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European Commission

Annual Activity Report 2021

Annexes

DG Health and Food Safety (SANTE)

Contents

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

Director in charge of risk management and internal control

"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, 25 March 2022

Acting 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)
John-F. Ryan
Brussels, 26 March 2022

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, 28 March 2022

ANNEX 2: Performance tables

General objective 1:	**A European Green Deal**		
Impact indicator: Pesticide risk **Source of the data:** Member States annually report data to Eurostat under Regulation (EC) No 1185/2009			
Baseline (2015 – 2017)	**Interim Milestone** [5] (2022)	**Target** (2024)	**Latest known results** (31/12/2019)
100	80	70	87 (13% decrease)

Specific objective 1.1: **Ensuring food and feed safety**			**Related to spending programme(s): Single Market Programme**
Result indicator 1.1.A (Animal health): Increase of the officially free areas from certain zoonoses (Bovine Brucellosis, Bovine Tuberculosis, Sheep and Goat Brucellosis) **Explanation:** 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. **Source of data:** 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 31/12/2021)
EU countries (or parts thereof) free from the above diseases	**+15%**	**+25%**	**+20**
Result indicator: 1.1.B (Plant health): Number of phytosanitary programmes successfully implemented / total number of phytosanitary programmes approved **Explanation:** 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. **Source of data:** Data can be procured using the Survey programs submitted by MS			
Baseline (2020)	**Interim Milestone** (2022)	**Target** (2024)	**Latest known results** (situation on 31/12/2021)
N/A[1]	**80%**	**90%**	**Not known for 2021**

[1] 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).

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

Explanation: 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.

Source of data: Commission internal (DG SANTE)

Baseline (2020)	**Interim Milestone** (2022)	**Target** (2024)	**Latest known results** (situation on 31/12/2021)
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 2017+2018+2019

Result indicator: 1.1.D (Burden reduction): Proportion of proposed legislative revisions that include burden reduction measures

Explanation: The indicator measures how the Commission upholds its commitment to ensure that proposals for legislative revisions incorporate burden reduction measures, in the broader context of REFIT programme and One-In, One-Out approach. The indicator shows how many proposed legislative revisions out of the total, for each relevant specific objective, include measures that concretely reduce burden.

Source of data: Commission internal (DG SANTE)

Baseline (2020)	**Interim Milestone** (2022)	**Target** (2024)	**Latest known results** (situation on 31/12/2021)
N/A	Positive trend	Positive trend	No proposals for legislative revisions were adopted in 2021

Main outputs in 2021:

Initiatives linked to regulatory simplification and burden reduction

Output	**Indicator**	**Target**	**Latest known results (situation on 31/12/2021)**
FSCAP IT System used in applications in the context of Transparency Regulation	Established	Q1 2021	FSCAP /ESFC operational since 29 March 2021 https://webgate.ec.europa.eu/esfc/
Implementing Regulation laying down rules for the application of Regulation (EU) 2016/429 of the European Parliament and of the Council with regard to registration and record keeping of	Adoption	Q1 2021	To be adopted in 2022, due to additional extensive consultations with Member States and additional work due to the implementation of the Animal Health Law.

Output	Indicator	Target	Latest known results (situation on 31/12/2021)
operators and establishments keeping terrestrial animals (PLAN/2020/7748)			
Implementing Regulation laying down rules for the application of Regulation (EU) 2016/429 of the European Parliament and of the Council with regard to registration of aquaculture establishments and record keeping of operators (PLAN/2020/8209)	Adoption	Q1 2021	Adopted. Commission Implementing Regulation (EU) 2021/2037 of 22 November 2021
Implementing act on the list of variations not requiring assessment (PLAN/2018/3968)	Adoption	Q1 2021	Adopted Commission Implementing Regulation (EU) 2021/17 of 8 January 2021
Implementing act on the necessary measures and practical arrangements for the Union database on veterinary medicinal products (PLAN/2018/3969)	Adoption	Q1 2021	Adopted Commission Implementing Regulation (EU) 2021/16 of 8 January 2021
Implementing Regulation as regards procedures and use of ADIS and EUROPHYT, the issuance of electronic official certificates and the use of electronic signatures, and the proper functioning of TRACES (PLAN/2020/8217)	Adoption	Q1 2021	Adopted Commission Implementing Regulation (EU) 2021/547 of 29 March 2021
COMMISSION NOTICE on the submission of notifications under Articles 13 and 17 of Directive 2001/18/EC of the European Parliament and of the Council on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC and under the relevant provisions	Adoption		Adopted Commission Notice (2021/C 80/01)

Output	Indicator	Target	Latest known results (situation on 31/12/2021)
of Regulation (EC) 178/2002, as amended by Regulation (EU) 2019/1381 (PLAN/2020/7743)			
Evaluations and fitness checks			
Evaluation of the food irradiation legislation (PLAN/2016/506)	Publication of SWD	Q2 2021	Published
External communication actions			
Press and Media			
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	At least 15 EU countries covered outbreaks, notably the African Swine Fever and Avian Influenza outbreaks
Social Media			
Sustained tweets throughout the year on the various aspects of Food and feed safety	Increase engagement on twitter Increase the number of followers on the EU Food Safety account	Average a minumum of 100 engagements per tweet. (all engagements) Increase the number of followers by another 5000 followers (shared with other specific objectives) (Baseline 28,000)	Reached 141 engagements on average with posts including #EUFoodSafety throughout 2021 Followers on 31.12.21: 34.8k (+6.8k, +24%)
Website			
Update of related webpages	Increase in the number of visitors to the SANTE food and feed related webpages	5% increase (Baseline 2020 - 4,522,879pageviews)	2021: 14,840,635 pageviews / 10,748,964 unique pageviews/ 5,466,009 entrances, representing an increase
Other important outputs			
Actions on animal and plant diseases under the Common Financial Framework/Single Market Programme			
2021 Eradication, surveillance and monitoring programmes (estimation: 2021 programmes will be submitted in 2021, after adoption of the SMP):			
Bovine brucellosis	No. of MSs with a veterinary programme approved for EU cofinancing	3	2

Output	Indicator	Target	Latest known results (situation on 31/12/2021)
Bovine tuberculosis	No. of MSs with a veterinary programme approved for EU cofinancing	5	5
Sheep and Goat brucellosis	No. of MSs with a veterinary programme approved for EU cofinancing	5	2
Sheep and Goat Plague	No. of MSs with a veterinary programme approved for EU cofinancing		2
Sheep and Goat Pox	No. of MSs with a veterinary programme approved for EU cofinancing		2
Swine diseases	No. of MSs with a veterinary programme approved for EU cofinancing	22	African Swine Fever – 19 Classical Swine Fever – 6
Avian influenza	No. of MSs with a veterinary programme approved for EU cofinancing	27	26
Transmissible Spongiform Encephalopathies (TSE), Bovine spongiform encephalopathy (BSE) and scrapie	No. of MSs with a veterinary programme approved for EU cofinancing	27	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	27	24
Lumpy Skin Disease (LSD)	No. of MSs with a veterinary programme approved for EU	2	3

Output	Indicator	Target	Latest known results (situation on 31/12/2021)
	cofinancing		
Bluetongue	No. of MSs with a veterinary programme approved for EU cofinancing	3	3
Emergency measures	Adoption	In course of 2021	Postponed to early 2022
ASF, LSD and Rabies strategies with non-EU countries (under emergency measures)	No. of grant agreements signed	6 to 8 for ASF 6 for LSD 4 for Rabies	ASF – 6 grants LSD – 4 grants Rabies – 0 grants
CFF Programme review	Launch	Q4 2021	Process launched
Actions in view of the next Multiannual Financial Frame (SMP) work (MFF) – Single Market Programme			
Guidelines and standard operating procedures to manage the new SMP food and feed strand	Adoption	Q1 2021	Ongoing for emergency measures
Transitional measure for the 2021 programmes	Adoption	Q1 2021	Completed
Establishment of the new management modes for the transfer of the programmes to an executive agency, including Validation of the Model of Grant Agreement Development of e-grants	Please provide indicator for 2021 activity Validation of the model Onboarding to e-Grant tool	Q1 2021 01/01/2021 Ongoing 2021 for onboarding on	Ongoing Ongoing Ongoing
New procedural technical guidelines	Guidelines approved	01/01/2022	Ongoing for emergency measures
Recruitment of the Agency staff	Staff recruitment by Q1 2021	Q1 2021	Completed
Transfer of the Food chain programme to the	Taking over by the Agency	Staff recruited	Completed

Output	Indicator	Target	Latest known results (situation on 31/12/2021)
Agency			
Preparation of the Memorandum of Understanding	MoU signed	Q2 2021	Preparation ongoing (expected signature in Q1 2022)
Signature of the grant agreements for 2021	Grants signed	Q3 or Q4 2021	Ongoing
BTSF seminars and conferences	No. of seminars and conference held	160 seminars and conferences help as virtual classroom courses as of January 2021	137 virtual classroom training events were delivered in 2021
Animal health and animal diseases			
Delegated Regulation (EU) as regards 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	Q2 2021	Adopted in Q3 2021
Implementing Regulation laying down rules for Identification and registration of equidae (PLAN/2019/5529)	Adoption	Q1 2021	Adopted Implementing Regulation (EU) 2021/963, OJ publication on 16/06/2021
Implementing Regulation laying down rules for the application of Regulation (EU) 2016/429 of the European Parliament and of the Council with regard to registration and record keeping of operators and establishments keeping terrestrial animals (PLAN/2020/7748)	Adoption	Q1 2021	Scheduled for adoption in Q1 2022

Output	Indicator	Target	Latest known results (situation on 31/12/2021)
Implementing Regulation laying down rules for the application of Regulation (EU) 2016/429 of the European Parliament and of the Council with regard to registration of aquaculture establishments and record keeping of operators (PLAN/2020/8209)	Adoption	Q1 2021	Adopted Implementing Regulation (EU) 2021/2037 of 22 November 2021
Commission decisions on handling evolving epidemiological situations	Adoption of emergency Decisions as necessary, according to the epidemiological situation	In course of 2021	Approximately 100 acts adopted for avian influenza and African swine fever
Commission rules on safe imports, trade and related aspects	Adoption of Commission implementing rules.	In course of 2021	REGULATION 2021/405 COMMISSION IMPLEMENTING REGULATION (EU) 2022/34 3 Residue decisions: COMMISSION IMPLEMENTING DECISION (EU) 2021/653 COMMISSION IMPLEMENTING DECISION (EU) 2021/800 COMMISSION IMPLEMENTING DECISION (EU) 2021/2315
Plant health and diseases			
Regulations on high-risk plants dossiers	Adoption	The no. of adopted Regulations depends on the number requests and of EFSA opinions	3 Regulations adopted
Commission Regulations on containment measures for some specific pests	Adoption	More than 10	-
Report on the enforcement and effectiveness of import requirements	Adoption	Q4 2021	Adopted on 10/12/2021

Output	Indicator	Target	Latest known results (situation on 31/12/2021)
Report on the experience gained from the extension of the plant passport system to all plants for planting	Adoption	Q4 2021	Adopted on 10/12/2021
Commission Decisions on emergency measures against some specific pests	Adoption according to (new) outbreak situations	In course of 2021	4 Decisions adopted
Commission Decisions with specific import requirements for trade lines where there are too many import interceptions	Adoption according to import interception notifications from Member States	In course of 2021	2 Decisions adopted
Evaluation of co-financing requests of Member States eradication measures	No. of co-financing requests for plant health programmes that received co-financing	27	24 co-funding programmes 65 co-funding requests for eradication/containment (2018-2019)
Market access for safe substances and products			
General plan on risk communication in the context of the Transparency Regulation	Preparatory work	In course of 2021	EFSA submitted to SANTE four reports to inform the General Plan on Risk Communications (GPRC), which were presented to SANTE in more detail on 28 June 21
Regulatory measures on contaminants in feed and food following EFSA opinions	Adoption	In course of 2021	Ongoing regular activity. In 2021, MLs in food were adopted for cadmium, lead, opium alkaloids, tropane alkaloids and ergot alkaloids
Authorisations of health and nutrition claims, generic descriptors.	Adoption	In course of 2021	None
Commission Regulations prohibiting, restricting or banning the use of substances other than vitamins and	Adoption	In course of 2021	1 adoption: C(2021) 1670

