and affordable medicines and medical devices</b>		Related to spending programmes EU4Health, Health Programme	
<b>Result indicator 2.2.A:</b> Access to centrally authorised medicines for unmet needs			
<b>Explanation:</b> This indicator measures the number of new marketing authorisations granted by the Commission for the EU market for the following medicinal products: (a) those including at least one of the following - orphan authorisations, Advanced Therapy Medicinal Products, Paediatric Use Medicinal Products and (b) vaccines. The data is corrected for the number of medicines which belong to more than one of those groups and concerns only medicines for humans. The measurement is the average annual number of marketing authorisations granted for this basket of medicinal products for each reference period.			
<b>Source of data:</b> European Commission European Medicinal Products database			
<b>Baseline</b>	<b>Interim Milestone</b>	<b>Target</b>	<b>Latest known results</b>
(2019)	(2022) Average number per calendar year for the period	(2024) Average number per calendar year	(year)

	2020-2021	for the period 2022-2023	
<b>7</b>	<b>Increase</b>	<b>Increase</b>	<b>24</b>
<p><b>Result indicator 2.2.B:</b> Number of audits conducted in the EU and in third countries to ensure good manufacturing practices and good clinical practices (Union control)</p> <p><b>Explanation:</b> This indicator shows to what extent the EU ensures high quality medicines and proper implementation of the clinical trial regulation and supports the implementation of the legislation. The EU has been supporting Member States in conducting audits of the national system on GMP for many years in the context of EU-US MRA and to ensure high quality API. This ensures increased control of GMP in the pharma industry and ascertains full implementation of the EU-US MRA. For clinical trials, the law will require to implement audits of the clinical trials system (Union control) as of 2022.</p> <p><b>Source of data:</b> European Commission</p>			
<b>Baseline</b> (2020)	<b>Interim Milestone</b> (2022)	<b>Target</b> (2024)	<b>Latest known results</b> (2020)
<b>10</b>	<b>20</b>	<b>40</b>	<b>Due to Covid-19 travel restrictions audits are reported to 2021</b>
<p><b>Result indicator 2.2.C:</b> Number of shortages of medicines in the single point of contact network</p> <p><b>Explanation:</b> This indicator measures the level of transparency on shortages of human and veterinary medicines by measuring the number of shortages of medicines that were either critical or had an impact on human/animal health reported by the SPOC (single point of contact) at EMA. This indicator will increase in the short term as Member States should improve their reporting practices and should decrease over the long term (where short term is 2020-2024 and long term is post-2024) once legislative measures and the actions of the pharmaceutical strategy are put into place.</p> <p><b>Source of data:</b> European Medicines Agency</p>			
<b>Baseline</b> (2019)	<b>Interim Milestone</b> (2022)	<b>Target</b> (2024)	<b>Latest known results</b> (2020)
<b>91<sup>20</sup></b>	<b>300</b>	<b>450</b>	<b>65<sup>21</sup></b>
<p><b>Result indicator 2.2.D (Burden reduction):</b> Proportion of proposed legislative revisions that include burden reduction measures</p> <p><b>Source of data:</b> DG SANTE</p>			
<b>Baseline</b> (2020)	<b>Interim Milestone</b> (2022)	<b>Target</b> (2024)	<b>Latest known results</b> (year)
<b>N/A</b>	<b>Positive trend</b>	<b>Positive trend</b>	<b>...</b>

<sup>20</sup> From April to December 2019

<sup>21</sup> Currently, the number of shortages is reported by the Member States on a voluntary basis, and in 2019, this was still a pilot project. The new health package linked to the European Medicines Agency will formalise the reporting and therefore, we can anticipate an increased reporting in the coming years.

<b>Main outputs in 2020:</b>			
<b>Output description</b>	<b>Indicator</b>	<b>Target</b>	<b>Latest known results</b> (situation on 31/12/2020)
<b>New Policy Initiatives</b>			
Communication on Pharmaceutical Strategy (PLAN/2020/6954)	Adopted	Q4 2020	Adopted COM/2020/761 final, 25/11/2020
<b>External communication actions</b>			
Public launch of Pharmaceutical Strategy		Q2 2020	Launched 16/06/2020. Closed 13/09/2020
<b>Press material</b> Media material produced for adoption.	Number of Online views, downloads of media material	Minimum of 200 online views, downloads	297 pageviews of the press release and 1426 downloads of Q&A and factsheet
	Geographical spread of news in various EU countries	Media items in the 27 member states (as per media monitoring)	Media coverage by at least 20 EU countries
<b>Social Media</b> Sustained tweets during adoption and as follow up.	Increase engagement on twitter per tweet	Average target of 100 engagements per tweet	2020: 94 engagements with the hashtag #EUPharmaStrategy
Paid promotion of tweets	Increase the number of followers on the EU Health twitter account	5 % increase in the number of followers	2020: +16.100 followers (= +27.5%) <sup>22</sup>
<b>Website</b> Update of Pharma-related webpages	Number of page views to the relevant section of the website (Medicinal Products)	5 % increase in the number of page views Baseline 2019: 332,357 page views	2020: 793,402 page views.
<b>Other important outputs</b>			
Commission BREXIT	Adopted		Adopted

<sup>22</sup> This figure represents the total number increase in 2020



<b>Main outputs in 2020:</b>			
<b>Output description</b>	<b>Indicator</b>	<b>Target</b>	<b>Latest known results</b> <i>(situation on 31/12/2020)</i>
Notice			OJ C 447 of 23 December 2020 and revised in OJ C 27, 25.January.2021
Support in the EU-UK TCA and negotiations on medicines for the Annex on medicines	EU-UK TCA adopted		Adopted OJ L 444, 31.December 2020
SANTE/ EMA And Health Canada Confidentiality Arrangement	Signed		Signed and published 13/3/2020
Implementing acts on EU Reference Laboratories (tasks, structure, fees)	Adopted	Q4 2020	Not adopted Foreseen for Q1 2021
Implementing Act for reprocessing of single use devices	Adopted		Published (EU)2020/1207
Migration of medical devices website from GROW to SANTE	Completed		Completed in Q3 2020
Guidance document on classification rules for medical devices	Completed	Q4 2020	Published
Study supporting the Impact Assessment for the review of the Paediatric regulation and the regulation on Medicines for Rare Diseases (Orphan medicines)	Launched	Q4 2020	Study contract to be launched early 2021
Study supporting the Impact Assessment for the revision of the EMA fees Regulation	Launched	Q3 2020	Study on-going
Audit of the clinical trials system	Launched	Q4 2020	Audits not possible yet, as the Regulation does not apply until 2022. No fact-finding studies carried out in 2020.

<b>Main outputs in 2020:</b>			
<b>Output description</b>	<b>Indicator</b>	<b>Target</b>	<b>Latest known results</b> <i>(situation on 31/12/2020)</i>
Recommendations for designations /notifications of Notified Bodies in accordance with the medical devices Regulation and the in vitro diagnostic medical devices Regulation	9 for MDR and 2 for IVDR	Q4 2020	Process and audits severely impacted by COVID-19 and travelling restrictions; in total 23 designations completed 19 under MDR & 4 under IVDR
Report to EP/Council on marketing authorisation procedures of medicinal products for human use	Launched	Q4 2020	Publication delayed to Q3 2021 to take into account the experience with COVID-19
Authorisations of medicinal products for human use	Adopted		1017 Commission implementing decisions adopted during 2020
Recommendations and templates to support the implementation of the Clinical Trials Regulation (CTR)	Adopted		5 adopted and published on Eudralex-10
Setting up Union Controls under the CTR	Launched		Q4 2021/Q1 2022
Study on shortages of medicines	Launched		Study launched in Q2 2020 (ongoing)

<b>Specific objective 2.3:</b> Effective response coordination of serious cross-border health threats		Related to spending programmes EU4Health, Health Programme	
<b>Result indicator 2.3.A:</b> Number of Member States with improved preparedness and response planning			
<b>Explanation:</b> This indicator shows the number of Member States who have completed the implementation of International Health Regulations (IHR) core capacities in accordance with Article 4 of Decision 1082/2013/EU on serious cross border health threats.			
<b>Source of data:</b> Member State reporting under Article 4 of Decision 1082/013/EU and the relevant implementing act			
<b>Baseline</b> (2019)	<b>Interim Milestone</b> (please introduce as many columns as the number of milestones) (2022)	<b>Target</b> (2024)	<b>Latest known results</b> (year)
<b>24</b>	<b>26</b>	<b>27</b>	<b>24</b>

<b>Main outputs in 2020:</b>			
<b>Output description</b>	<b>Indicator</b>	<b>Target</b>	<b>Latest known results</b> (situation on 31/12/2020)
<b>New policy initiatives</b>			
EU vaccines strategy	Adoption		Adopted on 17 June COM/2020/245 final
Building a European Health Union: Reinforcing the EU's resilience for cross-border health threats	Adoption		Communication adopted on 11 November 2020 (it includes reference to the creation of the European Health Emergency Response Authority)
Proposal for a Regulation on serious cross-border threats to health	Adoption		Adopted on 11 November 2020
Proposal to extend the mandate of the European Centre for Disease Prevention and Control	Adoption		Adopted on 11 November 2020
<b>External communication actions</b>			
Awareness raising on tackling vaccination	Increase twitter interactions per tweet	Averaging 100 interactions per	2020: 247 engagements per tweet

<b>Main outputs in 2020:</b>			
<b>Output description</b>	<b>Indicator</b>	<b>Target</b>	<b>Latest known results</b> <i>(situation on 31/12/2020)</i>
inequalities		tweet across all related tweets	on EU health Twitter account with the hashtag #VaccinesWork
Social media campaign around #VaccinesWork	Number of visits to relevant SANTE web section [crisis preparedness, communicable and non-communicable diseases (excluding cancer), vaccination and AMR]	5% increase (Baseline 2019: 205,785 page views)	2020: 408,370 page views, representing a 98% increase
Website		Media coverage by at least 20 EU countries	
Press and Media	National print media coverage		Media coverage by all 27 EU countries
<b>Other important outputs</b>			
Feasibility study for a common EU vaccination card	Launched	Q4 2020	Work is ongoing, in coordination with the eHealth network also regarding a vaccination certificate.
Feasibility study for physical stockpiling of vaccines	Launched	Q4 2020	Cancelled due to the developments regarding rescEU and the proposal to establish a EU Health Emergency Preparedness and Response Authority.
Report on State of Vaccine Confidence in the EU	Publication	Q4 2020	Published in December 2020 <sup>23</sup> .
Report on interoperability of Immunization Information Systems	Publication	Q4 2020	Delayed by at least 6 months due to the COVID-19 pandemic. .
One Health AMR country visits	country visits carried out	2 country visits	None carried out (postponed due to COVID-19)
Joint procurements contracts for personal protective equipment,	Signature of contracts		Framework contracts signed in Q2-Q4 2020

<sup>23</sup> [https://ec.europa.eu/health/vaccination/confidence\\_en](https://ec.europa.eu/health/vaccination/confidence_en)

<b>Main outputs in 2020:</b>			
<b>Output description</b>	<b>Indicator</b>	<b>Target</b>	<b>Latest known results</b> (situation on 31/12/2020)
ICU medicines, Veklury (Remdesivir), laboratory supplies, ventilators			
ESI procurement for rapid antigen tests	Signature of contract		Contract signed on 18 December 2020
ESI procurement for masks	Signature of contract		Contract signed
ESI procurement for Remdesivir	Signature of contract		Contract signed
Communication on preparedness for further outbreaks	Adoption		Adopted 15 July
Recommendation on the use of rapid antigen tests for the diagnosis of SARS-CoV-2 infection	Adoption		Adopted on 18 November
Staying safe from COVID-19 during winter	Adoption		Adopted on 2 December

<b>Specific objective 2.4:</b> More effective, accessible and resilient health systems		Related to spending programmes EU4Health, Health Programme	
<b>Result indicator 2.4.A:</b> Implementation of best practices by EU Member States			
<b>Explanation:</b> This indicator measures the number of Member States implementing best practices, demonstrating how the health challenges identified by the Steering Group on Promotion and Prevention are addressed through best practices at the national level with the support of the EU funding. The unit of measurement is the number of best practices over the number of Member States.			
<b>Source of data:</b> DG SANTE (Unit C1) and CHAFEA and/or its follow-on entity			
<b>Baseline</b> (2020)	<b>Interim Milestone</b> (2022)	<b>Target</b> (2024)	<b>Latest known results</b> (2020)
0	At least 1/2 of Member States implement at least one best practice selected by the SGPP	At least 2/3 of Member States implement at least one best practice	Four best practices implementation actions (best remap, DK wholegrain, SE physical activity, IT Cardio50/Young50):

		selected by the SGPP	25 MSs with at least one; Out of this 25, 6 MSs with two; Out of this 25, 2 MSs with three; Out of this 25, 2 MSs with four. Plus Serbia with one, Bosnia Herzegovina with two best practice implementation.
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<b>Main outputs in 2020:</b>			
<b>Output description</b>	<b>Indicator</b>	<b>Target</b>	<b>Latest known results</b> <i>(situation on 31/12/2020)</i>
<b>Initiatives linked to regulatory simplification and burden reduction</b>			
<b>External communication actions</b>			
Update of relevant webpages	Number of visits to relevant SANTE web sections	5% increase (baseline 2019: 364,729)	2020: 300.750 pageviews, representing a decrease of roughly 17% <sup>24</sup>
Social media	Number of engagements per tweet	Averaging 100 interactions per tweet across all related tweets	2020: 67 engagements for tweets
<b>Other important outputs</b>			
Impact Assessment on substances of human origin	Launched	Q4 2020	Inception Impact Assessment published in November 2020
Opinions of the Expert Panel on effective ways of investing in Health	Publication of one report		December 2020: publication of opinion on Organisation of resilient health and social care following the COVID-19

<sup>24</sup> Communication activities on the topics under section 2.4 were downscaled in light of the COVID-19 pandemic. Conversely, communication activities that were not included in the 2020 management plan were launched on the European Health Union and EU4Health. The health funding pages were visited 135,484 times, compared to 78,417 in 2019, an increase of 73%, and the newly created European Health Union page 10,328 times. Social media engagement was 67 per #EU4Health tweet and 72 per #HealthUnion tweet. Over 120 media articles were written following the launch of the Health Union response package in November 2020.

<b>Main outputs in 2020:</b>			
<b>Output description</b>	<b>Indicator</b>	<b>Target</b>	<b>Latest known results</b> <i>(situation on 31/12/2020)</i>
(EXPH)			pandemic
Report on Health Systems Resilience (by the group on Health Systems Performance Assessment)	Publication	Q2 2020	Q4 2020 (delayed to reflect implications of the COVID-19 pandemic relevant for the topic)
Statistical compendium "Health at a Glance: Europe 2020"	Publication	Q4 2020	Published in Q4 2020
Voluntary exchanges (knowledge transfer) between Member States on health system challenges	Launched	Q4 2020	October 2020 (exchange on Estonian health system)
Proposals for European Semester country-specific recommendations (CSRs) (on health system's resilience, accessibility and effectiveness)	Adoption	Q2 2020	Adopted by COM in May 2020 and by Council in July. Health-related CSRs to all 27 MS (+UK)
Projects to raise the capacity of Member States to make investments in health, address health workforce challenges and implement integrated care (financed from the Health Programme)	Signed/Launched	Q4 2020	<p>Joint Action on digitally-enabled integrated care launched on 01/10/2020.</p> <p>5 proposals were selected under a call for supporting the health workforce. Signature is expected in the first half 2021.</p> <p>No proposal selected in the AWP 2020 call of the Health Programme on 'investments in health', hence no project to launch for this area.</p>
Evaluation of Article 14 on eHealth of the Cross Border Healthcare Directive	Launched	Q2 2020	Evaluation launched in August 2020 to be completed in Q3 2021
Evaluation of the cross-	Publication of	Q4 2020	Published in January 2021

<b>Main outputs in 2020:</b>			
<b>Output description</b>	<b>Indicator</b>	<b>Target</b>	<b>Latest known results</b> (situation on 31/12/2020)
border healthcare Directive	evaluation roadmap		
Guidelines on emergencies in cross-border healthcare	Adoption	Q2 2020	Adopted in April 2020
Workshops on implementation of cross-border healthcare directive	Launched	Q4 2020	Will be completed in Q1 2021
Finalisation of pilot projects Cross-Border Health Care	On-going	Q4 2020	Will be completed in Q1 2020
Three meetings of Board of Member States of the ERNs, two meetings of ERN coordinators and the annual meeting of ERN hospital managers. Two meetings of the IT Advisory Group of the ERNs.	Organised	Q4 2020	Q4 2020, all meetings organised.
Assessment, Monitoring, Evaluation and Quality Improvements System (AMEQUIS) of ERNs	Launched	Q1 2020	Amequis contract signed in Q4 2020
Mobility programme of ERN professionals	Launched	Q2 2020	Programme launched in Q4 2020, start postponed due to Covid-19 pandemics
New Framework Contract for ERN IT Tool Clinical Patient Management System	Launched	Q4 2020	Negotiation finished. Contract to be signed beginning of 2021
Development of ERN clinical patient guidelines	Launched	Q1 2020	Project launched in Q1 2020
Two meetings of eHealth Network together with the respective Presidencies	Organised	Q4 2020	Meetings of eHN Plenary organised in June and November 2020, plus over 100 online meetings on COVID coordinated actions,



<b>Main outputs in 2020:</b>			
<b>Output description</b>	<b>Indicator</b>	<b>Target</b>	<b>Latest known results</b> <i>(situation on 31/12/2020)</i>
			including contact tracing and warning apps organised between March and December
Study (including expert workshops) on health data use in the EU	Completed	Q3 2020	Study to be finalised in Q1 2021
Study on regulatory gaps and obstacles to cross-border digital healthcare, including AI	Launched	Q2 2020	Study launched in Q3 2020
Terms of Reference for development of a Code of Conduct on secondary use of health data in accordance with Article 40 of GDPR	Completed	Q4 2020	Postponed to 2021
Joint Action supporting the development of the European Health Data Space	Signed	Q4 2020	Signed in Q4 2020
eHealth audits in Member States	90% of the requested audits carried out	Q4 2020	Due to COVID-19 pandemic, most of the audits planned for 2020 will take place in 2021.

## **ANNEX 3: Draft annual accounts and financial reports**

AAR 2020 Version 1

### **Annex 3 Financial Reports - DG SANTE - Financial Year 2020**

**Table 1 : Commitments**

**Table 2 : Payments**

**Table 3 : Commitments to be settled**

**Table 4 : Balance Sheet**

**Table 5 : Statement of Financial Performance**

**Table 5 Bis: Off Balance Sheet**

**Table 6 : Average Payment Times**

**Table 7 : Income**

**Table 8 : Recovery of undue Payments**

**Table 9 : Ageing Balance of Recovery Orders**

**Table 10 : Waivers of Recovery Orders**

**Table 11 : Negotiated Procedures**

**Table 12 : Summary of Procedures**

**Table 13 : Building Contracts**

**Table 14 : Contracts declared Secret**

**Table 15 : FPA duration exceeds 4 years**

**Additional comments**

<b>TABLE 1: OUTTURN ON COMMITMENT APPROPRIATIONS IN 2020 (in Mio €) for DG SANTE</b>					
			Commitment appropriations authorised	Commitments made	%
			1	2	3=2/1
<b>Title 05 Agriculture and rural development</b>					
05	05 01	Administrative expenditure of the 'Agriculture and rural development' policy area	3,94	3,71	94,20 %
	05 04	Rural development	0,50	0,35	70,00 %
<b>Total Title 05</b>			<b>4,44</b>	<b>4,06</b>	<b>91,48 %</b>
<b>Title 07 Environment</b>					
07	07 02	Environmental policy at Union and international level	0,12	0,12	100,00 %
<b>Total Title 07</b>			<b>0,12</b>	<b>0,12</b>	<b>100,00 %</b>
<b>Title 09 Communications networks, content and technology</b>					
09	09 03	Connecting Europe Facility (CEF) - Telecommunications networks	2,76	2,76	100,00 %
<b>Total Title 09</b>			<b>2,76</b>	<b>2,76</b>	<b>100,00 %</b>
<b>Title 11 Maritime affairs and fisheries</b>					
11	11 06	European Maritime and Fisheries Fund (EMFF)	0,38	0,38	100,00 %
<b>Total Title 11</b>			<b>0,38</b>	<b>0,38</b>	<b>100,00 %</b>
<b>Title 14 Taxation and customs union</b>					
14	14 02	Customs	0,20	0,20	100,00 %
<b>Total Title 14</b>			<b>0,20</b>	<b>0,20</b>	<b>100,00 %</b>
<b>Title 17 Health and food safety</b>					
17	17 01	Administrative expenditure of the 'Health and food safety' policy area	12,67	11,91	94,00 %
	17 03	Public health	251,24	248,98	99,10 %
	17 04	Food and feed safety, animal health, animal welfare and plant health	236,11	234,15	99,17 %
<b>Total Title 17</b>			<b>500,02</b>	<b>495,03</b>	<b>99,00 %</b>
<b>Title 18 Migration and home affairs</b>					
18	18 07	Instrument for emergency support within the Union	3.188,88	2.772,28	86,94 %
<b>Total Title 18</b>			<b>3.188,88</b>	<b>2.772,28</b>	<b>86,94 %</b>
<b>Title 22 Neighbourhood and enlargement negotiations</b>					
22	22 02	Enlargement process and strategy	0,00	0,00	0,00 %
<b>Total Title 22</b>			<b>0,00</b>	<b>0,00</b>	<b>0,00 %</b>
<b>Title 26 Commission's administration</b>					
26	26 01	Administrative expenditure of the 'Commission's administration' policy area	0,58	0,50	86,30 %
	26 03	Services to public administrations, businesses and citizens	0,30	0,30	100,00 %
<b>Total Title 26</b>			<b>0,88</b>	<b>0,80</b>	<b>91,00 %</b>
<b>Title 33 Justice and consumers</b>					
33	33 01	Administrative expenditure of the 'Justice and consumers' policy area	1,99	1,88	94,20 %
<b>Total Title 33</b>			<b>1,99</b>	<b>1,88</b>	<b>94,20 %</b>
<b>Total DG SANTE</b>			<b>3.699,67</b>	<b>3.277,51</b>	<b>88,59 %</b>

\* Commitment appropriations authorised include, in addition to the budget voted by the legislative authority, appropriations carried over from the previous exercise, budget amendments as well as miscellaneous commitment appropriations for the period (e.g. internal and external assigned revenue).

**% Outturn on Commitment Appropriations in 2020 for DG SANTE**

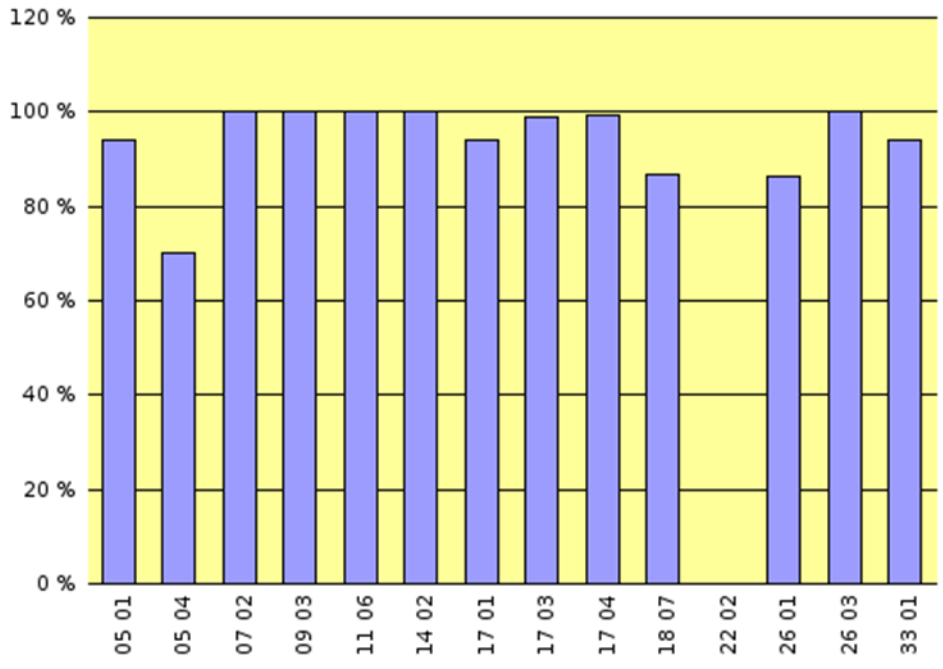


TABLE 2: OUTTURN ON PAYMENT APPROPRIATIONS in 2020 (in Mio €) for DG SANTE					
			Payment appropriations authorised	Payments made	%
			1	2	3=2/1
<b>Title 05 Agriculture and rural development</b>					
05	05 01	Administrative expenditure of the 'Agriculture and rural development' policy area	3,94	3,71	94,20 %
	05 04	Rural development	0,21	0,21	100,00 %
<b>Total Title 05</b>			<b>4,15</b>	<b>3,92</b>	<b>94,50%</b>
<b>Title 07 Environment</b>					
07	07 02	Environmental policy at Union and international level	0,13	0,13	100,00 %
<b>Total Title 07</b>			<b>0,13</b>	<b>0,13</b>	<b>100,00%</b>
<b>Title 09 Communications networks, content and technology</b>					
09	09 03	Connecting Europe Facility (CEF) - Telecommunications networks	3,63	3,63	100,00 %
<b>Total Title 09</b>			<b>3,63</b>	<b>3,63</b>	<b>100,00%</b>
<b>Title 11 Maritime affairs and fisheries</b>					
11	11 06	European Maritime and Fisheries Fund (EMFF)	0,28	0,28	100,00 %
<b>Total Title 11</b>			<b>0,28</b>	<b>0,28</b>	<b>100,00%</b>
<b>Title 14 Taxation and customs union</b>					
14	14 02	Customs	0,20	0,20	100,00 %
<b>Total Title 14</b>			<b>0,20</b>	<b>0,20</b>	<b>100,00%</b>
<b>Title 17 Health and food safety</b>					
17	17 01	Administrative expenditure of the 'Health and food safety' policy area	14,88	11,37	76,35 %
	17 03	Public health	234,62	231,45	98,65 %
	17 04	Food and feed safety, animal health, animal welfare and plant health	226,74	224,83	99,16 %
<b>Total Title 17</b>			<b>476,25</b>	<b>467,64</b>	<b>98,19%</b>
<b>Title 18 Migration and home affairs</b>					
18	18 07	Instrument for emergency support within the Union	3.099,42	2.514,77	81,14 %
<b>Total Title 18</b>			<b>3.099,42</b>	<b>2.514,77</b>	<b>81,14%</b>
<b>Title 22 Neighbourhood and enlargement negotiations</b>					
22	22 02	Enlargement process and strategy	0,28	0,28	100,00 %
<b>Total Title 22</b>			<b>0,28</b>	<b>0,28</b>	<b>100,00%</b>
<b>Title 26 Commission's administration</b>					
26	26 01	Administrative expenditure of the 'Commission's administration' policy area	0,80	0,46	57,37 %
	26 03	Services to public administrations, businesses and citizens	0,00	0,00	0,00 %
<b>Total Title 26</b>			<b>0,80</b>	<b>0,46</b>	<b>57,37%</b>
<b>Title 33 Justice and consumers</b>					
33	33 01	Administrative expenditure of the 'Justice and consumers' policy area	1,99	1,88	94,20 %
<b>Total Title 33</b>			<b>1,99</b>	<b>1,88</b>	<b>94,20%</b>
<b>Total DG SANTE</b>			<b>3.587,14</b>	<b>2.993,20</b>	<b>83,44 %</b>

\* Payment appropriations authorised include, in addition to the budget voted by the legislative authority, appropriations carried over from the previous exercise, budget amendments as well as miscellaneous payment appropriations for the period (e.g. internal and external assigned revenue).

**% Outturn on Payment Appropriations in 2020 for DG SANTE**

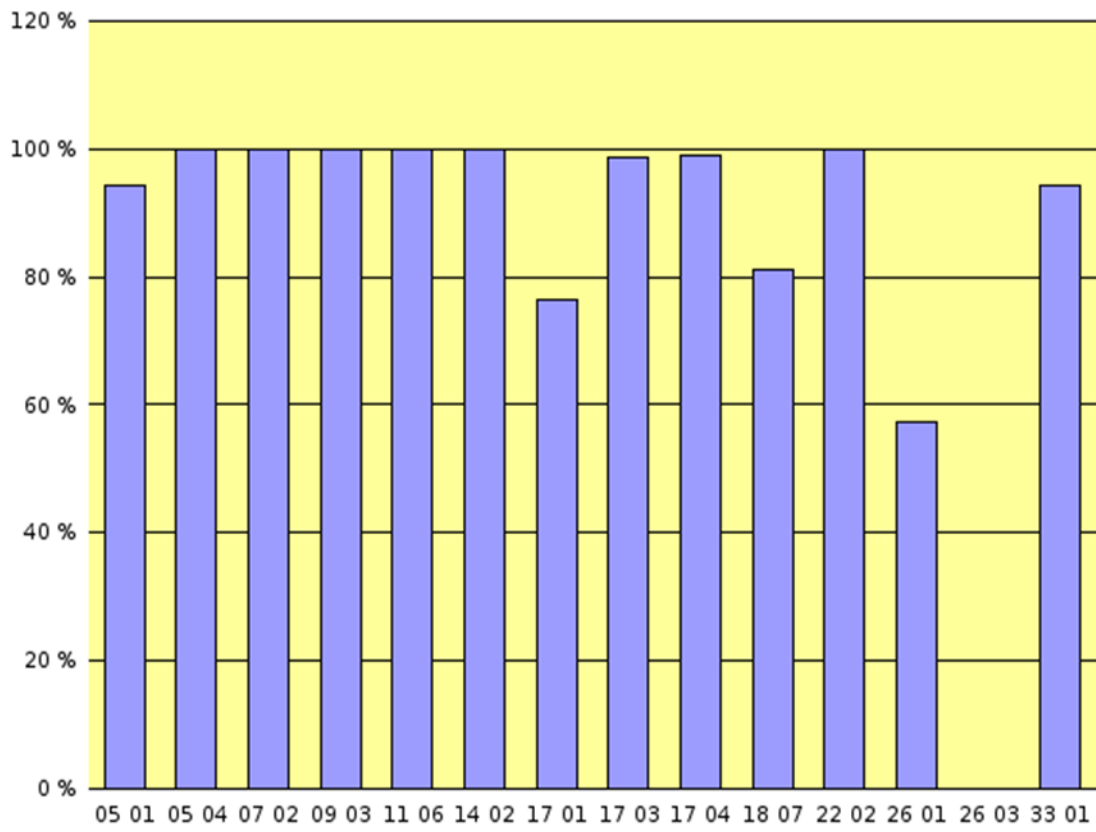
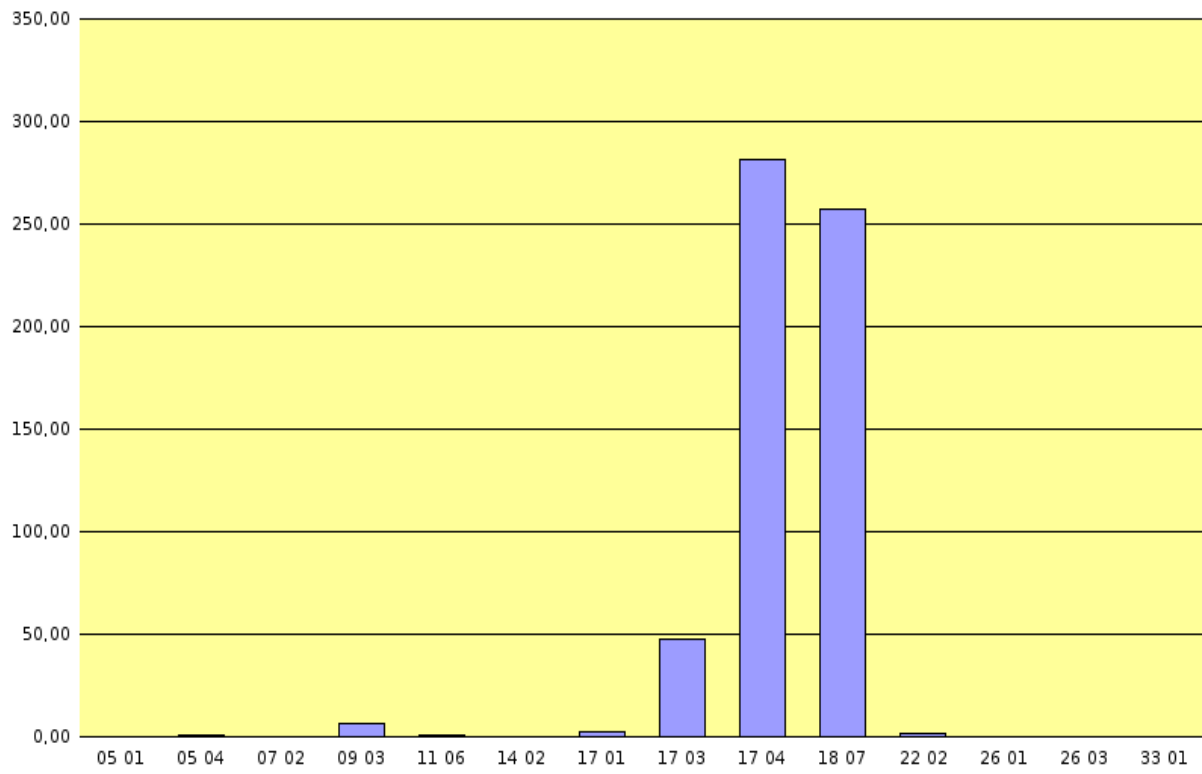


TABLE 3 : BREAKDOWN OF COMMITMENTS TO BE SETTLED AT 31/12/2020 (in Mio €) for DG SANTE									
Chapter			Commitments to be settled				Commitments to be settled from financial years previous to 2019	Total of commitments to be settled at end of financial year 2020	Total of commitments to be settled at end of financial year 2019
			Commitments	Payments	RAL	% to be settled			
			1	2	3=1-2	4=1-2/1	5	6=3+5	7
05	05 01	Administrative expenditure of the 'Agriculture and rural development' policy area	3,71	3,71	0,00	0,00%	0,00	0,00	0,00
	05 04	Rural development	0,35	0,00	0,35	100,00%	0,53	0,88	0,81
<b>Total Title 05</b>			<b>4,06</b>	<b>3,71</b>	<b>0,35</b>	<b>8,61%</b>	<b>0,53</b>	<b>0,88</b>	<b>0,81</b>
07	07 02	Environmental policy at Union and international level	0,12	0,06	0,06	48,89%	0,12	0,18	0,19
<b>Total Title 07</b>			<b>0,12</b>	<b>0,06</b>	<b>0,06</b>	<b>48,89%</b>	<b>0,12</b>	<b>0,18</b>	<b>0,19</b>
09	09 03	Connecting Europe Facility (CEF) - Telecommunications networks	2,76	0,00	2,76	99,97%	3,54	6,30	7,17
<b>Total Title 09</b>			<b>2,76</b>	<b>0,00</b>	<b>2,76</b>	<b>99,97%</b>	<b>3,54</b>	<b>6,30</b>	<b>7,17</b>
11	11 06	European Maritime and Fisheries Fund (EMFF)	0,38	0,00	0,38	100,00%	0,13	0,51	0,40
<b>Total Title 11</b>			<b>0,38</b>	<b>0,00</b>	<b>0,38</b>	<b>100,00%</b>	<b>0,13</b>	<b>0,51</b>	<b>0,40</b>
14	14 02	Customs	0,20	0,00	0,20	100,00%	0,16	0,36	0,36
<b>Total Title 14</b>			<b>0,20</b>	<b>0,00</b>	<b>0,20</b>	<b>100,00%</b>	<b>0,16</b>	<b>0,36</b>	<b>0,36</b>
17	17 01	Administrative expenditure of the 'Health and food safety' policy area	11,91	9,41	2,50	21,03%	0,00	2,50	2,21
	17 03	Public health	248,98	222,66	26,32	10,57%	21,65	47,96	30,86
	17 04	Food and feed safety, animal health, animal welfare and plant health	234,15	60,34	173,80	74,23%	107,66	281,46	309,78
<b>Total Title 17</b>			<b>495,03</b>	<b>292,41</b>	<b>202,62</b>	<b>40,93%</b>	<b>129,31</b>	<b>331,93</b>	<b>342,86</b>
18	18 07	Instrument for emergency support within the Union	2.772,28	2.514,77	257,51	9,29%	0,00	257,51	0,00
<b>Total Title 18</b>			<b>2.772,28</b>	<b>2.514,77</b>	<b>257,51</b>	<b>9,29%</b>	<b>0,00</b>	<b>257,51</b>	<b>0,00</b>
22	22 02	Enlargement process and strategy	0,00	0,00	0,00	0,00%	1,22	1,22	1,50
<b>Total Title 22</b>			<b>0,00</b>	<b>0,00</b>	<b>0,00</b>	<b>0,00%</b>	<b>1,22</b>	<b>1,22</b>	<b>1,50</b>
26	26 01	Administrative expenditure of the 'Commission's administration' policy area	0,50	0,25	0,24	48,69%	0,00	0,24	0,22
	26 03	Services to public administrations, businesses and citizens	0,30		0,30	100,00%	0,00	0,30	0,00
<b>Total Title 26</b>			<b>0,80</b>	<b>0,25</b>	<b>0,54</b>	<b>68,02%</b>	<b>0,00</b>	<b>0,54</b>	<b>0,22</b>
33	33 01	Administrative expenditure of the 'Justice and consumers' policy area	1,88	1,88	0,00	0,00%	0,00	0,00	0,00
<b>Total Title 33</b>			<b>1,88</b>	<b>1,88</b>	<b>0,00</b>	<b>0,00%</b>	<b>0,00</b>	<b>0,00</b>	<b>0,00</b>
<b>Total for DG SANTE</b>			<b>3277,510633</b>	<b>2813,09</b>	<b>464,4201824</b>	<b>14,17 %</b>	<b>135,007582</b>	<b>599,4277644</b>	<b>353,514388</b>



Breakdown of Commitments Remaining to be Settled (in Mio EUR) in 2020 SANTE



**TABLE 4 : BALANCE SHEET for DG SANTE**

BALANCE SHEET	2020	2019
<b>A.I. NON CURRENT ASSETS</b>	<b>163.319.095,21</b>	<b>28.213.116,30</b>
A.I.1. Intangible Assets	7.574.121,31	2.902.780,63
A.I.2. Property, Plant and Equipment	8.991.859,31	10.414.364,87
A.I.5. Non-Current Pre-Financing	146.753.114,59	14.895.970,80
<b>A.II. CURRENT ASSETS</b>	<b>831.098.560,52</b>	<b>1.209.001,58</b>
A.II.2. Current Pre-Financing	818.472.436,25	11.684.860,39
A.II.3. Curr Exch Receiv & Non-Ex Recoverables	1.015.245,07	1.282.811,99
A.II.4. Inventories	11.608.435,00	11.608.435,00
A.II.6. Cash and Cash Equivalents	2.444,20	2.614,98
<b>ASSETS</b>	<b>994.417.655,73</b>	<b>29.422.117,88</b>
<b>P.I. NON CURRENT LIABILITIES</b>	-	2.057.096,10
P.I.3. Non-Current Financial Liabilities	-	2.057.096,10
<b>P.II. CURRENT LIABILITIES</b>	338.459.277,95	244.556.614,38
P.II.2. Current Provisions	111.226.274,26	70.205.337,10
P.II.3. Current Financial Liabilities	2.056.200,99	2.053.565,05
P.II.4. Current Payables	21.650.179,11	13.978.087,45
P.II.5. Current Accrued Charges & Defrd Income	203.526.623,59	158.319.624,78
<b>LIABILITIES</b>	<b>338.459.277,95</b>	<b>246.613.710,48</b>
<b>NET ASSETS (ASSETS less LIABILITIES)</b>	<b>655.958.377,78</b>	<b>217.191.592,60</b>
P.III.2. Accumulated Surplus/Deficit	2.812.658.079,86	2.373.861.772,90
Non-allocated central (surplus)/deficit*	3.468.616.457,64	2.156.670.180,30
<b>TOTAL DG SANTE</b>	<b>-</b>	<b>-</b>

It should be noted that the balance sheet and statement of financial performance presented in Annex 3 to this Annual Activity Report, represent only the assets, liabilities, expenses and revenues that are under the control of this Directorate General. Significant amounts such as own resource revenues and cash held in Commission bank accounts are not included in this Directorate General's accounts since they are managed centrally by DG Budget, on whose balance sheet and statement of financial performance they appear. Furthermore, since the accumulated result of the Commission is not split amongst the various Directorates General, it can be seen that the balance sheet presented here is not in equilibrium.

Additionally, the figures included in tables 4 and 5 are provisional since they are, at this date, still subject to audit by the Court of Auditors. It is thus possible that amounts included in these tables may have to be adjusted following this audit.

**TABLE 5 : STATEMENT OF FINANCIAL PERFORMANCE for DG SANTE**

<b>STATEMENT OF FINANCIAL PERFORMANCE</b>	<b>2020</b>	<b>2019</b>
II.1 REVENUES	- 758.371.129,04	- 6.294.190,56
II.1.1. NON-EXCHANGE REVENUES	- 762.331.763,24	- 10.099.544,14
II.1.1.5. RECOVERY OF EXPENSES	- 1.762.673,04	- 505.941,31
II.1.1.7. OTHER NON-EXCHANGE REVENUES	- 760.569.090,20	- 9.593.602,83
II.1.2. EXCHANGE REVENUES	3.960.634,20	3.805.353,58
II.1.2.2. OTHER EXCHANGE REVENUE	3.960.634,20	3.805.353,58
II.2. EXPENSES	2.127.726.520,88	445.090.497,52
II.2. EXPENSES	2.127.726.520,88	445.090.497,52
II.2.10. OTHER EXPENSES	104.079.138,94	63.456.349,56
II.2.2. EXP IMPL BY COMMISS&EX AGENC. (DM)	1.796.353.714,94	203.021.870,13
II.2.3. EXP IMPL BY OTH EU AGENC&BODIES (IM)	219.564.410,27	175.027.620,86
II.2.4. EXP IMPL BY 3RD CNTR & INT ORG (IM)	8.127.383,99	3.331.194,73
II.2.5. EXP IMPL BY OTHER ENTITIES (IM)		239.286,69
II.2.6. STAFF AND PENSION COSTS	- 401.620,00	8.000,00
II.2.8. FINANCE COSTS	3.492,74	6.175,55
<b>STATEMENT OF FINANCIAL PERFORMANCE</b>	<b>1.369.355.391,84</b>	<b>438.796.306,96</b>

*Explanatory Notes (facultative):*

It should be noted that the balance sheet and statement of financial performance presented in Annex 3 to this Annual Activity Report, represent only the assets, liabilities, expenses and revenues that are under the control of this Directorate General. Significant amounts such as own resource revenues and cash held in Commission bank accounts are not included in this Directorate General's accounts since they are managed centrally by DG Budget, on whose balance sheet and statement of financial performance they appear. Furthermore, since the accumulated result of the Commission is not split amongst the various Directorates General, it can be seen that the balance sheet presented here is not in equilibrium.

Additionally, the figures included in tables 4 and 5 are provisional since they are, at this date, still subject to audit by the Court of Auditors. It is thus possible that amounts included in these tables may have to be adjusted following this audit.

**TABLE 5bis : OFF BALANCE SHEET for DG SANTE**

<b>OFF BALANCE</b>	<b>2020</b>	<b>2019</b>
OB.1. Contingent Assets	-	-
GR for pre-financing	-	-
OB.2. Contingent Liabilities	- 9.673.175,08	- 6.107.428,99
OB.2.6. CL Other	- 9.673.175,08	- 6.107.428,99
OB.2.7. CL Legal cases OTHER	-	-
OB.3. Other Significant Disclosures	- 372.631.109,45	- 177.230.344,73
OB.3.2. Comm against app. not yet consumed	- 372.631.109,45	- 177.230.344,73
OB.4. Balancing Accounts	382.304.284,53	183.337.773,72
OB.4. Balancing Accounts	382.304.284,53	183.337.773,72
<b>OFF BALANCE</b>	-	<b>0,00</b>

*Explanatory Notes (facultative):*

It should be noted that the balance sheet and statement of financial performance presented in Annex 3 to this Annual Activity Report, represent only the assets, liabilities, expenses and revenues that are under the control of this Directorate General. Significant amounts such as own resource revenues and cash held in Commission bank accounts are not included in this Directorate General's accounts since they are managed centrally by DG Budget, on whose balance sheet and statement of financial performance they appear. Furthermore, since the accumulated result of the Commission is not split amongst the various Directorates General, it can be seen that the balance sheet presented here is not in equilibrium.

Additionally, the figures included in tables 4 and 5 are provisional since they are, at this date, still subject to audit by the Court of Auditors. It is thus possible that amounts included in these tables may have to be adjusted following this audit.

**TABLE 6: AVERAGE PAYMENT TIMES in 2020 for SANTE**

Legal Times									
Maximum Payment Time (Days)	Total Number of Payments	Nbr of Payments within Time Limit	Percentage	Average Payment Times (Days)	Nbr of Late Payments	Percentage	Average Payment Times (Days)	Late Payments Amount	Percentage
7	1	1	100,00 %	6				0	0, %
15	1	1	100,00 %	9				0	0, %
28	3	3	100,00 %	18				0	0, %
30	1394	1366	97,99 %	20	28	2,01 %	41	509.342,90	0, %
38	1	1	100,00 %	31				0	0, %
45	41	41	100,00 %	15				0	0, %
47	1	1	100,00 %	28				0	0, %
60	82	82	100,00 %	28				0	0, %
74	1	1	100,00 %	26				0	0, %
88	2	2	100,00 %	45				0	0, %
90	210	194	92,38 %	63	16	7,62 %	112	11.108.780,16	8, %
94	1	1	100,00 %	18				0	0, %
212	1	1	100,00 %	24				0	0, %

Total Number of Payments	1739	1695	97,47 %		44	2,53 %		11.618.123,06	0, %
Average Net Payment Time	26			25			67		
Average Gross Payment Time	39			36			118		

Suspensions							
Average Report Approval Suspension Days	Average Payment Suspension Days	Number of Suspended Payments	% of Total Number	Total Number of Payments	Amount of Suspended Payments	% of Total Amount	Total Paid Amount
0	68	314	18,06 %	1739	130.323.244,84	4,35 %	2.993.201.538,88

DG	GL Account	Description	Amount (Eur)

**NB: Table 6 only contains payments relevant for the time statistics. Please consult its exact scope in the AAR Annex3 BO User Guide ([https://myintracomm.ec.europa.eu/budqweb/EN/abac/dwh/Pages/its-030-10-20\\_documentation.aspx](https://myintracomm.ec.europa.eu/budqweb/EN/abac/dwh/Pages/its-030-10-20_documentation.aspx)).**

TABLE 7 : SITUATION ON REVENUE AND INCOME in 2020 for DG SANTE								
Chapter		Revenue and income recognized			Revenue and income cashed from			Outstanding balance
		Current year RO	Carried over RO	Total	Current Year RO	Carried over RO	Total	
		1	2	3=1+2	4	5	6=4+5	
57	OTHER CONTRIBUTIONS AND REFUNDS IN CONNECTION WITH THE ADMINISTRATIVE OPERATION OF THE INSTITUTION	1.765.859,23	0,00	1.765.859,23	1.761.149,63	0,00	1.761.149,63	4.709,60
59	OTHER REVENUE ARISING FROM ADMINISTRATIVE MANAGEMENT	403.010,15	0,00	403.010,15	403.010,15	0,00	403.010,15	0,00
60	CONTRIBUTIONS TO UNION PROGRAMMES	203.820,00	0,00	203.820,00	203.820,00	0,00	203.820,00	0,00
66	OTHER CONTRIBUTIONS AND REFUNDS	752.752.109,04	145.254,51	752.897.363,55	752.749.117,22	98.130,92	752.847.248,14	50.115,41
<b>Total DG SANTE</b>		<b>755.124.798,42</b>	<b>145.254,51</b>	<b>755.270.052,93</b>	<b>755.117.097,00</b>	<b>98.130,92</b>	<b>755.215.227,92</b>	<b>54.825,01</b>

**TABLE 8 : RECOVERY OF PAYMENTS in 2020 for DG SANTE  
(Number of Recovery Contexts and corresponding Transaction Amount)**

INCOME BUDGET RECOVERY ORDERS ISSUED IN 2020	Irregularity		Total undue payments recovered		Total transactions in recovery context (incl. non-qualified)		% Qualified/Total RC	
	Year of Origin (commitment)							
	Nbr	RO Amount	Nbr	RO Amount	Nbr	RO Amount	Nbr	RO Amount
2011	1	-	1	-	1	-	100,00%	#DIV/0
2013	1	267.934,19	1	267.934,19	1	267.934,19	100,00%	100,00%
2014	2	101.421,20	2	101.421,20	2	101.421,20	100,00%	100,00%
2015	2	78.477,40	2	78.477,40	2	78.477,40	100,00%	100,00%
2016	7	484.347,96	7	484.347,96	7	484.347,96	100,00%	100,00%
2017	1	44.299,67	1	44.299,67	1	44.299,67	100,00%	100,00%
2018	2	14.534,84	2	14.534,84	3	23.427,99	66,67%	62,04%
2019					9	3.211.336,44		
2020					5	709.409,60		
<b>Sub-Total</b>	<b>16</b>	<b>991.015,26</b>	<b>16</b>	<b>991.015,26</b>	<b>31</b>	<b>4.920.654,45</b>	<b>51,61%</b>	<b>20,14%</b>

EXPENSES BUDGET	Irregularity		OLAF Notified		Total undue payments recovered		Total transactions in recovery context (incl. non-qualified)		% Qualified/Total RC	
	Nbr	Amount	Nbr	Amount	Nbr	Amount	Nbr	Amount	Nbr	Amount
INCOME LINES IN INVOICES							1	322,97		
NON ELIGIBLE IN COST CLAIMS	115	11.308.446,88			115	11.308.446,88	131	53.233.752,14	87,79%	21,24%
CREDIT NOTES	20	259.064,54			20	259.064,54	82	971.521,12	24,39%	26,67%
<b>Sub-Total</b>	<b>135</b>	<b>11.567.511,42</b>			<b>135</b>	<b>11.567.511,42</b>	<b>214</b>	<b>54.205.596,23</b>	<b>63,08%</b>	<b>21,34%</b>
<b>GRAND TOTAL</b>	<b>151</b>	<b>12.558.526,68</b>			<b>151</b>	<b>12.558.526,68</b>	<b>245</b>	<b>59.126.250,68</b>	<b>61,63%</b>	<b>21,24%</b>

**TABLE 9: AGEING BALANCE OF RECOVERY ORDERS AT 31/12/2020 for DG SANTE**

	Number at 1/01/2020	Number at 31/12/2020	Evolution	Open Amount (Eur) at 1/01/2020	Open Amount (Eur) at 31/12/2020	Evolution
2011	1	1	0,00 %	145.254,51	47.123,59	-67,56 %
2020		2			7.701,42	
	1	3	200,00 %	145.254,51	54.825,01	-62,26 %

**TABLE 10 :Recovery Order Waivers >= 60 000 € in 2020 for DG SANTE**

	Waiver Central Key	Linked RO Central Key	RO Accepted Amount (Eur)	LE Account Group	Commission Decision	Comments
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<b>Total DG SANTE</b>	
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<b>Number of RO waivers</b>	
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*Justifications:*

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**TABLE 11 : Negotiated Procedures in 2020 for DG SANTE**

**Internal Procedures > € 60,000**

Negotiated Procedure Legal base	Number of Procedures	Amount (€)
Annex 1 - 11.1 (b) - Artistic/technical reasons or exclusive rights or technical monopoly/captive market	2	7.415.000,00
Annex 1 - 11.1 (c) - Extreme urgency caused by unforeseeable events not attributable to the contracting authority	10	2.679.074.925,00
<b>Total</b>	<b>12</b>	<b>2.686.489.925,00</b>

**TABLE 12 : Summary of Procedures in 2020 for DG SANTE**

**Internal Procedures > € 60,000**

Procedure Legal base	Number of Procedures	Amount (€)
Negotiated procedure middle value contract (Annex 1 - 14.2)	1	98.000,00
Negotiated procedure without prior publication (Annex 1 - 11.1)	12	2.686.489.925,00
Open procedure (FR 164 (1)(a))	3	1.793.521,72
Restricted procedure without Dynamic purchasing system (FR 164 (1)(b))	1	1.673.496,56
<b>Total</b>	<b>17</b>	<b>2.690.054.943,28</b>

**Additional Comments:**

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**TABLE 13 : BUILDING CONTRACTS in 2020 for DG SANTE**

Legal Base	Procedure subject	Contract Number	Contractor Name	Contract Subject	Contracted Amount (€)

**TABLE 14 : CONTRACTS DECLARED SECRET in 2020 for DG SANTE**

Legal Base	LC Date	Contract Number	Contract Subject	Contracted Amount (€)



**TABLE 15 : FPA duration exceeds 4 years - DG**

*None of your FPA (if any) exceeds 4 years*


## **ANNEX 4 : Financial Scorecard**


The Annex 4 summarises the annual result of the standard financial indicators measurement. Six standard financial indicators are presented below, each with its objective, category, definition, and result for DG SANTE and for the EC as a whole (for benchmarking purposes):

- Commitment Appropriations (CA) Implementation
- CA Forecast Implementation
- Payment Appropriations (PA) Implementation
- PA Forecast Implementation
- Global Commitment Absorption
- Timely Payments

For each indicator, its value (in %) for DG SANTE is compared to the common target (in %). The difference between the indicator's value and the target is colour coded as follows:

- 100 – >95% of the target: dark green
- 95 – >90% of the target: light green
- 90 – >85% of the target: yellow
- 85 – >80% of the target: light red
- 80 – 0% of the target: dark red

<b>Indicator</b>	<b><u>Commitment Appropriations (CA) Implementation</u></b>
<b>Category</b>	Efficiency Controls / Budget
<b>Objective</b>	Ensure efficient use of commitment appropriations
<b>Result</b>	<p>DG SANTE achieved <b>100%</b> compared to the EC result of <b>99%</b></p>  <p>A horizontal bar chart with a scale from 0% to 100% in 20% increments. The bar is filled with red up to the 100% mark. A vertical line is drawn at the 99% mark, labeled 'EC (99%)'. The 100% mark is labeled '100%'.</p>
<b>Comment</b>	
<b>Definition</b>	<p><b>Formula:</b> Value A / Value B</p> <ul style="list-style-type: none"> <li>- Value A: Committed L1 Accepted Amount + Direct Committed L2 Accepted Amount (EUR)</li> <li>- Value B: Credit Accepted Com Amount (EUR)</li> </ul> <p><b>Scope:</b></p> <p>Commitments on all relevant Fund Sources, except for:</p> <ul style="list-style-type: none"> <li>- Internal assigned revenue in first year (C4)</li> <li>- Internal assigned revenue from lettings and sale of buildings and lands (CL)</li> <li>- Repaid advances (structural funds) (C6)</li> <li>- External assigned revenue except for EFTA (FCA ,FRT, PO, RO, TCA, TF5, TFC)</li> </ul>

<b>Indicator</b>	<b><u>Payment Appropriations (PA) Implementation</u></b>
<b>Category</b>	Efficiency Controls / Budget
<b>Objective</b>	Ensure efficient use of payment appropriations
<b>Result</b>	<p>DG SANTE achieved <b>94%</b> compared to the EC result of <b>99%</b></p>  <p>A horizontal bar chart with a scale from 0% to 100% in 20% increments. The bar is filled with red up to the 80% mark, then yellow up to the 94% mark. A vertical line is drawn at the 99% mark, labeled 'EC (99%)'. The 94% mark is labeled '94%'.</p>
<b>Comment</b>	The payment credits were not implemented in full, as a high amount of pre-financing which was scheduled to be paid in December to a vaccine producer had to be postponed as conditions for payment were not fulfilled. The payment credits were carried over to 2021.
<b>Definition</b>	<p><b>Formula:</b> Value A / Value B</p> <ul style="list-style-type: none"> <li>- Value A: Payment Accepted Amount (Eur)</li> <li>- Value B: Credit Accepted Pay Amount (Eur)</li> </ul> <p><b>Scope:</b></p> <p>Payments on all relevant Fund Sources, except for:</p> <ul style="list-style-type: none"> <li>- Internal assigned revenue in first year (C4)</li> <li>- Internal assigned revenue from lettings and sale of buildings and lands (CL)</li> <li>- Repaid advances (structural funds) (C6)</li> <li>- External assigned revenue except for EFTA (FCA ,FRT, PO, RO, TCA, TF5, TFC)</li> </ul> <p>Payments stemming from C1, C5, EO outstanding commitments on the non-staff budget positions that will be carried-forward as C8 to the next financial year</p>

<b>Indicator</b>	<b><u>CA Forecast Implementation</u></b>
<b>Category</b>	Efficiency Controls / Budget
<b>Objective</b>	Ensure the cumulative alignment of the commitment implementation with the commitment forecast in a financial year
<b>Result</b>	<p>DG SANTE achieved <b>46%</b> compared to the EC result of <b>98%</b></p>
<b>Comment</b>	<p><b>The actual commitment implementation in 2020 was 154% compared to the target.</b> DG SANTE exceeded the forecast implementation as it received additional funds further to the activation of the Emergency Support Instrument (ESI) in April 2020 to be committed by end of the year 2020.</p> <p>The forecast indicator calculates the absolute distance (in %) between the forecast implementation and the target of 100%, i.e. the forecast implementation of 54% above the forecast leads to a score of 46% (100% -54%).</p>
<b>Definition</b>	<p><b>Formula:</b> Value A / Value B<sup>*,**</sup></p> <ul style="list-style-type: none"> <li>- Value A: Committed L1 Accepted Amount + Direct Committed L2 Accepted Amount (Eur)</li> <li>- Value B: Commitment Forecast Amount (Eur)</li> </ul> <p><i>*if Value A / Value B between 100 and 200% then the result indicator will be equal to 1 - (ABS(Value B - Value A) / Value B)</i></p> <p><i>**if Value A / Value B &gt; 200 % then the result indicator will be equal to 0%</i></p> <p><b>Scope:</b></p> <ul style="list-style-type: none"> <li>- Commitments on all relevant Fund Sources</li> <li>- Commitment Forecast Amount (Eur) from the most up to date forecast version (Initial Mar-Aug, Revised Sep-Dec)</li> </ul>

<b>Indicator</b>	<b><u>PA Forecast Implementation</u></b>
<b>Category</b>	Efficiency Controls / Budget
<b>Objective</b>	Ensure the cumulative alignment of the payment implementation with the payment forecast in a financial year
<b>Result</b>	<p>DG SANTE achieved <b>25%</b> compared to the EC result of <b>99%</b></p>
<b>Comment</b>	<p><b>The actual payment implementation in 2020 was 175% compared to the target.</b> DG SANTE exceeded the forecast implementation as it received additional funds further to the activation of the Emergency Support Instrument (ESI) in April 2020 for actions to be implemented in the period from February 2020 until January 2022.</p> <p>The forecast indicator calculates the absolute distance (in %) between the forecast implementation and the target of 100%, i.e. the forecast implementation of 75% above the forecast leads to a score of 25% (100% -75%).</p>
<b>Definition</b>	<p><b>Formula:</b> Value A / Value B***</p> <ul style="list-style-type: none"> <li>- Value A: Payment Accepted Amount (Eur)</li> <li>- Value B: Payment Forecast Amount (Eur)</li> </ul> <p>*if Value A / Value B between 100 and 200% then the result indicator will be equal to 1 - (ABS(Value B - Value A) / Value B)</p> <p>**if Value A / Value B &gt; 200 % then the result indicator will be equal to 0%</p> <p><b>Scope:</b></p> <ul style="list-style-type: none"> <li>- Payments on all relevant Fund Sources</li> <li>- Payment Forecast Amount (Eur) from the most up to date forecast version (Initial Mar-Aug, Revised Sep-Dec)</li> </ul>

<b>Indicator</b>	<b><u>Global Commitment Absorption</u></b>
<b>Category</b>	Efficiency Controls / Absorption
<b>Objective</b>	Ensure efficient use of already earmarked commitment appropriations (at L1 level)
<b>Result</b>	<p>DG SANTE achieved <b>84%</b> compared to the EC result of <b>98%</b></p> <p>0%      20%      40%      60%      80%      100%</p> <p>84%      EC (98%)</p>
<b>Comment</b>	The relatively low absorption rate of global commitments made in 2019 concern mainly grants for animal health emergency measures that were not individualised in 2020 for administrative reasons and – inter alia – given the situation in the Member States and in neighbouring countries.
<b>Definition</b>	<p><b>Formula:</b></p> <ul style="list-style-type: none"> <li>- Value A: Com L1 Consumption amount (Eur)</li> <li>- Value B: Com L1 Initial amount (Eur) + Com L1 Complementary Amount (Eur) + (Com L1 Decommitment Amount (Eur) on all Fund Sources except for C8 and C9)</li> </ul> <p><b>Scope:</b></p> <ul style="list-style-type: none"> <li>- Com L1 with FDC ILC date from 01/01 to 31/12 of the current year</li> <li>- No movements to the Com L1 Consumption amount (Eur) after the FDC ILC date is taken into account (Generally decommitments of L2 which decrease the Com L1 consumption)</li> </ul> <p><b>Remark:</b> Due to technical limitation, the indicator does not take into account the Com L1 Consumption between the FDC ILC date and the FA FDI allowed as an exception in the external actions for Com L1 of type GF, i.e. with Financing Agreement, under the FR2018 Article 114.2. As a result, the actual Indicator score may be slightly higher than the one reported for DGs using the GF commitments.</p>

<b>Indicator</b>	<b><u>Timely Payments</u></b>
<b>Category</b>	Efficiency Controls / Timeliness
<b>Objective</b>	Ensure efficient processing of payments within the legal deadlines
<b>Result</b>	<p>DG SANTE achieved <b>100%</b> compared to the EC result of <b>99%</b></p> <p>The chart shows a horizontal axis from 0% to 100% with tick marks at 0%, 20%, 40%, 60%, 80%, and 100%. A red bar extends to the 100% mark, labeled '100%'. A yellow bar extends to the 99% mark, labeled 'EC (99%)'.</p>
<b>Comment</b>	In 2020, DG SANTE's indicator of timely payments (100% of payments made on time in amount) is higher than the Commission average of 99% thanks to performant monitoring of payment time limits. To be noted that DG SANTE processed several pre-financing payments of very large amounts under the Emergency Support Instrument.
<b>Definition</b>	<p><b>Formula:</b> Value A / Value B</p> <ul style="list-style-type: none"> <li>- Value A: Payment Accepted Amount (Eur) in time <ul style="list-style-type: none"> <li>o In Time: Payment Bank Value Date &lt; = Payment legal deadline</li> </ul> </li> <li>- Value B: Payment Accepted Amount (Eur)</li> </ul> <p><b>Scope:</b></p> <ul style="list-style-type: none"> <li>- Payments made in the current year</li> <li>- Payments valid for payment statistics (DWH Flag "Payment Time Status OK?" = "Y")</li> </ul>

## **ANNEX 5: Materiality criteria**

With regard to budget implementation, the concept of materiality provides the authorising officer by delegation with a basis for determining significant weaknesses that should be subject to a formal reservation to the declaration of assurance. The criteria used in DG SANTE for making reservations are based on the standing instructions for the preparation of Annual Activity Reports.

Risks or weaknesses leading to a reservation should fall within the scope of the declaration which covers a narrower area than the AAR itself:

- ⇒ The AAR includes an assessment of the results achieved by DG SANTE with the resources allocated. It is a "mirror" image of DG SANTE's annual Management Plan (MP).
- ⇒ The declaration expresses the Director's General responsibilities conferred under the Charter for Authorising Officers by Delegation and is restricted to the following areas (i) control systems, (ii) sound financial management, and (iii) legality and regularity of transactions.

**When defining whether a detected issue in internal control is material, DG SANTE assesses both qualitative and quantitative aspects:**

### **1. Qualitative criteria**

DG SANTE investigates the significance of any detected weakness and the expected potential for further weaknesses in qualitative terms by taking into account the nature and scope of the weakness, the possible impact of the weakness, as well as the existence of effective corrective actions.

#### **1.1 Significant repetitive errors**

Systematic errors caused by weaknesses in key controls and intentional misstatements are likely to entail a greater exposure to potential financial loss than random errors or faulty judgements. In the context of grant management and certain procurements, the exposure to potential financial loss is highest for errors in final payments. For errors in pre-financing payments, the risk is much lower because firstly, these funds remain the property of the EU and secondly, errors detected in pre-financing or interim payments can still be corrected at the final payment stage.

#### **1.2 Significant deficiencies in one of the control systems**

Identified weaknesses in the design or operation of internal controls of DG SANTE, final beneficiaries or Member States could significantly influence the appreciation of the Director's General Declaration.

This could be the case notably,

- if significant conflicts of interest existed;
- if personnel were unqualified;
- if the systems failed to provide complete and accurate information due to design flaws or misapplication of procedures;



- if appropriate verifications, approvals, reviews and audits of transactions and procedures were absent or largely insufficient or inadequate;
- if duties were not separated; or
- if controls were intentionally overridden and/or wilfully circumvented.

### **1.3 Issues outlined by auditors or OLAF**

A critical observation made by the Court of Auditors, the Commission's Internal Audit Service (IAS) or OLAF could lead to a reservation,

- if the observation is made in an area covered by the Director's Declaration, and
- if the issue is not solved immediately during the reporting period, and
- if the impact is material (financial loss exceeding 2 % of the implemented budget concerned (ABB activity; see point 2 below).

### **1.4 Significant reputational risks**

Besides a possible quantitative aspect of a reputational risk, its impact on the declaration of assurance is assessed mainly on the basis of qualitative criteria, such as sensitivity of the policy area concerned, high public interest or serious legislative concerns. It encompasses issues that could cause lasting damage to the Commission's image due to, for example, financial fraud inside DG SANTE or serious breaches on provisions of legislation (including the Treaty), further to DG SANTE's activities.

## **2. Quantitative criterion**

### **2.1 Erroneous transactions**

In the framework of a transaction-based approach, DG SANTE considers that identified erroneous transactions which expose DG SANTE to an actual financial loss could lead to a reservation to the Director's General declaration under the following conditions:

- (1) A significant weakness described in the AAR has been identified, and
- (2) The weakness affects at least one the areas of the declaration of assurance: (i) control systems, (ii) sound financial management, or (iii) legality and regularity of transactions, and
- (3) An actual financial loss or reputational issue has already occurred or is very likely to materialise, and
- (4) The amount has actually exceeded or is very likely to exceed the threshold of 2 % of the relevant payment budget actually implemented, that means if the issue is not already corrected during the reporting period, for example by recovery orders or offsetting with future payments due.

For on-the-spot controls of payments,

- Errors found in ex-ante controls are typically corrected prior to the final payment.
- Errors found during ex-post controls (after the final payment) are called detected errors and are typically corrected by recovery orders or other kinds of corrections.

The detected error rate is the basis to estimate the risk at payment and the risk at closure.

## **2.2 Error rate calculation**

For on-the-spot controls of payments, an error rate after corrective measures is called "residual error rate" The risk is calculated following Commission's guidelines built up along the lines of a "3+1 steps" approach and measured against the 2% materiality criterion.

- Step 1: calculating the representative detected error rate in a sample of transactions and taking account of any corrections made for the calculation of the residual error rate in the entire population;
- Step 2: estimating the financial exposure as (net) 'amount at risk' to the value of the relevant payments authorised during the reporting year, based on those error rates calculated for a population of transactions mostly authorised in previous years;
- Step 3: relating the 'amount at risk' for the activity considered to the relevant (ABB) aggregation level for determining whether a reservation would be due;
- Step 4: "if" a reservation is entered, then assessing its relative impact on the AOD's overall assurance and Declaration (the "scope"). The following 'de minimis' thresholds are applied: if the scope of the reservation is < 5% of total payments and the exposure is < EUR 5 million, then no financial reservation is to be made (without prejudice to a reservation for reputational reasons).

## **2.3 Non-representative sampling**

For selecting the sample of transactions to be controlled on the spot, DG SANTE applies a risk based and targeted approach rather than a statistical random method that would comply with the criteria of samples' representativeness. The risk based approach is considered more cost-effective given the heterogeneity and relatively small size of DG SANTE's audit population.

In this case the detected error rate is not representative and thus cannot be extrapolated to all payments made in the same policy area. When measuring against the 2% materiality level, DG SANTE calculates the weighted arithmetic average error rate from the audited sample and complements the information by a qualitative analysis of the origin, nature, impact and coverage of the errors found before deciding whether or not the materiality threshold of 2% is exceeded.

## **2.4 De minimis' threshold for financial reservations**

Since 2019 , a 'de minimis' threshold for financial reservations has been introduced. Quantified AAR reservations related to residual error rates above the 2% materiality threshold, are considered not substantial for segments representing less than 5% of a DG's total payments and with a financial impact below EUR 5 million. In such cases, quantified reservations are no longer needed.

;

## **ANNEX 6: Relevant Control Systems for budget implementation**

### **Annex 6.1 Relevant Control System for budget implementation under direct management**

This Annex is divided into two parts, firstly, DG SANTE's control strategy related to grants in the Food and Feed policy area and secondly, DG SANTE's control strategy for public procurement procedures.

#### **6.1.1.Type of expenditure: grants to Member States in direct management**

DG SANTE co-finances Member States' programmes for animal disease eradication and monitoring, veterinary emergency measures and phytosanitary measures through the reimbursement of eligible costs. Since 2016, the Common Financial Framework (CFF, Regulation (EU) No 652/2014) is the main basis for the corresponding expenditure.

The following descriptions focus on the national programmes for animal disease eradication and control as these account for about 52% of the grants in the Food and Feed policy area in 2020. The controls described below are implemented as far as applicable for other kinds of grants in the Food and Feed policy area.

This annex presents in schematic form the characteristics of the main management and control systems put in place by DG SANTE.

- ! Information on the costs and benefits of control is not always available for each single control stage, but for the process as a whole.
- ! Most of the benefits of control are non-quantifiable as they help ensure compliance and good quality of the funded actions which is impossible to quantify.
- ! For some control indicators, mere numbers and percentages do not give reliable information on the control effectiveness; only a qualitative analysis of the reasons behind the figures is relevant and useful.