Output	Indicator	Target	Latest known results (situation on 31/12/2021)
minerals in food (Article 8 procedure)			
Authorisations of vitamins and mineral substances that can be added to foods and/or to food supplements or foods for specific groups	Adoption	In course of 2021	2 adoptions: C(2021) 192 C(2021) 1452
Authorisation of novel foods under the Regulation on Novel Foods	Adoption	Up to 30 in course of 2021	18 – of which 9 were granted data protection
Authorisation of traditional foods from third countries under the Regulation on Novel Foods	Adoption	4 in course of 2021	1 adoption: C(2021)8876
Authorisations for new substances and new uses of already authorised substances used as food additives or food flavourings	Adoption	Ongoing regular activity in 2021; adoption of approx. 13 acts amending the uses and use levels for food additives and flavourings.	8 amendments of the Union Lists authorising new food additives (1) and flavourings (3) or amending their conditions of use and specifications
Implementing act on scientific data for the evaluation of the combination effects of chemicals *[Decide planning not yet requested]*	Preparatory work	In course of 2021	Preparatory work ongoing (contacts with EFSA and work within the CSS)
Authorisations for new substances and new uses of already authorised substances used in food contact materials	Adoption	Ongoing regular activity in 2021, for an estimated 15 substances.	None in 2021
Authorisations of GMO for food / feed uses	Adoption	Ongoing regular activity in 2021	Adoption of 12 implementing decisions to authorise new GMOs and of 6 implementing decisions for renewal authorisation of GMOs. Adoption of 7 implementing decisions on administrative changes.
Commission report on experience of Member	Adoption		Adoption of the report

Output	Indicator	Target	Latest known results (situation on 31/12/2021)
States with Directive 2009/41/EC on the contained use of genetically modified micro-organisms (period 2014 – 2018) - COM/2021/266 final (PLAN/2020/7777			COM/2021/266 final
Implementing Regulations renewing/non-renewing the approval of active substances for plant protection products	Adoption		11 Implementing Regulations adopted.
Implementing Regulations for approval/non-approval or amendment of conditions of approval of active substances for plant protection products	Adoption	Ongoing regular activity in 2021	14 Implementing Regulations adopted.
Regulations establishing maximum residues levels (MRL) for pesticides	Adoption	Ongoing regular activity in 2021	22 Regulations adopted setting maximum residue levels for 103 pesticides
Cumulative risk assessment method for pesticides residues	Development	Ongoing activity in 2021	EFSA-SANTE action plan adopted in February 2021 and ongoing implementation throughout the year.
Implementing Regulations renewing/non-renewing the approval of biocidal active substances	Adoption	Ongoing regular activity in 2021	No Regulation adopted.
Implementing Regulations for approval/non-approval of biocidal active substances included in the review programme	Adoption	Ongoing regular activity in 2021	10 Implementing Regulations approving 19 active substance/product-type combinations + 3 Implementing Decisions not approving 25 active substances/product- type combinations.
Implementing Regulations granting or amending Union authorisation of biocidal products	Adoption	Ongoing regular activity in 2021	4 Implementing Regulations granting a Union authorisation + 3 Implementing Regulations amending existing Union authorisations
Implementing Decisions	Adoption		4 implementing Decisions

Output	Indicator	Target	Latest known results (situation on 31/12/2021)
on disagreements between Member States on the authorisation of biocidal products			
Re-evaluations of authorisations, new authorisations, denial/suspension of authorisation, modifications of authorisations and renewal and non-renewal of authorisations of feed additives	Adoption	Ongoing regular activity in 2021	54 Implementing Regulations adopted, concerning a total of 80 feed additives
Revision of the Catalogue of feed materials (Regulation (EU) 68/2013) to include novel, more sustainable feed materials (PLAN/2020/8800)	Adoption	Q2 2021	Draft act agreed in 'PAFF' Committee in December 2021 – Adoption procedure to be launched early 2022
Authorisations of veterinary medicinal products	Adoption	Ongoing regular activity in 2021	14
Setting of MRLs for substances used in veterinary medicinal products	Adoption	Ongoing regular activity in 2021	1 (Imidacloprid) Commission Implementing Regulation (EU) 2021/621 of 15 April 2021
Delegated act amending Annex II to Regulation (EU) 2019/6 (PLAN/2018/4493)	Adoption	Q1 2021	Adopted Commission Delegated Regulation (EU) 2021/805 of 8 March 2021
Implementing act on the list of variations not requiring assessment (PLAN/2018/3968)	Adoption	Q1 2021	Adopted Commission Implementing Regulation (EU) 2021/17 of 8 January 2021
Implementing act on the necessary measures and practical arrangements for the Union database on veterinary medicinal products	Adoption	Q1 2021	Adopted Commission Implementing Regulation (EU) 2021/16 of 8 January 2021

Output	Indicator	Target	Latest known results (situation on 31/12/2021)
(PLAN/2018/3969)			
Implementing act on the good distribution practice for veterinary medicinal products (PLAN/2018/3983)	Adoption	Q4 2021	Adopted Commission Implementing Regulation (EU) 2021/1248 of 29 July 2021
Implementing act on the good distribution practice for active substances (PLAN/2018/3965)	Adoption	Q4 2021	Adopted Commission Implementing Regulation (EU) 2021/1280 of 2 August 2021
Implementing act on the good pharmacovigilance practice and on the content of the pharmacovigilance system master (PLAN/2018/3967 and former PLAN/2018/3982)	Adoption	Q4 2021	Adopted Commission Implementing Regulation (EU) 2021/1281 of 2 August 2021
Implementing act on the common logo for online sales (PLAN/2018/3981)	Adoption	Q4 2021	Adopted Commission Implementing Regulation (EU) 2021/1904 of 29 October 2021
Delegated act on the horse passport (PLAN/2020/6502)	Adoption	Q1 2021	Adopted Commission Delegated Regulation (EU) 2021/577 of 29 January 2021
Implementing act on the horse passport (PLAN/2019/5529)	Adoption	Q2 2021	Adopted Commission Implementing Regulation (EU) 2021/963 of 10 June 2021
Feasibility study of an active substance-based review system ('monographs') and other potential alternatives for the environmental risk assessment of veterinary medicinal products	Completed	Q4 2021	Study completed and published on 9 November 2021[2]

[2] https://op.europa.eu/en/publication-detail/-/publication/03055c4d-42a6-11ec-89db-01aa75ed71a1/language-en/format-PDF/source-243449059

Output	Indicator	Target	Latest known results (situation on 31/12/2021)
Commission rules on safe imports, trade and related aspects	Adoption of Commission implementing rules	In course of 2021	Several acts adopted mainly for avian influenza
Collection of data on food irradiation 2020	Completion	Q3 2021	Completed
Publication of the European Union One Health 2019 Zoonoses Report by EFSA	Publication	Q1 2021	Published on 27 February 2021
Approval of control programmes and special guarantees for Salmonella	Number of control programmes evaluated	27	24
Control Systems, including audits, and rapid alert systems			
European Reference Laboratories	Number of laboratories funded	27	44
European Reference Centres	Number of centres funded	3	4
Audits in the area of food safety and quality, animal health, animal welfare and plant health	Approx. 175 audits and similar controls completed	In the course of 2021	221 controls performed, including 142 audits and similar controls
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 experiences and the preparation of guidance to enhance official control systems	Number of meetings held	5 plenary meetings; 4 subgroup meetings	5 plenary meetings 0 subgroup meetings
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	Number of meetings held	2 meetings of the working group on the Sustainable Use Directive 1 to 2 meetings of	2 meetings held on animal welfare during transport with relevant national contact points 3 external stakeholder events on the revision of the sustainable

Output	Indicator	Target	Latest known results (situation on 31/12/2021)
exchange best practices identified		the National Contact Point group on animal welfare	use of pesticides Directive
Assessment of planned facilities of Border Control Posts (BCPs)	Assessments carried out	Approx. 30 per year, based on demand from the Member States	123 related to BCP notifications of which 88 were related to new or changes in infrastructure or operation of BCPs, 20 to changes in operation of BCPs to include designation for organic and in-conversion products as such products need to be checked at points of entry from 1 January 2022 onwards; and 15 other files were requests for clarification of minimum requirements for BCP facilities
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	All 27 MS plus Northern Ireland; Of 98 listed third countries, 48 countries' plans – 49% - (for commodities including casings) were assessed (102 evaluations in total).
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	No of listing requests – 553 No of modifications - 3363
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 2021	Query tools were developed for data analysis in Europhyt (Outbreaks). A report will be produced in early 2022. EUROPHYT (interceptions) has stopped being operational since June 2020. Only historical data can be retrieved. EUROPHYT has been replaced by IMSOC. Annual reports on interceptions are not published anymore. Monthly reports on interceptions are being made available to the public.

Output	Indicator	Target	Latest known results (situation on 31/12/2021)
Plant health surveys	Member States' survey results for harmful organisms presented to Standing Committee on PAFF	In course of 2021	Survey results for seven pests were presented.
Computerised systems + IT (e.g. TRACES, ADNS, EUROPHYT)			
Implementing Regulation as regards procedures and use of ADIS and EUROPHYT, the issuance of electronic official certificates and the use of electronic signatures, and the proper functioning of TRACES (PLAN/2020/8217)	Adoption	Q1 2021	Adopted Commission Implementing Regulation (EU) 2021/547 of 29 March 2021
TRACES	No of active end-users	54000	90.000
ADIS	No of active end-users	450	390
iRASFF	No of active user accounts	7211	7272
EUROPHYT (Interceptions and Outbreaks)	No of active end-users	1100	561 (EUROPHYT Outbreaks). EUROPHYT Interceptions were integrated in TRACES during 2020.
IT platform for submission of the Member States' Annual OC Reports	Launched	Q3 2021	Launched

Specific objective 1.2: Ensuring sustainable food systems – the 'Farm to Fork' strategy			**Related to spending programme(s) Single Market Programme**
Result indicator 1.2.A : Use of more hazardous pesticides **Explanation:** 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. **Source of data:** Member States report data on pesticide sales annually to Eurostat under Regulation (EC) No 1185/2009.			
Baseline (2015-17)[3]	**Interim Milestone** (2022)	**Target** (2024)	**Latest known results** (situation on 31/12/2019)
100	**85 (15% decrease)**	**70 (30% decrease)**	**88 (12% decrease)**
Result indicator 1.2.B : Sales of antimicrobials in farmed animals and aquaculture **Explanation:** This indicator measures the average volume of overall sales of antimicrobials in the EU, 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. **Source of data:** European Medicines Agency [European Surveillance of Veterinary Antimicrobial Consumption (ESVAC) Report]. Please note that the baseline set in 2020 is based on data from 2018 and that the interim milestone in 2022 and the target in 2024 will reflect data from 2021 and 2022, respectively.			
Baseline (2020)	**Interim Milestone** (2022)	**Target** (2024)	**Latest known results** (situation on 31/12/2021)
118.6 mg/PCU[4].	**95 mg/PCU**	**85 mg/PCU**	**101.6 mg/PCU** (data from 2020)
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" approach37 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)			
Baseline (2020)	**Interim Milestone** (2022)	**Target** (2024)	**Latest known results** (situation on 31/12/2021)
N/A	20	27	18

[3] The baseline period was incorrectly given as 2020 in the DG SANTE Strategic Plan 2020-24.

[4] 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. Hence, the baseline value has been updated accordingly.

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)

Baseline (2020)	**Interim Milestone** (2022)	**Target** (2024)	**Latest known results** (situation on 31/12/2021)
81% (based on recommendations 2010-2019)	83% (based on recommendations 2010-2021)	85% (based on recommendations 2010-2023)	77% (based on recommendations 2010-2020)

Result indicator: 1.2.E (Burden reduction): Proportion of proposed legislative revisions that include burden reduction measures

Explanation: The indicator measures how the Commission upholds its commitment to ensure that proposals for legislative revisions incorporate burden reduction measures, in the broader context of REFIT programme and One-In, One-Out approach. The indicator shows how many proposed legislative revisions out of the total, for each relevant specific objective, include measures that concretely reduce burden.

Source of data: Commission internal (DG SANTE)

Baseline (2020)	**Interim Milestone** (2022)	**Target** (2024)	**Latest known results** (situation on 31/12/2021)
N/A	Positive trend	Positive trend	No proposals for legislative revisions were adopted in 2021

Main outputs in 2021:

New policy initiatives

Output	**Indicator**	**Target**	**Latest known results (situation on 31/12/2021)**
Proposal for a revision of the Sustainable Use Directive for pesticides (SUD) (PLAN/2020/6975)	Preparatory work	In course of 2021	Draft Commission evaluation and impact assessment staff working documents submitted to Regulatory Scrutiny Board. Draft Commission legislative proposal prepared in parallel.
Commission Communication replying to the European Citizens' Initiative End the Cage Age' (PLAN/2020/9795)	Adoption	Q1 2021	Adopted
Impact Assessment on Front-of-pack nutrition labelling and nutrient profiles for health claims (PLAN/2020/9144 on nutrient profiles and PLAN/2020/8886 on front-of pack nutrition labelling, in synergy with PLAN/2021/11031	Launch of the supporting study	Q1 2021	Launched in August 2021

Output	Indicator	Target	Latest known results (situation on 31/12/2021)
on alcoholic beverages)			
Impact Assessment on origin indication for certain products (PLAN/2020/8886) in synergy with initiatives under PLAN/2020/9144 and PLAN/2021/11031	Launch of the supporting study	Q1 2021	Launched in August 2021
Impact Assessment on date marking (PLAN/2020/8886) in synergy with initiatives under PLAN/2020/9144 and PLAN/2021/11031	Launch of the supporting study	Q1 2021	Launched in August 2021
Impact Assessment on labelling of alcoholic beverages (PLAN/2021/11031 in synergy with initiative under PLAN/2020/8886 and PLAN/2020/9144)	Launch of the supporting study		Launched in August 2021
Impact assessment on sustainable food labelling as part of the IA on the framework of a sustainable food system	Publication of the IIA	Q3 2021	Published on 1st October 2021
Impact Assessment of the legislation on seeds and forest reproductive material (PLAN/2020/7576; PLAN/2020/7574)	Ongoing work	In course of 2021	Call for evidence published 15/6/2021 OPC ongoing, deadline 27/3/2022
Impact Assessment on FCM (PLAN/2020/7637)	Launched	Q1 2021	Open Public Consultation: Q1 2022 IA study/ies to be launched Q2 2022
Impact Assessment on ceramic FCM (PLAN/2018/4857)	Launched	Q1 2021	Study report completed in November 2021
PRM Study: Council requested the Commission under Article 241 TFEU to provide a study on the Union's options to update the existing legislation on the production and marketing of plant reproductive material (Council Decision (EU) 2019/1905	Preparation and finalisation of study on PRM		Finalised and submitted to Council 29 April 2021
Impact assessment on the revision of the animal welfare legislation (PLAN/2021/10238)	Publication of the IIA Launch of the 4 studies to		IIA published – feedback received OPC launched on 15

Output	Indicator	Target	Latest known results (situation on 31/12/2021)
	support the IA Launch of the Open Public Consultation (OPC)		October 2021 2 out of 4 study contract signed
Initiatives linked to regulatory simplification and burden reduction			
Proposal for a revision of Regulation (EC) No 1831/2003 on additives for use in animal nutrition (PLAN/2020/8500)	Adopted	Q4 2021	Q2 2022 (June)
Evaluations and fitness checks			
Evaluation of Regulation EC 1831/2003 on additives for use in animal nutrition (PLAN/2017/988)	Publication of SWD	Q4 2021	Postponed to Q2 2022 SWD on the evaluation is to be annexed to the IA Staff Working Document. The impact assessment (IA) will be carried out in parallel to the evaluation (so-called "back-to-back") as a single process.
Evaluation of the EU Animal Welfare Strategy (2012-15) (PLAN/2019/5270)	Adoption of SWD	Q1 2021	Completed
Fitness check of the animal welfare legislation (PLAN/2020/6933)	Adoption of SWD	Q4 2021	Still ongoing. New target for adoption Q2 2022
Evaluation of the Food Contact Material (FCM) legislation (PLAN/2016/436)	Ongoing work	In course of 2021	RSB positive opinion in Q4 2021, publication expected during Q1 2022
Public consultations			
Public consultation for the inception impact assessment of the review of the FIC Regulation (front-of-pack nutrition labelling and nutrient profiles, origin labelling and date marking)	Completed		472 contributions received
Public consultation for the inception impact assessment of the revision of Food Information to Consumers for what concerns labelling rules on alcoholic beverages	Completed		82 contributions received

Output	Indicator	Target	Latest known results (situation on 31/12/2021)
Public consultation for the impact assessment of the review of the FIC Regulation (front-of-pack nutrition labelling and nutrient profiles, origin labelling, date marking and alcoholic beverages labelling)	Launched on 13 December 2021		Ongoing
Enforcement actions			
External communication actions			
Press and Media			
Communicate on the various proposals	National print media coverage of EU's actions when proposals adopted	Media coverage by at least 10 EU countries	All EU MS press media covered some or all aspects of Farm to fork strategy including pesticides, animal welfare and the code of conduct
Farm To Fork Conference			
Organisation of a hybrid Conference on Farm to Fork in October 2021.	Number of attendees (online) per day Usefulness of event for attendees (survey amongst attendees) Percentage of attendees having a more positive opinion of the EU's Farm to Fork Strategy as a result of the event (survey amongst attendees)	9000 participants attending event across all platforms per day 85% useful or very useful as per survey during event (online) 85% positive or very positive when asked in survey during event (online)	First day: 10 500 participants Second day: 5 600 participants 86% of participants considered the Conference useful or very useful
Euronews campaign			
	Number of people reached Percentage of people having a positive opinion of Farm to Fork as a result of the campaign	Audience analysis: target 3 million citizens 80% positive satisfaction rate (when asked in survey)	4 million viewership reached over the course of ten magazine programmes

Output	Indicator	Target	Latest known results (situation on 31/12/2021)
Social Media			
Sustained tweets throughout the year on the various aspects of Farm to Fork and its implementation. The hashtag #EUFarm2Fork monitored continuously. Paid promotion of tweets	Increase engagement on Twitter (Also increase the number of followers on the food safety account as detailed under objective 1.1)	Average a minimum of 100 engagements per tweet. (all engagements)	Reached 146 engagements on average with posts including #EUFarm2Fork throughout 2021
Website			
Update of the Farm to Fork webpage to include any ongoing consultations and the implementation progress	Increase in the number of visitors Number of visitors to the site that have a positive view on the ongoing consultation process on F2F deliverables.	Resulting in increase in web traffic on the Farm to Fork pages. by 10% (when compared to 2020 baseline: 161,425 page views) 80% positive satisfaction rate (when asked in survey)	2021: 167,771 page views / 171,295 entrances, representing an increase No survey executed
Other important outputs			
Launch of IA on the legislative framework on sustainable food systems, including on sustainable food labelling	Publication of Inception Impact Assessment	Q3 2021	Publication on 28 September 2021-26 October 2021. 230 contributions received.
Code of Conduct for sustainable marketing practices	Signature by stakeholders	Q2 2021	Signature by stakeholders started end of June 2021 and launch event of the code took place on 5 July 2021. Currently 100+ signatories, including producers, retailers, service-industry and associations.
Member States expert group on the general food law and sustainability of food systems	Established	Q1 2021	Terms of reference of the revamped expert group published beginning of January 2021
Stakeholders subgroup on sustainability of food systems	Not	N/A	A revamp of the Advisory Group has been decided upon the expiry

Output	Indicator	Target	Latest known results (situation on 31/12/2021)
within the Advisory Group on the food chain and animal and plant health	established		of the mandate of the existing members of the Advisory Group as of July 2022, to enlarge participation for the purposes of the sustainability of food systems.
Contribution to Commission reccomendations to MS on CAP NSPs	Provided	In course of 2021	Contributions provided and included in COM/2020/846 final
Plant Protection Products and sustainable use thereof			
Regulation establishing a first list of non-acceptable co-formulants in plant protection products (PLAN/2017/1189)	Adoption	Q1 2021	Adopted Commission Regulation (EU) 2021/383 of 3 March 2021
Update of Communications accompanying the data requirements for active substances and plant protection products	Ongoing work	In course of 2021	Adoption delayed to 2022 due to numerous comments from Member States and stakeholders that need to be resolved.
Revision of the relevant implementing Regulations under the Plant Protection Products framework to facilitate placing on the market of plant protection products containing biological active substances - Amendment of Annex II of Regulation (EC) No 1107/2009 (PLAN/2020/9073) - Amendment of the uniform principles for evaluation and authorisation of plant protection products (PLAN/2020/8956) - Amendment of data requirements for applications for the approval of active substances (PLAN/2020/8955) - Amendment of data requirements for applications for the authorisation of plant protection products (PLAN/2020/8954)	Adoption	Q4 2021	Feedback mechanism completed on 23 November 2021. Adoption now envisaged in Q2 2022 after scrutiny of EP and Council.
Reduction in the use of antibiotics in animals to contribute to fight AMR			
Delegated act on the requirements for the collection of data on antimicrobial medicinal products used in animals	Adoption	Q4 2021	Adopted Commission Delegated Regulation (EU) 2021/578 of 29 January 2021

Output	Indicator	Target	Latest known results (situation on 31/12/2021)
(PLAN/2018/4495)			
Implementing act on the format for the collection of data on antimicrobials (PLAN/2018/3984)	Adoption	Q4 2021	Feedback mechanism ends on 21 December 2021 – adoption targeted for February 2022
Delegated act on the detailed rules on exports from third countries to the EU (Art. 118) (PLAN/2018/4503)	Adoption	Q4 2021	Q3-Q4 2022 (linked to the adoption of the IA on the list of antimicrobials reserved for human use (PLAN/2018/3966)
Delegated act to establish the criteria for designation in the EU of those antimicrobials to be reserved for human use (PLAN/2018/4510)	Adoption	Q3 2021	Adopted Commission Delegated Regulation (EU) 2021/1760 of 26 May 2021
Implementing act on the list of antimicrobials reserved for human use (PLAN/2018/3966)	Adoption	Q4 2021	Q3 2022, completion is pending upon reception of EMA scientific advice by end of February 2022
Implementing act on the list of antimicrobials that cannot be used outside the terms of their marketing authorisations subject to certain conditions (PLAN/2020/9134).	Ongoing work	In course of 2021	Q4 2022 Awaiting reception of EMA scientific advice expected by end of March 2022
Authorisation of feed additives improving the gut health of the animals, thus reducing the need for treatment with antibiotics	Adoption of authorisations		8 feed additives authorised (for gut flora stabilising feed additives)
Sustainable feeds			
Authorisation of feed additives contributing to more sustainable animal nutrition, in particular reducing negative impacts on the environment	Adoption of authorisations	In course of 2021	36 feed additives authorised (feed additives consisting in particular of amino acids, enzymes and micro-organisms or improving zootechnical parameters)
Commission Regulation on the revision of the feedban	Adoption by the Commission	Q3 2021	Adopted Commission Regulation (EU) 2021/1372 of 17 August 2021
Food loss and waste			
Operational support services for the EU Platform on Food Losses and Food Waste	Operation of digital platform and user activity	Ongoing regular activity in 2021	Done
Meetings of the EU Platform on Food Losses and Food Waste	2 meetings held	Q2 and Q4 2021	2 Plenary meetings held on 18 March and 18 November 2021.

Output	Indicator	Target	Latest known results (situation on 31/12/2021)
Meetings of the sub-groups of the EU Platform on Food Losses and Food Waste	7 meetings held	In course of 2021	5 meetings held (including webinar for Member States on food waste measurement)
Preparatory work for the adoption of legally binding food waste prevention targets	Launched	In course of 2021	Public consultation on the Inception Impact Assessment online from 1-31 October 2021. 85 contributions received.
Administrative arrangement with JRC to support assessment of food waste prevention initiatives	Signed	Q2 2021	JRC AA (36128), signed 07/12/2021
Action grant – European Food Banks Federation	Signed	Q4 2021	Will be implemented by HADEA in 2022
Grants for MS to improve food waste measurement programmes (under SMP)	Signed	Q4 2021	Will be implemented by HADEA in 2022.
Grants for stakeholders to support implementation of FW prevention programmes	Signed	Q4 2021	Will be implemented by HADEA in 2022.
Animal Welfare			
Pilot project on the welfare of dairy cows	Lauched	Q1 2021	Launched and still ongoing
Pilot project on the welfare of laying hens	Launched	Q1 2021	Launched and still ongoing
Study on animal welfare labelling	Launched	Q2 2021	Launched and still ongoing
Derived legislation on animal welfare conditions on EU livestock vessels	Adoption	Q4 2021	Interim results: two rounds of discussions on the draft text by end 2021. New target for adoption Q2 2022
Animal Welfare stakeholder conference, related to the Fitness check	Conference held	Q4 2021	Completed
Animal Welfare Platform renewal	Appointment of new members and renewal of the platform		Completed
EU Reference Centre for the welfare of Ruminants and Equidae	Selected and Appointed		Completed