## Grants to Member States

Main inherent risks	Mitigating controls	Control coverage	Costs and benefits of controls	Cost-Effectiveness indicators (three E's: effectiveness, efficiency, economy)
<p><b>Stage 1a) Programming: legal base and annual invitation to Member States to submit applications;</b>  <b>1b) Evaluating the national programmes and their EU funding</b></p> <p><i>Main control objectives: ensuring that the Commission selects the national programmes that contribute the most towards the achievement of the policy objectives (effectiveness and best value for public money); compliance (legality &amp; regularity); prevention of fraud (anti-fraud strategy)</i></p>				
<p>a) <b>Eligibility, selection and award criteria</b> should be adequate to evaluate the proposed national programmes and to ensure that the policy objectives are achieved.</p>	<ol style="list-style-type: none"> <li>1. Regulation (EU) No 652/2014 (CFF) applicable to programmes submitted after 15 May 2014 lays down the provisions for the management of expenditure relating – inter alia – to the national programmes for animal disease eradication and control.</li> <li>2. To ensure consistency with these criteria, standard requirements are set for Member States' applications to facilitate the process of submission, approval and assessment of progress during the implementation of the national programmes (Commission decision on a work programmes for the implementation of veterinary programmes).</li> <li>3. DG SANTE provided mandatory electronic templates and application guidelines for the Member States' submissions; information meetings are held to explain the requirements.</li> <li>4. Each year, DG SANTE invites the Member States to submit their proposed annual programmes according to the rules and timeframes.</li> </ol>	<p>The risk is assessed as low as the selection and attribution criteria, the submission modalities and the list of eligible programmes are rather stable over the last few years.</p> <p>Thus, at the programming stage the controls on an annual basis are quite low. They are embedded in stages 1b), 3) and 4) below.</p>	<p><b>Cost of control:</b></p> <ul style="list-style-type: none"> <li>- Included in general estimate of DG SANTE's staff costs for programming, evaluation and grant decision</li> </ul> <p><b>Benefits of control:</b></p> <p>As no significant errors are to be expected, the benefits are mainly administrative in nature and thus non-quantifiable in budgetary terms</p>	<ul style="list-style-type: none"> <li>- Ratio of rejected national programmes to total programmes submitted                      ⇒ Target: qualitative analysis of reasons for rejections and adjustments in relation to priority diseases</li> <li>- Timeliness of Commission work programmes                      ⇒ Target: by no later than 30 April of year N-1 for the submission of national programmes for year N by 30 May N-1</li> </ul>

## Grants to Member States

Main inherent risks	Mitigating controls	Control coverage	Costs and benefits of controls	Cost-Effectiveness indicators (three E's: effectiveness, efficiency, economy)
<p>b) The main challenge is to fund only national programmes of <b>good quality to ensure a high impact on the achievement of the policy objectives at reasonable costs</b> and adequate requests for co-financing.</p>	<ol style="list-style-type: none"> <li>1. To ensure a high level of expertise in the evaluation exercise                             <ul style="list-style-type: none"> <li>- Each national programme (technical and financial parts) is assessed by DG SANTE competent staff of the Unit concerned;</li> <li>- External experts, selected through an open call for expression of interest, advise in the technical evaluation; DG SANTE provides a guidance document with checklists and templates on the evaluation procedure; conflict of interest declarations.</li> </ul> </li> <li>2. To ensure high quality and reasonable costs of the national programmes, DG SANTE competent staff requests to Member States additional information or modifications to improve their programmes if deemed necessary.</li> <li>3. Based on the results of the evaluation, DG SANTE facilitates the Member States' finalisation of their national programmes.</li> <li>4. DG SANTE communicates to Member States (Standing Committee (PAFF)) by 30 November each year the list of national programmes technically approved and proposed for co-financing.</li> </ol>	<ol style="list-style-type: none"> <li>1a. 100% vetting of external experts for technical expertise and independence</li> <li>1b. 100% of national programmes are evaluated following a standard procedure (technical and financial parts)</li> <li>2. 100% supervision of work of external evaluators in DG SANTE</li> <li>3. 100% of national programmes modified as requested by DG SANTE</li> </ol>	<p><b>Cost of control:</b></p> <ul style="list-style-type: none"> <li>- Included in general estimate of DG SANTE's staff costs for programming, evaluation and grant decision</li> <li>- Estimated costs of the appointed external experts and logistics for the evaluation</li> </ul> <p><b>Benefits of control:</b></p> <p>The evaluation of the proposed national programmes helps to ensure that national programmes are compliant with the legislation and of good quality. This control is a very significant to ensure value for money through improved quality, but the benefit is not quantifiable.</p>	<ul style="list-style-type: none"> <li>- Ratio of modified programmes to total programmes retained after evaluation                             <ul style="list-style-type: none"> <li>⇒ Target: qualitative analysis of reasons for rejections and modifications</li> </ul> </li> <li>- Evaluation procedure finalised on-time to allow a timely launch of the national programmes.                             <ul style="list-style-type: none"> <li>⇒ Target: 100% on time fixed in the legislation</li> </ul> </li> </ul>

## Grants to Member States

Main inherent risks	Mitigating controls	Control coverage	Costs and benefits of controls	Cost-Effectiveness indicators (three E's: effectiveness, efficiency, economy)
<p><b>Stage 2 “Contracting”:</b> approving the national programmes and the EU financial contribution in a grant decision</p> <p><i>Main control objectives: ensuring that the actions and funds allocation is optimal (best value for public money; effectiveness, economy, efficiency) and compliant (legality &amp; regularity)</i></p>				
<p>The national programmes for which a grant decision is taken by the authorising officer by delegation (AOSD) should correspond to</p> <p>(a) the programmes and amounts communicated to the PAFF and/or</p> <p>(b) the budgetary commitment.</p>	<ol style="list-style-type: none"> <li>1. DG SANTE approves the annual national programmes and associated funding by 31 January each year (awarding decision by the AOSD; communication to the PAFF).</li> <li>2. Following ex-ante checks on administrative and legal aspects of the grant decisions, the AOSD approves formally in a grant decision (one for each Member State) the programmes and their associated funding. by 31 January each year.</li> </ol>	<ol style="list-style-type: none"> <li>1. 100% of programmes to be technically approved prior to preparing the grant decision</li> <li>2. 100% of grant decisions checked prior to approval (depth of checks depends on risk criteria)</li> </ol>	<p><b>Cost of control:</b></p> <ul style="list-style-type: none"> <li>- Included in general estimate of DG SANTE’s staff costs for programming, evaluation and grant decision;</li> </ul> <p><b>Benefits of control:</b></p> <p>Compliance</p>	<ul style="list-style-type: none"> <li>- Grant decisions taken on-time to allow a timely launch of the national programmes.</li> </ul> <p>⇒ Target: 100% on time fixed in the legislation</p>

## Grants to Member States

Main inherent risks	Mitigating controls	Control coverage	Costs and benefits of controls	Cost-Effectiveness indicators (three E's: effectiveness, efficiency, economy)
<p><b>Stage 3: Monitoring the implementation of national programmes and managing financial transactions</b></p> <p><i><b>Main control objectives:</b> ensuring that the operational results or progress from the national programmes are of good quality and meet the objectives and conditions (effectiveness &amp; efficiency); ensuring that the related financial operations comply with regulatory and contractual provisions (legality &amp; regularity); prevention of fraud (anti-fraud strategy); ensuring appropriate accounting of the operations (reliability of reporting, safeguarding of assets and information)</i></p>				
<p>Controls have to prevent that the national programmes' objectives are only partially achieved or not at all and/or that ineligible amounts are paid.</p>	<ol style="list-style-type: none"> <li>1. Member States' reporting requirements for each programme are set forth in Regulation (EU) No 652/2014.</li> <li>2. Competent staff assess intermediate technical and financial reports for each programme and, if need be, funds are reallocated between programmes and Member States.</li> <li>3. Member States' present the results of their programmes to PAFF on their own initiative or when requested by DG SANTE.</li> <li>4. Annual technical and financial reports are assessed by competent staff prior to initiating payments.</li> <li>5. For a few programmes, ex-ante financial on-the-spot controls are carried out; under certain circumstances, the final payment is postponed and only first tranches are paid.</li> <li>6. Payments follow DG SANTE's financial circuits with 1<sup>st</sup> and 2<sup>nd</sup> level financial verifications, authorisations and encodings in ABAC reviewed by DG BUDG.</li> <li>7. If deemed necessary, the file is referred to OLAF (DG SANTE's SOPs apply) .</li> </ol>	<ol style="list-style-type: none"> <li>1 to 4. 100% covered by reporting requirements, monitored at the desk at interim and at final reporting stage (control depth depends on risk criteria)</li> <li>5. Further to a risk assessment, a small number of programmes is audited on the spot prior to the final payment</li> <li>6. 100% of payments and ABAC encodings</li> <li>7. 100% if conditions are fulfilled</li> </ol>	<p><b>Cost of control:</b></p> <ul style="list-style-type: none"> <li>- Estimated staff costs for technical and financial monitoring of the Member States' programmes</li> <li>- Estimated staff costs for ex-ante audit activity</li> <li>- Mission costs for monitoring activities</li> </ul> <p><b>Benefits of control:</b></p> <ul style="list-style-type: none"> <li>- Estimated value of corrections made during 2<sup>nd</sup> level financial controls</li> </ul>	<ul style="list-style-type: none"> <li>- Programmes concerned by the reallocation exercise ⇒ Target: qualitative analysis of reasons for reallocation (e.g. change in legislation or modifications of the programmes)</li> <li>- Estimated value of the financial corrections made during ex-ante controls of the final payment ⇒ Target: &lt;2 %</li> <li>- Files with relevance for OLAF adequately transmitted to OLAF and followed up ⇒ Target: 100%</li> <li>- Time between receipt of the Member States' final financial report and the final payment ⇒ Target: 100% on time</li> <li>- Timely reallocation decision ⇒ Target: 100% on time</li> </ul>

## Grants to Member States

Main inherent risks	Mitigating controls	Control coverage	Costs and benefits of controls	Cost-Effectiveness indicators (three E's: effectiveness, efficiency, economy)
<p><b>Stage 4: Ex-post controls: on-the-spot controls and evaluation</b></p> <p><b>Main control objectives:</b></p> <p>a) <i>Measuring the effectiveness of ex-ante controls by ex-post controls; detect and correct any error or fraud remaining undetected after the implementation ex-ante controls (legality &amp; regularity; anti-fraud strategy); addressing systemic weaknesses in the ex-ante controls, based on the analysis of the findings (sound financial management); ensuring appropriate accounting of the recoveries to be made (reliability of reporting, safeguarding of assets and information);</i></p> <p>b) <i>Ensuring that the (audit) results from the ex-post controls lead to effective recoveries (legality &amp; regularity; anti-fraud strategy); Ensuring appropriate accounting of the recoveries made (reliability of reporting);</i></p> <p>c) <i>Monitoring disease eradication activities in Member States to improve the cost-benefit ratio of animal eradication programmes.</i></p>				
<p>a) Certain issues (errors or attempted fraud) cannot be detected and corrected during ex-ante controls at the desk; thus, <b>ex-post on-the-spot controls</b> should complement the desk checks.</p>	<p>1a. DG SANTE's ex-post control strategy aims at optimising the control impact through a risk based selection of national programmes to be audited and a sufficient audit coverage to lower the residual error rate.</p> <p>1b. The ex-post control strategy and the work plan are adopted annually by DG SANTE's Directors' Steering Committee.</p> <p>2. Ex-post controls are carried out by competent staff or external audit services independent of the policy Unit and according to professional standards; the audit programmes foresee anti-fraud measures.</p> <p>3. All audit reports undergo a contradictory procedure within DG SANTE and with the auditees (i.e. Member States).</p> <p>4. If deemed necessary, the file is referred to OLAF (DG SANTE's SOPs on handling allegations of fraud and contacts with OLAF).</p>	<ul style="list-style-type: none"> <li>- Risk based audit sample</li> <li>- 20% minimum audit coverage to maximise audit correction</li> </ul>	<p><b>Cost of control:</b></p> <ul style="list-style-type: none"> <li>- Estimated staff costs for ex-post controls</li> <li>- Estimated mission costs for ex-post controls</li> <li>- Cost of external audit services.</li> </ul> <p><b>Benefits of control:</b></p> <ul style="list-style-type: none"> <li>- Value of the financial corrections made during ex-post controls</li> </ul>	<ul style="list-style-type: none"> <li>- Detected error rate ⇒ Target: decreasing trend</li> <li>- Residual error rate in ABB activity ⇒ Target: &lt; 2%</li> <li>- Number of files referred to OLAF. ⇒ Target: 0</li> <li>- Time between audit visit and finalisation of audit report not exceeding the internal deadlines ⇒ Target: 100% on time</li> <li>- Implementation of the annual ex-post control work plan ⇒ Target: 100%</li> <li>- Percentage of audit recommendations accepted by the beneficiaries/Member States ⇒ Target: 100%</li> </ul>



## Grants to Member States

Main inherent risks	Mitigating controls	Control coverage	Costs and benefits of controls	Cost-Effectiveness indicators (three E's: effectiveness, efficiency, economy)
<p>b) <b>Detected errors, irregularities or suspicions of fraud should be addressed adequately and in a timely manner.</b></p>	<ol style="list-style-type: none"> <li>1. Systematic communication and registration of all results of ex-post controls.</li> <li>2. Financial and operational validation of recovery orders or additional payments following DG SANTE's financial circuit.</li> </ol>	<ol style="list-style-type: none"> <li>1. 100% of final control results</li> <li>2. 100% 2<sup>nd</sup> level financial control of recovery orders</li> </ol>	<p><b>Cost of control:</b></p> <ul style="list-style-type: none"> <li>- Estimated staff costs for technical and financial monitoring of the Member States' programmes</li> </ul> <p><b>Benefits of control:</b></p> <ul style="list-style-type: none"> <li>- Amount of actually corrected errors</li> </ul>	<ul style="list-style-type: none"> <li>- Audit results related to DG SANTE implemented ⇒ Target: 100%</li> <li>- "Time to recover" from final accepted audit report to debit note ⇒ Target: 100% on time</li> </ul>
<p>c) The main challenge is to <b>ensure a high impact on the achievement of the policy objectives at reasonable costs.</b></p>	<ol style="list-style-type: none"> <li>1. Indicators defined by DG SANTE with experts to evaluate the implementation and management of eradication programmes, the effectiveness of the measures implemented and to measure progress or the deficiency in a specific area. The results of previous years are checked by disease, Member State and programme.</li> <li>2. For specific diseases a task force sub-group has been created to give technical advice to the design and implementation of a programme .</li> </ol>	<ol style="list-style-type: none"> <li>1. All national programmes covered</li> <li>2. Depending on the disease</li> </ol>	<p><b>Cost of control:</b></p> <ul style="list-style-type: none"> <li>- Estimated staff costs for monitoring</li> </ul> <p><b>Benefits of control:</b></p> <p>The evaluation of the proposed national programmes helps ensure that they are compliant with the legislation and of good quality. This control is very significant to ensure value for money through improved quality, but the benefit is not quantifiable.</p>	<ul style="list-style-type: none"> <li>- Percentage of recommendations of the task force implemented by Member States ⇒ Target: 100%</li> <li>- Evolution of the progress measured by DG SANTE staff: achievement of the objectives of the programmes (for eradication, control and monitoring) in relation to the evolution of the disease in previous years ⇒ Target: positive trend</li> </ul>

### 6.1.2. Type of expenditure: procurement in direct management

Following the transfer of implementation tasks to the Executive Agency for Consumers, Health, Agriculture and Food (CHAFEA), public procurement in relation to the Public Health programmes as well as the procurement procedure for the initiative “Better Training for Saver Food” (BTSF) is managed by the agency. Consequently, the number of contracts managed by DG SANTE is very limited (see section 2.1.1.1.2 of the Annual Activity Report).

By far most of the procurement procedures are based on framework contracts of DG SANTE or another DG, in particular DGs DIGIT, COMM and BUDG. DG SANTE buys mainly services in the area of data collection, evaluation, training, information campaigns, IT and communication services, facilities management etc. The contractors are mainly institutes, laboratories, consultancy firms and other private companies.

**This annex presents in schematic form the characteristics of the main management and control systems put in place by DG SANTE.**

- ! Information on the costs and benefits of control is available for the entire control process, but not always for each single control stage.
- ! Most of the benefits of control are non-quantifiable as they help ensure compliance and good quality of the funded actions which is impossible to quantify.
- ! For some control indicators, mere numbers and percentages do not give reliable information on the control effectiveness; only a qualitative analysis of the reasons behind the figures is relevant and useful.

## Procurement

Main inherent risks	Mitigating controls	Control coverage	Costs and benefits of controls	Cost-Effectiveness indicators (three E's: effectiveness, efficiency, economy)
<b>Stage 1a) Programming: legal base</b> <b>1b) Needs assessment and definition of needs</b> <b>1c) Selection of the offers and evaluation</b> <b>Main control objectives:</b> <i>ensuring sound financial management (i.e. effectiveness, efficiency and economy); compliance (legality &amp; regularity); prevention of fraud (anti-fraud strategy)</i>				
<p>a) <b>Needs have to be well defined</b> (operationally and economically) and decision to procure have to be appropriate to meet the operational objectives.</p> <p>Poor planning or inadequate organisation of the procurement procedure could entail delays or interruptions of services leading to an underachievement of the policy objectives.</p>	<ol style="list-style-type: none"> <li>1. For operational credits in each policy area, a detailed annual work programme is adopted by the Commission specifying the areas for which calls for tenders or calls for proposals will be organised; it constitutes a financing decision.</li> <li>2. Planned external studies are listed in a register kept by Secretariat General.</li> <li>3. Each call for tenders fixes either a maximum value or a price range for the contract based on a pricing methodology.</li> <li>4. The timing and organisation of a procurement procedure is supervised by the Authorising Officer responsible.</li> <li>5. Timing is monitored and planning updated through budget implementation reports prepared by the central financial Unit for discussions in Directors' Steering Committees at least two times a year.</li> </ol>	<ol style="list-style-type: none"> <li>1. 100% of calls for tender are covered by a Commission financing decision.</li> <li>2. 100% of external studies are listed in a special register at the level of the Secretariat General.</li> <li>3. All calls for tender are based on a pricing methodology (depth depending on feasibility).</li> <li>4-5. All public procurements in the annual work programmes are approved by the Management</li> </ol>	<p><b>Cost of control:</b></p> <ul style="list-style-type: none"> <li>- Estimated staff costs for programming and planning and execution of the procurement procedures.</li> </ul> <p><b>Benefits of control:</b></p> <ul style="list-style-type: none"> <li>- Amount of rejection of unjustified purchases or services discontinued.</li> </ul>	<ul style="list-style-type: none"> <li>- Number of open calls covered by the annual work programme not launched in the same year as the work programme. ⇒ Target: 0%</li> <li>- Depth of price calculation using the pricing methodology (according to template) ⇒ Target: 100% in-depth</li> <li>- Timely launch of procurement procedures as specified in the annual work programmes ⇒ Target: 100%</li> </ul>

## Procurement

Main inherent risks	Mitigating controls	Control coverage	Costs and benefits of controls	Cost-Effectiveness indicators (three E's: effectiveness, efficiency, economy)
<p>b) <b>If the definition of tender specifications, exclusion, selection and award criteria are poor, or if the publication of a tender is insufficient, the best possible bids might not be received.</b></p>	<ol style="list-style-type: none"> <li>1. To ensure a high level of expertise in drafting the tender specifications, DG SANTE competent staff of the policy Units write the specifications with the support of the central procurement team in the horizontal Directorate.</li> <li>2. DG SANTE uses templates for terms of reference, exclusion and selection criteria that follow the Commission guidelines; the central procurement team organises the entire process and does a quality control.</li> <li>3. The central procurement committee (CMP) reviews the tender specifications prior to publication for certain sensitive procurements on special request of the policy Unit.</li> <li>4. The tender specifications are validated by the Authorising Officer responsible who launches the publication of the tender in pre-defined means.</li> </ol>	<ol style="list-style-type: none"> <li>1. Tender specifications are drafted in the Units concerned with central support on request (depth of the support depending on needs)</li> <li>2. 100% where applicable</li> <li>3. Central ex-ante review of tender specifications on special request</li> <li>4. 100% validation by Authorising Officer</li> </ol>	<p><b>Cost of control:</b></p> <ul style="list-style-type: none"> <li>- Estimated staff costs for drafting tender specifications</li> </ul> <p><b>Benefits of control:</b></p> <ul style="list-style-type: none"> <li>- Value of a contract, possibly at 100% if significant errors occurred</li> <li>- Benefit of “best value for money” is non-quantifiable as quality aspect is impossible to quantify in an objective, meaningful and reliable way.</li> </ul>	<ul style="list-style-type: none"> <li>- Number of open calls for tenders for which no offer is received (reasons to be analysed) ⇒ Target: 0%</li> <li>- Number of cancellations of open tender procedures (reasons to be analysed) ⇒ Target: 0%</li> <li>- For open calls for tender, number of requests for clarifications, complains or litigation regarding open tenders in relation to offers received ⇒ Target: negative trend /benchmark (to be defined)</li> <li>--Timeliness of procurement procedures relative to Commission Work Programmes</li> </ul>

## Procurement

Main inherent risks	Mitigating controls	Control coverage	Costs and benefits of controls	Cost-Effectiveness indicators (three E's: effectiveness, efficiency, economy)
<p>c) The most economically advantageous offer should be selected and the <b>evaluation process</b> should be <b>unbiased, fair and without error</b>. If procedures are not correctly followed, DG SANTE could be facing possible litigation and /or reputational damage.</p>	<ol style="list-style-type: none"> <li>1. The central procurement team in the horizontal Directorate organises the opening and evaluation procedures, sees to their correct implementation and documentation; members of committees are appointed by the Authorising Officer responsible.</li> <li>2. Persons involved in the formal procedures sign declarations of absence of conflict of interest.</li> <li>3. Bidders are checked against exclusion and selection criteria published with the tender specifications.</li> <li>4. The central procurement committee examines open call tender procedures &gt; €139.000 (in 2020) and gives an independent opinion to the Authorising Officer responsible.</li> <li>5. The Authorising Officer responsible validates the evaluation results and takes the award decision.</li> <li>6. After the award decision, a standstill period of two weeks applies in certain procedures before the contract is signed to give unsuccessful tenders the opportunity to raise concerns.</li> </ol>	<ol style="list-style-type: none"> <li>1. 100% of tender procedures are documented; for 100% of tender procedures &gt; €60.000 committees are formally appointed</li> <li>2. 100% of evaluators</li> <li>3. 100% of bidders checked</li> <li>4. For 100% of open call tender procedures above the threshold the CMP gives an opinion</li> <li>5. 100% validated</li> <li>6. 100% when conditions are fulfilled</li> </ol>	<p><b>Cost of control:</b></p> <ul style="list-style-type: none"> <li>- Estimated staff costs in the evaluation process</li> </ul> <p><b>Benefits of control:</b></p> <ul style="list-style-type: none"> <li>- Value of a contract, possibly at 100% if significant errors occurred</li> <li>- Benefit of “best value for money” is non-quantifiable as quality aspect is impossible to quantify in an objective, meaningful and reliable way.</li> </ul>	<ul style="list-style-type: none"> <li>- Number of valid complaints, Ombudsman cases or litigations received ⇒ Target: 0%</li> <li>- Number of cancellations of open tender procedures due to errors in evaluation process ⇒ Target: 0%</li> <li>--Ratio of average cost of control to budget spent on procurement</li> </ul>

## Procurement

Main inherent risks	Mitigating controls	Control coverage	Costs and benefits of controls	Cost-Effectiveness indicators (three E's: effectiveness, efficiency, economy)
<p><b>Stage 2: Monitoring of the implementation of the contract and financial transactions</b></p> <p><i><b>Main control objectives:</b> ensuring that the implementation of the contract is compliant with the signed contract and that the purchased products or services are of good quality and meet the contract's objectives and conditions (effectiveness &amp; efficiency); ensuring that the related financial operations comply with regulatory and contractual provisions (legality &amp; regularity); prevention of fraud (anti-fraud strategy); ensuring appropriate accounting of the operations (reliability of reporting, safeguarding of assets and information)</i></p>				
<p>The purchased products or services should be provided in accordance with the technical requirements and the contractor should deliver within the set schedule and price range.</p>	<ol style="list-style-type: none"> <li>1. The contract provisions follow the model contract of the Commission.</li> <li>2. Competent staff monitors the implementation of the contract and the progress made (frequency and depth depending on the size and sensitivity of the contract).</li> <li>3. Technical implementation reports are assessed and validated prior to initiating payments.</li> <li>4. DG SANTE makes use of contractual provisions for refusing technical reports, cutting payments, termination of the contract, penalties etc.</li> <li>5. Financial checks prior to payment are carried out according to DG SANTE's financial circuits with 1<sup>st</sup> and 2<sup>nd</sup> level financial verifications, authorisations and encodings in ABAC.</li> <li>6. If deemed necessary, the file is referred to OLAF (DG SANTE's SOPs on handling allegations and contacts with OLAF).</li> </ol>	<p>1 to 4. 100% covered by model contracts, monitoring of progress, financial circuits with assessment and validation of technical and financial reports (control depth depends on risk criteria);</p> <p>5. 100% if conditions are fulfilled</p>	<p><b>Cost of control:</b></p> <ul style="list-style-type: none"> <li>- Estimated staff costs for monitoring and financial transactions</li> <li>- Mission costs for monitoring activities</li> </ul> <p><b>Benefits of control:</b></p> <ul style="list-style-type: none"> <li>- Estimated value of the financial corrections made during ex-ante controls of the final payment</li> <li>- Benefit of "best value for money" is non-quantifiable as quality aspect is impossible to quantify in an objective, meaningful and reliable way.</li> </ul>	<ul style="list-style-type: none"> <li>- Estimated value of the financial corrections made during ex-ante controls of the final payment ⇒ Target: &lt; 2%</li> <li>- Time-to-pay (target: maximum 30 or 60 days as the case may be) ⇒ Target: 100% on time</li> <li>- Rate of late interest or damage payments to total value of all procurement contracts ⇒ Target: 0%</li> </ul>

Procurement				
Main inherent risks	Mitigating controls	Control coverage	Costs and benefits of controls	Cost-Effectiveness indicators (three E's: effectiveness, efficiency, economy)
<b>Stage 3: Supervisory measures</b>				
<i>Main control objectives: Measuring the effectiveness of ex-ante controls by supervisory controls; ensuring to detect and correct any error or fraud remaining undetected after the implementation ex-ante controls (legality &amp; regularity; anti-fraud strategy); addressing systemic weaknesses in the ex-ante controls, based on the analysis of the findings (sound financial management); ensuring appropriate accounting of the recoveries to be made (reliability of reporting, safeguarding of assets and information)</i>				
In some cases ex-ante controls at the desk might fail to prevent, detect and correct errors in procurement procedures or attempted fraud; <b>other internal controls</b> should be designed to prevent, detect or mitigate negative effects.	<ol style="list-style-type: none"> <li>DG SANTE's ex-post control strategy includes procurement contacts of exceptionally high amounts or other high risks; the audit work programme foresees anti-fraud measures.</li> <li>Follow-up on audit recommendations linked to procurement (Court of Auditors and IAS)</li> <li>Exceptions and internal control weaknesses are reported and analysed.</li> <li>The management of sensitive functions is centralised to ensure independent analysis and judgment.</li> <li>If deemed necessary, the file is referred to OLAF (DG SANTE's SOPs on handling allegations and contacts with OLAF).</li> </ol>	<ol style="list-style-type: none"> <li>Risk based audit sample (no minimum audit coverage foreseen as only on exceptional basis)</li> <li>100% of accepted recommendations implemented within the deadlines</li> <li>100% of financial procedures</li> <li>High risk operations</li> <li>100% if conditions are fulfilled</li> </ol>	<p><b>Cost of control:</b></p> <ul style="list-style-type: none"> <li>Estimated staff costs for ex-post controls, internal audits and other supervisory controls</li> <li>Estimated mission costs for audits or other controls</li> <li>Cost of external audit services</li> </ul> <p><b>Benefits of control:</b></p> <ul style="list-style-type: none"> <li>Value of the financial corrections made during ex-post audits or controls</li> </ul>	<ul style="list-style-type: none"> <li>Detected error rate ⇒ Target: decreasing trend</li> <li>Residual error rate ⇒ Target: &lt; 2%</li> <li>Ratio of corrected control weaknesses to total detected weaknesses in procurement procedures ⇒ Target: 100%</li> <li>Implementation of the annual work plans of audit and ex-post control on procurement ⇒ Target: 100%</li> <li>Average cost per audit to average amount of audit correction ⇒ Target: &gt; 100%</li> </ul>

## Annex 6.2 Relevant Control System for budget implementation through entrusted entities

**This Annex is divided into two parts: one that shows DG SANTE's control strategy related to the executive agency and one related to EU decentralised agencies for which DG SANTE is "parent".**

No control strategy is provided for cross-delegated funds to other Directors-General given that they are Authorising Officers by Delegation themselves and required to implement the appropriations subject to the same rules, responsibilities and accountability arrangements as DG SANTE. According to the cross-delegation agreements that DG SANTE signed with the authorising officers responsible, they report annually on the use made of the delegated appropriations.

### 6.2.1. DG SANTE transferred and cross-delegated budget implementation tasks

In 2020, DG SANTE managed financial operations under the following two policy areas: Public Health and Food and Feed Safety. DG SANTE entrusted the Consumers, Health, Agriculture and Food Executive Agency (CHAFEA) with the implementation of about EUR 59,5 million which amounts to about 20% of the 2020 operational budget.

DG SANTE finances parts of the running costs of CHAFEA through the payment of a subsidy of EUR 5,9 million to the executive agency's 2020 operating budget (other parent DGs also pay their part). The Director of the agency implements the agency's operating budget as authorising officer according to the standard financial regulation applicable to an executive agency. This means that the Director is accountable for the regularity and legality of this expenditure and is himself subject to the discharge decision of the Parliament.

The Act of Delegation specifies the agency's management tasks and duties, including internal control and risk management systems, and modalities on reporting relevant and reliable control results to the Commission. The Act of Delegation also specifies DG SANTE's scrutiny rights and obligations, including documentary and on-the-spot checks and audits at the agency.

- ! DG SANTE's control strategy for the executive agency encompasses both the delegated EU funds and the subsidy payments to the executive agency's operating budget as for both transactions the same internal control system applies.
- ! For some control indicators, mere numbers and percentages do not give reliable information on the control effectiveness; only a qualitative analysis of the reasons behind the figures is relevant and useful.



## 1. Budget implementation tasks delegated to the executive agency

Main inherent risks	Mitigating controls	Control coverage	Costs/benefits of controls	Cost-Effectiveness indicators (three E's: effectiveness, efficiency, economy)
<p><b>Stage 1. "Mandate of the entrusted entity": establishment, prolongation or adjustment of the delegation act of the executive agency</b></p> <p><i>Main control objectives: ensuring that the legal framework for the management of the relevant funds is fully compliant and regular (legality &amp; regularity), delegated to an appropriate entity (best value for public money, economy, efficiency), without any conflicts of interests (anti-fraud strategy)</i></p>				
<p>The <b>establishment (or prolongation) of the mandate of the executive agency</b> should be free of any legal issues, as these could undermine the legal basis for the agency's management of the EU funds transferred to it.</p>	<p>The legal framework ("statute") for executive agencies is laid down by Council Regulation (EC) 58/2003.</p> <ol style="list-style-type: none"> <li>1. A cost-benefit study is carried out prior to both the establishment and the prolongation of the agency's mandate (last cost-benefit study of 2013).</li> <li>2. The Member State Committee for executive agencies approves the Commission's proposals for establishing an agency and prolonging its mandate.</li> <li>3. DG SANTE follows the Commission's models for the decisions on establishment and task delegation to the agency.</li> <li>4. DG SANTE manages the interservice consultations and publications of the Commission Decisions.</li> </ol>	<p><b>100% in-depth</b> controls at each stage on DG SANTE's and DG BUDG's side</p> <p><b>Frequency:</b></p> <ul style="list-style-type: none"> <li>- Once in 2004-2005 when the agency was established</li> <li>- 2013 when the mandate of the agency was prolonged from 2014 to 2020</li> </ul>	<p><b>Cost of control:</b></p> <p>Estimated SANTE staff costs for technical, financial and legal preparation of the agency's mandate, approval by the Member State Committee and adoption by the Commission</p> <p><b>Benefits of control:</b></p> <p>The total budget amount delegated to the agency per year possibly at 100% if significant legal errors occurred</p>	<p>Number of legal issues a/o negative opinions during the interservice consultation ⇒ Target: 0</p> <ul style="list-style-type: none"> <li>- Quality of the legal work not challenged by auditors or OLAF ⇒ Target: 0</li> <li>- Timely adoption of all necessary legal acts for the extension of the agency ⇒ Target: not applicable in 2020</li> </ul>

## 1. Budget implementation tasks delegated to the executive agency

Main inherent risks	Mitigating controls	Control coverage	Costs/benefits of controls	Cost-Effectiveness indicators (three E's: effectiveness, efficiency, economy)
<p><b>Stage 2. Readiness assessment of the executive agency's control framework towards autonomy</b></p> <p><i>Main control objectives: ensuring that the entrusted entity is fully prepared to start/continue implementing the delegated funds autonomously respecting the five control objectives set forth in the Financial Regulation: (i) legality and regularity, (ii) sound financial management, (iii) true and fair view reporting, (iv) safeguarding assets and information, (v) anti-fraud strategy</i></p>				
<p>The <b>financial and control framework deployed by the executive agency</b> should be fully mature to guarantee that the control objectives are met.</p>	<ol style="list-style-type: none"> <li>DG SANTE carried out an ex-ante assessment of the agency's internal control system prior to granting full budget autonomy in 2007. This exercise was not repeated as the subsequent prolongations and amendments of the agency's mandate did not require a substantial change to the agency's control systems for the task delegated by DG SANTE.</li> <li>According to the Act of Delegation, the agency submits to DG SANTE for approval any substantial change in its manuals and procedures, in its model grant agreements and procurement contracts. This is done through the Steering Committee.</li> </ol>	<ol style="list-style-type: none"> <li><b>100% in-depth</b> control once when the agency was set up</li> <li>Each request for substantial change is examined in-depth</li> </ol> <p><b>Frequency:</b></p> <ul style="list-style-type: none"> <li>Once in 2005-2006 when the agency gained autonomy</li> </ul>	<p><b>Cost of control:</b></p> <p>Not applicable per year and not in 2019, as estimated staff costs for ex-ante assessment only once when agency is established</p> <p><b>Benefits of control:</b></p> <p>The total budget amount delegated to the agency per year possibly at 100% if significant legal errors occurred</p>	<p>Granting budget autonomy without significant delay</p> <p>⇒ Target: Not applicable in 2020 (agency gained full autonomy in 2007)</p> <p>- Time between establishment of the agency and granting of autonomy</p> <p>⇒ Target: 100% on time according to internal planning</p> <p><i>(comment: not applicable after 2007 when the agency gained full autonomy)</i></p>

## 1. Budget implementation tasks delegated to the executive agency

Main inherent risks	Mitigating controls	Control coverage	Costs/benefits of controls	Cost-Effectiveness indicators (three E's: effectiveness, efficiency, economy)
<p><b>Stage 3: Operations: DG SANTE's monitoring and supervision (“control with the executive agency”)</b></p> <p><i>Main control objectives: ensuring that DG SANTE is fully and timely informed of any relevant management issues encountered by the executive agency, in order to possibly mitigate any potential financial and/or reputational impacts</i></p>				
<p>DG SANTE should be informed timely of <b>relevant management issues encountered by the executive agency</b>; DG SANTE should react upon notified issues timely and adequately. If not, this could reflect negatively on the Commission's reputation.</p>	<p>The Act of Delegation specifies the agency's management tasks and duties, including internal control and risk management systems, and modalities on reporting relevant and reliable control results.</p> <p>The Act of Delegation also specifies DG SANTE's scrutiny rights and obligations, including documentary and on-the-spot checks and audits at the agency.</p> <ol style="list-style-type: none"> <li>1. Regular meetings between the agency and DG SANTE are held at the level of the Units concerned to ensure the necessary co-ordination of activities.</li> <li>2. Memorandum of Understanding (MoU) for the day-to-day co-ordination between DG SANTE and the agency are established; where necessary, the MoU is complemented by specific guidelines for certain delegated tasks.</li> <li>3. The Steering Committee, chaired by DG SANTE, meets four times a year and adopts (i) the agency's annual work programme, after approval by the Commission, and (ii) the draft</li> </ol>	<p><b>Coverage:</b> 100% of the tasks delegated to the agency monitored and supervised</p> <p><b>Depth of control:</b> risk based; DG SANTE has full access to the agency's internal control information, if need be</p> <p><b>Frequency:</b> quarterly, annually and in day-to-day contacts as deemed necessary</p>	<p><b>Cost of control:</b></p> <ul style="list-style-type: none"> <li>- Estimated SANTE staff costs for monitoring and supervising the agency's activities</li> <li>- Mission costs for monitoring activities</li> </ul> <p><b>Benefits of control:</b></p> <p>The total budget amount delegated to the agency per year possibly at 100% if significant legal errors occurred</p>	<p>--Regular programme meetings between the agency and DG SANTE at operational level ⇒ Target: to be defined per delegated programme</p> <ul style="list-style-type: none"> <li>- Steering Committee meetings with adequate quorum for voting ⇒ Target: 4 times a year</li> <li>- Reported monitoring issues, supervisory control failures and/or exception reports relative to DG SANTE's monitoring of and co-operation with the agency ⇒ Target: qualitative analysis of reasons for the reported issues</li> <li>- Budget execution rates of the operational budget transferred to the agency ⇒ Target: 99% for commitments 100% for payments</li> <li>- Director's annual report on control results and error rates endorsed by Steering Committee prior to finalisation of DG SANTE's Annual Activity Report ⇒ Target: qualitative analysis</li> </ul>

## 1. Budget implementation tasks delegated to the executive agency

Main inherent risks	Mitigating controls	Control coverage	Costs/benefits of controls	Cost-Effectiveness indicators (three E's: effectiveness, efficiency, economy)
	<p>administrative budget, including the establishment plan, after adoption of the general EU budget by the budgetary authority.</p> <p>4. The agency reports quarterly to the Steering Committee and to the operational Units concerned on the achievement of objectives, budget implementation, audit and control issues.</p> <p>5. DG SANTE's central financial Unit reports regularly (several times a year) on the implementation of the budget delegated to the agency.</p> <p>6. The agency's Annual Activity Report follows the Commission's instructions, is adopted by the Steering Committee and published in the same way as DG SANTE's Annual Activity Report.</p> <p>7. If deemed necessary, issues are referred to OLAF (DG SANTE's SOPs on handling allegations and contacts with OLAF).</p>			<ul style="list-style-type: none"> <li>- Timely endorsement by the Steering Committee of the agency's annual work programme and administrative budget (target: December N-1 at the latest) ⇒ Target: 100% on time</li> <li>- Ratio of annual supervision costs to annual operational budget delegated and subsidy paid to the annual administrative budget of the agency ⇒ Target: Commission benchmark (not yet available)</li> </ul>

## 6.2.2. DG SANTE paid subsidies to the operating budgets of EU decentralised agencies

DG SANTE is responsible for five EU agencies. While one of these agencies is fully fee-financed (CPVO), DG SANTE pays annual subsidies from the EU budget to four agencies, including the Chemicals Agency (ECHA) for its biocides activities (the responsible DG for ECHA is DG GROW).