Output	Indicator	Target	Latest known results (situation on 31/12/2021)
Food Fraud			
Food fraud audits	No. of audits carried out	5 Fact Finding Studies	4 Fact Finding Studies
Empowering consumers to make food sustainable and healthy food choices through the provision of information			
Support to innovation (including plant reproductive material and innovative techniques)			
Implementation of the plant reproductive material marketing Directives			
Implementation of the plant reproductive material marketing Directives including equivalence requests, common catalogue updates and CPVR legislation including extension of variety protection of some species	Adoption according to the need to adapt requirements technical progress	Q4 2021	In course of 2021 Amendment of CPVR Regulation published 26/10/2021
Amendment of the Annexes of Directives on marketing seed of agricultural crops, including requirements on BMT (PLAN/2018/3686)	Adoption	Q4 2021	Adopted 16/06/2021 C(2021) 4221
New genomic techniques			
Commission study on new genomic techniques requested by the Council under 241 TFEU (SWD(2021) 92 final)	Adoption		Adopted on 29 April 2021
Preparatory work for the legislation for plants produced by certain new genomic techniques (PLAN/2021/11456)	Publication of Inception Impact Assessment		Published 24 September (open until 22 October 2021)
High level event "New genomic techniques - the way forward for safe and sustainable innovation in the agri-food sector"	Completed		Held on 29 November 2021
Implementation of the Organic Regulation			
Delegated Act on organic heterogeneous material (PLAN/2019/5552)	Adoption	Q1 2021	Adopted 7/5/2021 C(2021)3163
Implementing Act on temporary experiment on organic varieties (PLAN/2020/7562)	Adoption	Q4 2021	Ongoing
Article 241 TFEU study on PRM	Delivered		Submitted to Council 29 April

Output	Indicator	Target	Latest known results (situation on 31/12/2021)
			2021
Article 241 TFEU study on NGT (PLAN/2020/6573)	Delivered	Q2 2021	Sent to EP and Parliament 29/04/2021 SWD (2021) 92
Food Contact Materials			
Authorisation of recycling processes for plastics used in food contact materials	Adoption	Around 160 processes authorised in the course of 2021	Postponed to 2022, as the corresponding Regulation needs to be replaced first. Now over 200 processes need individual authorisations and decisions on confidentiality
Food for Specific Groups			
Delegated act extending the transition period in respect of formulae manufactured from protein hydrolysates (PLAN/2020/9047)	Adoption		Adopted Q1 2021 (C(2021) 155)
Preparatory work, including an Impact Assessment, for a Commission Regulation setting minimum and maximum amounts of vitamins and minerals in foods and food supplements (PLAN/2020/8927)	Launched	In course of 2021	Setting-up of the ad-hoc task force and organisation of three meetings in 2021.

Specific objective 1.3: International promotion of EU food safety standards	**Related to spending programme(s) Single Market Programme**

Result indicator 1.3.A: Percentage of DG SANTE's audit recommendations that third countries have satisfactorily addressed with corrective action

Explanation: 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

Source of data: Commission internal (DG SANTE)

Baseline (2019)	**Interim Milestone** (2022)	**Target** (2024)	**Latest known results** (situation on 31/12/2021)
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	62% Based on sum of audits carried out in years 2017+2018+2019

Main outputs in 2021:

External communication actions

Output	Indicator	Target	Latest known results (situation on 31/12/2021)
Website			
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 2020: 170,052 page views)	71,729 page views in 2021, representing a decrease

Other important outputs

Multilateral SPS relations			
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 2021	193
Coordinated EU position for the OIE aquatic and terrestrial Code and Manual	Delivered	In course of 2021	Delivered during the General Session in May 2021
Coordinated EU Statements for the World Organisation for Animal Health (OIE) General Assembly	Delivered	In course of 2021	Delivered during the General Session in May 2021
Coordinated EU positions for the European and Mediterranean Plant Protection Organization (EPPO)	Delivered	In course of 2021	Working Party on Phytosanitary Regulations: dates 16-18 June 2021, positions – 20; EPPO Council: dates – 28-29 Sep 2021, positions – 13
Coordinated EU positions for the International Plant Protection Convention (IPPC)	Delivered	In course of 2021	Number of positions – 38, dates 16 & 18 March, 1 April 2021.
Coordinated EU positions for the International Union for the Protection of New Varieties of Plants (UPOV)	Delivered	In course of 2021	8 written consultations on draft EU positions for UPOV and 3 Council Working Party meetings (virtual).
Coordinated EU positions in the resolutions of the Governing Body of the International Treaty on Plant Genetic Resources for Food	Delivered	In course of 2021	1 written consultation on draft EU position 1 virtual coordination meeting of the European Regional Group (18

Output	Indicator	Target	Latest known results (situation on 31/12/2021)
and Agriculture (ITPGRFA)			November) 1 virtual meeting of the ITPGRFA Governing Body (Special Session 7 December)
Input to the coordination for the Commission on Genetic Ressources for Food and Agriculture	Delivered	In course of 2021	1 Council WP on Genetic Resources and Innovation in Agriculture (informal videoconference) of 8 and 9 September 2021 1 virtual coordination meeting of the European Regional Group (22 September 2021) 10 written consultations on draft EU positions 5 days (27/9-1/10) virtual meetings of the 18th session of CGRFA
Coordinated EU positions in OECD Seed and OECD Forest schemes	Delivered	In course of 2021	Seed Schemes: 7 written consultations on draft EU positions and 3 Council Working Party meetings (virtual) Forest Scheme: 2 written consultations on draft EU positions and 1 Council Working Party (virtual)
Coordinated EU positions in the World Trade Organisation SPS	Delivered	In course of 2021	33
Coordinated EU statements and position, as well as negotiations, for the Conference of the Parties of the Cartagena Protocol on Biosafety and Coordinated EU position regarding synthetic biology and gene drives for the Conference of the Parties of the Convention on Biological Diversity	Delivered	In course of 2021	Both conferences postponed to 2022
Priorities of the EU and its Member States established for the 2021 UN Food Systems Summit	Delivered	In course of 2021	Completed

Output	Indicator	Target	Latest known results (situation on 31/12/2021)
SPS Bilateral relations			
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	Ongoing
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 2021	EU harmonised certificate for the export of poultry meat to Canada EU harmonised certificate for bovine and ovine meat with Iran.
Coordinate EU position in negotiations of Agreements with non-EU countries	Delivered	In course of 2021	Ongoing
Coordinate EU position on the management of the SPS Committees of the Agreements in force	Delivered	In course of 2021	Ongoing
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	2 AHTWG and 2 PHTWG meetings held	In course of 2021	1 AHTWG and 2 PHTWGs meeting held
Meetings of the EU-Japan Animal Health Technical Working Group: Facilitate trade and better cooperation on animal health issues with Japan (regionalisation)	1 to 2 meeting held	Q2 2021	Delayed - due to COVID-19 restrictions and governmental re-shuffling, Parties decided to postpone the meeting in Q1-Q2 2022.
EU-Japan mutual recognition on animal health	Regular meetings		Ongoing: regionalisation applies to five MSs for the HPAI and 10 MSs are in the pipeline. For the ASF the

Output	Indicator	Target	Latest known results (situation on 31/12/2021)
regionalisation			regionalisation applies for 1 MS and other 4 MSs have almost completed the steps for achieving it.
EU-GACC MoU	Delivered by July		Entered into force
EU-ESA FTA	2 meetings held		SPS chapter almost closed.
Closure of the SPS chapter under the EU-Indonesia FTA	Delivered		It will enter into force once the complete FTA text will be agreed
Closure of the SPS and SFS Chapter under the EU-Chile modernised Agreement			SPS Chapter concluded
Meetings with the UK in the framework of the implementation of the SPS Chapter of the EU-UK TCA	1 Trade Specialised Committee meeting and 2 technical meetings.		Meetings held: 22 -23 September 2021
Biotech dialogues set up under WTO / DSB with US, Canada and Argentina	2 meetings with US, 1 with Canada and 1 with Argentina		Meetings held: US: 18/06/21 & 09/12/21 CAN: 03/12/21 ARG: 15/10/21

General objective 2 : Promoting our European way of life			
Impact indicator: Healthy life years at birth **Source of the data:** Eurostat (Eurostat data code: [hlth_hlye])			
Baseline (2018)	**Interim Milestone** [5] (2022)	**Target** (2024)	**Latest known results** (2019)
Males: 63.7 years Females: 64.2 years Total: 64.0 years	Increase	Increase	Males: 64.2 years Females: 65.1 years Total: 64.6 years

Specific objective 2.1: Diminishing the impact of cancer in Europe			Related to spending programmes EU4Health, Health Programme
Result indicator 2.1.A: Age-standardised five-year net survival of cervical, breast and colorectal cancer **Explanation:** 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. **Source of data:** EUROCARE (Joint Research Centre) and CONCORD Programme, London School of Hygiene and Tropical Medicine			
Baseline (2014)	**Interim Milestone** (2022)	**Target** (2024)	**Latest known results** (2021)
Cervical cancer: 63% (EU average) **Breast cancer**: 83% (EU average) **Colorectal cancer**: 59% (EU average)	Increase Increase Increase	Increase, with at least 2/3 of Member States above baseline	63% 83% 59%
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 EUROCARE			
Baseline (2015)	**Interim Milestone** (2022)	**Target** (2024)	**Latest known results** (2021)
CRs reporting cervical cancer stage at diagnosis: 51% CRs reporting breast cancer stage at diagnosis: 53% CRs reporting colorectal cancer stage at diagnosis: 52%	Increase in all ...	Increase, at least 2/3 of Cancer Registries above baseline.	51% 53% 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		All Member States reporting the information on cancer stage	20 20 20

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** (2021)
29%	**25%**[5]	**21%**[6]	**25%**

Main outputs in 2021:

New policy initiatives

Output	**Indicator**	**Target**	**Latest known results (situation on 31/12/2021)**
Europe's Beating Cancer Plan (PLAN/2020/6485)[7]	Adoption	Q1 2021	Published on 3 February 2021
EU NCDs Initiative	Document/toolkit completed		Discussions started with MS and stakeholders in Dec 2021

Enforcement actions

First report on the application of the Tobacco Products Directive (TPD)	Publication	Q2 2021	Published
Support study for TPD application report	Publication	Q2 2021	Published
Perception study of different tobacco	Publication	Q2 2021	Published

[5] Estimated prevalence reduction as a result of the Tobacco Products Directive.

[6] 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 gainst a baseline in 2010. The 2024 target has been calculated on that basis.

7 Commission work programme 2020 annex I initiative

Output	Indicator	Target	Latest known results (situation on 31/12/2021)
products (for TPD implementation report)			
Joint Action on Tobacco Control II (policy-oriented around the full package of tobacco control actions)	Launched	Q4 2021	Launched
Compliance checks of TPD	Ongoing	Q4 2021	Ongoing
Audit of the concession contract holder of the secondary repository for the track and trace system for tobacco products	Completed	Q4 2021	Completed
Track and trace: full audit cycle of the repositories system	Completed	Q3 2021	Completed
External communication actions			
On line Conference on the impact of Covid-19 on mental health 6 May 2021	Number of participants	500 participants expected	More than 1500 online participants.
Press and media material			
The Cancer Plan	Number of online views, downloads of media material	Minimum of 200 online views, downloads	15.554 page views
The Cancer Plan	Number of media items mentioning Commissioner Kyriakides/President von der Leyen	Minimum of 20 articles	50 articles were published that linked either the Commissioner or the President to the Cancer
The Cancer Plan	Geographical spread of news in various EU countries	Media items in the 27 Member States (as per media monitoring)	Coverage of the Cancer Plan was witnessed in all 27 Member States
Social media and Audiovisual			
Social media communication around main actions, through	Number of engagements per	Average of 100 engagements	Reached 153 engagements on average with posts including

Output	Indicator	Target	Latest known results (situation on 31/12/2021)
owned and paid content. The hashtag #EUCancerPlan monitored continuously	tweet	per tweet	#EUCancerPlan throughout 2021
Video showing the benefit of the EU Cancer Plan for citizens	Number of views, embeds and downloads	Minimum 10,000	65.000 (AV portal) 3.5m video views on Facebook (paid social media)
Website			
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 2020: 20,428 pageviews	2021: 33,385 page views, representing an increase
Other important outputs			
Meetings with Member States on the implementation of the TPD and its implementing rules	Organised	Ongoing	Organised, including one Expert Group and several Subgroup meetings
Advertising and smoke-free monitoring study	Completed	Q3 2021	Completed and published
Eurobarometer on smoking prevalence	Ongoing	Q4 2021	Published, see: Special Eurobarometer 506
Ad hoc mandate for COP 9	Adopted	Q2 2021	Not necessary given the abridged agenda
COP 9/MOP2 preparation and participation	Completed	Q3 2021	Completed, COP9/MOP2 attended

Specific objective 2.2: Patients' access to safe, innovative and affordable medicines and medical devices	**Related to spending programmes EU4Health, Health Programme**
Result indicator 2.2.A: Access to centrally authorised medicines for unmet needs **Explanation:** 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. **Source of data:** European Commission European Medicinal Products database

Baseline (2019)	**Interim Milestone** (2022) Average number per calendar year for the period 2020-2021	**Target** (2024) Average number per calendar year for the period 2022-2023	**Latest known results** (2021)
7	**Increase**	**Increase**	**22**

Result indicator 2.2.B: Number of audits conducted in the EU and in third countries to ensure good manufacturing practices and good clinical practices (Union control) **Explanation:** 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. **Source of data:** European Commission

Baseline (2020)	**Interim Milestone** (2022)	**Target** (2024)	**Latest known results** (2021)
10	**20**	**40**	**10 + 7 (other postponed due to travel restrictions)**

Result indicator 2.2.C: Number of shortages of medicines in the single point of contact network **Explanation:** 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. **Source of data:** European Medicines Agency

Baseline (2019)	**Interim Milestone** (2022)	**Target** (2024)	**Latest known results** (2021)
91[8]	**300**	**450**	**43**

[8] From April to December 2019

Result indicator: 2.2.D (Burden reduction): Proportion of proposed legislative revisions that include burden reduction measures

Explanation: The indicator measures how the Commission upholds its commitment to ensure that proposals for legislative revisions incorporate burden reduction measures, in the broader context of REFIT programme and One-In, One-Out approach. The indicator shows how many proposed legislative revisions out of the total, for each relevant specific objective, include measures that concretely reduce burden.
Source of data: Commission internal (DG SANTE)

Baseline (2020)	**Interim Milestone** (2022)	**Target** (2024)	**Latest known results** (situation on 31/12/2021)
N/A	Positive trend	Positive trend	No proposals for legislative revisions were adopted in 2021

Main outputs in 2021:

New policy initiatives

Output	**Indicator**	**Target**	**Latest known results (situation on 31/12/2021)**
Proposal on EMA fees (PLAN/2018/4193)	Adopted	Q4 2021	To be adopted in Q2 2022
Proposal on transitional provisions for certain in vitro diagnostic medical devices (PLAN/2021/...)	Adopted		Adopted 14 Oct 2021 COM(2021)627 amending Regulation (EU)2017/746 Council and EP endorsed the proposal end 2022. Formal adoption by Council and EP expected Jan 2022.
Proposal for an amendment to the Variation system for human medicinal products to cater for variant vaccines (PLAN/2021/10450)	Adopted		Adopted - Commission Delegated Regulation (EU) 2021/756 of 24 March 2021 amending Regulation (EC) No 1234/2008
Evaluations and fitness checks			
Evaluation of basic legislation on medicines for human use, Directive 2001/83/EC and Regulation (EU) No 726/2004	Study launched	Q2 2021	Study launched as planned. Evaluation started Q3 2021 and is ongoing. Impact assessment (IA) started Q4 2021
Public consultations			
Public consultation for the evaluation and the inception impact assessment of the general pharmaceutical legislation	Completed	Q4 2021	Consultation closed on 21 December 2021. 478 contributions received.
Public consultation for the impact assessment of the review of the legislation on medicines for rare diseases	Completed	Q2 2021	Consultation closed on 30 July 2021.

Output	Indicator	Target	Latest known results (situation on 31/12/2021)
and children			304 contributions received
Targeted stakeholder consultation on the amendments to Commission Implementing Regulation (EU) 520/2012 on pharmacovigilance activities	Completed	Q3 2021	Consultation closed on 15 October 2021. 14 contributions received
Enforcement actions			
External communication actions			
Press Material			
 Implementation of Pharmaceutical Strategy	Geographical spread of news in various EU countries	Media items in the 27 Member States (as per media monitoring)	Coverage was found in 25 Member States[9]
Social Media			
Sustained tweets during adoption of proposals and as follow up - Paid promotion of tweets	Increase engagement on twitter per tweet	Average target of 100 engagements per tweet	Reached 157 engagements on average with posts including #EUPharmaStrategy throughout 2021
Website			
Update of Pharmaceutical Strategy webpage	Number of page views to the relevant section of the website (Medicinal Products)	5% increase in the number of page views Baseline 2020: 82,869 page views	**43,024 page views, representing a decrease**
Update of Medical Device webpages	Continuous updates of numerous webpages on DG SANTE website. Indicative number of views on the Medical Device Sector Overview		218,566 page views in 2021 The same webpage was available at SANTE website only from June 2020; total nr of views from June-December 2020: 10,790

[9] The media coverage linked to medicines and medical devices were mostly in the context of the COVID-19 pandemic. Aside from this, coverage of the entry into application of the Medical Devices Regulation and the EU-Swiss agreement on the medical devices received separate coverage in 10 member States

Output	Indicator	Target	Latest known results (situation on 31/12/2021)
Other important outputs			
Implementation of the Pharmaceutical Strategy (PLAN/2020/6954)	Ongoing implementation	Ongoing	28 actions described in the Communication were due and delivered in 2021 including 24 for DG SANTE
Study on medicine shortages	Launched	Q2 2021	Published Q4 2021
Commission Implementing Regulation (EU) 2021/2078 laying down rules as regards the European database for medical devices and in-vitro medical devices (EUDAMED) (PLAN/2018/4311)	Adopted	Q1 2021	Adopted in Q4
Commission Implementing Regulation (EU) 2021/2226 of 14 December 2021 laying down rules for the application of Regulation (EU) 2017/745 of the European Parliament and of the Council as regards electronic instructions for use of medical devices	Adopted	Q3 2021	Q4 2021
Implementing acts on EU Reference Laboratories (tasks and criteria; fees; designations)	Adopted	Q2 2021	Ongoing. Publication for feedback ended Dec 2021, adoption expected Q1 2022. Delay was mainly due to interservice discussions and COVID related priorities both al EU and national levels.
Implementing act on the MDR/IVDR standardisation request (PLAN/2020/9231)	Adopted	Q1 2021	Finalised. Q2 2021.
Implementing acts listing harmonised standards under Regulation EU 2017/745 and Regulation EU 2017/746 (PLAN/2020/9232; PLAN/2020/9233)	Adopted	Q1 2021	Finalised. Q2 2021.
Implementing act laying down common specifications for the group of products without an intended medical purpose listed in Annex XVI (EU) 2017/745 (PLAN/2018/4271)	Adopted	Q2 2021	Ongoing. ISC has closed; publication for feedback next and planned adoption Q2 2022. Delay due to very long discussions with national experts and Legal Service.
Implementing act on reclassification of groups of	Adopted	Q2 2021	Based on advice from Legal Service and following discussions

Output	Indicator	Target	Latest known results (situation on 31/12/2021)
active devices without an intended medical purpose, by way of derogation from Annex VIII to Regulation (EU) 2017/745 (PLAN/2018/4271)			with experts this will be withdrawn at this point in time. Reconsideration could take place following possible formal requests/notifications from one or more Member States.
Several common specifications for in vitro diagnostic medical devices	Adopted	Q4 2021 and continuous activity	Ongoing. ISC is being finalised, thereafter publication for feedback. Planned adoption Q1 2022 (first set of CS)
Common specifications regarding clinical evaluation of cardiac stents (Regulation EU 2017/745)	Delivered	Q4 2021	Put on hold due to more urgent priorities identified by EC and MS.
Set up and ensure UDI help desk	Make available	Q4 2021	Finalised in Q2 2021.
Guidance documents on in vitro diagnostic medical devices for implementation of Regulation (EU) 2017/746 including on performance evaluation and on state of the art of rapid antibody tests and on antigen tests	Ongoing	Q4 2021	Finalised and continuous task. 28 NEW guidance documents and two revisions were produced throughout the year in addition to others e.g. Q&A on COVID-19 tests and Q&A on EMDN (European Medical Device Nomenclature)
Call for application for EURLs	Launched	Q1 2020	Ongoing. Draft ready and will be published as soon as the corresponding legal act is adopted (expected Q1 2022); Delays follow from the delay related to the implementing acts on EURLs (see above)
Health Technology Assessment - tender focusing on core activities	Launched	Q2 2021	Finalised. Service contract awarded and launched. Contract will run until September 2023
Negotiation with Council and Parliament on a Proposal for a Regulation on health technology assessment amending Directive 2011/24/EU	Concluded	Q3 2021	Finalised. Negotiation concluded in Q2 2021, formal adoption in Q4 2022.
Preparatory work for the implementation of the new EU HTA framework (pending adoption of Commission proposal for Regulation on health technology assessment amending Directive	Launched	Q4 2021	Ongoing and continuous task.

Output	Indicator	Target	Latest known results (situation on 31/12/2021)
2011/24/EU)			
Advancing synergies between regulators, HTA bodies and pricing and reimbursement authorities to improve access to medical technologies	Launched	Q2-2021	Ongoing. Joint meetings regulatory authorities, some HTA bodies and some pricing and reimbursement authorities (e.g. extended Pharmaceutical Committee meeting 17 Nov) Draft joint work-plan regulators (EMA) and HTA bodies Q4 .
Commission Decision to allow the Clinical Trials Regulation to enter into force (PLAN/2018/4022)	Adopted	Q2 2021	Commission Decision was adopted and the CTR enters into application on 31/01/2022
Report to the European Parliament and the /Council on marketing authorisation procedures of medicinal products for human use PLAN/2018/3058	Adopted	Q1 2021	Adopted in Q2 2021. Delay due to the decision to add a section on initial lesson learnt from COVID-19 as regards authorisation and monitoring procedures
Commission Notice 2021/C 76/01 – Handling of duplicate marketing authorisation applications of pharmaceutical products under Article 82(1) of Regulation (EC) No 726/2004 (PLAN/2020/8873)	Adopted		Adopted in Q1 2021. Delay due to workload in DGT at end 2020 for translations of EU-UK agreement
Authorisation of new medicinal products, variations to existing marketing authorisations, including Brexit related modifications, decisions following referral procedures, Periodic Safety Update Reports, orphan designations, etc.	Adoption of more than 1000 decisions	During course 2021	1523. This number includes Commission decisions related to central (1196) and national (22) marketing authorisations of medicinal products intended for human use plus orphan designations (305).

Specific objective 2.3: Effective response coordination of serious cross-border health threats	**Related to spending programmes EU4Health, Health Programme**
Result indicator 2.3.A: Number of Member States with improved preparedness and response planning **Explanation:** 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. **Source of data:** Member State reporting under Article 4 of Decision 1082/013/EU and the relevant	

implementing act			
Baseline (2019)	**Interim Milestone** (2022)	**Target** (2024)	**Latest known results** (2021)
24	**26**	**27**	Survey on IHR core capacities not carried out during the COVID-19 pandemic. Reporting obligations under Decision 1082/2013 have been halted since the proposal for a new Regulation on serious cross-border threats to health was published in November 2020.