- ❑ **European Centre for Disease Prevention and Control (ECDC)** located in Stockholm, Sweden<sup>25</sup> (Budget 2020: total sum of human resources 285; EU funding 100%: EUR 62,5 million)  
ECDC works to prevent threats to human health from disease outbreaks and to react quickly and effectively to minimise their impact. To this end, ECDC operates dedicated surveillance networks, provides scientific opinions, operates the early warning and response system (EWRS) and provides scientific and technical assistance and training.
- ❑ **European Food Safety Authority (EFSA)** in Parma, Italy<sup>26</sup> (Budget 2020: total sum of human resources 508; EU funding 100%: EUR 103,0 million)  
EFSA provides independent scientific opinions and scientific and technical advice on food and feed safety, animal and plant health. EFSA's outputs form the scientific basis for the Commission's decision-making as regards the authorisation of regulated products in the food and feed sectors; and for EU initiatives in all fields which have a direct or indirect impact on food and feed safety, including animal health and welfare, and plant health.
- ❑ **European Medicines Agency (EMA)** in Amsterdam, The Netherlands<sup>27</sup> (Budget 2020: total sum of human resources 854; EU funding 16,4%: EUR 58,9 million)  
EMA evaluates and supervises medicines for human and veterinary use; it provides the Member States and the institutions of the European Union with independent scientific advice on medicinal products for human or veterinary use. EMA's scientific opinions form the basis for the Commission's decision-making on the authorisation of medicines. EMA's total 2020 budget amounted to EUR 358,1 million which is to a large extent fee-financed.

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<sup>25</sup> ECDC was established by Regulation (EC) No 851/2004 of the European Parliament and of the Council of 21 April 2004; OJ L 142/1, 30.4.2004.

<sup>26</sup> EFSA was established by Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002; OJ L 31/1 of 1.2.2002.

<sup>27</sup> EMA was established by Council Regulation (EEC) No 2309/93 of 22 July 1993, which was replaced by Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004; OJ L 214/1 of 24.8.1993 and OJ L 136/1 of 30.4.2004. With regard to the location of the seat of the EMA see Regulation (EU) 2018/1718 of the European Parliament and of the Council amending Regulation (EC) No 726/2004, OJ L 291, 16.11.2018, p. 3). EMA left its London premises on 1 March 2019 to relocate to Amsterdam.

- ❑ **Community Plant Variety Office (CPVO)** in Angers, France<sup>28</sup> (Budget 2020: total sum of human resources 52; EU funding 0%: EUR 0 million)  
CPVO supports the innovative patenting of new plant varieties throughout the EU; it decides on applications for Community plant variety rights on the basis of a formal examination and a technical examination of the candidate variety. CPVO does not receive any EU subsidies; its 2020 budget amounted to EUR 20 million (fully fee-financed).
- ❑ **European Chemicals Agency (ECHA)** located in Helsinki<sup>29</sup> - relevant for DG SANTE are ECHA's biocides activities (Budget 2020 for biocides: total sum of human resources 69 for the biocides activities; EU funding: 62,5%: EUR 7,2 million).  
ECHA's biocides activities encompass the implementation of technical and scientific tasks in accordance with the Biocidal Products Regulation (EU) No 528/2012, which came into force on 1 September 2013. ECHA's biocides activities provide the scientific basis for the Commission's decision-making on the authorisation of biocidal products and approval of active substances. ECHA's budget for biocides in 2020 amounted to EUR 12 million.

## 2. Subsidy payments to EU decentralised agencies

Main inherent risks	Mitigating controls	Control coverage	Costs/benefits of controls	Cost-Effectiveness indicators (three E's: effectiveness, efficiency, economy)
<b>Stage 1. "Mandate of the agency": founding regulation</b> <i>Main control objectives: ensuring that the legal framework for the management of the relevant funds is fully compliant and regular (legality &amp; regularity), that the agency spends the money as intended (best value for public money, economy, efficiency), without any conflicts of interests (anti-fraud strategy)</i>				
The <b>establishment (or amendment) of the mandate of an EU agency</b> should be free of any legal issues, as these could undermine the legal basis for the agency's management of the EU funds paid by	The legal framework of the EU agency is laid down in its founding regulation (see above) without expiry date. Amendments follow the Commission's legislative procedures and, since July 2012 the "Common Approach" <sup>30</sup> laid down by the Interinstitutional working group on EU agencies, e.g. <ul style="list-style-type: none"> <li>- An impact assessment is carried out prior to establishing an EU agency and when amending its mandate;</li> </ul>	<b>100% in-depth</b> once in establishment phase  <b>100% in-depth</b> case by case if amendment or review is	<b>Cost of control:</b> - Estimated SANTE staff costs involved in establishing an EU agency or the review or amendment of its founding regulation	Number of legal issues a/o negative opinions during interservice consultations ⇒ Target: 0  - Quality of the legal work not challenged by auditors or OLAF ⇒ Target: 100%

<sup>28</sup> The CPVO was created by Council Regulation (EC) No 2100/94 of 27 July 1994; OJ L 227/1 of 01/09/1994.

<sup>29</sup> ECHA was set up by Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006; OJ L 396, 30.12.2006, p. 1.

<sup>30</sup> [http://europa.eu/about-eu/agencies/overhaul/index\\_en.htm](http://europa.eu/about-eu/agencies/overhaul/index_en.htm)

## 2. Subsidy payments to EU decentralised agencies

Main inherent risks	Mitigating controls	Control coverage	Costs/benefits of controls	Cost-Effectiveness indicators (three E's: effectiveness, efficiency, economy)
DG SANTE to subsidise its running costs.	<ul style="list-style-type: none"> <li>- Standard provisions including appropriate legal provisions are used as a reference point when a new agency is created or when existing founding acts are revised on a case by case basis.</li> <li>1. In case of an establishment of an agency or an amendment of its founding regulation, DG SANTE manages the interservice meetings/consultations.</li> <li>2. DG SANTE also manages all subsequent procedural steps (Council, Parliament, etc.) towards the adoption of the regulation by the Council and the Parliament.</li> </ul>	<p>foreseen</p> <p><b>Frequency:</b></p> <p>In 2018 for the amendment of EMA's founding regulation;</p> <p>in 2018/2019 for the amendment of EFSA's founding regulation</p>	<ul style="list-style-type: none"> <li>- Cost for external service contract for impact assessments, etc.</li> </ul> <p><b>Benefits:</b></p> <p>The total annual budget amount paid as subsidy to the agency's running costs possibly at 100% if significant legal errors occurred.</p>	
<p><b>Stage 2. Assessment of the agency's control framework and financial rules</b></p> <p><i>Main control objectives: ensuring that the entrusted entity is fully prepared to start/continue implementing the delegated funds autonomously respecting the five control objectives set forth in the Financial Regulation: (i) legality and regularity, (ii) sound financial management, (iii) true and fair view reporting, (iv) safeguarding assets and information, (v) anti-fraud strategy</i></p>				
The financial and control framework deployed by the EU agency should be fully mature to guarantee that the control objectives are met.	<ol style="list-style-type: none"> <li>1. Implementing rules to the Staff Regulations (SR) adopted by the Commission apply by analogy to the agencies. The agency's Management Board, after having obtained the Commission's agreement, may decide to depart from these rules, not apply them or adopt rules on other subjects. DG SANTE, in co-operation with DG HR, consults and monitors.</li> <li>2. The agency's Management Board adopts the financial regulation (FR) of the agency based on the Commission's "framework financial regulation" (FFR) for EU agencies. Deviations from the FFR need the Commission's prior</li> </ol>	<p><b>100% in-depth</b> per agency as need be, e.g. if amendments are to be made</p> <p><b>Frequency:</b></p> <p>In 2018-2019 due to the new FFR and Internal Control Framework;</p>	<p><b>Cost of control:</b></p> <p>Included in general estimate of SANTE's staff costs for monitoring and supervising the agency's activities</p> <p><b>Benefits of control:</b></p> <p>The total subsidy paid to the agency</p>	<ul style="list-style-type: none"> <li>- EU agencies adopting their own control framework in compliance with the Commission's framework ⇒ Target: all agencies</li> <li>- EU agencies adopting their own rules of independence and conflict of interest compliant with the Commission's guidelines ⇒ Target: all agencies</li> </ul>

## 2. Subsidy payments to EU decentralised agencies

Main inherent risks	Mitigating controls	Control coverage	Costs/benefits of controls	Cost-Effectiveness indicators (three E's: effectiveness, efficiency, economy)
	<p>consent; DG SANTE, in co-operation with DG BUDG consults and monitors. All SANTE agencies have adopted in 2019 Financial Regulations which are in line with the Framework Financial Regulation.<sup>31</sup></p> <p>3. Each agency adopts its rules of "independence" and "conflict of interest". DG SANTE actively monitors compliance with the Commission's guidelines on independence in DG SANTE's task force with the agencies and through bilateral contacts with the agencies. In addition to monitoring compliance, DG SANTE identifies and disseminates good practices in collaboration with the agencies.</p>	Annual meeting of the DG SANTE inter-agency task force on independence	per year possibly at 100% if significant legal errors occurred	
<p><b>Stage 3: Operations: DG SANTE's monitoring and supervision ("control with the EU agency")</b></p> <p><i>Main control objectives: ensuring that DG SANTE is fully and timely informed of any relevant management issues encountered by the agency, in order to possibly mitigate any potential financial and/or reputational impacts</i></p>				
DG SANTE should be informed timely of <b>relevant management issues encountered by the EU agency</b> ; DG SANTE should react upon notified issues timely and adequately; if not, this could reflect negatively on the	<ol style="list-style-type: none"> <li>1. A coordinating Unit in DG SANTE ensures a coherent approach towards all agencies and exchange of good practises following the "guidance paper on relations with decentralised agencies"; the Commission guidelines for the programming document and the template for the activity report (since 2015) are applicable.</li> <li>2. Regular bilateral meetings with the agencies take place with the aim to ensure efficient exchange of information and good co-operation at the level of (i) operational and financial Units and</li> </ol>	<p><b>Coverage:</b> all of the agency's activities are monitored and supervised</p> <p><b>Depth</b> of control: risk based; if need be, DG SANTE has access to the agency's internal</p>	<p><b>Cost of control:</b></p> <ul style="list-style-type: none"> <li>- Included in the general estimate of DG SANTE's staff costs for monitoring and supervising the agency's activities;</li> <li>- Mission costs for monitoring</li> </ul>	<ul style="list-style-type: none"> <li>- Regular meetings between the agency and DG SANTE at management and technical level ⇒ Target: to be defined with each agency</li> <li>- Management Board meetings with DG SANTE participation ⇒ Target: depends on the agency (about 3 to 4 times</li> </ul>

<sup>31</sup> The CPVO as fully self-financed agency is not bound by the FFR, but aligned its 2019 financial rules largely with the FFR. The deviations were consulted with the Commission and the Court of Auditors.



## 2. Subsidy payments to EU decentralised agencies

Main inherent risks	Mitigating controls	Control coverage	Costs/benefits of controls	Cost-Effectiveness indicators (three E's: effectiveness, efficiency, economy)
Commission's reputation.	<p>(ii) Directors/DDG/DG. In addition, DG SANTE regularly convenes meetings bringing together all Heads of its partner agencies and DG SANTE management.</p> <p>3. The Management Board (MB) of an EU agency meets about 4 times a year with participation of DG SANTE; it adopts the agency's Single Programming Document (SPD, combining multiannual and annual strategic and resource programming) as well as "strategy documents", e.g. on independence. DG SANTE comments through the MB and prepares a formal Commission Opinion on the SPD.</p> <p>4. The agency reports to its MB (DG SANTE being a member) on the achievement of objectives, budget implementation and all other important issues relating to operational and financial management and internal audit; in addition, if applicable, DG SANTE participates in the agency's Audit Committee meetings.</p> <p>5. The "Template for Consolidated Annual Activity Report" for decentralised agencies foresees that the agencies report on the "Assessment of the effectiveness of the internal control systems". All SANTE agencies that receive a Union subsidy adhere to this template. DG SANTE monitors that the information is provided and assesses.</p> <p>6. After adoption by the MB, the agency publishes its annual report, final accounts and report on financial management.</p> <p>7. If need be, DG SANTE informs the Internal Audit Service (IAS), refers issues to OLAF or as member of the MB triggers the "warning system" (SG note to all DGs Ref. Ares(2013)231088 - 21/02/2013).</p>	<p>control information</p> <p><b>Frequency:</b> depending on legal obligations of the agency (e.g. n° of MB meetings per year); working relations established with DG SANTE; in addition on special request or in specific cases</p>	<p>activities.</p> <p><b>Benefits of control:</b> The total subsidy paid to the agency per year possibly at 100% if significant legal errors occurred</p>	<p>per year)</p> <p>- Relevance and reliability of control data reported by the agency ⇒ Target: qualitative analysis done for the document sent to the Management Board</p>

## 2. Subsidy payments to EU decentralised agencies

Main inherent risks	Mitigating controls	Control coverage	Costs/benefits of controls	Cost-Effectiveness indicators (three E's: effectiveness, efficiency, economy)
<b>Stage 4: Audit and evaluation, discharge</b> <i>Main control objectives: ensuring that independent sources provide DG SANTE with information which may confirm or contradict the management reporting received from the agencies themselves</i>				
DG SANTE should get sufficient <b>information from independent sources on the EU agency's management achievements</b> to draw conclusions on the assurance for the subsidies paid to the agency; if not, this might reflect negatively on the Commission's reputation.	<ol style="list-style-type: none"> <li>1. The Internal Audit Service of the Commission (IAS) is the internal auditor of EU agencies and has the same rights and obligations towards EU agencies as towards the Commission (exception: the fully fee financed CPVO).</li> <li>2. Every year, the European Court of Auditors (ECA) audits the accounts and transactions of the agency and issues a declaration of assurance; in addition, the ECA issues Special Reports on agencies; DG SANTE monitors the agency's follow-up on the Court's recommendations.</li> <li>3. Every year, the agency undergoes the discharge procedure; DG SANTE monitors the agency's follow-up on the recommendations made by the discharge authorities.</li> <li>4. Founding regulations foresee regular external evaluations of the agencies:               <ul style="list-style-type: none"> <li>- EMA every 10 years (ongoing in 2019);</li> <li>- EFSA every 6 years (last completed 2018);</li> <li>- ECDC every 5 years (last completed 2019).</li> </ul>               DG SANTE participates in the Steering Committee and Technical Evaluation Committee.             </li> <li>5. Through its representation in the agency's Management Boards and Audit Committees, DG SANTE encourages that evaluation reports and audit reports are timely sent to DG SANTE and that adequate actions are defined and timely implemented by the agency to address the issues identified in those reports.</li> </ol>	<p><b>Coverage:</b> 100% of the agency's activities audited and evaluated</p> <p><b>Depth of control:</b> risk based; auditors have full access to the agency's internal control information</p> <p><b>Frequency:</b></p> <ul style="list-style-type: none"> <li>- Regularly by the IAS</li> <li>- Annually by the Court of Auditors</li> <li>- Frequency of external evaluations varies with the agencies</li> </ul>	<p><b>Cost of control:</b></p> <ul style="list-style-type: none"> <li>- Included in the general estimate of SANTE's staff costs for monitoring and supervising the agency's activities</li> </ul> <p><b>Benefits of control:</b></p> <p>The total amount of the subsidy paid to the agency per year possibly at 100% if significant legal errors occurred</p>	<ul style="list-style-type: none"> <li>- DG SANTE's analysis of critical and very important audit findings of internal and external auditors and the agency's implementation of the audit findings ⇒ Target: all analysed and discussed</li> <li>- Court of Auditors' assurance on the accounts and operating budget ⇒ Target: positive assurance ⇒ Target: all recommendations implemented</li> <li>- Discharge authorities grant discharge to the agency ⇒ Target: discharge granted ⇒ Target: all recommendations of the discharge authorities implemented</li> <li>- External evaluation concluding positively on the agency's activities</li> </ul>

## 2. Subsidy payments to EU decentralised agencies

Main inherent risks	Mitigating controls	Control coverage	Costs/benefits of controls	Cost-Effectiveness indicators (three E's: effectiveness, efficiency, economy)
<p><b>Stage 5: DG SANTE's payments of the subsidy</b></p> <p><i><b>Main control objectives:</b> ensuring that DG SANTE fully assesses the management situation at the EU agency, before either paying out the (next) instalment of the subsidy to the agency or deciding to cut, suspend or interrupt the (next) payment (legality &amp; regularity, sound financial management, anti-fraud strategy)</i></p>				
<p>DG SANTE might not be aware of management issues that could lead to financial and/or reputational damage for the Commission as it pays the subsidy to the agency.</p>	<ol style="list-style-type: none"> <li>1. On the basis of the agency's annual budget and work programme adopted by the Management Board, DG SANTE pays the subsidy to the agency's administrative budget in several instalments: <ul style="list-style-type: none"> <li>- An instalment is paid in year N on request of the agency based on a cash forecast;</li> <li>- Prior to the subsidy payment, financial checks are carried out according to DG SANTE's financial circuits with 1<sup>st</sup> and 2<sup>nd</sup> level financial verifications, authorisations and encodings in ABAC;</li> </ul> </li> <li>2. All instalments remain pre-financing payments until the agency's accounts have been audited by the Court of Auditors and the agency has submitted its final accounts (in general by July N+1);</li> <li>3. On the basis of the agency's final accounts, DG SANTE clears all pre-financing payments in year N+1 and, if applicable, recovers unspent amounts of the instalments paid to the agency; no additional payment is made.</li> </ol>	<p><b>Coverage:</b> 100% of DG SANTE's subsidy payments through the established financial circuits</p> <p><b>Depth of control:</b> risk based</p> <p><b>Frequency:</b> Administrative budget of the agency annually audited by the Court of Auditors</p>	<p><b>Cost of control:</b></p> <ul style="list-style-type: none"> <li>- Estimated staff costs for budget and finance in central financial Unit;</li> </ul> <p><b>Benefits of control:</b></p> <p>The total subsidy paid to the agency per year possibly at 100% if significant legal errors occurred.</p>	<ul style="list-style-type: none"> <li>- Number of reported monitoring issues, incidences of payment suspensions or reductions and/or exception reports relative to DG SANTE's subsidy payment to the agency ⇒ Target: qualitative analysis of reasons for the reported issues; all issues adequately followed up</li> <li>- Ratio of recovery of the positive budgetary outturn of year N plus interest earned on subsidy paid in year N-1</li> <li>- Files with relevance for OLAF adequately transmitted to OLAF and followed up ⇒ Target: 100%</li> <li>- Time-to-pay (target: maximum 30 days) ⇒ Target: 100% on time</li> </ul>

## ANNEX 7: Specific annexes related to "Financial Management"

### 7.1 Effectiveness = the control results and benefits

#### 7.1.1. Legality and regularity of the transactions

DG SANTE has set up internal control processes aimed to ensure the adequate management of the risks relating to the legality and regularity of the underlying transactions, taking into account the annual character of programmes as well as the nature of the payments concerned.

##### 7.1.1.1 Grants to Member States in Food and Feed Safety

In the policy area Food and Feed Safety, DG SANTE follows an integrated approach with the aim to ensure a high level of food safety, animal health, animal welfare and plant health within the European Union through coherent farm-to-fork measures and adequate monitoring. The grants refer mainly to DG SANTE's specific objective 1.1 "Food and feed safety" to cover disease prevention, emergency measures and crisis management. Smaller parts of the budget support specific objectives 1.2 "Sustainable food systems – the 'Farm to Fork' Strategy" and 1.3 "International promotion of EU food safety standards".<sup>32</sup>

**Table 7.1 Food and Feed Safety**

<b>Commitment credits implemented by DG SANTE (without CHAFEA)<sup>33</sup></b>	<b>2020 M€</b>	<b>2019 M€</b>	<b>2018 M€</b>
Animal disease eradication programmes (grants to Member States)	<b>117,2</b>	130,6	137,6
Veterinary emergency fund (grants to Member States)	<b>56,9</b>	58,6	49,9
Phytosanitary expenditure (grants to Member States)	<b>13,1</b>	37,6	15,9
Other veterinary, plant health and food safety expenditure (grants to Member States, EURL, etc.) <sup>34</sup>	<b>7,2</b>	24,7	41,6
<b>Sub-total grants</b>	<b>194,4</b>	251,5	245,0
Procurement Food and Feed Safety	<b>32,6</b>	18,2	15,4
Administrative support credits <sup>35</sup>	<b>0,7</b>	0,7	1,1
<b>Total budget implemented</b>	<b>227,7</b>	270,4	261,5

<sup>32</sup> Latest Programme Statement Food and Feed  
[https://ec.europa.eu/info/sites/info/files/about\\_the\\_european\\_commission/eu\\_budget/db\\_2021\\_programme\\_statement\\_food\\_and\\_feed.pdf](https://ec.europa.eu/info/sites/info/files/about_the_european_commission/eu_budget/db_2021_programme_statement_food_and_feed.pdf).

<sup>33</sup> Without credits co-delegated to other DGs.

<sup>34</sup> See for example, the work programme of 2018 to 2020 for the Union contribution to the EU reference laboratories and the EU reference centres adopted on 17 October 2017 (C(2017) 6889 final); work programme and the financing for the year 2018 of activities in the food and feed area to ensure the application of the food and feed legislation was adopted on 25 January 2018 (C(2018) 296 final).

<sup>35</sup> Without credits co-delegated to other DGs: EUR 1,0 million in 2020 (EUR 0,8 million in 2019; EUR 0,4 million in 2018).

Provisions for the management of expenditure for the policy area Food and Feed are set out in the Common Financial Framework (CFF)<sup>36</sup>. Direct financial contributions to Member States is by far (more than 80%) the most important budget implementation instrument:

- In 2020, 27 Member States and the UK implemented a total of 146 animal disease eradication and control programmes.
- In addition, a total of 26 files for cost reimbursements were handled in relation to the veterinary emergency fund, to combat, first and foremost, Avian Influenza (EUR 28,1 million) but also African Swine Fever (EUR 21,9 million), and Lumpy Skin Disease (EUR 1,2 million). An additional amount of EUR 5,7 million was earmarked for animal health emergency measures.
- Addressing the combat of organisms harmful to plants, 24 Member States submitted their 2020 "pest survey programmes"<sup>37</sup> of a total amount of EUR 12,7 million. EUR 0,4 million were committed for emergency plant health measures.
- Other non-typical grants concern the Union financial aid towards a coordinated control plan for antimicrobial resistance (AMR) in zoonotic agents<sup>38</sup> (28 Member States for a total of EUR 2,2 million) and international organisations such as FAO, OIE, UPOV, OECD (EUR 4,1 million).
- Other measures to contain animal disease outbreaks are the purchase of vaccines. In 2020, DG SANTE concluded a contract worth EUR 6,9 million for Food and Mouth Disease antigens through public procurement (see part 7.1.3 below).
- The administrative support credits (EUR 0,7 million) were used mainly for IT and communication services.

The 2020 commitment appropriations at the end of the year of EUR 194,4 million, and the 2020 payment credits of EUR 188,8 million, were each fully consumed<sup>39</sup>.

The control process is divided into four distinct stages, each with specific control objectives. The description focuses on the national programmes for animal disease eradication and monitoring which account for more than 60% of the grants in the Food and Feed policy area (see table 7.1 above). Other grants in the policy area Food and Feed Safety follow the same control procedures as far as applicable. Procurement procedures are described in part 7.1.1.2 below.

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<sup>36</sup> Regulation (EU) No 652/2014 of the European Parliament and of the Council of 15 May 2014

<sup>37</sup> Commission Implementing Decision C(2018) 2491 on the adoption of the work programme for 2019-2020 for the implementation of survey programmes for pests amended by C(2019)3509, and the financing decision C(2018) 6531

<sup>38</sup> Commission Implementing Decision C(2019) 8393 of 26 November 2019 on the financing and the adoption of the work programme for 2020 for activities in the food and feed area

<sup>39</sup> In the Food and Feed Safety policy area, Annex 3 shows implementation rates of 99,2% for EUR 234,2 million of commitment credits and 99,2% for EUR 224,8 million of payment credits. The difference to the figures above are the subsidy payment to the EU decentralised agency ECHA-biocides which is included in Annex 3 under "Food and Feed Safety": EUR 7,2 million commitments and payments.

## Stage 1: Programming and evaluating national programmes

In compliance with the Commission work programme<sup>40</sup> to implement the Common Financial Framework (CFF)<sup>41</sup> for the Food Chain, Member States submitted their 2020 disease eradication and control programmes by 31 May 2019. DG SANTE, assisted by external experts, evaluated the national programmes to ensure their good quality and their added value to achieve the policy objectives at reasonable costs. Of the 147 programmes submitted, one was rejected as it did not meet the eligibility or award criteria as set out in the work programme. The grant decisions were signed on 30 January 2020 meeting the legal deadline.

At the programming and evaluation stage the key controls were mostly directive and preventive: application guidelines for the Member States, mandatory IT tool for electronic submission of applications; assessment of the technical quality and financial analysis of the national programmes; and selection of independent external evaluators. On the basis of the evaluation results, DG SANTE facilitated the Member States' finalisation of their programmes.

In 2020, DG SANTE started preparing the multi-annual work programme for the implementation of the EU co-funded animal disease eradication and phyto-sanitary programmes of Member States for the years 2021 to 2022. The work programmes covering all other activities to be co-funded under the food-strand of the Single Market Programme (SMP) Regulation advanced as well. However, due to the late adoption of the new Multiannual Financial Framework (2021-2027)<sup>42</sup> in December 2020, and the postponement of the Single Market Programme (2021-2027), invitations to submit the 2021-2022 national programmes could not be sent out to Member States. In December 2020, letters were sent to the Chief Veterinary Officers (CVOs) and Chief Officers of Plant Health Services (COPHS) to explain the situation. As from 1 January 2021, Member States will have to continue implementing the planned surveillance and eradication measures (programmes) for a number of animal diseases and pests, in line with the provisions of the EU legislation, taking into account the epidemiological situation in their territories and neighbouring countries. Decisions on the possible co-financing will be taken after the adoption of the Single Market Programme and of the working programmes to implement the related food strand activities, in the course of 2021.

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<sup>40</sup> Commission Implementing Decision C(2017)2841 of 2 May 2017 on the adoption of the multiannual programme for 2018, 2019 and 2020 for the implementation of veterinary programmes for animal diseases and zoonoses, and the related financing decision Commission Implementing Decision C(2017)3524 of 31 May 2017

<sup>41</sup> Regulation (EU) No 652/2014 of the European Parliament and of the Council of 15 May 2014

<sup>42</sup> From 2021, the CFF will be replaced by the new Single Market Programme Regulation (SMP), which will be adopted after the MFF (2021-2027). It is expected in the first quarter of 2021.

## Stage 2: Approving national programmes and Grant Decisions

The list of the national programmes for animal disease eradication and monitoring in 2020 was technically approved in November 2019 and the final EU contribution allocated to each programme was communicated to the Standing Committee on Plants, Animals, Food and Feed (PAFF) in January 2020. Subsequently, the authorising officer by sub-delegation took the award decision and signed the corresponding grant decisions. As in previous years, the deadlines fixed in the legislation were respected allowing a timely launch of the 2020 programmes in the Member States.

As explained above, work on the 2021 national programmes could not proceed as the Single Market Programme (2021-2027) Regulations is not yet adopted. Thus, the indicators in Table 7.2.1 below are not applicable in 2020.

As a simplification measure, introduced in 2014, only one grant decision per Member State was signed, covering the eradication and control programmes for all diseases for each Member State. To reduce the burden of calculating eligible costs, the concept of unit costs was introduced in 2014 and updated in 2018<sup>43</sup>. Unit costs also help reduce the risk of errors in the cost claims. The IAS made an audit recommendation to improve the unit cost methodology and actions are on-going with deadlines in mid-2022; important milestones have already been achieved with the support of the JRC (see Annex 8.1.2 below).

**Table 7.2.1 Indicators for grants at control stages 1 and 2**

Indicators	Targets	2020	2019	2018
<b>Stage 1: Programming and evaluation</b>				
Ratio of rejected national programmes to total programmes submitted: in 2020, no programmes for 2021 were submitted; (in 2019: 1 out of 147 programmes for 2020; in 2018: 5 out of 147 programmes for 2019)	<i>n/a</i>	<b>N/A</b>	1%	3%
Ratio of modified programmes to total programmes retained after evaluation: in 2020 no evaluation took place (in 2019: 85 out of 146; in 2018: 98 out of 142)	<i>n/a</i>	<b>N/A</b>	58%	69%
<b>Stage 2: Grant Decision on the national programmes and EU funding</b>				
Communication of the list of programmes to be funded by 30/11 in year N for programmes of year N+1 (Art. 13 of the CFF)	100%	<b>N/A</b>	100%	100%
Grant decisions taken on-time by end of January year N+1 for programmes of year N+1 (Art. 13 of the CFF)	100%	<b>N/A</b>	100%	100%

<sup>43</sup> Commission Decision C(2018)2315 of 23 April 2018 authorising the use of unit costs under the annual and multiannual programmes for the eradication, control and surveillance of animal diseases and zoonoses and under the veterinary emergency measures repealing Commission Decision C(2014)1035 of 24 February 2014.

### Stage 3: Monitoring national programmes and managing financial transactions

Throughout the year, DG SANTE monitored the implementation of the national programmes. Firstly, the progress made by the Member States was assessed on the basis of interim technical and financial reports pertaining to the 2020 programmes. The objectives were (i) to ensure that the national programmes are implemented as planned and meet the objectives and conditions, and (ii) to increase the efficiency of the use of the credits. One of the results of the financial monitoring at the interim stage is the in-year redistribution of EU funds between the different national programmes.

Secondly, DG SANTE examined the Member States' final technical reports on their 2019 programmes and checked the correctness of the final cost claims. Due to the COVID-19 pandemic, DG SANTE granted the Member States one additional month to submit the final reports by 30 May instead of 30 April 2020. The depth of the desk controls depended on a risk analysis. The controls took place prior to the processing of financial transactions by the operational and financial actors involved in DG SANTE's financial circuit (decentralised in the operational Unit, with counterweight on a sample basis ensured by the horizontal financial Unit: 2<sup>nd</sup> level control)<sup>44</sup>. The aim was to detect and correct errors before authorisation of a financial operation.

Thirdly, on the basis of a risk analysis, a number of ex-ante financial controls was carried out on-the-spot, in the Member States, to verify cost claims that were assessed as being exposed to a relatively high risk of error. In 2020, this ex-ante on-the-spot control focused on the high risk areas as follows: veterinary emergency fund and plant health emergency measures for which the request for funding exceeded EUR 2 million or other exceptionally high amounts.

In the period 2017 to 2020, the audit plan had to account for the specific situation arising from the Avian Influenza and African Swine Fever crises. The audit results show an average correction rate of around 17%. DG SANTE made the following main observations: (a) the Member States faced difficulties to understand some of the eligibility criteria or did not apply them correctly; (b) in several cases, Member States lacked sufficiently detailed data to evidence the costs in their claim as contracts with suppliers rarely include clauses for the provision of details on the work performed; (c) with regard to compensation for the animals culled an over-evaluation was noticed when animals were compensated based on experts' evaluations rather than pre-defined value scales.

**Table 7.2.2 Indicators for grants at control stage 3**

Indicators	Targets	2020	2019	2018
<b>Stage 3: Monitoring and financial management</b>				
Member States' interim reports received and analysed	100% 100%	<b>100%</b> <b>100%</b>	100% 100%	100% 100%
Number of registered " <b>exception reports</b> "	<i>n/a</i>	<b>1</b>	3	3

<sup>44</sup> The selection of operations for the second-level verification is supported by the IT application "MUS-DICE", based on a risk analysis with a set of risk criteria.



Indicators	Targets	2020	2019	2018
Instances of Article 93 FR <sup>45</sup>	<i>n/a</i>	<b>0</b>	0	0
Percentage of implemented final <b>commitment</b> appropriations after global transfers	<i>99%</i>	<b>99,2%</b>	99,4%	99,0%
Percentage of implemented <b>payment</b> credits after global transfers	<i>100%</i>	<b>99,2%</b>	99,7%	98,6%
<b>Desk ex-ante 2<sup>nd</sup>-level verification coverage:</b> % of transactions % of total amounts	<i>10%</i> <i>50%</i>	<b>17%</b> <b>72%</b>	21% 74%	20% 72%
<b>Desk ex-ante 2<sup>nd</sup>-level verification: rejection rate</b> % of amounts corrected	<i>&lt; 2% in value</i>	<b>0,0%</b>	0,1%	0,0%
<b>Late interest payments</b> relative to total value of grants (in 2020: no case; in 2019: 1 case of €443,58; in 2018: 2 cases of €631,32)	<i>0%</i>	<b>0,0%</b>	0,0%	0,0%
<b>On-the-spot ex-ante controls: correction rate</b> (average of all corrections) - Veterinary emergency fund	<i>n/a</i>	<b>17%</b>	13,0%	-

The “exception report” submitted in 2020 pertains to one case in which a Member State informed DG SANTE that its bank account had changed while the grant decision had already expired. DG SANTE decided to make the final payment to the new bank account without signing an amendment. The “exception report” does not have any bearing on the Director-General’s declaration of assurance.

The systematic registration of so-called “exceptions” and internal control weaknesses is a supervisory tool to improve the functioning of the internal control system. The underlying causes behind these exceptions and weaknesses were analysed and reported in an overview table.

#### Stage 4: Managing ex-post controls and error corrections for grants

There is a risk that not all errors in the Member States' cost claims are detected and corrected during ex-ante controls at the desk; thus, DG SANTE complements its desk checks by ex-post controls in the Member States. The aim of ex-post controls is to provide reasonable assurance on the legality and regularity of expenditure on an annual basis.