Main outputs in 2021:

New policy initiatives

Output	**Indicator**	**Target**	**Latest known results (situation on 31/12/2021)**
Preparatory action on establishing the EU Health Emergency Preparedness and Response Authority (HERA)	Ongoing	Q2 2021	Summary on HERA 'preparatory actions' under EU4Health: 1) A Study on bringing AMR Medical Countermeasures to the Market (Under evaluation) 2) Feasibility Study on Stockpiling of Medical Countermeasures in the Area of AMR (Under evaluation) 3) Horizontal -Intelligence gathering & threat assessment Unsuccessful. Funds transferred to 'Service Contract for Flexible EU Manufacturing and Access of Covid-19 Therapeutics'. 4) Service Contract for Flexible EU Manufacturing and Access of Covid-19 Therapeutics Terms of reference still being finalized. Not published. 5) Study assessing Scientific, Engineering, Regulatory and Economic Considerations of Flexible EU Manufacturing and Innovation Capacity of Medical Countermeasures (Under evaluation) 6) Interactive mapping platform of COVID-19 therapeutics development and supply. (Under evaluation)
Impact Assessment on establishing the EU	Completed	Q4 2021	Commission established HERA as an internal commission

Output	Indicator	Target	Latest known results (situation on 31/12/2021)
Health Emergency Preparedness and Response Authority (HERA)			service, therefore a formal Impact Assessment supporting a legislative proposal was no longer necessary. Preliminary results were nevertheless used to prepare the HERA package
Consultation on establishing the EU Health Emergency Preparedness and Response Authority (HERA)	Completed	Q2	The Inception Impact Assessment was published for feedback between 27/01-24/02 2021 (154 replies were received). The public consultation questionnaire was available online from 31/03 to 12/05 (135 replies were received).
Proposal to establish the EU Health Emergency Preparedness and Response Authority (HERA)	Adopted	Q4 2021	Commission Decision establishing HERA adopted on 16/09/2021. Political Agreement on Council Regulation on the emergency framework reached on 20/12/2021.
External communication actions			
Press and media			
Awareness raising on tackling vaccination inequalities	National print and audiovisual media coverage	Media coverage in all 27 EU countries	Media coverage in all 27 Member States[10]
Social media			
Actions on the #HealthUnion throughout the year, including a focus on COVID-19 vaccines and the adoption of HERA proposal	Increase in number of interactions per tweet Increase the number of followers on the EU Health twitter account	Averaging 100 interactions per tweet across all related tweets 5% increase in the number of followers on the @EU_Health Twitter account (Baseline 2020, 73.4K)	Reached 150 engagements on average with posts including #HealthUnion throughout 2021 Number of followers by 31.12.21: 81.7k, +11.3%

[10] The media coverage linked to Cross border health threats were mostly in the context of the COVID-19 pandemic while the topic was also mentioned by the media in relation to HERA and the expanded roles of EMA and ECDC

Output	Indicator	Target	Latest known results (situation on 31/12/2021)
Website			
	Number of visits to the relevant SANTE web sections [health security and infectious diseases; forthcoming HERA page]	5% increase (Baseline 2020 414,629 page views)	120,124 page views, representing a decrease
Other important outputs			
Implement the EU Strategy for COVID-19 vaccines and the Communication on Preparedness for COVID-19 vaccination strategies and vaccine deployment	Ongoing	Q4 2021	Strategy implemented. Contracts for the supply of up to 4.2 billion of vaccines signed.
Final report for feasibility study on options and recommendations for an EU citizens' vaccination card	Publication	Q4 2021	Delayed due to the COVID-19 pandemic, delivery of the final report expected in Q1/2022
Joint European Medicines Agency / European Centre for Disease Prevention and Control platform for post-marketing authorisation studies assessing the safety and the effectiveness of vaccines/urgent studies of COVID-19 vaccines	Establishment	Q1-3 2021	Platform established in Q2/2022, current focus of the studies is on COVID-19 vaccines.
Several deliverables from the Joint Action on vaccination regarding immunisation information systems, vaccine supply and stock management, priority setting of vaccine research and development and vaccine hesitancy	Ongoing	Q4 2021	The activities of the Joint Action on vaccination are delayed due to COVID-19, will be delivered in Q1/2/3 in 2022.
Feasibility study for physical stockpiling of vaccines	Evaluation is concluded, signing of tender expected before end Q4 2020.	Q2x 2022	Call for tender cancelled due to establishment of rescEU stockpiling facility and HERA.

Output	Indicator	Target	Latest known results (situation on 31/12/2021)
Report on interoperability of Immunisation Information Systems	Publication	Q3x 2021	This is a deliverable of the Joint Action and publication is delayed due to the COVID-19 pandemic.
JP contract for pandemic influenza vaccines	Signature	Q1 2021	Not signed, handed over to HERA.
Lessons learned from Joint Procurements	Event organised	Q2 2021	Not held due to COVID-19 pandemic. JP handed over to HERA.
JP contracts for botulinum antitoxin, diphteria antitoxin and tuberculosis vaccine	Signature	Q2-Q4 2021	Not signed, joint procurement in 2021 focused on medical countermeasures against COVID-19. Joint procurement handed to HERA now.
Dissemination of results and learnings from the Joint Action on integrating prevention, testing and link to care strategies across HIV, Viral Hepatitis, TB & STIs in Europe" (INTEGRATE) through Health Security Committee and networks	Dissemination	Q1 2021	Results of the Joint Action on vaccination will be shared with the HSC once available.
One Health AMR country visits	2 country visits carried out	in course of 2021	On hold due to COVID-19 pandemic.
Dissemination of results and learning from Joint Action on Antimicrobial Resistance and Healthcare Associated Infection through Health Security Committee and AMR networks	Dissemination	Q4 2021	Dissemination continues.
5-year work plan for collaboration with Transatlantic Taskforce on Antimicrobial Resistance 2021-2026	Launch	Q3 2021	Endorsed in principle at TATFAR meeting of 14/15 Sept 2021

Specific objective 2.4: More effective, accessible and resilient health systems	Related to spending programmes EU4Health, Health Programme

Result indicator 2.4.A: Implementation of best practices by EU Member States

Explanation: 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.

Source of data: DG SANTE (Unit C1) and CHAFEA and/or its follow-on entity

Baseline (2020)	**Interim Milestone** (2022)	**Target** (2024)	**Latest known results** (2021)
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 selected by the SGPP	Two joint actions will be transferred: 1: joint action on Reverse diabetes type 2 now with 18 Member States participating in it. 2 : joint action on healthy lifestyles (Smart family and Grunau moves) with 17 Member States participating in it.

Main outputs in 2021:

New policy initiatives

Output	Indicator	Target	Latest known results (situation on 31/12/2021)
Proposal for a European health data space (PLAN/2020/8701)	Ongoing	Q2 2022	Adoption of the legislative proposal foreseen for 5 April 2022
External study supporting Impact Assessment for the legislative proposal on the European Health Data Space	Completed		Contract signed for the impact assessment study in May 2021. Final report is in the process of finalisation
External study feeding into the impact assessment concerning the digital infrastructure for European Health Data Space	Completed		Contract signed in March 2021, final report in the course of finalisation
External study on regulatory gaps, including the evaluation of digital aspects of the Directive 2011/24/EU, feeding into the impact assessment and legislative proposal	Completed		Final report approved in Q3 2021. Procedure for the publication of the study is ongoing
External study concerning the assessment of the EU Member States' rules on	Completed		Study published on 12

Output	Indicator	Target	Latest known results (situation on 31/12/2021)
health data in the light of GDPR, feeding into the legislative proposal and impact assessment			February 2021
Impact Assessment Report for the legislative proposal on the European Health Data Space (SWD)	Completed	Q3/Q4 2021	Impact assessment submitted to RSB in Q3 2021. Following negative opinion of RSB, resubmission of the IA on 21 December 2021
Initiatives linked to regulatory simplification and burden reduction			
Proposal to revise blood, tissues and cells legislation (PLAN/2020/8495)	Adopted	Q4 2021	To be adopted end Q1 2022
Evaluations and fitness checks			
Evaluation of digital aspects and Article 14 on eHealth of Directive 2011/24/EU (voluntary eHealth Network established within the Cross-border healthcare directive)	Completed	Q2 2021	Study on the regulatory gaps, including the evaluation of digital aspects of the Directive 2011/24/EU – finalised in Q3 2022 Evaluation included in the impact assessment on EHDS, submitted to RSB
Evaluation of Directive 2011/24/EU on the application on patient rights in cross-border healthcare (patients´ rights part) – replaces implementation report 2021	Launched	Q2 2021	Public consultation May-July. Study supporting the evaluation completed.
Study on regulatory gaps and obstacles to cross-border digital healthcare, including AI and evaluation of Article 14 of Directive 2011/24/EU	Completed	Q3 2021	Final report approved in Q3 2021. Procedure for the publication of the study is ongoing
Public consultations			
Public consultation for the legal proposal on the European Health Data Space	Completed		The public consultation was finalised in July 2021.
Enforcement actions			
Workshops on implementation of cross-border healthcare directive	Launched	Q2 2021	3 workshops organised in March, May and September

Output	Indicator	Target	Latest known results (situation on 31/12/2021)
(CBHC)			
Closing Finalisation of pilot projects Cross-Border Health Care if possible	Ongoing	Q2 2021	Pilot projects closed in April.
Infringement procedures on CBHC	Ongoing	Q2 2021	No progress
2-3 meetings of National Contact Points	Ongoing	Q2 2021	Meetings organised in May and September
Data collection on CBHC	Ongoing	Q2 2021	Annual report on patient mobility 2020 published
External communication actions			
European Health Data Space			
Press material			
Press material produced for adoption of proposals/actions	Number of online views, downloads of media material	Minimum of 200 online views downloads	3.599 page views
	Geographical spread of news in various EU countries	Media items in the 27 Members States (as per media monitoring)	Media coverage in 10 countries[11]
Social Media			
Sustained tweets during adoption of proposals and as follow up.	Increase engagement on twitter per tweet	Average target of 100 engagements per tweet	Reached 147 engagements on average with posts including #EHDS throughout 2021
Paid promotion of tweets			2021: 435,612 page views representing an increase
Update of relevant webpages	Number of visits to relevant SANTE web sections (EHealth)	5% Increase (baseline 2020 96.348 page views)	Number of views of the eHealth : Digital health and care (https://ec.europa.eu/health/ehealth/home_en): 30 532 in 2021 Number of views of eHealth and

[11] The media coverage was mostly linked to in the context of the COVID-19 pandemic and related to the Cross Border Health Directive. While there was some coverage linked to blood, tissue and cells and the European Health Data Space 2021, these files will only generate significant media attention as from 2022

Output	Indicator	Target	Latest known results (situation on 31/12/2021)
			COVID-19 (https://ec.europa.eu/health/ehealth/covid-19_en): 96 776 in 2021
Other important outputs			
Joint Action supporting the development of the European Health Data Space	Launched	Q1 2021	Ongoing work on governance for EHDS, data quality, infrastructure for secondary use of data, data altruism.
3rd State of Health cycle – country profiles and companion report	Publication	Q4 2021	Full set of (29) Country Health Profiles and Companion Report 2021 published in Q4 2021 (launch date 13 December 2021)
Voluntary exchanges (knowledge transfer) between Member States on health system challenges	Launched	Q3 2021	None carried out due to pandemic.
Roundtable on Pact for skill in the health ecosystems	Organised		Roundtable on skills for the health workforce chaired by Commissioners Kyriakides, Schmit and Breton on 16 Feb 2021.
Mapping of national health workforce planning and policies in EU (outcome of tender)" and Projects to raise the capacity of Member States to address health workforce challenges and a Joint Action 'JADECARE' to implement best practices in integrated care (financed from the Health Programme)	Published/Launched	Q4 2021	Mapping of nationals health workforce planning and policies in the EU: The Report was published in February 2021 (see http://healthworkforce.eu/wp-content/uploads/2021/02/D4_Final-study-report_EB-02-20-972-2A-N.pdf) as Deliverable nr.4 in the "SEPEN project" tender . The related Member States country fiches can be found on SEPEN website: http://healthworkforce.eu/countrysheets/ Projects to raise the capacity of Member States to address health workforce challenges : the call for projects was finalised in Q1 2021 and the cluster of 5 projects launched officially in Q3 2021 JADECARE is ongoing until Q3 2023)
Conference on "Investing in the health systems of the future", to provide impetus and enhance the capacity of health authorities and investors in planning and	Organised	Q4 2021	Organised in collaboration with the Slovenian Presidency, as a High-level Conference of the Presidency "Implementing Innovative Solutions for Resilient Health Systems" on 15-16 July 2021. The conference

Output	Indicator	Target	Latest known results (situation on 31/12/2021)
implementing investments in health			addressed both the needs of 'investing' and 'implementing' innovative solutions in health systems.
Three Opinions of the Expert Panel on effective ways of investing in health	Publication	Q1 2021	Three opinions have been published: Public procurement in healthcare systems (17/05/2021) Supporting mental health of the health workforce and other essential workers (14/10/2021) European solidarity in public health emergencies (8/12/2021)
Mapping of national health workforce planning and policies in EU (outcome of tender)"	Publication	Q1 2021	Merged with other workforce related projects and JADECARE (see above)
Health Programme funded) project on designing and implementing integrated care models at national and regional level in several EU countries	Publication	'SCIROCCO Exchange' project in Q3 2021 'VIGOUR' project in Q1 2022	The projects have been prolonged: SCIROCCO Exchange until February 2022, and VIGOUR until June 2022
Marketplace of good practices in primary care	Organised		Took place on 01-02 June 2021
Healthcare Systems Performance Assessment expert group Report on "Improcing access to healthcare through more powerful measurement tools"	Published		Published on 14 April 2021
Study providing the methodology to assess the impact of health benefits on reduction of poverty (with ESTAT)	Publication	Q3 2021	Due to resource constraints and COVID-19 restrictions, the delivery of the project was delayed. The draft report was discussed with DG SANTE in Q3 2021. Publication of the report was postponed to 2022.
Preparations of Joint Action on ERN integration into national healthcare systems and publication of the call			Due to resource constrains, the JA was postponed for 2022
Three meetings of Board of Member States of the ERNs two meetings of ERN coordinators and meetings of	Organised	Q4 2021	Completed (all meetings organised online).

Output	Indicator	Target	Latest known results (situation on 31/12/2021)
the ERN working groups			
Organise the annual meeting of ERN hospital managers (if possible in view of the Covid-19 situation)	Organised	Q3 2021	Completed. Event organised online.
Assessment, Monitoring, Evaluation and Quality Improvements System (AMEQUIS) of ERNs	Completed	Q1 2022	The project contract will expire on 21/01/2022 and by that date the final deliverables of the project should be available.
Mobility programme of ERN professionals	Ongoing	Q4 2021	Due to Covid-19 restrictions, the mobility programme was temporarily suspended in December 2021. The decision about the continuation of the programme should be taken at the end of February 2022.
New Framework Contract for ERN IT Tool Clinical Patient Management System	Procurement launched	Q4 2021	Procurement launched in Q4 2021.
Development of ERN clinical patient guidelines	Ongoing	During 2021	Ongoing. Support for fist 5 ERNs for the development of their clinical practice guidelines completed.
2 one-day online meetings of the eHealth Network For MyHealth@EU: 3 one day online meetings of eHMSEG and 2 one day online eHMSEG Communities meetings; monthly eHOMB meetings, as well as online meeting of eHMSEG task forces and communities 283 online meetings of eHealth Network inn different groups organised in 2021 on COVID, digital health and infrastructures (on EU DCC, contact tracing apps), in different groups and configurations	Organised		Completed, organised online
Organise, with CNECT, two meetings of the e-health stakeholder Group	Organised	Q4 2021	Completed. Meetings organised online.
Cross-border sharing of patients' data through	Ongoing		9 Member States share patient summaries and ePrescriptions through

Output	Indicator	Target	Latest known results (situation on 31/12/2021)
MyHealth@EU			MyHealth@EU. FR and ES joined the system in 2021
eHealth audits in Member States	90% of the requested audits carried out	Q4 2021	Most of the audits/compliance checks requested by MS have been provided, except for ES (HU was prioritised instead, but was not ready technically). However, due to COVID crisis, Member States had to prioritise other activities (eg EU DCC) and the requests were slower than initially forecasted.
Pilot project on secondary use of health data	Launched	Q4 2021	The call was published, applications expected in 2022
Pilot project on patients' access to their health data	Launched		The call was published, applications expected in 2022
Connect existing contact tracing and warning applications developed with GAEN API to the European Federation Gateway Service (EFGS). Business owner, with CNECT, for the EU infrastructure EFGS	Ongoing/Completed	Q4 2021	19 countries connected Preparations are ongoing for the transfer of the project to ECDC
EU Digital COVID Certificate: EU DCC regulation (JUST chef de file, cooperation with CNECT)	Completed		Adopted. Regulation (EU) 2021/953 on 14 June 2021 Regulation (EU) 2021/954 on 14 June 2021
3 EU DCC implementing decisions and 1 delegated act, supporting the implementation of EU DCC Regulation	Completed		Adopted Commission Implementing Decision (EU) 2021/1073 of 28 June 2021 Commission Implementing Decision (EU) 2021/2014 of 17 November 2021 Commission Delegated Regulation (EU) 2021/2288 of 21 December 2021 Commission Implementing Decision (EU) 2021/2301 of 21 December 2021 30 Commission Implementing Decisions (EU) on the equivalence of COVID-19 certificates issued by non-EU countries
Guidance of the eHealth Network supporting the	Completed		Adopted

Output	Indicator	Target	Latest known results (situation on 31/12/2021)
implementation of EU Digital COVID Certificate			
Business owner, together with CNECT, for the infrastructure for EU Digital COVID Certificate	Completed		EU-wide infrastructure set up By end of 2021: 1 billion certificates issued 60 countries around the world connected to the system 21 countries around the world in different phases of analysis of their compliance with EU DCC system
Support development of the ERN mobile application	Launched	Q4 2021	Included in the procurement for new CPMS that was launched in Q4 2021.
Support development of the virtual ERN Academy	Launched	Q2 2021	Required documentation submitted to HADEA. HADEA is preparating IT documentation in accordance with PM2 methodology.
Framework contract for an Independent Assessment and Evaluation Body for the periodic 5year evaluation of all existing ERNs and their members	Launched	Q4 2021	Draft ToR were prepared and submitted to HADEA. The procurement will be launched in Q1 2022 once the final results of the Amequis project are available.

ANNEX 3: Draft annual accounts and financial reports

Annex 3 Financial Reports - DG SANTE - Financial Year 2021

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

TABLE 1: OUTTURN ON COMMITMENT APPROPRIATIONS IN 2021 (in Mio €) for DG SANTE					
			Commitment appropriations authorised	Commitments made	%
			1	2	3=2/1
Title 01 Research and Innovation					
01	01 01	Support administrative expenditure of the "Research and Innovation" cluster	14,07	13,59	96,62 %
Total Title 01			**14,07**	**13,59**	**96,62 %**
Title 02 European Strategic Investments					
02	02 03	Connecting Europe Facility (CEF)	0,00	0,00	0,00 %
	02 04	Digital Europe programme	0,00	0,00	0,00 %
Total Title 02			**0,00**	**0,00**	**0,00 %**
Title 03 Single Market					
03	03 01	Support administrative expenditure of the `Single Market¿ cluster	3,56	3,56	99,95 %
	03 02	Single Market Programme	62,68	58,77	93,77 %
	03 05	Cooperation in the field of customs (Customs)	0,50	0,50	100,00 %
	03 10	Decentralised agencies	10,32	10,32	100,00 %
	03 20	Pilot projects, preparatory actions, prerogatives and other actions	0,65	0,65	100,00 %
Total Title 03			**77,71**	**73,80**	**94,97 %**
Title 06 Recovery and Resilience					
06	06 01	Support administrative expenditure of the `Recovery and Resilience¿ cluster	10,34	10,33	99,91 %
	06 06	EU4Health Programme	65,97	65,76	99,69 %
	06 07	Emergency support w ithin the Union	623,49	253,86	40,72 %
	06 10	Decentralised gencies	342,68	334,89	97,73 %
	06 20	Pilot projects, preparatory actions, prerogatives and other actions	0,00	0,00	0,00 %
Total Title 06			**1.042,48**	**664,85**	**63,78 %**
Title 08 Agriculture and Maritime Policy					
08	08 01	Support administrative expenditure of the "Agriculture and Maritime Policy" cluster	0,89	0,89	100,00 %
	08 03	European Agricultural Fund for Rural Development (EAFRD)	0,48	0,48	100,00 %
	08 04	European Maritime and Fisheries Fund (EMFF)	0,33	0,33	100,00 %
Total Title 08			**1,70**	**1,70**	**100,00 %**
Title 09 Environment and Climate Action					
09	09 02	Programme for the Environment and Climate Action (LIFE)	0,17	0,17	100,00 %
Total Title 09			**0,17**	**0,17**	**100,00 %**
Title 14 External Action					
14	14 20	Pilot projects, preparatory actions, prerogatives and other actions	0,33	0,33	100,00 %
Total Title 14			**0,33**	**0,33**	**100,00 %**

Title 15 Pre-accession Assistance					
15	15 02	Instrument for Pre-accession Assistance (IPA III)	4,00	4,00	100,00 %
Total Title 15			**4,00**	**4,00**	**100,00 %**
Title 20 Administrative expenditure of the European Commission					
20	20 01	Members, officials and temporary staff	0,41	0,39	95,33 %
	20 02	Other staff and expenditure relating to persons	0,14	0,13	93,93 %
	20 03	Administrative Operating expenditure	4,20	4,13	98,24 %
	20 04	Information and communication technology related expenditure	0,40	0,40	100,00 %
Total Title 20			**5,14**	**5,04**	**98,03 %**
Total Excluding NGEU			**1.145,60**	**763,49**	**66,65 %**

Title 01 Research and Innovation					
01	01 01	Support administrative expenditure of the "Research and Innovation" cluster	16,82	1,84	10,95 %
Total Title 01			**16,82**	**1,84**	**10,95 %**
Total NGEU Only			**16,82**	**1,84**	**10,95 %**

Total DG SANTE	**1.162,42**	**765,33**	**65,84 %**

** 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).*

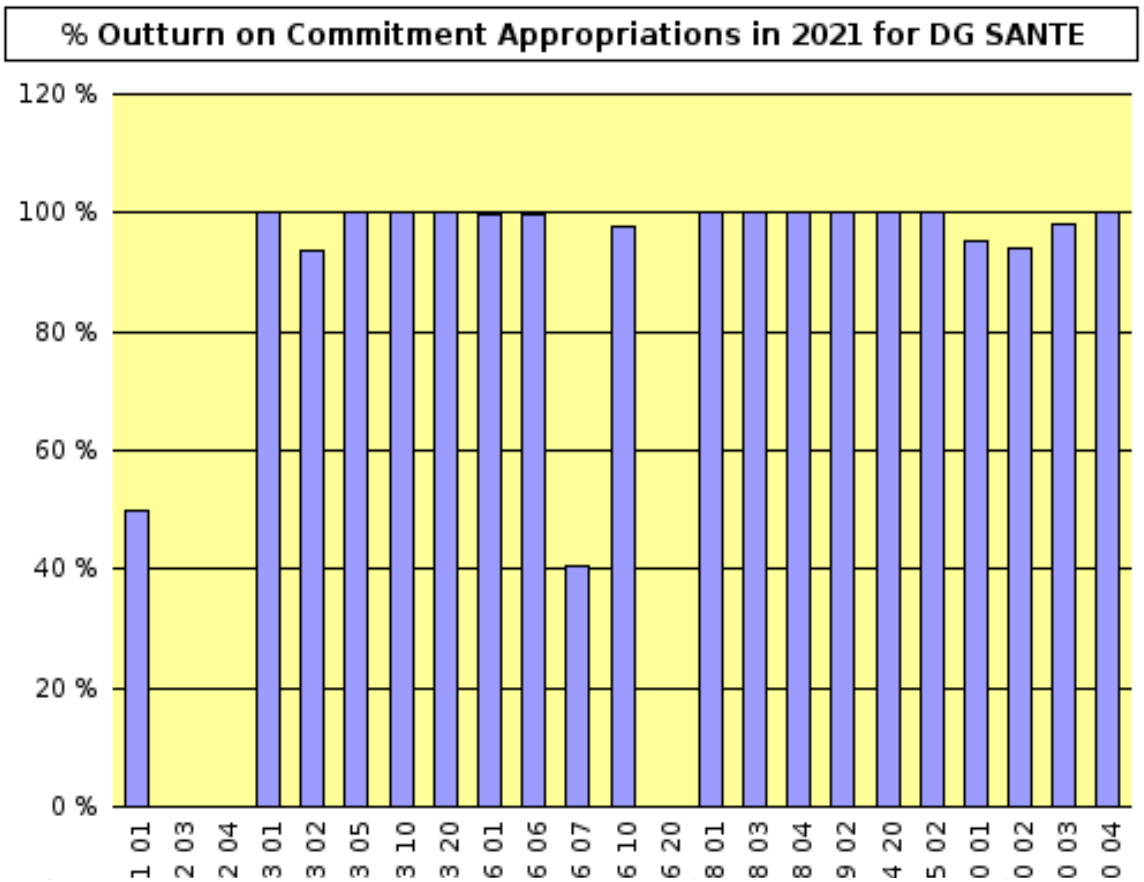


TABLE 2: OUTTURN ON PAYMENT APPROPRIATIONS in 2021 (in Mio €) for DG SANTE					
			Payment appropriations authorised *	Payments made	%
			1	2	3=2/1
Title 01 Research and Innovation					
01	01 01	Support administrative expenditure of the "Research and Innovation" cluster	14,07	13,59	96,62 %
Total Title 01			**14,07**	**13,59**	**96,62%**
Title 02 European Strategic Investments					
02	02 03	Connecting Europe Facility (CEF)	3,60	3,60	100,00 %
	02 04	Digital Europe programme	0,10	0,08	73,83 %
Total Title 02			**3,70**	**3,67**	**99,27%**
Title 03 Single Market					
03	03 01	Support administrative expenditure of the `Single Market¿ cluster	4,16	2,88	69,27 %
	03 02	Single Market Programme	62,10	59,12	95,20 %
	03 05	Cooperation in the field of customs (Customs)	0,22	0,22	100,00 %
	03 10	Decentralised agencies	10,32	10,32	100,00 %
	03 20	Pilot projects, preparatory actions, prerogatives and other actions	0,45	0,45	100,00 %
Total Title 03			**77,24**	**72,99**	**94,49%**
Title 06 Recovery and Resilience					
06	06 01	Support administrative expenditure of the `Recovery and Resilience¿ cluster	10,84	8,48	78,21 %
	06 06	EU4Health Programme	16,00	15,65	97,80 %
	06 07	Emergency support within the Union	869,90	401,08	46,11 %
	06 10	Decentralised gencies	333,66	325,87	97,66 %
	06 20	Pilot projects, preparatory actions, prerogatives and other actions	2,58	2,58	100,00 %
Total Title 06			**1.232,98**	**753,66**	**61,12%**
Title 08 Agriculture and Maritime Policy					
08	08 01	Support administrative expenditure of the "Agriculture and Maritime Policy" cluster	0,89	0,89	100,00 %
	08 03	European Agricultural Fund for Rural Development (EAFRD)	0,58	0,58	100,00 %
	08 04	European Maritime and Fisheries Fund (EMFF)	0,18	0,18	100,00 %
Total Title 08			**1,66**	**1,66**	**100,00%**
Title 09 Environment and Climate Action					
09	09 02	Programme for the Environment and Climate Action (LIFE)	0,13	0,13	100,00 %
Total Title 09			**0,13**	**0,13**	**100,00%**
Title 14 External Action					
14	14 20	Pilot projects, preparatory actions, prerogatives and other actions	0,33	0,33	100,00 %
Total Title 14			**0,33**	**0,33**	**100,00%**