Ex-post controls are carried out on a sample of payments DG SANTE made based on Member States' cost declarations. The audit samples are taken on the basis of a risk analysis rather than following a statistical random selection. The risk based approach is considered more cost-effective given the heterogeneity and relatively small size of DG SANTE's audit population. A key indicator is the estimated residual error rate, calculated as an average error rate from the audited sample and complemented with a qualitative analysis of the errors found before comparing it to the materiality threshold of 2% (for more information on materiality see Annex 5).

In December 2019, the Directors' Steering Committee of DG SANTE endorsed the 2020 audit work plan which was confirmed by the Management Board. The aim was to optimise the control impact through a risk based selection of payment transactions to be audited

<sup>45</sup> Article 93 of the FR(2018) on the financial irregularities panel

and sufficient audit coverage to lower the residual error rate. As priority had to be given to ex-ante controls on cost claims for Avian Influenza and African Swine Fever, the 2020 audit plan included seven ex-ante audits on emergency files and 11 ex-post audits (eight audits on veterinary programmes and three on plant health surveys).

Due to closed borders and the sanitary containment in general, on-the-spot audits had to be suspended in mid-March 2020. To a large extent, audit work continued and took place at the desk. Two of the planned audits had to be postponed while two other audits foreseen in 2021 were anticipated. The changes did not affect the basis for the Director-General's declaration of assurance for 2020.

In 2020, a total of eight ex-post audits were completed. This is lower than the average number of ex-post audits finalised in previous years (16), as priority had to be given to finalise ex-ante controls on Avian Influenza. The errors detected during the ex-post controls finalised in 2020 resulted in an error rate of 0,9% (EUR 0,2 million) for the audited national programmes for animal disease eradication and monitoring of the years 2015 to 2018. The situation in the files giving rise to corrections were common to a number of audited cost claims of Member States, and were due mainly to the inclusion of ineligible costs.

<b>Ex-post control in the Food and Feed policy area</b>	<b>2020</b>	<b>2019</b>	<b>2018</b>	<b>2017</b>	<b>2016</b>	<b>2015</b>	<b>2014</b>
Residual error rate	<b>0,8%</b>	0,4%	1,9%	2,5% (1%)	1,1%	1,2%	0,8%
Reservation	<b>No</b>	No	No	No	No	No	No

Between January and March 2021, DG SANTE issued recovery orders for about 39% of the amounts to be recovered further to the eight ex-post controls finalised in 2020.

DG SANTE is confident that the mitigating actions taken in the past are still effective to keep the residual error rate in the national programmes for animal disease eradication and monitoring<sup>46</sup> below the materiality threshold.

On 26 April 2016, the Court published its Special Report (SR 28/2016) on a performance audit on animal disease eradication programmes and drew overall positive conclusions on DG SANTE's management of the programmes. A follow-up audit finalised by the Court in late 2019 concluded that all but one recommendation have been implemented (in most respects<sup>47</sup>). For one recommendation actions are still on-going: the Animal Disease Information System (ADIS) is expected to be launched on 21 April 2021 using the new legal basis recently adopted by the Commission<sup>48</sup>. The work on interoperability with the OIE-WAHIS<sup>49</sup> continues and the two systems already performed connection tests in 2020. The actual exchange of data between ADIS and OIE-WAHIS will occur between the second and third quarter of 2021.

<sup>46</sup> Common Financial Framework 2014-2020 (CFF, Regulation (EU) No 652/2014)

<sup>47</sup> One action can only be finalised in the framework of the next Feed and Food programme 2021-2027.

<sup>48</sup> Commission Implementing Regulation (EU) 2020/2002

<sup>49</sup> Since 2012, a joint project between the Commission and OIE has worked on linking the ADNS and WAHIS systems with a common interface called Animal Disease Information System (ADIS). OIE is the World Organisation for Animal Health, operating the World Animal Health Information System (WAHIS).

**Table 10.2.3 Indicators for grants at control stage 4**

Indicators	Target	2020	2019	2018
<b>Stage 4: Ex-post controls</b>				
Ex-post control <b>detected error rate</b> (ABB activity: Food and Feed Safety)	<i>n/a</i>	<b>0,9%</b>	0,5%	2,0%
Ex-post control <b>residual error rate</b> (policy area Food and Feed) (Without one exceptional file)	<b>&lt; 2,0%</b>	<b>0,8%</b>	0,4%	1,9%
Amount of net financial corrections identified in year N compared with amount of transactions audited	<i>n/a</i>	<b>0,2 M€</b> <b>26,3 M€</b>	0,2 M€ 34,2 M€	0,9 M€ 45,3 M€
<b>Financial corrections</b> in year N linked to audits finalised in year N (until 31/12/year N)	<i>n/a</i>	<b>0,0 M€</b> <b>0%</b>	0,0 M€ 0%	0,05 M€ 5%
Total financial correction of detected errors by 26/03/2021	<i>100%</i>	0,1 M€ 39%	0,2 M€ 100%	0,4 M€ 47% <sup>50</sup>

### **Conclusion on legality and regularity in grants**

In conclusion, the analysis of the available control results, the assessment of the weaknesses identified and that of their relative impact on legality and regularity has not revealed any significant issues, which could have a material impact as regards the legality and regularity of the financial operations. It is possible to conclude that the control objectives as regards legality and regularity have been achieved.

DG SANTE's 2020 residual error rate amounts to 0,8% in the policy area "Food and Feed Safety" as a whole. Thus, it does not exceed the materiality threshold of 2%. It has to be noted that the error rate is based on a relatively low number of audits closed in 2020. As the audit findings are in line with previous years' observations on the same kind of cost claims, DG SANTE believes that it is still possible to conclude on the residual error rate in 2020.

Against this background, DG SANTE does not consider it appropriate to make a reservation in the Director-General's 2020 declaration of assurance. To reduce the error rate, in the past few years, DG SANTE has taken a series of mitigating actions; their cumulative effect is expected to keep the error rate at an acceptable level.

The audit samples are taken on the basis of a risk analysis rather than following a statistical random selection. Thus, DG SANTE calculates an average error rate rather than a statistically representative one. The detected error rate in the non-representative sample, however, is considered a reasonable source of information in the assurance building process as the audit coverage (ex-ante and ex-post) is deemed sufficient and as most of the findings were systemic.

The benefits of the controls are mostly unquantifiable in monetary terms. The evaluation of the proposed national programmes helps ensure that national programmes are compliant

<sup>50</sup> The remaining 53% will not be recovered as the audit findings were dropped after further discussions with the Member States concerned.

with the legislation and of good quality. This control is very significant to ensure value for money through improved quality, but the benefit is not quantifiable. The same can be said for DG SANTE's on-the-spot controls in the Member States: the benefits in non-financial terms include, first and foremost, compliance with regulatory provisions and deterrent effects but also improvements of the reporting systems in the Member States, especially thanks to the management recommendations made in the control reports. The number and amount of errors detected in ex ante controls and financial corrections and recoveries are only a very small part of the "benefits" of controls.

### **7.1.1.2 Public procurement in DG SANTE**

The following paragraphs describe the provisions for the management of public procurement in the policy areas Food and Feed Safety and Public Health, including the Emergency Support Instrument (ESI).

About 60% of the Health Programme budget for 2020<sup>51</sup> was transferred to CHAFEA. Around 40% was implemented by DG SANTE mostly using public procurement procedures. Under the general objective 2 "Promoting our European way of life", DG SANTE aims to complement, support and add value to the policies of Member States in improving the health of EU citizens and reducing health inequalities, encouraging innovation in health and increasing the sustainability of health systems<sup>52</sup>.

In mid-April 2020, the Council activated the Emergency Support Instrument (ESI)<sup>53</sup> to fight the COVID-19 pandemic: DG SANTE received commitment credits of EUR 2 772,3 million which were spent, first and foremost, for six Advance Purchase Agreements for vaccines (APA) worth EUR 2 484,1 million, the purchase of face masks (EUR 29,5 million), the antiviral treatment Veklury/Remdesivir (EUR 70 million), services to support the interoperability between national tracing applications (EUR 10,0 million) and training in intensive care units (EUR 2,5 million). In addition, EUR 100 million were earmarked for the purchase of rapid antigen tests; a framework contract was signed on 18 December 2020.

DG SANTE also awarded grants to increase Member States' capacity for COVID-19 testing (EUR 35,5 million) and for COVID-19 Convalescent Plasma Collection (EUR 35,7 million). In addition, EUR 5 million for actions supporting the repurpose of medicines to treat COVID-19 patients were earmarked. These credits are not included in the table below as they are grants rather than procurement.

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<sup>51</sup> The Health Programme contributes to several specific objectives under the first and second general objective described in section 1; Regulation (EU)282/2014 of 11/03/2014 and annual work programme C(2020)368 of 28 January 2020.

<sup>52</sup> Latest Programme Statement on the Union action in the field of health (Health Programme) [https://ec.europa.eu/info/sites/info/files/about\\_the\\_european\\_commission/eu\\_budget/db\\_2021\\_programme\\_statement\\_union\\_action\\_in\\_the\\_field\\_of\\_health\\_health\\_programme.pdf](https://ec.europa.eu/info/sites/info/files/about_the_european_commission/eu_budget/db_2021_programme_statement_union_action_in_the_field_of_health_health_programme.pdf)

<sup>53</sup> Emergency support under Regulation (EU) 2016/369

**Table 7.3 Procurement in the two policy areas, including ESI**

<b>Commitment credits implemented by DG SANTE (without CHAFEA)<sup>54</sup></b>	<b>2020 M€</b>	<b>2019 M€</b>	<b>2018 M€</b>
Health Programme implemented directly by DG SANTE	<b>24,6</b>	11,5	10,9
Administrative budget of the Health programme implemented by DG SANTE	<b>0,7</b>	0,8	1,3
Pilot projects/preparatory actions implemented by DG SANTE through procurement	<b>0,0</b>	0,6	0,8
<b>Public Health sub-total</b>	<b>25,3</b>	12,9	13,0
<b>Emergency Support Instrument (ESI) procurement</b>	<b>2 696,1</b>	-	-
Food and Feed Safety: DG SANTE procurement expenditure	<b>32,6</b>	18,2	15,4
Administrative budget Food and Feed implemented by DG SANTE	<b>0,7</b>	0,7	1,1
<b>Food and Feed Safety sub-total</b>	<b>33,3</b>	18,9	16,5
Procurement other policy areas (operational credits mainly)	<b>4,1</b>	4,6	3,8
Building expenditure Ireland and other administrative credits	<b>4,9</b>	5,0	4,9
<b>Total budget implemented</b>	<b>2 763,7</b>	41,4	38,2

In 2020, as in previous years, DG SANTE made extensive use of framework contracts concluded by itself or other DGs (for example DGs DIGIT and COMM). In addition to the more than 150 specific contracts, DG SANTE awards every year a rather low number of contracts following an open, restricted or negotiated procedure (table 7.4 below).

The share of different procedures thus fluctuates significantly from year to year: while in 2020, the negotiated procedure without prior publication was used in almost 70% of the limited number of cases included in table 7.4 below (11 out of 16), in 2019, it was applied in 23% of the cases (3 out of 13) and it was not used at all in 2018. Expressed in amounts, in 2020, 99% of the total contract value was awarded through the negotiated procedure (in 2019: 7% and in 2018: 0,0%). The main reason for using negotiated procedures in 2020 was the purchase of medical countermeasures and vaccines to fight the COVID-19 pandemic. In addition, as in previous years, DG SANTE managed the demand driven purchase of vaccines and antigens for animal diseases in which DG SANTE often faces situations such as monopoly or extreme urgency due to unforeseen events. Another reason is that DG SANTE often needs services in specialised fields with only one or two suitable providers.

### **Joint procurement**

In 2020, DG SANTE reinforced its work on joint procurement considerably. Already in 2014, a voluntary cooperation was established<sup>55</sup> enabling participating Member States to

<sup>54</sup> Without credits co-delegated to other DGs or transferred to CHAFEA.

purchase jointly medical countermeasures for serious cross-border health threats. Its aim is to improve Member States' preparedness to mitigate serious cross-border threats to health; ensure more equitable access to specific medical countermeasures and ensure more balanced prices. After having signed the first joint procurement framework contract in March 2019, DG SANTE negotiated nine framework contracts in 2020 for the supply of a range of medical countermeasures to fight the COVID-19 pandemic, such as personal protective equipment for healthcare workers, medical equipment to support the breathing of patients, laboratory testing and support equipment, pharmaceuticals, Veklury (Remdesivir), and medical equipment for COVID-19 vaccination. Under the Joint Procurement framework contracts Member States have the possibility to order what they need, but they do not have an obligation to use the framework contracts.

**The control process for public procurement is divided into three distinct stages, each with specific control objectives as described below.**

### **Stage 1: Assessing procurement needs and selecting the offer**

DG SANTE starts planning a procurement procedure by assessing the procurement needs when preparing the annual work programmes in each policy area. With regard to the choice of the right procurement procedure, the most important criterion is the size of the contract and the kind of service needed.

With a view to achieving a good quality in terms of tender documents, harmonisation and efficiency gains, since mid-2014 DG SANTE has centralised its administrative management of public procurement procedures covering new procurement procedures above EUR 15.000, including specific contracts on Framework Contracts with re-opening of competition. The central team also gives support to all procedures involving pilot projects and preparatory actions, be it through public procurement or through grants. In 2020, a few exceptions to the centralisation still existed for organisational/technical or geographical reasons; these concerned mainly communication, and local calls for tender managed by and for DG SANTE's site in Grange, Ireland.

Striving to reduce administrative burden, DG SANTE published 2020 calls above the Directive threshold (currently EUR 139.000) through the e-tendering platform of the Commission. Since the beginning of 2019, DG SANTE also uses e-submission as unique tool for the open calls and e-ordering for the automatic generation of the procurement contract.

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<sup>55</sup> See the Joint Procurement Agreement to procure medical countermeasures adopted in 2014 pursuant to Article 5 of Decision 1082/2013/EU on serious cross-border threats to health

**Table 7.4 Procurement contracts above EUR 60.000<sup>56</sup>**

Type of procedure	2020		2019		2018	
	N° of contracts	Amount M€	N° of contracts	Amount M€	N° of contracts	Amount M€
Open (Financial Regulation)	3	1,8	3	6,8	6	3,6
Negotiated without prior publication	3	9,9	3	0,7	-	-
Negotiated under extreme urgency	8	2 576,6	-	-	-	-
Negotiated middle value contract	1	0,1	4	0,4	-	-
Restricted (FR 164 (1)(b))	1	1,7	3	2,2	1	0,3
<b>TOTAL</b>	<b>16</b>	<b>2 590,1</b>	<b>13</b>	<b>10,1</b>	<b>7</b>	<b>3,9</b>

### ***Main open, negotiated and restricted procedures***

In the health policy area, due to the COVID-19 pandemic, eight negotiated procedures under extreme urgency were managed under the Emergency Support Instrument for six Advance Purchase Agreements for vaccines (EUR 2 484,1 million), one contract for the supply of Veklury (Remdesivir) for the treatment of COVID-19 patients (EUR 63,0 million) and one contract for protective equipment for health care works (EUR 29,5 million).

With the European Society of Intensive Care Medicine (ESICM) DG SANTE negotiated a contract for the provision of training on intensive care medicine skills for healthcare professionals for EUR 2,5 million.

Two negotiated procedures were used in the food safety policy area, to purchase antigens against food and mouth disease for EUR 7,3 million and for an advertising campaign on the farm to fork strategy (EUR 0,1 million).

To procure services from 2020 to 2024 related to DG SANTE's site management in Grange, Ireland, DG SANTE used an open procedure to secure childcare services for EUR 1,4 million; a restricted procedure was related to security services (EUR 1,7 million).

### ***Public Procurement Committee***

Procurement procedures (open calls for tender and negotiated procedures) for contracts above the Directive threshold (EUR 139.000 in 2020), are examined by DG SANTE's "Public Procurement Committee". It is designed as an ex-ante control prior to an authorising officer by sub-delegation (AOSD) taking an award decision. It gives an opinion on the compliance with Commission rules and procedures for public procurement, including the use of adequate contract provisions. The Committee consists of representatives of the central financial cell, the decentralised financial cells and the legal affairs Unit. Furthermore, at the discretion of the competent authorising officer, the Committee may be asked to review the draft tender documents before the publication of the contract notice in the Official Journal. In 2020, this voluntary additional check was applied for one file.

<sup>56</sup> Annex 3 table 12

**Table 7.5.1 Indicators for procurement at stage 1**

Indicators	Targets	2020	2019	2018
<b>Stage 1: Assessing procurement needs and selecting the offer</b>				
Rate of open calls for tenders for which - No offer was received (in 2020: 0 out of 2; in 2019: 1 out of 6; in 2018: 4 out of 10) - The procedure had to be cancelled (in 2020: 0; in 2019: 1; in 2018: 1)	0% 0%	<b>0%</b> <b>0%</b>	<b>17%</b> <b>17%</b>	40% 10%
Rate of negotiated procedures <sup>57</sup> for which - No offer was received - The procedure had to be cancelled	0% 0%	<b>5%</b> <b>5%</b>	<b>0,0%</b> <b>8%</b>	0,0% 0,0%
Number of procurement procedures within the scope of the PPC	<i>n/a</i>	<b>22</b>	9	5
Number of procurement procedures examined by the PPC	<i>n/a</i>	<b>5</b>	9	5
% of procurement procedures examined by PPC	100%	<b>23%</b>	100%	100%
Positive (negative) opinions of the Public Procurement Committee	<i>n/a</i>	<b>100%</b>	<b>90%</b> (1 negative)	100%
Public Procurement Committee opinions followed by the authorising officers responsible	100%	<b>100%</b>	<b>100%</b>	100%

In 2020, one negotiated procedure (out of 20) above EUR 60.000, had to be cancelled because no bid was submitted.

In 2020, the Public Procurement Committee provided five opinions on procurement contracts with a total maximum value EUR 296,8 million (EUR 341,9 million in 2019). In both years a high value Joint Procurement Framework Contract was included in these figures, taking into account the amounts that may be committed by Member States, while the contract share of the Commission is limited. The value of contracts awarded for the Commission amounted to EUR 28,8 million in 2020 and EUR 13,2 million in 2019. All opinions were positive.

The PPC examined only 23% of the files that fell under its remit. Due to extreme urgency to conclude procurement contracts for the supply of medical countermeasures under Joint Procurement, Advance Purchase Agreements to secure vaccines against COVID-19 and other procurement procedures under the Emergency Support Instrument, the Director-General approved an exception report to waive the PPC opinion (see also Annex 8, point 8.2.2.2). DG SANTE assessed the possible negative impact of the derogations on the reasonable assurance as relatively low.

<sup>57</sup> Procurement procedures above EUR 60.000



## Stage 2: Monitoring the implementation of procurement contracts and managing financial transactions

The second stage of control procedures for procurement concerns the technical and financial monitoring of the implementation of the contracts. This is the responsibility of the operational Units and thus is not part of the centralisation of the procurement procedures. The frequency and depth of the controls depends on the size, complexity and sensitivity of the contract.

The objective is, firstly, to ensure that the contractor meets the objectives, delivers good quality, on time, and complies with the contract provisions. Secondly, DG SANTE aims to detect and correct errors before a financial operation is authorised. The financial circuits foresee a first-level verification of each financial transaction by the responsible financial Unit; a second-level verification is carried out by the central financial Unit on a sample of transactions (commitments, payments and recovery orders). Checks are done at the desk prior to the authorisation of the transaction (ex-ante).

The selection of operations for the second-level verification is supported by the IT application "MUS-DICE", based on a risk analysis with a set of risk criteria. As no file was rejected for financial corrections, there was thus no situation of the authorising officer overruling a blockage by the second-level verifying officer.

**Table 7.5.2 Indicators for procurement at stage 2**

Indicators	Targets	2020	2019	2018
<b>Stage 2: Monitoring of contract implementation and financial management</b>				
<b>Ex-ante 2<sup>nd</sup>-level verifications coverage:</b>				
% of transactions	10%	<b>17%</b>	9%	8%
% of amounts	50%	<b>99%</b>	58%	44%
<b>Ex-ante rejection rate</b> of 2 <sup>nd</sup> -level verifications: no cases of financial errors	< 2% in value	<b>0,0%</b>	0,0%	0,0%
<b>Late interest payments</b> relative to total value of contracts (in 2020: no case; in 2019: 2 cases of €496,50; in 2018: no case)	0%	<b>0,0%</b>	0,0%	0,0%
Percentage of implemented final commitment appropriations	99%	<b>86,9%</b>	99,5%	100%
Percentage of implemented payment credits after global transfers	100%	<b>81,1%</b>	91,1%	100%

The rates of implementation of the total commitment and payment credits (86,9% and 81,1% respectively) are relatively low as they include Member States' contributions to the top-up of the Emergency Support Instrument for the EU strategy for COVID-19 vaccines. The credits of EUR 750 million became available only in November 2020 and were implemented to 44% in 2020. The remaining amounts have been carried forward to 2021 and are expected to be used for the signature of two additional Advance Purchase Agreements.

The 2020 must-use commitment and payment credits were implemented to 100% and 94% respectively. A high amount of pre-financing, which was scheduled to be paid in

December to a vaccine producer, had to be postponed as conditions for payment were not fulfilled. The remaining payment credits were therefore carried over to 2021<sup>58</sup>.

### Stage 3: Supervisory measures

In order to measure the effectiveness of ex-ante controls, DG SANTE has established diverse supervisory measures such as the reporting on exceptions and non-compliance events, defined as control over-rides or deviations from policies and procedures, and the results of other supervisory activities. In addition, DG SANTE's procurement procedures are audited by the Court of Auditors and the IAS.

Ex-post controls on procurement contracts at the contractor's site are conducted only in exceptional cases when high risks have been identified during ex-ante controls. In 2020, no such audit was conducted. DG SANTE considers that adequate procurement procedures ensuring a good price-quality ratio as well as the technical and financial checks prior to payment are sufficient to give reasonable assurance that error rates are very low. Therefore, DG SANTE believes, there is little added value to carry out ex-post controls of payments linked to procurement on a systematic basis.

**Table 7.5.3 Indicators for procurement at stage 3**

Indicators	Targets	2020	2019	2018
<b>Stage 3: Supervisory measures</b>				
Number of registered " <b>exception reports</b> " relative to procurement procedures	<i>n/a</i>	<b>23</b>	3	2
Instances of Article 93 FR <sup>59</sup>	<i>n/a</i>	<b>0</b>	0	0
<b>On-the-spot control: detected error</b> rate in a procurement contract	< 2%	<b>n/a</b>	<i>n/a</i>	<i>n/a</i>
<b>Recovery orders</b> of year N: (in number) in amount	<i>n/a</i>	<b>(0)</b> <b>n/a</b>	(1) 0,5 M€	(0) <i>n/a</i>
For procurement: <b>Ombudsman</b> cases or legal proceedings open in year N	<i>n/a</i>	<b>0</b>	0	0

The systematic registration of so-called "exceptions" and internal control weaknesses is a supervisory tool to improve the functioning of the internal control system. The underlying causes behind these exceptions and weaknesses were analysed and reported to the Directors' Steering Committee. The 23 "exception reports" of 2020 mainly pertain to derogations from the Financial Regulation and/or the Joint Procurement Agreement when DG SANTE purchased medical countermeasures and vaccines facing extreme urgency and numerous uncertainties as to the needs in Member States and the supplies on the market (a description of the "exceptions" is given in point 8.2.2.2 below). DG SANTE assesses that these derogations have no bearing on the Director-General's declaration of assurance as

<sup>58</sup> Non-automatic carry over of payment credits in accordance with Article 12(2)(c) of the Financial Regulation

<sup>59</sup> Article 93 of the FR(2018) on the financial irregularities panel

they were discussed at DG level and in consultation with horizontal services in the Commission.

### ***Conclusion on legality and regularity in procurement***

In conclusion, the analysis of the available control results, the assessment of the weaknesses identified and that of their relative impact on legality regularity has not unveiled any significant weakness which could have a material impact as regards the legality and regularity of the financial operations. DG SANTE considers it possible to conclude that the control objective as regards legality and regularity has been achieved.

The benefits of the controls are mostly unquantified such as the reduced risk of fraud and prevention of conflict of interests as well as other deterrent effects through a high degree of segregation of duties and independent oversight. The centralisation of the administrative management of public procurement procedures is a control to ensure compliance with rules and regulations as well as good quality of all steps in the procurement procedures.

#### **7.1.1.3 Budget implementation tasks entrusted to other services and entities**

DG SANTE has entrusted parts of its budget for indirect management implementation by the Executive Agency CHAFEA. In addition, DG SANTE finances, partially or in full, the operating budgets of CHAFEA and a number of EU decentralised agencies. In each case, DG SANTE's supervision arrangements are based on the principle of controlling 'with' the relevant entity. For details, see Annex 6.2 (relevant internal control system).

#### ***Consumers, Health, Agriculture and Food Executive Agency (CHAFEA)***

The Consumers, Health, Agriculture and Food Executive Agency (CHAFEA, formerly the Executive Agency for Health and Consumers – EAHC<sup>60</sup>) was created on 1 January 2005. Since 2014, the agency's mandate includes the implementation of the Public Health Programme and the Better Training for Safer Food (BTSF) initiative, for both of which DG SANTE is the parent DG. Other parent DGs are AGRI, GROW and JUST. DG SANTE pays a subsidy to CHAFEA to cover its running costs (administrative or operating expenditure) for the implementation of the tasks transferred to it. Other parent DGs also pay their share of the total costs to implement the transferred tasks related to their programmes.

CHAFEA is subject to an individual discharge procedure by the European Parliament for the implementation of its own budget (administrative expenditure). The operational budget implemented by the agency stems from the Commission budget and is part of the general discharge given to the Commission.

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<sup>60</sup> Commission Implementing Decision No 2013/770/EU of 17 December 2013 establishing the Consumers, Health, Agriculture and Food Executive Agency and repealing Decision 2004/858/EC establishing the Executive Agency for Health and Consumer; Commission Decision C(2013)9505 of 20 December 2013 delegating powers to the Consumers, Health, Agriculture and Food Executive Agency with a view to performance of tasks linked to the implementation of Union programmes, as amended by Commission Decisions C(2015)2856 of 4 May 2015 and C(2015)8752 of 11 December 2015.

The use made of the subsidy is audited – inter alia – by the European Court of Auditors, which gave – since the founding of the agency – a positive declaration of assurance to CHAFEA.

**Table 7.6 Subsidies paid by DG SANTE to CHAFEA**

<b>CHAFEA</b> (former EAHC)	<b>2020</b>	<b>2019</b>	<b>2018</b>
	<b>M€</b>	<b>M€</b>	<b>M€</b>
Subsidy for administrative budget	<b>5,9</b>	5,9	5,7
Operational budget transferred from SANTE	<b>59,5</b>	65,6	64,1

The control process is divided into three distinct stages, each with specific control objectives (for more detail see Annex 6.2).

### **Stages 1 and 2: Mandate of CHAFEA and readiness assessment of the executive agency's control framework towards autonomy**

The agency gained full autonomy in 2007. Since then, no re-assessment of the agency's autonomy was necessary. The latest changes of the mandate (delegation act) took place in 2015. Thus, the control stages 1 and 2 were not applicable in 2020.

In the framework of the new Multi-annual Financial Framework (MFF 2021-2027), the Commission adopted the Commission Implementing Decision (EU) 2021/173<sup>61</sup>. Accordingly, the DG SANTE programmes currently managed by CHAFEA will be transferred to the new established European Health and Digital Executive Agency (HaDEA) as from 1 April 2021.

HaDEA will be entrusted with the implementation of the following (parts of) Union programmes:

- EU4Health programme<sup>62</sup>;
- Horizon Europe: Pillar II, Cluster 1: Health;
- Single Market Programme: Food safety: health for humans, animals and plants along the food chain and better training for safer food;
- Digital Europe Programme;
- Connecting Europe Facility: Digital;
- Horizon Europe: Pillar II, cluster 4: Digital, industry and space.

<sup>61</sup> Commission Implementing Decision (EU) 2021/173 of 12/02/2021, establishing the European Climate, Infrastructure and Environment Executive Agency, the European Health and Digital Executive Agency, the European Research Executive Agency, the European Innovation Council and SMEs Executive Agency, the European Research Council Executive Agency, and the European Education and Culture Executive Agency and repealing Implementing Decisions 2013/801/EU, 2013/771/EU, 2013/778/EU, 2013/779/EU, 2013/776/EU and 2013/770/EU.

<sup>62</sup> Regulation (EU)2021/522 of 24 March 2021

According to HaDEA's Act of delegation<sup>63</sup>, DG SANTE will be the lead parent Directorate-General and will have specific responsibilities in relation with the monitoring and supervision of horizontal issues in the agency, as was already the case for CHAFEA.

### **Stage 3: DG SANTE's monitoring and supervision (“control with the executive agency”)**

DG SANTE supervises the activities of the agency and carries out supporting and steering activities, in particular through the quarterly meetings of the Steering Committee, which are chaired by DG SANTE's Deputy Director-General responsible for Health. The Steering Committee consists of five members, out of which one external member (DG HR) and the chair (from DG SANTE)<sup>64</sup>. Furthermore, in 2020, two persons had observer status: a Director in DG GROW and the Head of Unit responsible for 'Finance, Budget and Controls' of DG SANTE.

The Steering Committee is responsible for the adoption of the agency's annual work programme and administrative budget, including the establishment plan. The agency sends quarterly reports to the Steering Committee on the achievements of objectives, audit findings and relevant follow-up, as well as of any other important issue relating to internal control, financial management and audit.

Furthermore, regular bilateral meetings at the level of the Units concerned in DG SANTE and CHAFEA ensure the necessary co-ordination of activities.

DG SANTE follows up on the agency's consumption of both the administrative and the operational budget. In 2020, no serious control issue came to the attention of DG SANTE that would warrant a financial or reputational reservation in DG SANTE's 2020 Annual Activity Report. Nevertheless, the following issues require special attention:

- Although CHAFEA shows an implementation rate of the 2020 operational budget close to 100%, the level of individualisation of commitments by signing grants or procurement contracts is relatively low: 29% of the credits transferred to CHAFEA for the Health Programme and only 1% for the Better Training for Safer Food initiative (BTSF);
- In the light of the COVID-19 pandemic and due to the closure of CHAFEA in 2021, the Steering Committee approved on 21 September 2020 the request for the partial return to the EU budget of €0,7 million of administrative credits that could not be consumed by the year-end.

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<sup>63</sup> Under preparation: Commission Decision on delegating powers to the European Health and Digital Executive Agency with a view to the performance of tasks linked to the implementation of Union programmes in the field of EU4Health, Single Market, Research and Innovation, Digital Europe, Connecting Europe Facility – Digital, comprising, in particular, implementation of appropriations entered in the general budget of the Union.

<sup>64</sup> Commission Decision C(2019) 4550 of 26.6.2019 appointing the members and observers of the Steering Committee of the Consumers, Health, Agriculture and Food Executive Agency and repealing Decision C(2017) 4532.

The use made of the subsidy is audited – inter alia – by the European Court of Auditors, which gave – since the founding of the agency – a positive declaration of assurance to CHAFEA. In 2020, the Court of Auditors gave the agency a positive opinion on both its provisional 2019 accounts and its transactions in 2019.

In the CHAFEA's 2020 Annual Activity Report, the Director reported reasonable assurance on the delegated budget managed by the agency on behalf of DG SANTE and made no reservation (see the agency's 2020 Annual Activity Report). As the residual error rate for the Health Programme of 1,96% is below the threshold, CHAFEA does not make a reservation.

**Table 7.7 Indicators of control effectiveness as regards legality and regularity**

Executive agency CHAFEA	Targets	2020	2019	2018
Steering Committee meetings with adequate quorum for voting (info: DG SANTE is one of three parent DGs)	4	<b>4</b>	4	4
Number of "exception reports" relative to the guidelines on the co-operation between DG SANTE and CHAFEA	<i>n/a</i>	<b>0</b>	0	0
Budget execution rates of the operational budget transferred to the agency:				
commitments	99%	<b>100%</b>	100%	100%
payments	100%	<b>100%</b>	100%	100%
Director's report on control results and error rates endorsed by Steering Committee or Management Board prior to finalisation of DG SANTE's Annual Activity Report	<i>yes</i>	<b>yes</b>	yes	yes
Court of Auditors' assurance on the agency's accounts and implementation of the administrative budget of year N-1 without qualification	<i>yes</i>	<b>yes</b>	yes	yes
Discharge granted for year N-1 and discharge recommendations implemented for year N-2	<i>yes</i>	<b>yes</b>	yes	yes
Ratio of recovery of the positive budgetary outturn of year N to subsidy paid in year N-1	<i>n/a</i>	<b>6,9%</b>	11,8%	15,6%

With regard to internal control in general, CHAFEA highlighted the most significant details in the report to the Steering Committee. Following the annual risk assessment exercise that took place in the fourth quarter of 2020 and covered the internal and external factors at all organisational levels, no significant risks were identified. Moreover, no critical or high risks were reported in the framework of the COVID-19 targeted risk assessment launched in June 2020 by SG and DG BUDG. In 2020, there were no open cases by OLAF relevant to the funds transferred by DG SANTE to CHAFEA.

### **EU decentralised agencies**

In 2020, DG SANTE was responsible for four EU decentralised agencies, of which three received an annual subsidy from the EU budget. In addition, DG SANTE contributes to the running costs of ECHA for its biocides activities (the responsible DG for ECHA is DG GROW).

- European Centre for Disease Prevention and Control (ECDC) located in Stockholm, Sweden<sup>65</sup>.  
ECDC works to prevent threats to human health from disease outbreaks and to react quickly and effectively to minimise their impact. To this end, ECDC operates dedicated surveillance networks, provides scientific opinions, notably risk assessments, operates the early warning and response system (EWRS) and provides scientific and technical assistance and training.
- European Food Safety Authority (EFSA) located in Parma, Italy<sup>66</sup>.  
EFSA provides independent scientific opinions and scientific and technical advice on food and feed safety. EFSA's outputs build the scientific basis for the Commission's decision-making as regards the authorisation of regulated products in the food and feed sectors; and for EU initiatives in all fields which have a direct or indirect impact on food and feed safety, including animal health and welfare, and plant health.
- European Medicines Agency (EMA) located in Amsterdam, The Netherlands<sup>67</sup>.  
EMA evaluates and supervises medicines for human and veterinary use; it provides the Member States and the institutions of the European Union with independent scientific advice on medicinal products for human or veterinary use. EMA's scientific opinions are the basis for the Commission's decision-making on the authorisation of medicines. EMA is to a large extent fee-financed.
- Community Plant Variety Office (CPVO) located in Angers, France<sup>68</sup>.  
CPVO supports innovation through the protection of new plant varieties throughout the EU; CPVO is fully fee-financed.
- European Chemicals Agency (ECHA) located in Helsinki<sup>69</sup>.  
ECHA's main tasks are to ensure a high level of protection of human health and the environment as well as the free movement of substances on the internal market. Relevant for DG SANTE are ECHA's biocides activities which provide the scientific basis for the Commission's decision-making on the authorisation of biocidal products and approval of active substances. ECHA's biocides activities are partially fee-financed.

In addition, DG SANTE is involved in the governance of Eurofound<sup>70</sup> (lead partner DG is EMPL) and EMCDDA<sup>71</sup> (DG HOME is the lead partner DG), but does not contribute to their running costs.

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<sup>65</sup> ECDC was established by Regulation (EC) No 851/2004 of the European Parliament and of the Council.

<sup>66</sup> EFSA was established by Regulation (EC) No 178/2002 of the European Parliament and of the Council.

<sup>67</sup> EMA was established by Council Regulation (EEC) No 2309/93, which was replaced by Regulation (EC) No 726/2004 of the European Parliament and of the Council. With regard to the location of the seat of the EMA see Regulation (EU) 2018/1718 of the European Parliament and of the Council amending Regulation (EC) No 726/2004, OJ L 291, 16.11.2018, p. 3). EMA left its London premises on 1 March 2019 to relocate to Amsterdam.

<sup>68</sup> CPVO was created by Council Regulation (EC) No 2100/94.

<sup>69</sup> ECHA was set up by Regulation (EC) No 1907/2006 of the European Parliament and of the Council.

<sup>70</sup> European Foundation for the Improvement of Living and Working Conditions; DG SANTE's involvement is limited to Eurofound's activities on quality of life and public services.

<sup>71</sup> European Monitoring Centre for Drugs and Drug Addiction; the synergies with DG SANTE's work cover addictions and drug use associated communicable diseases.

**Table 10.8 EU decentralised agencies – subsidies**

EU decentralised agencies	Number of staff *			EU contribution		
	2020	2019	2018	2020 M€	2019 M€	2018 M€
ECDC	285	285	285	62,5	59,2	58,1
EFSA	508	467	459	103,0	79,9	79,1
EMA <sup>72</sup>	854	854	810	58,9	35,5	32,6
CPVO <sup>73</sup>	52	51	51	n/a	n/a	n/a
ECHA-biocides <sup>74</sup>	69	67	64	7,2	3,1	4,9
<b>Total</b>	<b>1.768</b>	<b>1.669</b>	<b>1.658</b>	<b>231,6</b>	<b>174,7</b>	<b>170,4</b>

\*: Total number of human resources as authorised under the budget for officials and temporary agents and as estimated for contract agents and seconded national experts.

Overall, the establishment plan posts of agencies correspond to the Commission's communication on the programming of human and financial resources for decentralised agencies (2014-2020)<sup>75</sup>. In 2020, the increase in DG SANTE agencies' total number of staff, is most importantly due to the reinforcement of EFSA in the framework of the General Food Law (GFL) proposal, and the increased complexity of mandates.

Compared to 2019, the EU contribution to the agencies' budgets increased by EUR 56,9 million, as follows:

- The contribution to EFSA covered the additional cost of staff and operational budget related to the increased workload and complexity of mandates on top of the forecasted impact of the revised General Food Law proposal;
- The EU contribution to the ECHA-biocides budget fluctuates over the years due to the variations in fee income;
- As a response to COVID-19 outbreak, additional resources were deployed to strengthening ECDC;
- The contribution to EMA increased further to the entry into force of the new Veterinary Medicines Regulation (VMR).

<sup>72</sup> EMA's total 2020 budget amounted to EUR 358,1 million (in 2019: EUR 339,9 million; in 2018: EUR 337,7 million), mainly financed by fees. The EU contribution is a balancing grant (in 2020: 16,4%; in 2019: 10,4%; in 2018: 9,6%).

<sup>73</sup> CPVO does not receive any EU subsidies; its 2020 budget amounted to EUR 20 million (2019: EUR 16,4 million; 2018: EUR 16,9 million).

<sup>74</sup> Since 2015, DG SANTE contributes to the biocides activities of ECHA in accordance with the Biocidal Products Regulation (EU) No 528/2012, which came into force on 1 September 2013. ECHA's budget for biocides in 2020 amounted to EUR 12 million (in 2019: EUR 12,7 million; in 2018: 10,9 million). The EU contribution is a balancing grant (in 2020: 60%; in 2019: 59%; in 2018: 45%).

<sup>75</sup> COM(2013) 519 final of 10/07/2013. ECHA's biocides establishment plan was not subject to the staff reduction target over 2013-2018 as the biocides activities were in start-up phase during 2014 and 2015 and additional tasks were assigned in 2017 (three more product types becoming eligible).



**The control process is divided into five distinct stages, each with specific control objectives (for more detail see Annex 6).**

### **Stage 1: Ensuring the founding Regulation of the agency is free of legal issues**

This control applies whenever an agencies' founding Regulation is amended. In response to COVID-19 pandemic, the role of the agencies will be strengthened as part of the Health Union Package<sup>76</sup>.

In June 2019, the European Parliament and Council adopted an amendment to EFSA's founding Regulation.<sup>77</sup> In line with the Common Approach on decentralised agencies, EFSA's Management Board will include from July 2022 a member from each Member State, and the Commission will carry out an evaluation of the Agency's performance every five years.

### **Stage 2: Assessing the agency's control framework and financial rules**

In December 2018, the Commission adopted a revised Framework Financial Regulation (FFR)<sup>78</sup> for decentralised agencies. All DG SANTE partner agencies aligned their financial rules to the new FFR by the end of 2019. Through the Commission representative on the agencies' Management Boards and the Commission Opinions agencies' Single Programming Documents, DG SANTE also monitors the alignment of the agencies' Internal Control Frameworks (ICF) with the Commission's Internal Control Framework. In addition, the Agencies developed their anti-fraud strategy, adopted by the respective Management Boards, and updated regularly. On request, DG SANTE provides feedback and support on the Internal Control strategy and the relevant control principles.

### **Stage 3: DG SANTE's monitoring and supervision ("control with the agency")**

DG SANTE is a member of the agencies' Management Boards and participates in the meetings throughout the year (2 to 4 meetings depending on the agency). The role of the Management Boards includes the approval of the agencies' annual budgets as well as the adoption of both the multiannual and annual work programmes and the annual activity reports. They are regularly informed on the achievements of the agencies' objectives as well as on all other important issues relating to operational and financial management, internal control, evaluations and audits.

Bilateral meetings between DG SANTE and its partner agencies take place both at senior management and technical level. DG SANTE steered a close cooperation of the agencies on IT matters, by organising workshops in the framework of the Health Policy Agencies Collaboration. In addition, in June 2020, DG SANTE convened a meeting bringing together the Heads of all its partner agencies and DG SANTE management.

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<sup>76</sup> COM(2020) 724 final of 11/11/2020. Building a European Health Union: Reinforcing the EU's resilience for cross-border health threats.

<sup>77</sup> Regulation (EU) 2019/1381 of the European Parliament and of the Council on the transparency and sustainability of the EU risk assessment in the food chain amending Regulation (EC) No 178/2002.

<sup>78</sup> Commission Delegated Regulation (EU) 2019/715 on the framework financial regulation for the bodies set up under the TFEU and Euratom Treaty and referred to in Article 70 of Regulation (EU, Euratom) 2018/1046 of the European Parliament and of the Council.

Five operational Units in DG SANTE are the primary interlocutors for the agencies. Since February 2016, a horizontal Unit in Directorate A "Resource management and better regulation" took over a central coordination role to promote a coherent approach towards all agencies and to exchange good practices. DG SANTE monitored actively compliance with the Commission's guidelines on independence in DG SANTE's task force with the agencies and through bilateral contacts.

#### Stage 4: Audit and evaluation, discharge

While the Director-General of DG SANTE is accountable for the legality and regularity of the payments of the subsidies to the agencies, the accountability for the regularity and legality of this expenditure resides ultimately with the agencies themselves.

##### Agencies are subject to periodical external evaluations<sup>79</sup>.

- **ECDC:** in 2020, the ECDC Management Board approved the recommendations of the third external evaluation of ECDC for the years 2013-2017, based on the external evaluation finalised in 2019.
- **EFSA:** in 2018 and 2019, EFSA held two external evaluations, one ex-post (STEP 2018 project) and one mid-term (EFSA Strategy 2020 implementation). Pending follow-up actions identified by the ex-post evaluation of the "STEP 2018" project will be implemented in 2021 in the context of the new EFSA strategy and performance framework. The results and conclusions of the mid-term evaluation fed into the preparation of the new strategy to be finalised in 2021.
- **EMA:** a formal Commission report on the study on the operation of centralised and decentralised mutual recognition procedures for the authorisation and monitoring of medicinal products for human use is being finalised and will be delivered to the European Parliament and to the Council. The study includes among other aspects, an assessment of the effectiveness and efficiency of the overall structure of EMA's committees, working parties, scientific advisory and expert groups.
- **CPVO:** the CPVO organized regularly (at least every six years) an evaluation of its activities. An evaluation was organized in 2016-2017. The next retroactive evaluation will be launched in 2021.

##### European Court of Auditors

Each year, the Court examines the accounts of all agencies, as well as the received revenue and the payments made by the agencies. On 22 October 2020, the Court published its "Annual report on EU agencies for the financial year 2019". The Court gave a positive declaration of assurance to all five agencies to which DG SANTE is parent (or associated).

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<sup>79</sup> According to their Founding Regulations, external evaluations are to be commissioned for ECDC every five years, for EFSA every six years (every five according to the amendment to EFSA's founding act adopted in 2019), for EMA every 10 years.

Not calling the positive opinion into question, the Court commented on internal control issues related to some aspects of procurement procedures of ECHA, EFSA and EMA.

### Discharge

In May 2020, taking into account the Court of Auditors reports on the agencies annual accounts 2018, the European Parliament granted the four agencies which receive a subsidy from the EU budget discharge in respect of the 2018 budget implementation.

All agencies included in their final 2019 accounts a comment on the COVID-19 outbreak: as a non-adjusting event, the outbreak of the coronavirus does not require any adjustments to the 2019 annual accounts but the financial effects of the outbreak on subsequent reporting periods cannot be estimated reliably.

EMA included in its final 2019 accounts published in early July 2020 a comment on its premises in London: in July 2019, EMA reached an agreement with its landlord to sublet its former office premises to a subtenant under conditions that are consistent with the ones of the headlease, including the sublease term that extends until the expiry of EMA's headlease in June 2039. Since EMA remains a party to the headlease with its Canary Wharf landlords, should the subtenant not be able to meet its obligations, the agency could be exposed for all the amounts remaining payable under the headlease contractual obligations. The EMA Management Board informed the Commissioner that the risk is high. DG SANTE remains in contact with EMA monitoring the situation.

DG SANTE, within the limits of its role on the EU agencies' Management Boards and Audit Committees, if applicable<sup>80</sup>, follows up closely the improvements to be made by the agencies in follow-up to audits, evaluations and discharge recommendations.

### Court of Auditors' performance audit on the agencies

On 22 October 2020, the Court published its Special Report 22/2020 "Future of EU agencies – Potential for more flexibility and cooperation". The audit identified a need for more flexibility in the set-up and functioning of the agencies. The auditors also found that insufficient support from Member States, industry, Commission or other agencies prevents some agencies from fully performing their role.

The Court recommends that the Commission and the agencies evaluate more carefully the coherence of agencies over their lifetime, and adjust resources accordingly (e.g. EMA and ECHA); assess inefficiencies in the area of governance and improve performance reporting to focus not only on agencies' activities, but also on their important contribution to policy implementation; facilitate agencies' efforts to cooperate as centres of expertise and networking.

No issue was addressed directly to DG SANTE or its partner agencies. DG SANTE stays abreast of the implementation of the Court's recommendations by the horizontal services and the agencies as a whole.

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<sup>80</sup> DG SANTE has two nominated members in ECDC's and one member in EFSA's Audit Committee; EMA and CPVO do not have an Audit Committee and all audit related issues are brought directly to the Management Board and the Administrative Council respectively.

## Stage 5: DG SANTE's payments of the subsidy

The control issues that came to the attention of DG SANTE did not affect the legality and regularity of DG SANTE's payments of subsidies to the agencies (Table 7.9 below summarises the indicators of control effectiveness as regards legality and regularity).

Further to the Court of Auditors assurance received in the second quarter of 2020, DG SANTE cleared all pre-financing payments made to the agencies in 2019 and made the final payments of the 2019 subsidies. Thus, no reservation to DG SANTE's declaration of assurance is warranted.

**Table 7.9 Indicators of control effectiveness as regards legality and regularity**

EU decentralised agencies	Targets	2020	2019	2018
<b>Court of Auditors' assurance</b> on EFSA's, EMA's, ECDC's, CPVO's and (since 2015) ECHA's accounts and implementation of their administrative budget of year N-1 without qualification	Yes 5 out of 5	<b>yes</b> <b>5 out of 5</b>	yes 5 out of 5	yes 5 out of 5
<b>Discharge</b> granted for year N-1 and discharge recommendations implemented for year N-2	yes	<b>yes</b>	yes	yes
Ratio of recovery of the positive budgetary outturn of year N to subsidy paid in year N-1	n/a	<b>1,2%</b>	9,7%	9,4%

### **Conclusion on legality and regularity of subsidy payments to agencies**

For the 2020 reporting year, the executive agency CHAFEA has reported reasonable assurance on the delegated budget managed on DG SANTE's behalf. CHAFEA has signalled no serious control issues and no reservation was made.

For all five EU agencies (EFSA, EMA, ECDC, CPVO and ECHA for its biocides activities) for which DG SANTE was responsible in 2020, the Court of Auditors gave a positive declaration of assurance for the year 2019. The comments made by the Court did not call into question DG SANTE's reasonable assurance on the operating budget managed by the EU agencies.

From its own monitoring and supervision work as a responsible DG, DG SANTE did not become aware of anything that would indicate that the reporting from the agencies would not be reliable. Consequently, in view of DG SANTE's residual responsibility for the management of the parts of the budget cross-subdelegated to authorising officers in other DGs and transferred to the executive agency, CHAFEA, as well as for the funds paid to the operating budgets of the agencies, DG SANTE concludes that there are no control weaknesses affecting the assurance building in terms of the control objective as regards legality and regularity.

The benefits resulting from the controls are not quantifiable. Examples of unquantified benefits are the reduced risk of fraud and deterrent effects of the audits by the Court of Auditors and the Commission's Internal Audit Service (IAS) as well as DG SANTE's following-up on the agencies' Internal Control Frameworks, including the agencies' anti-fraud strategies and policies to prevent "conflicts of interest".

## 7.1.2 Fraud prevention, detection and correction

The controls to prevent and detect fraud are basically the same as those intended to ensure the legality and regularity of the transactions. In 2020, risk of fraud was included in the limited risk assessment in June on the COVID-19 impact on sound financial management and in the annual risk management exercise finalised in November. The fraud risks are addressed by specific controls designed and implemented to mitigate the risks.

DG SANTE has developed and implemented its own anti-fraud strategy since 2013, on the basis of the methodology provided by OLAF<sup>81</sup>. The strategy is updated regularly. It was last updated in July 2017 covering the years 2017 to 2020. The implementation of the associated action plan (2017-2020) is monitored and the results are reported to DG SANTE management twice a year, at mid-term and at year-end.

Especially important to DG SANTE are the following areas covered by existing procedures; they contribute to the Commission anti-fraud strategy:

- Actions linked to handling "conflict of interest" in agencies, scientific committees and expert groups;
- Active participation in the network "Fraud Prevention and Detection" (FPD) chaired by OLAF;
- Standing operating procedures for the handling of allegations of fraud, other irregularities and OLAF cases;
- Arrangements for an appropriate level of cooperation with OLAF: in 2020, the existing channels for exchanging fraud related information with OLAF were further elaborated, especially in the area of food fraud.

In 2020, DG SANTE became aware of allegations of fraud in connection with the purchase of medical countermeasures, but without having an effect on DG SANTE's budget. Upon completing its selection activities, OLAF decided not to open a case as the suspicions of fraud were insufficient. All follow-up actions to implement OLAF recommendations from previous OLAF cases were closed since 2013; no new recommendation has been issued since.

**Table 7.10 Indicators for fraud prevention and detection**

Indicators	Targets	2020	2019	2018
Update of the current anti-fraud strategy and action plan (2017-2020)	2020	Postponed to 2021	n/a	n/a
% of implementation of actions planned in the anti-fraud strategy: relevant for 2020 reporting are 26 permanent actions (for 2019 reporting, 26 actions; for 2018 reporting, 31 actions)	100%	<b>88%</b>	92%	90%
Awareness raising: % of financial officers reached in financial cell network meetings	100%	Postponed to 2021	100%	100%

<sup>81</sup> Last update of April 2019: Communication from the Commission 'Commission Anti-Fraud Strategy: enhanced action to protect the EU budget', COM(2019) 176 of 29 April 2019 – 'the CAFS Communication' – and the accompanying action plan

Indicators	Targets	2020	2019	2018
EU decentralised agencies task force meeting on independence once per year with participants and contributions from all 5 EU agencies for which DG SANTE is parent	100% (all 5 agencies)	Postponed to 2021	100%	100%
Participation in all FPDnet meetings	yes	yes	yes	yes
OLAF recommendations in investigation reports covered by appropriate follow-up and reporting (no new actions since 2013)	100%	n/a	n/a	n/a

Relevant for the monitoring in 2020 were 26 permanent actions. Due to the difficult working conditions during the COVID-19 crisis, only about 88% of the actions were implemented since the usual awareness raising actions could not take place as planned. They will resume in 2021. Moreover, addressing the COVID-19 pandemic in the frame of the Health policy, DG SANTE faced significant changes in its control environment and became aware of new risks and fraud patterns in its new activities. Therefore, the planned update of the anti-fraud strategy has been postponed to 2021.

### 7.1.3 Other control objectives: safeguarding of assets and information, reliability of reporting

In its balance sheet, DG SANTE identifies current assets (inventories) of a total value of EUR 11,6 million at 31 December 2020. The assets pertain to antigen stocks for food and mouth disease in order to carry out emergency vaccination. No other vaccines or antigens were in stock at the end of 2020.

The Common Financial Framework<sup>82</sup> provides that a Union financial contribution may be awarded for the establishment of stocks of biological products or the acquisition of vaccines doses if the occurrence or the development in a third country or Member State of one of the animals diseases and zoonoses listed in the Common Financial Framework might constitute a threat to the Union. Reserves of foot-and-mouth disease vaccines were already established in 1991 by Council Decision<sup>83</sup>.

DG SANTE signed contracts with different companies for the purchase, storage and delivery of the vaccines mainly through open calls for tender or negotiated procedures (the controls in procurement procedures are described in Annexes 6.1 and 7.1.1.2). The contracts set forth that the manufacturer shall store the vaccine according to the principles of the last existing update of the [Manual of Diagnostic Tests and Vaccines for Terrestrial Animals of the World Organisation for Animal Health](#) (OIE). The contractors' reports did not point to any breaches to these principles.

<sup>82</sup> Article 6(5) of Regulation (EU) No 652/2014 with Article 7 or 10

<sup>83</sup> Council Decision 91/666/EEC of 11 December 1991 establishing Community reserves of foot-and-mouth disease vaccines (OJ L 368, 31.12.1991, p. 21)

The stock is determined at the acquisition value (without VAT). At the end of their validity, if still in stock, the vaccines and antigens are bought back by the companies at a price determined in the relevant contracts.

The main aim of accounting controls is to assure the quality and reliability of the accounts and underlying transactions through methodical checks on the accounting records (data) and timely communication and correction of the errors. The controls carried out in 2020 have followed the Annual Accounting Quality Plan. The controls performed are additional to the ex-ante controls performed by Financial Verifying Agents and Authorising Officers by Sub Delegated on each transaction, in compliance with the Financial Regulation.

The Court of Auditors carries out annual audits on DG SANTE's accounts. In the past few years, no observation was made that would affect the vaccines stocks.

In conclusion, DG SANTE considers the current control arrangements for accounting and financial reporting to be sufficient. They work in practice as intended. Proper safeguarding of the DG SANTE inventories, EUR 11,6 million vaccines stocks, was ensured throughout the year as stated in the reports received by the contractors.

## **7.2 Efficiency = the Time-to-indicators and other efficiency indicators**

### **Economy = the cost of controls**

#### **Conclusions on cost-effectiveness of controls**

This section outlines the indicators used to monitor the efficiency and economy of the control systems. The main indicators monitored in 2020 focussed on the timeliness of procedures and the resources employed. The resources employed for control activities encompass DG SANTE's staff carrying out the monitoring tasks through the different stages of the control processes as defined in Annex 6. The costs are calculated on an all-cost basis, including direct costs plus indirect costs such as central budget management, internal control, legal advice and central management of procurement procedures as well as accounting without including an overhead rate.

The results for 2020 by type of expenditure are as follows:

### **7.2.1 Grants to Member States**

**Based on an assessment of the most relevant key indicators and control results, DG SANTE has assessed the effectiveness, efficiency and economy of the control system and reached a positive conclusion on the control efficiency in its grant management.**

**Table 7.11 Efficiency = the Time-to-indicators and other efficiency indicators related to grant management in the policy area Food Safety**

Indicators per stage of the grant procedure	Targets	2020	2019	2018
<b>Stages 1 and 2: Programme, evaluation, approval, EU funding</b>				
Ratio of decisions taken on-time (legal deadlines) to allow a timely start of the national programmes	100%	<b>100%</b>	100%	100%
<b>Stage 3: Monitoring and financial management</b>				
Payments made on time (in number) in amount	95%	(95%) 95%	(92%) 90%	(83%) 84%
Average payment time	90 days	<b>50 days</b>	55 days	60 days
<b>Stage 4: Ex-post controls and error corrections</b>				
Timely implementation of the annual ex-post control work programme (18 audit visits carried out in 2020 and 18 were planned; in 2019: 16 audits; in 2018: 14 audits)	100%	<b>100%</b>	88%	88%
“Time to recover”: average days from finalising the control to issuing the debit note (in 2020: 10 debit notes; in 2019: no debit notes; in 2018: 13)	n/a	<b>59 days</b>	n/a	55 days

DG SANTE did not face any undue delays in its procedures related to grants to Member States in the policy area Food and Feed Safety. In 2020, DG SANTE’s payments made on time for grants to Member States were just on target. Timeliness has much improved in comparison to the last two years thanks to a range of the corrective actions taken. The indicator “time to recover” remains within the margin of the last few years.

**Table 7.12 Economy = the cost of controls related to grant management in the policy area Food Safety**

Indicators per stage of the grant procedure (average FTE times standard annual costs) <sup>84</sup>		2020 M€	2019 M€	2018 M€
<b>Stages 1 and 2: Programming, evaluation and operational monitoring</b>				
Cost of operational staff in the policy Units concerned	2020: FTE: 7,9	<b>1,3</b>	1,1	1,0
Financial resources spent on external experts assisting in the evaluation of national programmes in the policy area Food and Feed Safety		<b>0,1</b>	0,1	0,1
<b>Stage 3: Monitoring of financial transactions</b>				
Cost of financial staff in the policy Units concerned	2020: FTE: 8,0	<b>0,8</b>	1,0	1,0
Cost of staff involved in second-level ex-ante and other internal controls of the central financial Unit	2020: FTE: 1,9	<b>0,2</b>	0,3	0,2

<sup>84</sup> FTE = full time equivalent; standard annual costs in the 2020 AAR according to DG BUDG instructions to distinguish between administrators and assistants who are officials/temporary agents, seconded national experts and contractual staff in the different function groups.



<b>Indicators per stage of the grant procedure</b> (average FTE times standard annual costs) <sup>84</sup>		<b>2020</b> <b>M€</b>	<b>2019</b> <b>M€</b>	<b>2018</b> <b>M€</b>
<b>Stage 4: On-the-spot controls (ex-ante and ex-post)</b>				
Cost of DG's internal staff dealing with on-the-spot controls	2020: FTE: 4,0	<b>0,5</b>	0,6	0,6
Financial resources spent on external audit services In the policy area Food and Feed Safety		<b>0,1</b>	0,1	0,1
<b>Total annual cost</b> (without overhead rate)	<b>FTE: 21,8</b>	<b>3,0</b>	3,2	3,0
<b>Payments made for grants in the policy area Food Safety</b> (“benefit” of the controls)		<b>188,8</b>	211,9	218,7
<b>Total cost as % of relevant payments</b>		<b>1,6%</b>	<b>1,5%</b>	<b>1,4%</b>

The costs of control cover the annual costs of both DG SANTE staff and external service providers carrying out the control tasks through the different stages of the control procedure. The figures in the table below are calculated on an all-cost basis without including an overhead rate; they are mainly based on estimates made in the 2020 Unit Management Plans which were discussed within the Directorates and approved at the level of the Directorate-General.

Main cost-drivers are the relatively high amount of annual national programmes (on average around 145) to evaluate and monitor every year. In addition, more than 26 emergency files for veterinary and plant emergency measures of the Member States had to be treated. Both the programmes and the emergency files are quite diverse and complex from a technical and financial point of view entailing a high workload for operational and financial staff in the policy Unit.

Several simplification measures apply since 2013, for example, the introduction of unit costs for several elements in the Member States’ animal disease eradication programmes<sup>85</sup>; the use of the “grant decisions” such that only one decision is taken for each Member State, grouping together its programmes and including a flexibility clause that allows a Member State to shift up to 20% of the allocated funds between its programmes without the Commission’s intervention; the compulsory online submission tool for Member States’ applications using predefined templates for each disease.

Further to a recommendation made by the IAS in late 2019, DG SANTE started to overhaul the unit-cost methodology in co-operation with the JRC with a view to simplifying it and possibly broadening its application.

<sup>85</sup> Commission Decisions C(2014)1035 of 24 February 2014 repealed by C(2018)2315 of 23 April 2018

### **Conclusion on cost effectiveness of controls related to grants**

The control strategy for grants in direct management is considered cost-efficient overall. The main focus is on ensuring high quality of the actions co-financed, low error rate, on-time payments and reasonable costs of control.

DG SANTE quantifies the costs of the resources and inputs required for carrying out the controls described in Annex 6.1. For some control indicators, mere numbers and percentages do not give reliable information on the effectiveness of control; only a qualitative analysis of the reasons behind the figures is relevant and useful.

Analysing the evolution of the efficiency and timeliness indicators over time and taking the simplification measures of the past few years into consideration, DG SANTE believes that the cost of control cannot be reduced below 1% of the annual budget spent through grants to Member States. Therefore, DG SANTE reached a positive conclusion as to the relative efficiency of the controls of these grants and will maintain the control strategy in this regard.

### **7.2.2 Public procurement in DG SANTE**

Based on an assessment of the most relevant key indicators and control results, DG SANTE has assessed the effectiveness, efficiency and economy of the control system and reached a positive conclusion on the control efficiency of its public procurement procedures.

**Table 7.13 Efficiency = the Time-to-indicators and other efficiency indicators related to procurement**

<b>Indicators on control efficiency in procurement</b>	<b>Targets</b>	<b>2020</b>	<b>2019</b>	<b>2018</b>
<b>Stage 1:</b> Rate of timely launched procurement procedures as specified in the annual work programmes	100%	<b>63%</b>	78%	72%
<b>Stage 2:</b> Average payment times	30 days	<b>18 days</b>	19 days	16 days
Ratio of payments made on time				
(in number)	95%	(98%)	(98%)	(99%)
in amount		100%	99%	99%
<b>Stage 3:</b> "Time to recover": average days from information/confirmation date to issuing the debit note (in 2020: none; in 2019: 1 case; in 2018: 1 case)	n/a	<b>n/a</b>	72	29

DG SANTE did not face any undue delays in its procedures related to public procurement in all policy areas. The indicator on the timely launch of procurement procedures is lower than in previous years due to the COVID-19 crisis and the inclusion of new actions in line with the work programmes objectives, allowing an optimal consumption of the budget.

**Table 7.14a Economy = the cost of controls related to procurement without the Emergency Support Instrument (ESI) and Joint Procurement (JP)**

<b>Indicators for procurement (without ESI and JP)</b> (average FTE times standard annual costs) <sup>86</sup>		<b>2020</b> <b>M€</b>	<b>2019</b> <b>M€</b>	<b>2018</b> <b>M€</b>
<b>Stages 1 and 2: ex-ante controls</b>				
Cost of operational staff in the policy Units concerned	2020: FTE: 7,1	<b>1,0</b>	1,0	0,7
Cost of central staff involved in procurement and financial procedures	2020: FTE: 11,4	<b>1,4</b>	1,2	1,5
Cost of staff involved in the CMP activities	2020: FTE: 0,1	<b>0,01</b>	0,01	0,01
Cost of staff involved in 2 <sup>nd</sup> -level ex-ante and other internal controls of the central financial Unit	2020: FTE: 1,8	<b>0,2</b>	0,3	0,2
<b>Stage 3: ex-post controls</b>				
Cost of DG's internal staff dealing with on-the-spot controls	2020: FTE 0,0	<b>0,0</b>	0,0	0,0
<b>Total annual cost</b> (without overhead rate)	<b>FTE: 20,4</b>	<b>2,6</b>	2,5	2,4
<b>Payments made for procurement without ESI</b> ("benefit" of the controls)		<b>51,5</b>	36,5	39,2
<b>Total cost as % of relevant payments</b>		<b>5%</b>	<b>7%</b>	<b>6%</b>

**Table 7.14b Economy = the cost of controls related to ESI and JP implementation**

<b>Indicators for ESI and JP implementation</b> (average FTE times standard annual costs) <sup>87</sup>		<b>2020</b> <b>M€</b>	<b>2019</b> <b>M€</b>	<b>2018</b> <b>M€</b>
<b>Stages 1 and 2: ex-ante controls</b>				
Cost of staff involved in the implementation of the ESI credits	2020: FTE: 26,2	<b>3,5</b>	-	-
Cost of staff involved in the CMP activities	2020: FTE: 0,0	<b>0,0</b>	-	-
<b>Stage 3: ex-post controls</b>				
Cost of DG's internal staff dealing with on-the-spot controls	2020: FTE 0,0	<b>0,0</b>	-	-
<b>Total annual cost</b> (without overhead rate)	<b>FTE: 26,6</b>	<b>3,5</b>	-	-
<b>Payments made for "procurement" and "grants" under ESI</b> ("benefit" of the controls)		<b>2 565,5</b>	-	-
<b>Total cost as % of relevant payments</b>		<b>0,2%</b>	-	-

<sup>86</sup> FTE = full time equivalent; standard annual costs in the 2020 AAR according to DG BUDG instructions to distinguish between administrators and assistants who are officials/temporary agents, seconded national experts and contractual staff in the different function groups.

<sup>87</sup> FTE = full time equivalent; standard annual costs in the 2020 AAR according to DG BUDG instructions to distinguish between administrators and assistants who are officials/temporary agents, seconded national experts and contractual staff in the different function groups.

The tables above cover the annual costs of DG SANTE staff carrying out the control tasks through the different stages of the control procedure and are calculated on an all-cost basis without including an overhead rate. For procurement procedures other than to implement the Emergency Support Instrument (ESI), the estimates are mainly based on the 2020 Unit Management Plans which were discussed within the Directorates and approved at the level of the Directorate-General. However, the exceptionally high number of Joint Procurement procedures was not foreseen in the estimates.

Main cost-drivers are firstly, the highly regulated public procurement procedures requiring in-depth knowledge and experience of staff to ensure compliance and good quality of each process; secondly, open calls for tender for new tasks and actions in technically complex environments entailing a relatively high workload for drafting tender specifications; thirdly, the high number of relatively small-value contracts increasing the work load indicator “cost over budget spent”.

From April 2020, DG SANTE started to receive credits from the ESI which were to 97% implemented through public procurement procedures. Teams of colleagues were established from different Directorates and Units to help cope with the workload under high political pressure and extreme urgency. Although the workload was intense for many colleagues, the indicator “cost over payments made” remains very low given the high amounts involved.

#### ***Conclusion on cost effectiveness of controls related to procurement***

The control strategy for public procurement in direct management is considered cost-effective overall. The main focus is on ensuring low errors in the procurement process and financial procedures, value for money, on-time payments and reasonable costs of control.

DG SANTE quantifies the costs of the resources and inputs required for carrying out the controls described in Annex 6.1. DG SANTE analyses the evolution of the efficiency and timeliness indicators over time to reach a conclusion as of the relative efficiency of the controls.

Through the centralisation of the administrative management of procurement procedures DG SANTE improved the quality of its procedures and their documentation. Common guidelines and the use of e-tender and e-submission streamlined some important elements. For the usual type, number and size of contracts related to DG SANTE’s spending programmes in the Health and Food Safety policy areas, DG SANTE believes that the cost of control cannot be reduced further. Therefore, DG SANTE reached a positive conclusion as to the relative efficiency of the controls.

The Emergency Support Instrument was implemented ad hoc and under extreme urgency and pressure. Although many colleagues were involved across the DG, the “cost over payments made” remains very low given the high amounts involved.

### 7.2.3 Budget implementation tasks entrusted to other services and entities

**Based on an assessment of the most relevant key indicators and control results, DG SANTE has assessed the effectiveness, efficiency and economy of the control system and reached a positive conclusion on the control efficiency with regard to entrusted entities.**

The table below shows the costs of control. They cover the annual costs of DG SANTE staff carrying out the control tasks in the different stages of the control procedure and are calculated on an all-cost basis without including an overhead rate; they are mainly based on estimates made in the annual Unit Management Plans which were discussed within the Directorates and approved at the level of the Directorate-General.

**Table 7.15 Economy = the cost of controls related to entrusted entities**

<b>DG SANTE's cost of monitoring the agencies in relation to the subsidies paid</b> (average FTE times standard annual costs) <sup>88</sup>		<b>2020</b>	<b>2019</b>	<b>2018</b>
		<b>M€</b>	<b>M€</b>	<b>M€</b>
Cost of staff in the central Unit ensuring co-ordination within DG SANTE and with the agencies	2020: FTE: 0,9	<b>0,1</b>	0,1	0,3
Cost of operational staff involved in monitoring the operations of the agencies	2019: FTE: 4,2	<b>0,6</b>	0,5	0,5
Cost of staff involved in budgetary, financial, audit matters, evaluation of the agencies and other internal controls	2020: FTE: 1,7	<b>0,2</b>	0,3	0,2
<b>Total annual cost</b> (without overhead rate)	<b>FTE: 6,8</b>	<b>0,9</b>	0,9	1,0
<b>Subsidies paid to the agencies</b>		<b>238,8</b>	187,5	181,3
<b>Total cost as % of relevant payments</b>		<b>0,4%</b>	<b>0,5%</b>	<b>0,6%</b>

Overall, the costs of monitoring and supervision represent less than 1% of the total subsidy payments to the agencies' administrative budget. It is worth noting that none of the EU decentralised agencies for which DG SANTE is responsible carry out budget implementation tasks on behalf of the Commission that would require an in-depth monitoring.

Main cost-drivers are the work intense yearly exercises of drafting the Commission opinions on the agencies' Strategic Programming Documents (SPDs), DG SANTE's preparations and attendance of Management Boards and, where applicable, Audit Committees, and the follow-up of the regular external evaluations of the agencies.

For the costs of control, no targets are defined in monetary terms. As most of the controls are directive and preventive in nature, the overall control benefit is non-quantifiable. However, each agency undergoes an external evaluation on a regular basis.

<sup>88</sup> FTE = full time equivalent; standard annual costs in the 2019 AAR according to DG BUDG instructions to distinguish between administrators and assistants who are officials/temporary agents, seconded national experts and contractual staff in the different function groups.

**Conclusion on the cost-effectiveness of controls related to “entrusted entities”**

The control strategy for entrusted entities in indirect management is considered cost-efficient overall.

DG SANTE quantifies the costs of the resources and inputs required for carrying out the controls described in Annex 6.2. Analysing the evolution over time of DG SANTE's supervisory role and related monitoring costs, DG SANTE believes that its cost of control cannot be reduced below 1% of the annual budget spent on the subsidies to agencies.

Therefore, DG SANTE reached a positive conclusion as to the relative efficiency of the controls and will maintain the control strategy in this regard.

**Table 7.16 Overview of the estimated cost of controls at Commission (EC) level**

Title of the Relevant Control System (RCS)	Ex ante controls			Ex post controls			Total	
	(a)	(b)	(c) (a)/(b)	(d)	(e)	(f) (d)/(e)	(g) (a)+(d)	(h) (g)/(b)
	EC total costs (in EUR)	Related funds managed <sup>[1]</sup> (in EUR)	Ratio %	EC total costs (in EUR)	Total value verified and/or audited <sup>[2]</sup> (in EUR)	Ratio %	EC total estimated cost of controls (in EUR)	Ratio %
Grants to Member States in the Food & Feed policy area (direct management)	2.523.790	188.848.354	1,3%	508.517	15.991.098	3,2%	3.032.306	1,6%
Public procurement and other grants (direct management)	6.148.531	2.565.510.329	0,2%	-	-	-	6.148.531	0,2%
Subsidy payments to agencies (indirect management)	896.539	238.839.588	0,4%	-	-	-	896.539	0,4%
DG-horizontal control tasks not attributable to a single RCS	-	-	-	-	-	-	-	-
<b>OVERALL total estimated cost of control at EC level</b>	<b>9.568.860</b>	<b>2.993.198.272</b>	<b>0,3%</b>	<b>508.517</b>	<b>15.991.098</b>	<b>3,2%</b>	<b>10.077.376</b>	<b>0,3%</b>

[1] Funds managed = payments made

All funds managed are subject to ex-ante controls; ex-ante control costs include direct costs plus indirect costs such as central budget management, internal control, legal advice and central management of procurement procedures as well as accounting.

[2] The total value verified and/or audited represents the EU contribution audited during ex-post control missions actually carried out in 2020 by DG SANTE own staff and external audit services. This is compared to the estimated costs of the audits (staff costs and external audit firm).

## **7.2.4 Initiatives to improve economy and efficiency**

In its 2020 Management Plan, DG SANTE identified two initiatives (number 1 and 2 below) to improve efficiency and economy. The following progress was made in 2020 also in other areas (number 3 to 5 below):

### **1) Public procurement procedures**

After a successful on-boarding in the last quarter of 2019, DG SANTE started using the corporate IT tool PPMT (Public Procurement Management Tool) from the beginning of 2020. This web-based application allows operational and procurement staff to support and monitor the procurement process from early need identification to contract signature, generating pre-filled templates and liaising automatically with ARES. The tool is currently only mandatory for open calls but DG SANTE is encouraging colleagues to use it for other types of procedures. Depending on the next releases of the tool, DG SANTE expects to cover all kinds of procurement procedures in the course of 2021.

### **2) Planning process**

In January 2020, DG SANTE centralised its financial planning and monitoring tasks, including the coordination of the adoption of the annual work programmes/financing decisions for the operational budget. Good progress was made on the simplification and standardisation of the existing documents for planning and monitoring. DG SANTE participates in the discussions and attends the workshops for the development of a common corporate initiative to address the problems of programming, planning and forecasting. This “EC Multi-annual Programming and Planning solution” is developed by DGs DIGIT and BUDG and is expected to provide :

- A ‘Financial Forecasting’ solution for the high level forecasts that are required for central financial management;
- A ‘Multi-annual Programming & Planning’ for program planning and implementation.

Additional workshops and tests will be held during the first semester of 2021 with potential launching of pilot projects during the summer months. A roll-out of the solution is expected as from autumn 2021.

### **3) Electronic workflows in financial transactions and qualified electronic signature**

Since the introduction of electronic workflows for IT payments in 2013, DG SANTE broadened the use of the system and enhanced its functionalities on a regular basis due to the continuous need to reduce administrative burden and keep an eye on the cost of controls. In 2020, DG SANTE applied its electronic workflows also to operational domains (such as Food Safety) which had not previously been included.

Moreover, DG SANTE embedded the qualified electronic signature technology (QES)<sup>89</sup> into its electronic workflows which allows to sign electronically – inter alia – procurement contracts and grant agreements that normally require hand-written signatures under the Financial Regulation. The QES technology does not only help realise efficiency gains, it speeds up the contracting procedure considerably, especially under the teleworking conditions imposed by the COVID-19 pandemic.

#### **4) IT solution AGM: A new Advanced Gateway to EU Meetings**

In the framework of its stakeholder relations, since 2018, DG SANTE uses the IT tool AGM, a corporate solution in the Commission with PMO as system owner and DIGIT as system provider. The tool assists DG SANTE in managing the entire process from planning a meeting to inviting and reimbursing experts using one single electronic tool. It encompasses all experts and comitology meetings as well as special groups and one-off events. This increases not only the efficiency of organising the meetings but also reduces the financial risks and delays linked to a paper-based process for reimbursement of experts and paying the special indemnities to the members of specific groups.

The IT tool WebDOR<sup>90</sup> for the room management is now embedded in AGM with regard to the part relevant for the reimbursement of experts' charges. This reduces manual encodings and thus administrative burden even further.

In 2020, DG SANTE reorganised its internal approval procedures with a view to streamlining the workflow while at the same time, strengthen internal controls.

#### **5) IT solution KOEL (Knowledge Online on European Legislation)**

DG SANTE uses the KOEL (Knowledge Online on European Legislation) database to manage and share information regarding its vast legislative acquis. KOEL allows services in the DG to monitor and manage legislation (and changes to it) more effectively, efficiently and transparently. KOEL is interoperable with DECIDE and a link has now been developed which links all acts in the SANTE KOEL repository (down to article level) with the interpretation thereof provided by the ECJ case-law. At present, comprehensive and tailored training activities are being organised to familiarise staff with this tool.

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<sup>89</sup> The QES is a standard under the eIDAS Regulation Regulation (EU) No 910/2014 of the European Parliament and of the Council of 23 July 2014 on electronic identification and trust services for electronic transactions in the internal market and repealing Directive 1999/93/EC.

<sup>90</sup> The WebDOR (Web based "Demande d'Organisation de réunions") is a tool to book either a SCIC meeting room or SCIC interpretation, or both.



## **ANNEX 8: Specific annexes related to "Assessment of the effectiveness of the internal control systems"**

### **8.1 Audit observations and recommendations**

This part includes audits of the European Court of Auditors (Court) and the Commission's Internal Audit Service (IAS) as well as DG SANTE's audit follow-up.

#### **8.1.1 European Court of Auditors**

##### **A. Court's financial audits: 2020 DAS**

On 10 November 2020, the Court published its annual report (2019 DAS) on the implementation of the 2019 budget. The structure of the Court's annual report is adapted to the budget headings of the Multi-annual Financial Framework (MFF) 2014-2020. DG SANTE is part of the policy chapter "Security and Citizenship". In its report, the Court did not address a finding directly to DG SANTE.

##### **B. Court's review on the EU's initial contribution to the public health response to COVID 19**

On 18 January 2021, the Court published its review on the EU's initial contribution to the public health response to COVID-19. The review covered only actions taken from 3 January to 30 June 2020 and highlights some of the challenges faced by the EU in its support to Member States' public health response to the pandemic given the scale and speed of the required actions. The Court did not make conclusions or recommendations.

The Court acknowledged that it was a challenge for the EU to rapidly complement the measures taken within its formal remit as public health is primarily a national competence. With regard to the Commission's financial support to vaccine development, the Court highlighted that the Commission mitigated the inherent risk linked to vaccine development by investing in a range of vaccine technologies and companies. The strategy included funding research on vaccine hesitancy as well as fighting disinformation, which could harm the success of mass immunisation campaigns.

##### **C. Court's special reports on performance audits in DG SANTE**

In 2020, the Court of Auditors finalised the following two audits to which DG SANTE was associated.

###### *C.1 Audit on "protection of pollinators" (SR 2020/15)*

The Court published its report on pollinators on 9 July 2020. DG ENV was in the lead for this audit and DGs SANTE and AGRI were associated. The Court concluded that overall the Commission had not taken a consistent approach to the protection of wild pollinators in the EU. The auditors identified gaps in key EU policies addressing the main threats to wild pollinators, and considered that the Pollinators Initiative does not have the tools and mechanisms to address those gaps.

In addition, the Court emphasised that the biodiversity and agricultural policies, as well as the pesticides legislation did not offer adequate measures for the protection of wild pollinators; two recommendations were addressed to DG SANTE:

- (i) Propose to amend or create implementing regulations for PPPs to include safeguards for a representative range of wild pollinator species which are comparable to those for honey bees, and to require that Member States duly justify emergency authorisations granted, including specific information on activities conducted to find alternative solutions and their results;
- (ii) Prepare, together with Member States, a work plan for the development of test methods focusing on wild pollinators, and the definition of specific protection goals for wild pollinators

In order to address the Court's recommendations, DG SANTE drafted an action plan, which includes actions and milestones to improve the protection of wild pollinators in the pesticides risk assessment process. DG SANTE plans to implement the recommendations in close co-operation with EFSA and the Member States by 2022.

#### *C.2 Audit on "Future of EU agencies – potential for more flexibility and cooperation (SR 2020/22)*

In September 2020, the Court published the performance audit on EU agencies. The audit was the first Court's overall assessment of the conditions put in place by the EU to ensure that the agencies are effectively delivering its policies to the benefit of all citizens. The auditors concluded that there was a lack of flexibility in the set-up, functioning, and possible wind-up of agencies; they also found cases of overly complex or weak governance arrangements. In addition, the Court pointed out that performance information focused on outputs and activities rather than on their contribution to policy implementation. Furthermore, the audit showed that a lack of cooperation with and/or support from Member States, industry, Commission or other agencies prevents some agencies from fully performing their role.

The Court's recommendations will be addressed by the central services and the agencies as a whole rather than by individual partner DGs or agencies:

- Ensure the relevance, coherence and flexibility of the set-up of agencies;
- Allocate resources in a more flexible manner;
- Improve governance, accountability and reporting on performance;
- Strengthen the role of agencies as centres of expertise and networking.

## **8.1.2 Internal Audit Service of the Commission (IAS)**

### **8.1.2.1 IAS limited conclusion on 2019**

The IAS contributed to DG SANTE's Annual Activity Report for 2020 by submitting a "limited conclusion on the state of internal control" in mid-February 2021. Based on the audit work performed in the period 2018 to 2020, the IAS points to four open recommendations rated 'very important', and as a result concludes that "the internal control systems in place for

the audited processes are effective, except for the observations giving rise to the 'very important' recommendations" as listed below.

**(1) IT audit on TRACES: one 'very important' recommendation open at 31/01/2021**

The IAS issued the final audit report on 27 June 2018. The objective of the audit was to assess whether the IT tool TRACES<sup>91</sup> is adequately managed to provide and maintain over time, a reliable and efficient service supporting official controls and trade operations. The audit covered issues of IT governance, IT security, business continuity, project management and operations. The IAS made four recommendations: two recommendations were rated "very important" and two "important". DG SANTE accepted all recommendations and produced an action plan. Several actions have already been implemented in 2018, 2019 and 2020.

DG SANTE believes that thanks to the mitigating measures put in place the effectiveness of DG SANTE's internal control system is not put into question.

The main IAS conclusions and DG SANTE actions were the following:

Recommendation on IT security

- IAS observations: TRACES users with privileged access were not regularly reviewed to check whether the level of access granted is actually needed in practice. The IAS observed weaknesses in the production environment and in the testing and user training environments. In addition, the IAS found that DG SANTE had not yet formalised and/or finalised a number of key IT security procedures for example, those related to control access and to vulnerability assessment and performance testing. Certain actions identified in the TRACES IT security plan were still to be implemented and the cost-benefit of secure hosting for TRACES was not yet formally assessed. The IAS also found that the involvement of DG SANTE's Local Informatics Security Officer (LISO) in TRACES security was limited.
- DG SANTE has taken actions without delay to address the weaknesses identified by the IAS. The procedure of vulnerability assessment and performance testing was formalised in late 2018. In 2020, DG SANTE finalised the "Access Control and Authentication Management Plan" and a "logging and monitoring policy" document; the LISO function was taken over by DG DIGIT. Moreover, DG SANTE well advanced its update of the IT security plan with the support of an external service provider; full implementation is expected in the first half of 2021.

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<sup>91</sup> Trade Control and Expert System (TRACES) established by Commission Decision 2004/292/EC pursuant to Council Directive 90/425/EEC

**(2) IAS audit on the efficiency and effectiveness of the Health and Food Audits and Analysis Directorate: two 'very important' recommendations open at 31/01/2020**

In October 2019, the IAS finalised its performance audit on the efficiency and effectiveness of the work of DG SANTE's Directorate F "Health and food audits and analysis". Two recommendations were rated "very important". DG SANTE accepted the recommendations and produced an action plan in November 2019. Several actions have been launched, but could not be completed in 2020 as initially planned mostly due to the COVID-19 crisis.

DG SANTE management assesses that the on-going mitigating actions have already reduced the residual risk to an acceptable level.

The main IAS conclusions and DG SANTE actions are the following:

Recommendation 1 on the staffing of activities

- IAS observations: DG SANTE Audits and Analysis Directorate had experienced significant changes to the nature and extent of its responsibilities since its creation, which presented key challenges in relation to staffing of its activities. Although the situation was monitored, there was no detailed assessment of the human resources needed for audit and other activities in the medium to long term. The IAS recommended carrying out a comprehensive analysis of the impact of Directorate F's remote location in Grange, Ireland, and also of the recruitment needs per area in the next 3 to 5 years. This analysis should be used as a basis for developing a human resources strategy, covering in particular recruitment and training aspects. Regarding audit activities for other Commission services, the IAS recommended re-assessing the audit and resource needs in the medium to long term considering risks and legal obligations and, where relevant, proposing amendments to the existing working arrangements.
- DG SANTE has already taken actions to reduce Directorate F's policy work and finalised its analysis during the exercise to draft the 2021 Management Plan. Audit work for other DGs is evaluated on the basis of an assessment of risks and legal obligations. In co-operation with DG HR, DG SANTE will carry out an assessment of the impact of its location on recruitment and will develop a HR strategy for the medium and long term. Actions are delayed due to the COVID-19 pandemic.

Recommendation 2 on time reporting and performance monitoring

- IAS observations: the IAS found room to improve Directorate F's performance monitoring of audit work and to further develop the work on the audit universe and risk based audit frequencies. The IAS recommended assessing the scope for introducing a time recording system in DG SANTE.F and collecting and analysing systematically performance information. The IAS also urged to finalise the development of the coverage of DG SANTE.F's audit universe by establishing risk based audit frequencies per audit areas and reassess these on a regular basis.

- DG SANTE has taken first steps to introduce a pilot time recording system in early 2020 and to produce a guidance document for SANTE.F management to enhance its performance monitoring of audit work. The pilot scheme however, had to be deferred due to the cancellation of audits and exceptional working arrangements during the COVID-19 pandemic as much of the data would not be useful. This will have to be re-launched when stability returns. In view of current projections, this is unlikely to be before the end of 2021.

**(3) IAS audit on the management of food and feed programmes, including emergency measures: one 'very important' recommendation open at 31/01/2020**

In January 2020, the IAS finalised its financial audit in the food and feed policy area. One recommendation was rated "very important". DG SANTE accepted the recommendation and produced an action plan in late February 2020. Actions are well advanced and expected to be fully implemented by 2023.

DG SANTE believes that the mitigating measures already in place do not put the effectiveness of DG SANTE's internal control system into question.

The main IAS conclusions and DG SANTE actions are the following:

Recommendation on the unit-cost methodology

- IAS observations: the IAS found weaknesses in DG SANTE's organisation of the process for reviewing the unit costs methodology, including the estimation of the value of each unit cost per Member State and per disease. These comprised gaps in relation to the internal consultation, the prior analysis and assessment of the impact of the proposed changes, the timing of internal and external communication and in the business continuity arrangements. The IAS recommended involving all relevant actors within the DG, consulting, as appropriate, other Commission services to use their expertise on the basis of clearly defined working modalities. DG SANTE should also inform Member States well in advance of the financial impact of any change in the methodology and of the resulting actual amounts of unit costs, lump sums and/or ceilings.
- DG SANTE actions are already under way, and in late 2019, an administrative arrangement was signed with JRC to assist DG SANTE in improving the unit cost methodology, which delivered positive results in 2020.

### **8.1.3 DG SANTE's audit follow-up**

DG SANTE addresses all audit recommendations by proportionate action plans and monitors their implementation regularly. The Director in charge of Risk Management and Internal Control (RMIC) reports on the progress made twice a year, firstly, in the context of the mid-term report on internal control, and secondly, during the annual activity reporting.

### **8.1.3.1 Follow-up on audits of the Court**

The follow-up of the Court's recommendations as well as recommendations made by the discharge authorities in previous years is organised by DG BUDG through the RAD-database (Recommendations, Audit and Discharge). DG SANTE launches systematic updates at least twice a year (May/June and December/January).

Further to having closed all open recommendations of audits finalised before 2016, DG SANTE was the lead DG for a total of 16 audit recommendations open at 31 December 2020 with target dates in 2021 or later. Currently, DG SANTE monitors the implementation of the recommendations of nine performance audits as follows:

#### **(1) EU implementation of animal disease eradication and monitoring programmes** (Special Report 2016/06 published in April 2016)

The audit covered Member States' animal disease eradication programmes from 2009 to 2014 and focussed on the Commission's role and control instruments, objectives, performance indicators, and the amount of EU funds involved. The Court's conclusions were overall positive: the Court assessed that the approach taken by the Commission was generally sound and that Member State programmes were well designed and implemented.

The Court made recommendations (i) to improve the exchange of epidemiological information between Member States; (ii) to possibly update the existing indicators to provide better information on veterinary control activities and the cost-effectiveness of programmes; (iii) including the wildlife aspect in the veterinary programmes more systematically, when relevant; (iv) to give support to Member States in acquiring vaccines, when this is epidemiologically justified.

In its follow-up audit in 2019, the Court concluded that DG SANTE had implemented three of the four recommendations without undue delay. One action is ongoing with a revised deadline in April 2021 (initial deadline in late 2017).

The Animal Disease Information System (ADIS) will be launched on 21 April 2021 in conjunction with the Animal Health Law using the new legal basis recently adopted by the Commission<sup>92</sup>. This will centre the notification process on priority diseases which went through the risk assessment and categorisation exercise carried out in the framework of the Animal Health Law. The work on interoperability with the OIE-WAHIS<sup>93</sup> continues and the two systems already performed connection tests in 2020. The actual exchange of data between ADIS and OIE-WAHIS will occur between the second and third quarter of 2021.

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<sup>92</sup> Regulation (EU) 2016/429 of the European Parliament and of the Council and Commission Implementing Regulation (EU) 2020/2002

<sup>93</sup> Since 2012, a joint project between the Commission and OIE has worked on linking the ADNS and WAHIS systems with a common interface called Animal Disease Information System (ADIS). OIE is the World Organisation for Animal Health, operating the World Animal Health Information System (WAHIS).

**(2) Dealing with serious cross-border threats to health in the EU: important steps taken but more needs to be done** (Special Report 2016/28 published in December 2016)

In its report, the Court recognised that a key milestone in building a stronger EU health security framework was the adoption in 2013 of a Decision on serious cross-border threats to health; it then aimed at assessing whether it was adequately implemented.

In 2019, the Court concluded that DG SANTE had fully implemented ten out of twelve recommendations. Several actions were achieved only through broad co-ordination work between the Commission and the Health Security Committee, working groups and networks. The remaining two recommendations are linked to the third Health Programme (2014-2020) and can be considered implemented. In 2020, four Joint Actions were on-going: on Antimicrobial Resistance (AMR); on vaccination; on points of entry, and on preparedness and International Health Regulations implementation and laboratory strengthening.

A new Joint Action on strengthening health preparedness and response to biological and chemical terror attacks has been launched. The contract started on 1 January 2021 and is expected to run for three years.

In 2020, the Joint Actions also contributed to the COVID-19 response. Sustainability of the Joint Actions is ensured through the work package on "Sustainability and policy development" focusing on uptake and sustainability of results at Member States level.

On 11 November 2020, as part of the EU Health Union package, the Commission adopted a proposal to reinforce the cross-border health threats legislation, drawing on lessons learned from the coronavirus crisis.

**(3) Combating Food Waste: an opportunity for the EU to improve the resource-efficiency of the food supply chain** (Special Report 2016/34 published in January 2017)

The audit report made three recommendations:

- (i) Strengthen and better coordinate the EU strategy to combat food waste;
- (ii) Consider food waste in future impact assessments and better aligning the different EU policies which can combat food waste including assessment of the need to intervene in order to prevent labelling practices that generate food waste;
- (iii) Promote the option of donating food that is safe for consumption and that would otherwise be wasted, in particular by clarifying relevant EU legal provisions.

All actions refer to long-term strategies and measures developed by the Commission in close co-operation with the Member States.

The first recommendation on better-coordinated EU efforts to combat food waste has been implemented in May 2020. As called for by the European Green Deal, the European Commission adopted, on 20 May 2020, the "Farm to Fork Strategy" to design a fair, healthy and environmentally-friendly food system. Reducing food

losses and food waste is a key action strand of this strategy. The strategy reaffirms the Commission's commitment to halve per capita food waste at retail and consumer levels by 2030, and established a set of further actions building on those undertaken as part of the 2015 Circular Economy Action Plan<sup>94</sup>.

The third recommendation related to promoting food donation was finalised in March 2020, when the Commission received the final version of the Pilot Project's report on the mapping and analysis of policy and regulatory frameworks in Member States in the area of food redistribution. As part of the Circular Economy Action Plan, the Commission had already clarified relevant provisions laid down in EU legislation through the adoption of EU guidelines on food donation (16 October 2017), including also a section clarifying the application of VAT rules to food redistribution in the Member States and providing examples as to how Member States implement fiscal incentives to stimulate food donation at national level.

Moreover, in June 2020, on the basis of scientific advice from EFSA<sup>95</sup>, the Commission adopted a Notice providing guidance on food safety management systems for food retail activities, including food donations<sup>96</sup>. Meanwhile, the Commission is proposing to amend EU food hygiene rules in order to lay down certain requirements to promote and facilitate food donation, whilst guaranteeing its safety for consumers. The amendments are expected to be published by mid-2021.

Whilst work has been undertaken to prevent labelling practices that generate food waste, the recommendation number two will be addressed by end 2022. While the Commission had initiated, earlier in 2018, the preparation of technical guidance,

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- <sup>94</sup> . Integrating food loss and waste prevention in other EU policies. This covers on the one hand, those initiatives, which are included in the Annex of the Farm to Fork Strategy, but also other initiatives undertaken as part of the Green Deal. Furthermore, the Commission is also monitoring initiatives and policy developments beyond the above mentioned (e.g. Commission's own catering activities; FEAD) with the objective to integrate food loss and food waste prevention as and where relevant;
- Using the new methodology adopted by the Delegated Decision (EU) 2019/1597 of 3 May 2019 for measuring food waste and new data on food waste levels expected from Member States in 2022, the Commission will set a baseline and propose, by end of 2023, legally binding targets to reduce food waste across the EU.
  - The Commission will propose, by end of 2022, to revise EU rules on date marking in order to avoid food waste linked to the misunderstanding of the meaning of these dates ("use by", "best before");
  - In addition to quantifying food waste levels, the Commission will investigate food losses at the production stage and explore ways of preventing them;
  - The Commission will continue to coordinate action in relation to food loss and waste at EU level in order to reinforce action at national level, in the framework of the EU Platform on Food Losses and Food Waste.
  - Through the Single Market Programme, the Commission will support Member States and stakeholders in measuring food waste and implementing effective food waste prevention initiatives.
  - The contingency plan will be the EU's first mechanism to monitor the structural resilience of the food supply chain and a response to the lessons learned from the COVID-19 crisis. It will give the necessary political signal that food security is part of the critical infrastructure of the EU in terms of natural and marine resources.

<sup>95</sup> EFSA Journal 2018;16(11):5432, 64 pp.

<sup>96</sup> Commission Notice C/2020/199/01 adopted on 12 June 2020, <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=OJ:C:2020:199:FULL&from=EN>



with the support of EFSA, to promote consistent date marking practices in line with the current EU date marking rules, the Farm to Fork Strategy has introduced in May 2020 a more ambitious approach to address the misunderstanding and misuse of date marking rules. As part of this Strategy, the Commission will propose, by end of 2022, to revise EU rules on date marking. In order to inform this legislative proposal, the Commission launched, in December 2020, a tender to procure consumer behaviour research in order to explore options for more effective use and understanding of date marking. As regards date marking practices in market, EFSA's scientific opinion<sup>97</sup> (the first part of which was adopted in October 2020) will support food business operators in taking a risk-based approach, focussed on ensuring food safety, when making decisions about date marking,

**(4) Animal welfare in the EU: closing the gap between ambitious goals and practical implementation** (Special Report 2018/31 published in November 2018)

The audit examined the welfare of farm animals and the overall implementation of the latest EU strategy of 2012, focusing on the strategy's two key objectives: to achieve compliance with the minimum standards and to optimise synergies with the CAP (DG AGRI was associated to this audit).

The Court concluded that EU actions on animal welfare have improved compliance with animal welfare requirements and supported higher standards with a clear positive impact on animal welfare. However, certain weaknesses persist in some areas related to welfare issues on the farm (in particular, the routine tail docking of pigs), during transport and at slaughter (use of the derogation for slaughter without stunning and inadequate stunning procedures). In addition, Member States took a long time to address some of the recommendations made by the Commission following its audits.

The Court addressed five recommendations to DG SANTE to:

- (i) Improve the procedures for the monitoring and enhancement of all food and health legislation, which covers the follow-up to recommendations arising from DG SANTE's audits in Member States;
- (ii) Determine together with Member States, possible improvements in the TRACES system to support the preparation of the Member States' risk analyses for inspections on the transport of live animals;
- (iii) Carry out an evaluation of the 2012 animal welfare strategy;
- (iv) Define baseline and target indicators to measure Member States' degree of compliance;
- (v) On the basis of the evaluation results, to consider the need for a new strategy, with a possible review of the legislation.

The first recommendation is considered implemented as DG SANTE strengthened its arrangements for a faster escalation of audit recommendations. In regard to

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<sup>97</sup> Guidance on date marking and related food information: part 1 (date marking)' (EFSA Journal 2020;18(12):6306)

tail docking, DG SANTE followed up the improvement of implementation of the rules on the prevention of tail biting and avoidance of routine tail docking in pigs. Nine audits took place, questionnaires were sent to all Member States, as well as correspondence at political level. The Commissioner sent letters to all Member States on compliance issues related to the Farm to Fork strategy, which for 25 Member States<sup>98</sup> included the issue of tail docking.

In January 2020, the Commission fully addressed the second recommendation, by modifying access rights to Traces. Member States' Authorities can now access all data regarding transporters they have approved and transporters arriving to control points placed in their territory. The Commission also provided trainings to the Member States' National Contact Points for animal welfare during transport on how to better use TRACES for target checks on animal transport and how to perform better retrospective checks on this area using data recorded by Satellite Navigation Systems.

The [study report addressing the third recommendation](#) was finalised and published on 7 December 2020. The Commission Staff Working Document (SWD) on the evaluation of the animal welfare strategy has been drafted and is scheduled for publication in the first quarter of 2021.

The last two recommendations have to be accomplished by late 2021. Important milestones have already been achieved. The new standard model form for Member States annual reports was adopted on 2 May 2019<sup>99</sup>. Member States will submit for the first time the new reporting template in 2021, to report on controls carried out in 2020, including on animal welfare on farm and during transport. Meanwhile, the project on Animal Welfare indicators is ongoing.

**(5) Chemical hazards in our food: EU food safety policy protects us but faces challenges** (Special Report 2019/02 published in January 2019)

The subject of the audit was to examine whether the EU food safety model is based on sound principles, and whether the way it is implemented is effective in keeping the products we consume in the EU safe. In conclusion, the Court emphasised that the EU food safety model is soundly based and respected worldwide. The Court also found that the model is currently over-stretched, as the Commission and Member States do not have the capacity to implement it fully.

The audit report included five recommendations covering the following main topics:

- (i) Assess potential changes to the legislation governing chemical hazards in the light of the capacity to apply it consistently and further encourage complementarity, so that Member State public authorities can rely more extensively on checks carried out by the private sector;

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<sup>98</sup> All Member States, except FI/SE

<sup>99</sup> Commission Implementing Regulation (EU) 2019/723 of 2 May 2019 laying down rules for the application of Regulation (EU) 2017/625 of the European Parliament and of the Council as regards the standard model form to be used in the annual reports submitted by Member States (OJ L 124, p. 1).

- (ii) Explain what action the Commission will take on pesticide residues in food to maintain the same level of assurance for both EU produced and imported food while remaining compliant with WTO rules;
- (iii) Give Member States further guidance on the application of enforcement measures and enhance its procedures for monitoring compliance with EU food rules and put into action the opportunities it has identified to enhance its procedures for monitoring compliance with EU food rules.

The recommendation to enhance the procedures for monitoring compliance with EU food rules has been implemented. Standard Operating Procedures and trainings for staff were completed already in 2018 and 2019. Reminder letters continue to be sent out to third countries which have either not submitted residue monitoring plans or where they have not responded to Commission assessments of plans which have been submitted.

The REFIT evaluation regarding the pesticides legislation has been finalised and the [Report to Council and Parliament was adopted on 20 May 2020](#). The report was accompanied by a Commission Staff Working Document (SWD) containing the detailed findings. In its Farm to Fork Strategy, adopted in May 2020, the Commission highlighted that imported food must continue to comply with relevant EU regulations and standards. All established Maximum Residue Levels (MRLs) must be safe for consumers regardless of their origin. The Commission will take into account environmental aspects when assessing requests for import tolerances for pesticides substances no longer approved in the EU while respecting WTO standards and obligations.

As regards the evaluation and future revision of the Food Contact Materials legislation, several actions are ongoing. The Inception Impact Assessment (roadmap) was published in December 2020 for feedback. Preparatory work for the Commission Staff Working Document continued for the evaluation to be published in 2021.

To facilitate consistent application of EU food law, the Commission gives Member States further guidance on the application of enforcement measures. Consultations with Member States on the document serving as a basis to establish the methodology for the monitoring of food additives and flavourings have been completed. In order to finalise the draft common methodology, the Commission will consult EFSA and other stakeholders. The slight delay is caused by competing priorities and longer than expected consultation time. The voting procedure of the Guidance document is thus now envisaged in second quarter of 2021.

**(6) The control system for organic products has improved, but some challenges remain** (Special Report 2019/04 published in March 2019)

The audit on "organic products" was an extended follow-up audit of a previous audit of the Court finalised in 2012 to examine whether the control system governing the production, processing, distribution and import of organic products can provide confidence in organic products. The Court found that the control system had improved and that the previous audit recommendations of 2012 had generally been implemented.

The Court addressed one recommendation to DG SANTE, to follow-up on the remaining weaknesses the Court found in the Member States' control systems. DG SANTE implements the recommendation in close co-operation with DG AGRI.

The weaknesses identified by the Court were the subject of specific recommendations made in DG SANTE audit reports for Italy, the Czech Republic and France. The responses from Italy and the Czech Republic have partly addressed the weaknesses and will be followed up further. A general follow-up audit is planned in Italy, in March 2021. In case of France, the recommendations have been fully addressed. An audit carried out in Bulgaria in late 2019 highlighted significant improvements, many of them introduced after the visit of the Court. In addition, Bulgaria submitted a satisfactory action plan for remaining shortcomings and the follow-up is ongoing.

An audit to Spain in October 2020 addressed the weakness identified by the Court. An issue found by the auditors is being followed up.

**(7) EU actions for cross-border healthcare: significant ambitions but improved management required** (Special Report 2019/07 published in June 2019)

The Court focussed its audit on the Commission's monitoring and supervision of the implementation of the Directive, the results achieved to date, and the effectiveness of the EU funding framework. Priority areas were eHealth and rare disease treatment. The audit report makes eight recommendations addressed to DG SANTE on the following main topics:

- (i) Provide more support for National Contact Points;
- (ii) Better prepare for cross border exchanges of health data;
- (iii) Improve support to facilitate rare disease patients' access to healthcare.

DG SANTE's actions to implement the recommendations strive to achieve long-term objectives such as the monitoring of the 2012 eHealth Action Plan and the 2018 eHealth strategy's implementation, or the assessment of the cost-effectiveness of the eHealth Digital Service Infrastructure (eHDSI). Most of the actions are expected to be finalised by the end of 2023.

All recommendations are being addressed. Several milestones such as the publication of the National Contact Points (NCP) toolbox and full translations in all EU languages, as well as the dissemination of Guidance, minutes and material related to the NCP meeting were already implemented in 2019 and 2020.

The Implementation Report has been combined with the evaluation of the Cross-border Healthcare Directive and is expected to be adopted in the second quarter of 2022.

To better prepare for cross border exchanges of health data, DG SANTE is monitoring and reporting the results achieved through the eHDSI governance structures. Quarterly data are published on the CEF Monitoring dashboard portal<sup>100</sup>.

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<sup>100</sup> CEF: Connecting Europe Facility <https://ec.europa.eu/cefdigital/wiki/display/CEFDIGITAL/eHealth+dashboard>

In order to provide an overall assessment, a critical mass of Member States is needed and this will be achieved, at the earliest, by 2023.<sup>101</sup> Member States have adopted the new eHDSI Monitoring and Reporting Framework, which will enable gathering more detailed and qualitative Key Performance Indicators. Its production deployment is foreseen by mid-2021.

An integrated system of Assessment, Monitoring, Evaluation and Quality Improvement (AMEQUIS) of the European Reference Networks (ERNs) will be developed by an external service provider in collaboration with the ERN-CG, the ERN Board of Member States and all other related experts. The procurement contract was signed at the end of December 2020 and has to be launched in January 2021.

The newly adopted EU4Health Programme<sup>102</sup> foresees that the ERNs will be beneficiaries of multi-annual direct grants. The approval of the 2021 Annual Work Programme (AWP) is still ongoing and the first call for direct grants is foreseen to be launched in 2021 (for 1 ERN) and 2022 (for 23 ERNs).

**(8) Addressing antimicrobial resistance (AMR): progress in the animal sector, but this health threat remains a challenge for the EU** (Special Report 2019/21 published in November 2019)

The audit concluded “that the activities of the Commission and agencies have led to some progress, for example, in veterinary and food related issues. However, there is little evidence to date that the health burden of AMR has been reduced in the European Union”. The Court makes four recommendations on the following main topics

- (i) Improve the EU response to AMR through better support to Member States’ national action plans;
- (ii) Promote prudent use of veterinary antimicrobials and better surveillance of AMR;
- (iii) Strengthen strategies for boosting AMR research in the EU.

DG SANTE prepared an action plan to implement the recommendations by 2022. The Management Board adopted the action plan in June 2020, but asked for a revision in September 2020 to take the COVID-19 situation into considerations.

Important milestones have already been achieved. The Commission Implementing Decision (EU) 2020/1729 on the monitoring and reporting of antimicrobial resistance in zoonotic and commensal bacteria and repealing Implementing Decision 2013/652/EU was published on 19 November 2020. The evaluation report of the orphan and paediatric Regulations was published on 11 August 2020; the inception impact assessment for the review of the two legislations was published on 25 November 2020.

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<sup>101</sup> Currently, seven Member States are already exchanging data. Another seven Member States are getting ready to start the exchanges by mid-2021, facing a delay due to the COVID-19 situation.

<sup>102</sup> Regulation (EU)2021/522 of 24 March 2021

A few actions had to be postponed due to the COVID-19 pandemic. Hence, the planned HSC work for 2020 will be performed in 2021, One Health Network will take place in March 2021, and JAMRAI final conference will be held on 11-12 February 2021.

By the first quarter of 2021, DG SANTE plans to provide a screening of AMR in the European Semester Country Reports for 2019 and 2020, in the State of Health in the EU and in the Technical Support Instrument 2021. In the first quarter of 2022, DG SANTE will perform a screening of any investments in AMR in national Recovery and Resilience Plans. As a parallel process, the Commission negotiates with each Member State its investment plans to be financed by European structural and investment funds in the programming period 2021-2027 and will be able to screen for AMR investments by the first quarter 2022.

To promote prudent use of antimicrobials in animals, the new Regulation on veterinary medicinal products, applicable as of January 2022, sets the obligation for Member States to collect data on their volume of sales of antimicrobials and on their use of antimicrobials per animal species. To support this provision, on 29 January 2021, the Commission adopted a delegated act setting the requirements for this data collection<sup>103</sup>. The delegated act will apply as of January 2022.

The Pharmaceutical Strategy for Europe, published on 25 November, acknowledges the importance of tackling AMR. It will address several challenges, such as inappropriate use of antimicrobials, lack of economic interest in R&D, access and availability of new and old antibiotics. The Strategy takes into consideration the EU strategic approach to pharmaceuticals in the environment<sup>104</sup> and the EU One Health action plan on antimicrobial resistance<sup>105</sup> that set out targeted actions that are currently being implemented. Through international cooperation, the Commission addresses the environmental risks in other countries where pharmaceutical emissions from manufacturing and other sources may contribute to the spread of AMR.

**(9) *Audit on the SUD – sustainable use of pesticides (SUD)*** (Special Report 2020/05 published in January 2020)

The overall objective of the audit was to assess whether EU action has reduced the risk related to the use of Plant Protection Products (PPP). The Court published its special report on the sustainable use of plant protection products, on 5 February 2020, emphasising that the Commission and Member States have taken action to promote the sustainable use of plant protection products (PPPs), but there has been limited progress in measuring and reducing the associated risks.

Two recommendations were addressed to DG SANTE:

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<sup>103</sup> C(2021)435 COMMISSION DELEGATED REGULATION (EU) supplementing Regulation (EU) 2019/6 of the European Parliament and of the Council with regard to requirements for the collection of data on the volume of sales and on the use of antimicrobial medicinal products in animals.

<sup>104</sup> COM(2019) 128. The Commission has also provided [additional information on the progress of the implementation of the strategic approach to pharmaceuticals in the environment](#).

<sup>105</sup> COM(2017) 339.

- (i) Check that the Member States convert the general IPM principles into practical and measurable criteria and that they verify these criteria at farm level;
- (ii) Improve the harmonised risk indicators, or develop new ones that take into account, for Harmonised Risk Indicator II, agricultural areas or volumes of active substance, for Harmonised Risk Indicator I, the way PPPs are used. The Commission committed itself to enable integrated pest management (IPM) enforcement, improve access to PPP statistics and develop better risk indicators in close cooperation with the Member States.

Following the bilateral discussion with the associated DGs AGRI and ESTAT, DG SANTE drafted an action plan. The target implementation date of the recommendations is planned for late 2023.

Several milestones were already implemented during 2020, with a slight delay due to the COVID-19 outbreak. Following the adoption of the Farm to Fork Strategy in May 2020, the Commissioner sent individual letters to Member States, highlighting the importance of the implementation of the rules on the sustainable use of pesticides. In addition, the SUD Working Group (WG) meeting was held on 04-05 November, and the BTSF Workshop “SUD: Experiences on its current implementation and possible future perspectives” took place on 17-19 November 2020. In 2020, one SUD audit was performed remotely to the Netherlands.

In the meantime, DG SANTE continues its work with the SUD Working Group (WG) to support Member States in developing criteria for integrated pest management (IPM) enforcement and verification of compliance at farm level. DG SANTE also sees to the maintenance and regular up-date of the SUD web-portal to reflect any recent developments on SUD implementation at Member State level, including providing relevant links to general and crop-specific IPM Guidelines.

In the “Farm to Fork Strategy” of May 2020, targets are established for the reduction of risk and use of Plant Protection Products (PPPs) measured through Harmonised Risk Indicator 1 (HRI 1), which will be proposed to become obligatory targets for Member States.

### **8.1.3.2 Follow-up on audits of the IAS**

DG SANTE organises its follow-up work using the corporate IT tool managed by the IAS. DG SANTE addresses all audit recommendations by proportionate action plans and monitors their implementation regularly.

DG SANTE's management assesses that the follow-up of audit recommendations is satisfactory given the mitigating actions already put in place before the deadlines. However, some delays occurred as priority had to be given to the new tasks to fight the COVID-19 pandemic and due to the new working conditions imposed by the health crisis (see part 8.1.2.1 above).

#### Audit on TRACES Recommendation 1 on IT governance

- IAS observations: under the governance arrangements in place at the time of the audit, DG SANTE did not have a High Level IT Steering Committee at DG or DDG level and no formal body or committee at TRACES that would bring together the

various DGs using TRACES to discuss and agree key strategic IT issues. Furthermore, the project steering committees for each TRACES domain still had to be formally established. Although some working arrangements had been set up with other DGs, they were not fully consistent and were lacking clear criteria for charging back and sharing costs. In addition, the information reflected in GovIS2 (tool for reporting to the Commission IT governance bodies) as regards structure, ownership and budget was not fully consistent and complete.

- DG SANTE implemented the recommendation on TRACES governance by having established a TRACES steering committee and TRACES project steering committees. Meetings took place in 2020. With regard to IT governance in general, since early 2019, DG SANTE's policy pillar meetings, chaired by the Director-General or Deputy-Director-General, include more general and specific steer on IT matters.

## **8.2 Assessment of the effectiveness of internal control systems**

### **8.2.1 Changes in DG SANTE's control environment**

In 2020, the following major changes to DG SANTE's control environment took place:

- ❑ In late September 2020, the Director-General left DG SANTE; she was DG SANTE's authorising officer by delegation for two years. The new Director-General took on her responsibilities on 16 October 2020. She was DG SANTE's Deputy Director-General for Health since July 2020 and acting Director-General since 1 October 2020. The outgoing Director-General handed over all tasks and responsibilities to the acting Director-General. In her handover note she provided reasonable assurance that the resources assigned to the activities of the DG had been used for their intended purpose, in accordance with the principles of sound financial management, and under the control procedures put in place to offer the necessary guarantees concerning the legality and regularity of the underlying transactions.
- ❑ The new Director-General handed over her tasks as Deputy Director-General for Health to her successor who joined DG SANTE on 1 December 2020. The handover process went smoothly.
- ❑ On 1 July 2020, a new Deputy Director-General for food sustainability took up her duties to fill the long-term vacancy. She became the Authorising Officer by Subdelegation (AOSD) for food and feed expenditure replacing the Acting Director for Directorate D in this role, who prepared a hand-over report.
- ❑ On 1 September 2020, DG SANTE welcomed a new Director of Directorate D for "food sustainability, international relations"; she received a handover report prepared by the Acting Director D. The new Director of Directorate F for "health and food audits and analysis" was appointed in December and took up her duties on 1 January 2021. The acting Directors of Directorates D and F ensured a smooth handover process.



## **8.2.2 Annual assessment of internal control by management**

In its internal control system, DG SANTE embedded continuous monitoring measures to ensure that its management and internal control framework is effective. DG SANTE has also considered the risks and focuses its control resources on those areas where risks are the highest, while ensuring adequate control coverage over all activities. DG SANTE followed the methodology proposed in the “implementation guide of the internal control framework of the Commission”.

As soon as it became apparent that the COVID-19 pandemic would require teleworking for all staff, business continuity measures were established to ensure that all critical and essential functions continued without interruption and to exchange best practices on a range of topics with all staff in the DG. The Business Continuity Management Sub-group met initially once or twice a week, thereafter every two to three weeks, to review and discuss working arrangements, human resources matters and SANTE internal communication and advice to staff as well as issues related to IT, building security, document management and financial management. The surveys ran by DG HR throughout 2020 show that DG SANTE staff coped relatively well with the new ways of working.

### **8.2.2.1 Annual assessment methodology**

The annual assessment on the implementation of the Internal Control Principles (ICP) was finalised in the first quarter of 2021, was brought to the attention of the Directors' Steering Committee on 10 March 2021 and was endorsed by the Management Board in its meeting on 22 March 2021. The following four elements built the basis of the annual assessment since several years:

- (a) Internal control monitoring criteria: evaluation of the indicators as defined in the Management Plan; several indicators are based on the results of staff surveys organised by DG HR to get a better insight into the effectiveness of selected control principles. In 2020, the usual staff survey was postponed to mid-2021 and a series of short surveys introduced to get some insights into how staff is coping with the different working conditions imposed by the COVID-19 pandemic;
- (b) Exceptions to rules and procedures, including non-compliance events or cases of “confirmation of instructions” as well as issues raised in management reports received from the authorising officers by sub-delegation: scrutiny of the reports that could point to control deficiencies;
- (c) Audit observations of the IAS and the Court of Auditors as well as findings from DG BUDG's validation of local systems: analysis of the results of the audits and audit follow-up work to assess the impact on the internal control system;
- (d) Results of the internal desk review including contributions of key staff supporting important elements of the set up and functioning of internal controls and the follow-up of management action plans stemming from management's risk assessment and the anti-fraud strategy.

### 8.2.2.2 Results of the annual assessment

#### (a) Internal control monitoring criteria

The assessment on the basis of the defined internal control monitoring criteria led to a positive conclusion on the effectiveness of the internal control system, meaning that the components and principles are present and functioning, but some improvements are needed for minor deficiencies. As in 2019, these relate to the following five Internal Control Principles: ICP 1 on ethical values and integrity; ICP 4 on staff allocation and professional development, functions which are only partially under DG SANTE management; ICP 6 on “objective setting”; ICP 10 on control activities; ICP 11 on control activities over technology.

- ICPs 1 and 4: further to the introduction of the HR delivery model in 2017, the Commission’s HR community still saw the need to consolidate and fine-tune certain aspects. In 2020, the main issues remain, for example, the central HR services still rely heavily on the DGs to ensure the coordination of basic HR transactions which directly impacts on DG SANTE's staff. This also effects DG SANTE's implementation of internal control principles with regard to ethics, staff allocation and professional development – functions which are only partially under DG SANTE management.
- ICP 6: the staff surveys in 2018 and 2019 showed that staff perception of the role of DG SANTE senior management is rather weak when it comes to guidance on “missions, objectives and tasks”. Actions already took place to include all staff in DG SANTE shaping for the future, but they had to be suspended due to the COVID-19 crisis. In 2020, DG SANTE was re-organised and top management changed: in the second half of 2020, DG SANTE welcomed a new Director-General, two new Deputy Directors-General and two new Directors.
- ICPs 10 and 11: with regard to control activities, the IAS (see part 8.1.2 above) found a need to improve (i) the unit costs methodology applied in the policy area Food and Feed, (ii) the time reporting and performance monitoring in DG SANTE's Directorate “Health and food audits and analysis”, and (iii) certain aspects of IT security in the IT tool TRACES. All issues are addressed already partially.

#### (b) Exceptions to rules and procedure

Throughout the year, the functioning of the internal control system was closely monitored by the systematic registration of so-called "exceptions", non-compliance events and internal control weaknesses to ensure transparency and accountability despite derogations from rules and procedures. In 2020, the most important exceptions were the following:

- ❑ The COVID-19 pandemic required the Commission to act under extreme urgency and considerable uncertainties with regard to both the needs and the supplies on the market. To shorten the time needed to conclude procurement procedures, and to ensure the successful purchase of urgently needed goods, the following non-compliances with the Financial Regulation were recorded in seven joint procurement procedures:
  - At the beginning of the COVID-19 crisis, the needs for certain products or services multiplied within days and new needs for different products or services materialised. To cope with these additional needs in a swift manner, tender specifications were amended at different stages in the procurement procedures with regard to product specifications and minimum or maximum quantities.
  - To react swiftly to significant changes of the market conditions, an offer that was only partially compliant with the minimum requirements was accepted under certain conditions given that no other offer was received. The deadline for submission of tenders was extended after its expiry to allow additional tenders to participate in a procedure. In addition, new tenders were admitted to a procedure during the submission phase or even after the deadline for submitting offers since the offered products were needed urgently and in huge quantities; these measures saved the significant time that would have been lost if it had been necessary to cancel and relaunch the procurement procedures.
  - To be able to accept offers that were only valid for a short time, DG SANTE allowed bidders more time to submit supporting documents for the selection criteria and, in some cases, carried out the verifications of the evidence after the award decision. DG SANTE also used a certain amount of flexibility when it came to handling procurement procedures divided into several lots and when implementing multiple framework contracts in cascade.
  - DG SANTE amended the Commission model contract beyond what is possible under the financial regulation (e.g. 100% pre-financing) to meet requests of the suppliers. Not accepting the suppliers' requests would have resulted in no contract.
- ❑ To shorten internal decision making procedures, the ex-ante assessment of DG SANTE's Public Procurement Committee was waived in 17 procedures so that award decisions could be taken immediately after the finalisation of the evaluations.
- ❑ DG SANTE also applied a number of derogations to the Joint Procurement Agreement (JPA) and to Decision 1082/2013 to speed up the conclusion of framework contracts for the supply of medical countermeasures. Each derogation was brought to the attention of the participating Member States and met their approval. For example

- The Commission added contracting authorities after the launch of the joint procurement procedure since national authorities, faced with extreme urgency and strain, could not always reply within the usual deadlines, or joined the JPA after the launch of a procurement procedure.
  - The Commission signed a framework contract with a supplier on behalf of and for the account of all the participating contracting parties. This implies a derogation from the Legal Service guidance stating that each Member State should sign a separate framework contract. However, Article 22(3) of the JPA provides that in cases of urgency the Member States can authorise the Commission to sign the framework contract on behalf of all the participating contracting parties.
- In agreement with DG BUDG, DG SANTE anticipated the new mechanism of the Emergency Support Instrument (ESI) before it was operational. A direct purchase contract under the Health programme was signed rather than a framework contract under the Joint Procurement Agreement. Due to the extreme urgency to sign the contract within two days after receipt of the offer, there was no time to conclude a framework contract followed by specific contracts by the Member States. DG SANTE informed the Member States without delay that the Commission purchased the products to make them available to the Member States. The commitment for this contract was subsequently regularised in order to ensure that ESI credits rather than Health programme credits were implemented for this contract.

The underlying causes behind the exceptions and weaknesses were analysed for each file. A complete list of all derogations was submitted to the authorising officers by sub-delegation for their annual reports to the Director-General.

**(c) Audit observations**

- The feedback received from the Court of Auditors and the IAS did not reveal any significant internal control issues and no OLAF investigation, IDOC report or Ombudsman case was addressed to DG SANTE that would point to serious control weaknesses (see part 8.1.1 above for more detail).
- The audit observations of the IAS rated "very important" and open in 2020 are related to DG SANTE's IT tool TRACES, the work of the Directorate for "health and food audits and analysis" and the methodology of unit costs used in the Food and Feed expenditure. The main actions to address the weaknesses are ongoing. DG SANTE believes that the mitigating measures it has in place do not put the effectiveness of DG SANTE's internal control system into question (see part 8.1.2 above for more detail on the audits and DG SANTE's actions).
- DG SANTE's centralised function to follow up on audit recommendations ensures a timely management of and reporting on the implementation of audit recommendations. Auditors did not point to any long outstanding audit recommendations with undue delays.

#### **(d) Results of the internal desk review**

- ❑ The second-level financial verifying agent, the central function for managing procurement procedures and the public procurement committee assisted the authorising officers by sub-delegation in the review and validation of transactions and procedures. Their ex-ante controls and checks, embedded in the procedures, did not reveal any significant internal control weaknesses.
- ❑ With regard to budget implementation in 2020, all authorising officers by sub-delegation prepared their annual reports for the Director-General. The Directors in charge of EU decentralised agencies also prepared a report on any policy, financial and/or control issue or risk that came to attention and could have an impact on the Director-General's declaration. DG SANTE assessed that the issues highlighted do not impact negatively on the Director-General's declaration of assurance.

#### **8.2.2.3 Risk management and reputational events**

Risk management in DG SANTE facilitates the establishment of specific internal control strategies focussing on the activities and domains representing the highest risks. To be effective, risk management is fully integrated into DG SANTE's planning and control cycle. Since 2010, this is achieved by including the identification of risks and mitigating actions into the harmonised template for Unit Management Plans (UMPs).

The risk assessment exercise for the annual Management Plan starts each year in September and is finalised in November. Further to the input received from all Units, the results of the risk assessment are discussed in the Director's Steering Committee and the Management Board to identify DG SANTE's critical risks to be reported in the Management Plan.

With a view to monitoring the implementation of the action plans, each year in August/September DG SANTE prepares a progress report and communicates it to the Commissioner in the context of the mid-term report. The then Director-General discussed the 2020 report with the Commissioner in late September 2020 as part of her hand-over before leaving DG SANTE.

In 2020, no major event impacting the Director-General's declaration of assurance occurred. However, the following issues are worth mentioning:

#### **◆ Horizontal risk due to Article 50 consequences**

DG SANTE, under the leadership of the Commission's UK task force, has discussed with UK certain temporary conditions for the implementation of the Irish protocol in the Sanitary and phytosanitary agreements and pharmaceutical products area and the corresponding unilateral declarations. Notices have been published. DG SANTE is also organising for the Union presence in Northern Ireland for the purpose of the implementation of the Irish protocol in the SPS area. Despite all efforts, DG SANTE might be unable to deliver, given the issues currently encountered with the implementation of the Irish protocol under the withdrawal agreement and the major

importance and sensitivity of the following areas most affected by an exit of the UK: medicinal products (possibility of an increase in shortages) and trade with the UK (Sanitary and Phytosanitary (SPS) manufacturing authorisations, certificates of good manufacturing practices, authorisations of medicines, authorisations of products and substances.

◆ **Delayed or incomplete implementation of the new Regulations on medical devices (MDR) and In vitro diagnostic medical devices (IVDR) resulting in shortages of certain medical devices having a negative impact on the Commission reputation**

The date of application of the Medical Device Regulation (MDR) was postponed by one year, from May 2020 to May 2021, in April 2020 (following proposal by Commission to allow all actors to focus their efforts on COVID-19). But, despite many mitigating actions, the situation remains critical in particular regarding the capacity of notified bodies (and current difficulties to conduct audits due to COVID-19) both under MDR and IVDR.

◆ **Performance issues in public procurement related to COVID-19 (outside of the Joint Procurement Agreement): health risks and reputational damage**

At the beginning of the COVID-19 crisis, DG SANTE concluded direct purchase contracts for medical countermeasures that were delivered from the producer directly to the Member States, outside the Joint Procurement Agreement. As the goods were urgently needed, DG SANTE was not in a position to proceed with the testing of the procured goods before their distribution to the Member States as foreseen. Physical quality checks prior to shipping or other safeguards, for example, the requirement of marketing authorisations for medicines and vaccines, were introduced in further contracts, but a risk remains that poor quality products are introduced into the EU. Besides the negative impact on the safety of health care workers and patients, this could lead to criticism by the Member States and other stakeholders and could cause reputational damage to the Commission.

## ANNEX 9: Reporting – Human resources, digital transformation and information management and sound environmental management

This annex is the annex of section 2.2 “Modern and efficient administration – other aspects”.

### Staff figures

DG SANTE Human Resources	Establishment plan posts <sup>106</sup>		
	At 31/12/2020	At 31/12/2019	At 31/12/2018
Administrators	427	432	431
Assistants and secretaries	200	208	212
Contractual agents	99	97	92
National experts	43	35	43
<b>Total</b>	<b>770</b>	<b>772</b>	<b>778</b>

### Human resource management

**Objective:** DG SANTE employs a competent and engaged workforce and contributes to gender equality at all levels of management to effectively deliver on the Commission's priorities and core business

Output	Indicator	Target	Results 2020
Updated organisation chart	Validation by the College	16/05/2020	01/09/2020
Recruitment of new female middle managers	# Appointments validated	2 by end 2020	2 first recruitments of female HoU (67%)
COVID-19 crisis management accompanying measures: temporary reinforcements, creation of SANTE@Home project, weekly COVID19 management meetings	Actions implemented	During the COVID-19 period	7 new health crisis staff were recruited, special crisis time management arrangements for COVID19 crisis team were implemented, Weekly COVID19 business continuity meetings were held
DG SANTE staff engagement index	DG SANTE staff engagement index	>= 70%	72% (DG HR Pulse Surveys 13+14; Commission average 69%)

<sup>106</sup> The Human Resource data rely on the snapshot of Commission personnel (establishment plan posts) in each DG/service as of 31 December of the reporting year. These data do not necessarily constitute full-time-equivalents throughout the year.

## Digital transformation

To steer the digital transformation of the Commission, the digital strategy of November 2018 identified 11 core principles that should be respected by all digital solutions. These principles form the cornerstone of all new digital solutions developed by DG SANTE and many are available in existing solutions. For some systems, DG SANTE has reached the highest level of eGovernment maturity level, namely Transformed Government. These systems provide fully automated activities, full electronic case handling and electronic signatures for the processes implemented for user centric interaction with Member States, business and citizens respecting the highest level of security and privacy and making use of reusable solutions. Examples are EFGS, eHDSI and TRACES.

In 2020, DG SANTE also contributed actively to the corporate digital modernisation strategy focused on identifying synergies across the Commission. DG SANTE led the initiative “Health Policy Agencies Collaboration (HPAC)” focusing on solving common digital challenges for both DG SANTE and the health policy decentralised agencies by bringing about efficiencies and sharing good ideas, best practices and project delivery. The newly created HPAC governance structure will provide the basis of collaboration as of 2021, especially in light of the EU4Health programme.

Unfortunately, the COVID-19 pandemic limited progress in many areas, including the evaluation and modernising of the existing portfolio of solutions. COVID-19 itself became the priority and diverted many of the scarce resources to help support policy units to address challenges that arose. This resulted in DG SANTE developing a number of systems in record time and providing adequate operational solutions (including EFGS, Covid-19 Clearing House and Convalescent Plasma – CCP). At the same time, COVID-19 acted as a catalyst in transforming DIGIT’s plans to provide DGs with modern collaborative tools like M365 that can be used anywhere, for which DG SANTE became a forerunner.

### ***Collaborative Working***

DG SANTE has established a collaboration policy and provides a digital collaboration platform and tools that promote modern ways of working within, or away from the office. This forms the standard framework for the coordination of work with operational units and projects, follow-up of Unit Management Plans and different management committees within DG SANTE. During the COVID-19 crisis, this model has been put into more use with DG SANTE being among the forerunners using M365 collaboration. Thanks to DG SANTE’s pilot engagement in digital signatures (a corporate initiative) and eSubmission solutions, truly and fully paperless remote work became possible for the whole DG, allowing the high degree of collaboration and procedure development during the COVID-19 crisis.

A network of volunteers supports this activity, pursuing and pioneering new digital forms of collaboration in different policy and administrative activities.



**Objective:** DG SANTE is using innovative, trusted digital solutions for better policy-shaping, information management and administrative processes to forge a truly digitally transformed, user-focused and data-driven Commission

**Indicator 1: Degree of implementation of the digital strategy principles by the most important IT solutions**<sup>107</sup>

**Source of data:** DG SANTE

Baseline (2018)	Interim milestone (2021 <sup>108</sup> )	Target (2024)	Results
N/A	85%  (Data for EFGS, eHSDI, TRACES as reviewed by DIGIT)	100% (all digital solutions)	<b>2020</b> <b>85%</b>

Output 2020	Indicator	Target	Results
Information systems and processes are at the highest level of maturity (transformed government) operating as e-services for the digital single market.	Percentage of information systems and processes at the highest level of maturity (transformed government) operating as e-services for the digital single market.  <i>Source of data: DG SANTE IT projects and IT MP.</i>	65% <i>no change between 2019 and 2021</i> <sup>109</sup>	2019: 65%  <b>2020</b> <b>65%</b>
Modern collaborative tools are the standard tools to manage activities, store and share information	Percentage of units and projects using collaborative tools to manage their activities  <i>Source of data: Sharepoint usage and applications in SANTE</i>	45% by Q4 2020	2019: 50% in total; 100% for activities applicable to all Units;  <b>2020</b> <b>50% in total; 100% for activities applicable to all Units</b>

<sup>107</sup> The European Commission Digital Strategy (C(2018)7118) calls on Commission services to digitally transform their business processes by developing new innovative digital solutions or make evolve the existing ones in line with the principles of the strategy. At the beginning of the year N+1, the Solution Owner and IT Investments Team will assess the progress made on the basis of the proposed modernisation plan. For each of the 3 solutions, a table will reflect – per principle - the progress achieved during the last year.

<sup>108</sup> As this is a new indicator, there is no baseline in 2018, and in the DSF of 04/03/2020 SG instructed the DGs to provide the value as from 2021.

<sup>109</sup> No change since 2019, DG SANTE is preparing an IT modernisation plan and DIGITAL strategy action plan to be delivered in 2021 addressing the necessary changes and evolution of IT systems for the coming years. The target achievement will increase as of the following year, as the implementation of these plans will be realised.

## Information Management

### ***Data<sup>110</sup>, information and knowledge management***

During 2020 SANTE prepared for the development of its first **Data Strategy** and an annual **data work plan**. Due to the COVID-19 pandemic, the development of the data strategy had to be postponed to 2021. Based on available information of SANTE data needs an intervention logic for a data strategy was prepared. Specific actions focussed on updating the data needs at DG and unit level, increasing the in-house data-searching capabilities for available information, promoting collaborative work and data sharing, and raising staff's general awareness on the need to effectively manage records and data. DG SANTE identified immediate needs of priority policy initiatives related to the COVID-19 crisis as well as to the Europe's Beating Cancer Plan, the Farm to Fork Strategy, and the Pharmaceuticals Strategy. DG SANTE developed a COVID-19 knowledge hub serving as a one-stop shop for all related data and information held in the Commission and EU agencies.

DG SANTE is following the Environment Knowledge Community (EKC) for the purpose of the European Green Deal contributing to areas of relevance for the Farm to Fork Strategy and participating in its biodiversity working group. DG SANTE responded to corporate requests under the Data governance and data policies,<sup>111</sup> such as on country knowledge held by the DG on both health and food.

### ***Data protection***

As in previous years, DG SANTE followed the five objectives specified in the Commission's Data Protection Action Plan (C(2018)7432). In particular, in the first half of 2020, DG SANTE completed, within the set deadline, the conversion of all legacy notifications related to processing operations already in place before the entry into force of Regulation (EU) 2018/1725 to records. This exercise served also as an opportunity to review existing processing operations and to adapt them to the new legal framework, where necessary. Several newly identified processing operations were recorded.

Awareness raising activities continued throughout the year. In the teleworking environment, however, DG SANTE focused on specifically designed trainings/presentations based on needs expressed by the staff, rather than on general trainings.

As a frontline DG in the fight against the COVID-19 crisis, DG SANTE managed many related files, several with important data protection implications (EU Covid-19 Convalescent Plasma Platform, European Federation Gateway Service (EFGS), vaccination certificates).

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<sup>110</sup> For the purpose of this paper data, information and knowledge is referred as data.

<sup>111</sup> [Data governance and data policies at the European Commission Ref. Ares\(2019\)7468514.](#)

For the European Federation Gateway Service, the Commission adopted an implementing decision<sup>112</sup> that describes the roles and responsibilities of the Commission as a processor and of Member States as joint controllers, in the exchange of personal data from contact tracing apps through EFGS (EU Federation Gateway Server). DG SANTE also carried out a part of the data protection impact assessment relating to the infrastructure that it operates and made this available to Member States that will use it for the impact assessments of this processing operation that they will carry out.

Based on the instructions of the EDPS, DG SANTE carried out a mapping exercise of transfers of personal data to third countries (for more information see Annex 9).

### **Data protection – additional outputs**

Currently, one Data Protection Impact Assessment is carried out (relating to Clinical Patient Management System for European Reference Networks). It is expected to be finalised in the first half of 2021.

In 2020, DG SANTE formally consulted European Data Protection Supervisor EDPS on five legislative files:

- Proposal for a Regulation on serious cross-border threats to health,
- Proposal for a Regulation establishing a European Centre for Disease Prevention and Control (ECDC),
- Proposal for a Regulation of the European Parliament and of the Council on a strengthened Union framework addressing public health emergencies with an impact on medicinal products and medical devices,
- Commission Implementing Regulation amending Implementing Regulation (EU) 2019/1715 as regards procedures for the establishment and use of ADIS and EUROPHYT, the issuance of electronic animal health certificates, official certificates, animal health/official certificates and commercial documents, the use of electronic signatures, and the functioning of TRACES,
- Commission Implementing Decision (EU) 2020/1023 of 15 July 2020 amending Implementing Decision (EU) 2019/1765 as regards the cross-border exchange of data between national contact tracing and warning mobile applications with regard to combatting the COVID-19 pandemic.

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<sup>112</sup> Commission Implementing Decision (EU) 2020/1023 of 15 July 2020 amending Implementing Decision (EU) 2019/1765 as regards the cross-border exchange of data between national contact tracing and warning mobile applications with regard to combatting the COVID-19 pandemic

**Objective:** DG SANTE is using innovative, trusted digital solutions for better policy-shaping, information management and administrative processes to forge a truly digitally transformed, user-focused and data-driven Commission

**Indicator 2: Percentage of DG SANTE's key data assets<sup>113</sup> for which corporate principles for data governance<sup>114</sup> have been implemented**

**Source of data:** [each service]

Baseline (2019)	Interim milestone (2022)	Target (2024)	Results 2020
20%	50%	80%	<b>20%</b> <sup>115</sup>

**Indicator 3: Percentage of staff attending awareness raising activities on data protection compliance**

**Source of data:** DG SANTE

Baseline (2019)	Interim milestone (2022)	Target (2024)	Results 2020
98% newcomers 17% rest of the staff	50%	100% of staff	<b>15% of newcomers</b> <b>5% of rest of staff</b>

Output 2020	Indicator	Target	Results 2020
The corporate data inventory includes well managed SANTE key data assets		30% by Q4 2020	<b>20%</b> <sup>116</sup>
Other available relevant data assets included in the local data inventory	Percentage of SANTE key data assets for which corporate principles for data governance have been	100% of other relevant data assets included in the local data inventory;	<i>Due to COVID-19 urgency no info collected</i>

<sup>113</sup> A key data asset is defined as any entity that comprises a source of data based on projects or administrative processes, structured or semi-structured in an information system, a database or a repository of data or corpora of text. A data asset can include multiple datasets or files somehow linked, e.g. by common codes or metadata. Commission key data assets have been documented in the data inventory Ares(2019)2586155.

<sup>114</sup> This indicator follows up on the progress of services in implementing corporate data governance and data policies for their key data assets included in the EC data inventory. See [Ares\(2019\)4441343](#) in the context of the [DataStrategy@EC action plan](#). In summary, this means that for each key data asset, services should assess if the following principles have been respected:

- Identify and designate the data owner and the data steward(s).
- Instruct their data stewards to share the metadata of their data assets in the Commission's data catalogue and to keep them up to date.
- Design and document processes for data collection/creation, acquisition, access, sharing, use, processing preservation, deletion, quality, protection and security. Information concerning these processes should be made available to anyone interested, as long as any confidentiality restrictions are respected.
- Make any necessary changes and updates to the IT systems used for storing, managing and disseminating these data assets to implement the aforementioned requirements and processes.

A data governance hub will shortly offer a single point of access on the intranet for related guidance and information. It will be complemented by further practical guidance in the course of 2020.

<sup>115</sup> No information collected on progress of this indicator.

<sup>116</sup> No information collected on progress of this indicator

Output 2020	Indicator	Target	Results 2020
	implemented  The available other relevant data assets included in the local data inventory		
Results of the second survey collected	Percentage of units providing additional data assets identified.	75% of the units responded to the second survey for additional other data assets.	<i>Due to COVID-19 urgency second survey was not undertaken</i>
Data strategy elaborated in response to the DG's needs and priorities	Percentage of data needs identified (classification short-, medium- and long-term) Data strategy adopted by Management Board	95% of the DG SANTE needs identified  Data strategy adopted in Q4 2020.	<i>Due to COVID-19 urgency data strategy postponed to 2021</i>
Transition data work plan 2020	Transition data work plan 2020 adopted	Transition data work plan 2020 adopted in Q3 2020; focus in COVID-19, Europe's Beating Cancer Plan, Farm to Fork, Pharma Strategy.	<i>Due to COVID-19 urgency transition data workplan was not adopted</i>
Work plan 2021	Percentage of the short term needs included in work plan 2021 Work plan 2021 adopted by Management board	At least 50% of the short term needs included in the work plan 2021 and Work plan 2021 adopted by Management board by Q4 2020	<i>Due to COVID-19 urgency work plan postponed to Q1 2021</i>

## Sound environmental management

Due to the COVID-19 pandemic, initiatives were not carried out as planned. DG SANTE's buildings in Brussels and Luxembourg fall under the responsibility of OIB and OIL respectively; DG SANTE itself manages the day to day running of the site in Grange, Ireland. As the building site in Ireland was closed most of the year, lighting was reduced to the minimum necessary and heating was programmed only to kick-in when internal temperatures dropped below 15°C. Nonetheless, a few initiatives were implemented as indicated in the table below.

**Objective: SANTE takes full account of its environmental impact in all its actions and actively promotes measures to reduce the related day-to-day impact of the administration and its work**

Output 2020	Indicator	Target (2019 as baseline)	Results 2020
<b>Corporate EMAS Indicator 1a, Total energy consumption of buildings (MWh/p or kW/m<sup>2</sup>)</b>			
<b>Corporate Target 2014-2020: -5,2%</b>			
Promote staff awareness actions about optimal energy use and "switching off, when not in use", in line with the EMAS corporate action on resource efficiency during March.	No. actions No. staff informed	Address all SANTE Grange staff	<i>Due to the pandemic, planned initiatives were not carried out. Nonetheless, the Grange business management system turns office lights and PCs off at the end of the working day. In addition, external lighting was reduced to the minimum necessary for security between 19.00 and 07.00.</i>
Raise awareness about SANTE Grange's total energy consumption; and communicate observed trends to staff (once per year), based on verified data from Commission's Environmental Statement (2018 data – per building).	No. staff informed	Address all DG/service staff Reduce energy consumption (0.85%) (compared with the previous year)	<i>As the building was closed, lighting was reduced to the minimum necessary and heating was programmed only to kick-in when internal temperatures dropped below 15°C.</i>
<b>Corporate EMAS Indicator 1d, Water consumption (m<sup>3</sup>/p or L/m<sup>2</sup>)</b>			
<b>Corporate Target 2014-2020: -5,4% and -4,8%</b>			
Promote staff awareness actions about optimal water use and promotion of technical services hotline in case of water leaks, in line with the EMAS corporate action on resource efficiency during March.	No. of actions No. of staff informed	Address all Grange staff	<i>Due to the pandemic, planned initiatives were not carried out. Nonetheless, infrared taps were installed throughout the Grange building, which both avoids the need to touch the tap and ensures the water cuts off immediately after use thus reducing consumption.</i>

<b>Output 2020</b>	<b>Indicator</b>	<b>Target</b> (2019 as baseline)	<b>Results 2020</b>
Raise awareness about SANTE Grange's water consumption; and communicate observed trends to staff), based verified data from Commission's Environmental Statement (2018 data – per building).	No. staff informed	Address all Grange staff	<i>Due to the pandemic, planned initiatives were not carried out.</i>
<b>Corporate EMAS Indicator 1e</b> Office paper consumption (Tonnes/person or Sheets/person/day)			
<b>Corporate Target 2014-2020: -34%</b>			
Promote staff awareness actions about optimal office paper use in line with the EMAS corporate action on resource efficiency during March.	No. actions No. staff informed	Address all DG/service staff	<i>Due to the pandemic, planned initiatives were not carried out.</i>
Raise awareness about DG/service's office paper use and communicate observed trends to staff), based verified data from Commission's Environmental Statement.	No. staff informed	Address all DG/service staff Reduce paper consumption (0.85%%)(compared with the previous year)	<i>Due to the pandemic, planned initiatives were not carried out.</i>
Introduce paperless working methodologies at DG/service level: e.g. e-signatories, financial circuits, collaborative working tools.	No. new actions introduced	1 action per year	<i>Before 2020, the Grange building had already introduced electronic workflows for financial circuits and signatories. The final step to paperless workflows was imposed by the pandemic when report signataires became completely electronic.</i>
Reducing CO <sub>2</sub> , equivalent CO <sub>2</sub> and other atmospheric emissions			
<b>Corporate EMAS Indicator 2 - Reducing emissions, (actions with non-numeric indicators)</b>			
Increase in use of VC meeting rooms in the SANTE Grange, in collaboration with DG SCIC.	No. of VC meeting rooms/sessions	Increase use by 5% (compared with the previous year)	<i>Due to the compulsory teleworking regime, figures are not comparable to any "normal" year.</i>

## **ANNEX 10: Implementation through national or international public-sector bodies and bodies governed by private law with a public sector mission (not applicable)**

Not applicable to DG SANTE.

## **ANNEX 11: EAMR of the Union Delegations (not applicable)**

Not applicable to DG SANTE.

## **ANNEX 12: Decentralised agencies**

DG SANTE does not provide Annex 12 since Annexes 6.2 and 7.1.1.3 already include all information requested in Annex 12:

- List of EU decentralised agencies and the policy area concerned;
- Per agency, the annual budgetary amount entrusted, namely the DG's subsidy paid for the administrative/operating budget, and/or any operational funds provided and their contribution;
- Per agency, information on assurance.