Title 15 Pre-accession Assistance					
15	15 02	Instrument for Pre-accession Assistance (IPA III)	0,42	0,42	100,00 %
Total Title 15			**0,42**	**0,42**	**100,00%**
Title 20 Administrative expenditure of the European Commission					
20	20 01	Members, officials and temporary staff	0,59	0,33	55,28 %
	20 02	Other staff and expenditure relating to persons	0,40	0,21	51,65 %
	20 03	Administrative Operating expenditure	5,23	3,83	73,21 %
	20 04	Information and communication technology related expenditure	0,57	0,33	57,51 %
Total Title 20			**6,79**	**4,69**	**69,07%**
Total Excluding NGEU			**1.337,33**	**851,14**	**63,64%**

Title 01 Research and Innovation					
01	01 01	Support administrative expenditure of the "Research and Innovation" cluster	5,79	1,84	31,83 %
Total Title 01			**5,79**	**1,84**	**31,83%**
Total NGEU Only			**5,79**	**1,84**	**31,83%**

Total DG SANTE	**1.343,12**	**852,99**	**63,51 %**

** 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).*

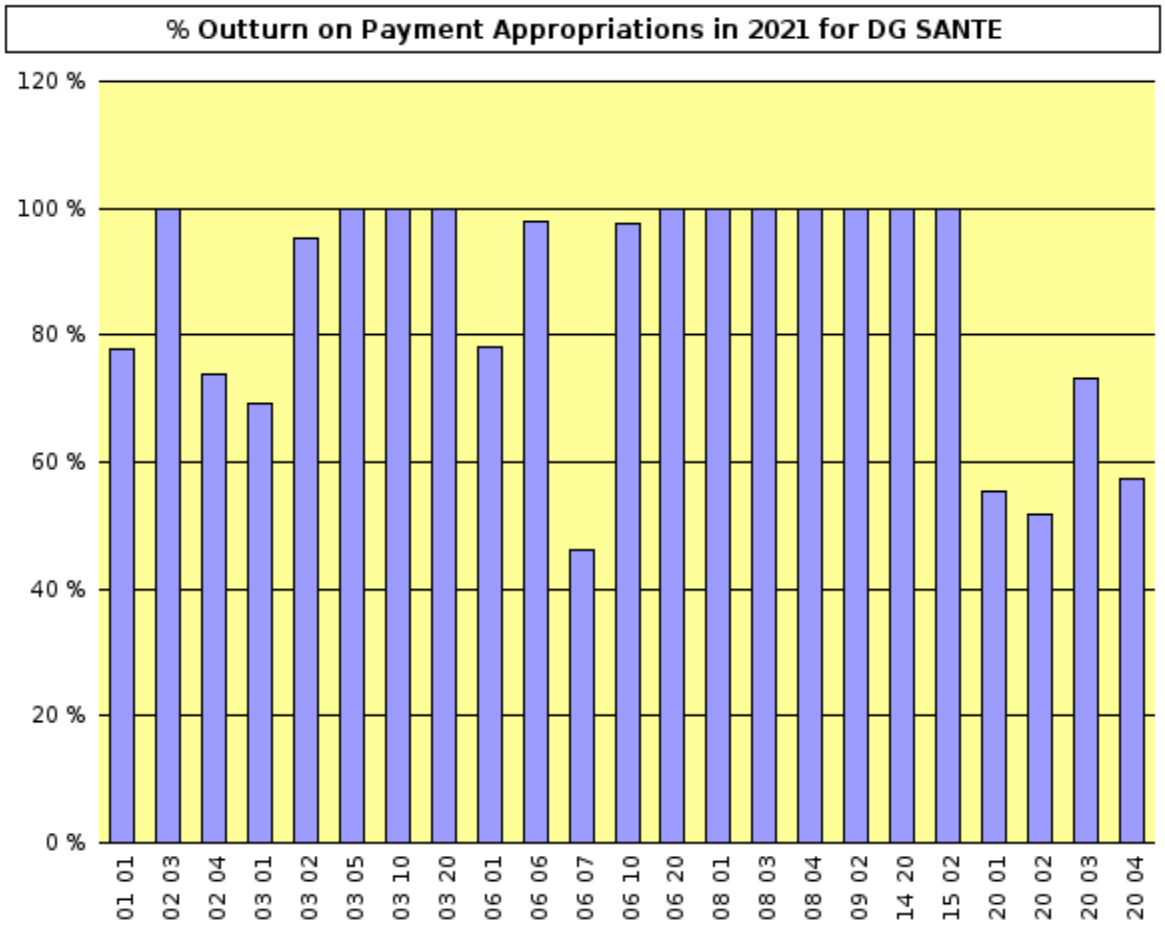


TABLE 3 : BREAKDOWN OF COMMITMENTS TO BE SETTLED AT 31/12/2021 (in Mio €) for DG SANTE									
Chapter			Commitments to be settled				Commitments to be settled from financial years previous to 2020	Total of commitments to be settled at end of financial year 2021	Total of commitments to be settled at end of financial year 2020
			Commitments	Payments	RAL	% to be settled			
			1	2	3=1-2	4=1-2/1	5	6=3+5	7
01	01 01	Support administrative expenditure of the "Research and Innovation" cluster	13,59	13,59	0,00	0,00%	0,00	0,00	0,00
Total Title 01			**13,59**	**13,59**	**0,00**	**0,00%**	**0,00**	**0,00**	**0,00**

TABLE 3 : BREAKDOWN OF COMMITMENTS TO BE SETTLED AT 31/12/2021 (in Mio €) for DG SANTE									
Chapter			Commitments to be settled				Commitments to be settled from financial years previous to 2020	Total of commitments to be settled at end of financial year 2021	Total of commitments to be settled at end of financial year 2020
			Commitments	Payments	RAL	% to be settled			
			1	2	3=1-2	4=1-2/1	5	6=3+5	7
02	02 03	Connecting Europe Facility (CEF)	0,00	0,00	0,00	0,00%	2,70	2,70	6,30
	02 04	Digital Europe programme	0,00	0,00	0,00	0,00%	0,22	0,22	0,30
Total Title 02			**0,00**	**0,00**	**0,00**	**0,00%**	**2,93**	**2,93**	**6,60**

TABLE 3 : BREAKDOWN OF COMMITMENTS TO BE SETTLED AT 31/12/2021 (in Mio €) for DG SANTE									
Chapter			Commitments to be settled				Commitments to be settled from financial years previous to 2020	Total of commitments to be settled at end of financial year 2021	Total of commitments to be settled at end of financial year 2020
			Commitments	Payments	RAL	% to be settled			
			1	2	3=1-2	4=1-2/1	5	6=3+5	7
03	03 01	Support administrative expenditure of the `Single Market¿ cluster	3,56	2,31	1,25	35,13%	0,00	1,25	0,60
	03 02	Single Market Programme	58,77	21,77	37,00	62,96%	48,20	85,20	115,41
	03 05	Cooperation in the field of customs (Customs)	0,50	0,00	0,50	100,00%	0,14	0,64	0,36
	03 10	Decentralised agencies	10,32	10,32	0,00	0,00%	0,00	0,00	0,00
	03 20	Pilot projects, preparatory actions, prerogatives and other actions	0,65	0,33	0,33	50,00%	1,82	2,14	1,94
Total Title 03			**73,80**	**34,73**	**39,08**	**52,95%**	**50,15**	**89,23**	**118,30**

TABLE 3 : BREAKDOWN OF COMMITMENTS TO BE SETTLED AT 31/12/2021 (in Mio €) for DG SANTE									
Chapter			Commitments to be settled				Commitments to be settled from financial years previous to 2020	Total of commitments to be settled at end of financial year 2021	Total of commitments to be settled at end of financial year 2020
			Commitments	Payments	RAL	% to be settled			
			1	2	3=1-2	4=1-2/1	5	6=3+5	7
06	06 01	Support administrative expenditure of the `Recovery and Resilience¿ cluster	10,33	8,09	2,25	21,73%	0,00	2,25	0,50
	06 06	EU4Health Programme	65,76	2,20	63,56	96,65%	18,76	82,32	32,47
	06 07	Emergency support within the Union	253,86	158,38	95,48	37,61%	39,50	134,98	257,18
	06 10	Decentralised gencies	334,89	325,87	9,01	2,69%	10,58	19,59	10,58
	06 20	Pilot projects, preparatory actions, prerogatives and other actions	0,00	0,00	0,00	0,00%	1,26	1,26	4,03
Total Title 06			**664,85**	**494,54**	**170,30**	**25,62%**	**70,10**	**240,40**	**304,77**

TABLE 3 : BREAKDOWN OF COMMITMENTS TO BE SETTLED AT 31/12/2021 (in Mio €) for DG SANTE									
Chapter			Commitments to be settled				Commitments to be settled from financial years previous to 2020	Total of commitments to be settled at end of financial year 2021	Total of commitments to be settled at end of financial year 2020
			Commitments	Payments	RAL	% to be settled			
			1	2	3=1-2	4=1-2/1	5	6=3+5	7
08	08 01	Support administrative expenditure of the "Agriculture and Maritime Policy" cluster	0,89	0,89	0,00	0,00%	0,00	0,00	0,00
	08 03	European Agricultural Fund for Rural Development (EAFRD)	0,48	0,00	0,48	100,00%	0,31	0,79	0,88
	08 04	European Maritime and Fisheries Fund (EMFF)	0,33	0,03	0,30	89,92%	0,36	0,65	0,51
Total Title 08			**1,70**	**0,93**	**0,78**	**45,59%**	**0,66**	**1,44**	**1,39**

TABLE 3 : BREAKDOWN OF COMMITMENTS TO BE SETTLED AT 31/12/2021 (in Mio €) for DG SANTE									
Chapter			Commitments to be settled				Commitments to be settled from financial years previous to 2020	Total of commitments to be settled at end of financial year 2021	Total of commitments to be settled at end of financial year 2020
			Commitments	Payments	RAL	% to be settled			
			1	2	3=1-2	4=1-2/1	5	6=3+5	7
09	09 02	Programme for the Environment and Climate Action (LIFE)	0,17	0,00	0,17	100,00%	0,04	0,21	0,18
Total Title 09			**0,17**	**0,00**	**0,17**	**100,00%**	**0,04**	**0,21**	**0,18**

TABLE 3 : BREAKDOWN OF COMMITMENTS TO BE SETTLED AT 31/12/2021 (in Mio €) for DG SANTE									
Chapter			Commitments to be settled				Commitments to be settled from financial years previous to 2020	Total of commitments to be settled at end of financial year 2021	Total of commitments to be settled at end of financial year 2020
			Commitments	Payments	RAL	% to be settled			
			1	2	3=1-2	4=1-2/1	5	6=3+5	7
14	14 20	Pilot projects, preparatory actions, prerogatives and other actions	0,33	0,33	0,00	0,00%	0,05	0,05	0,05
Total Title 14			**0,33**	**0,33**	**0,00**	**0,00%**	**0,05**	**0,05**	**0,05**

TABLE 3 : BREAKDOWN OF COMMITMENTS TO BE SETTLED AT 31/12/2021 (in Mio €) for DG SANTE									
Chapter			Commitments to be settled				Commitments to be settled from financial years previous to 2020	Total of commitments to be settled at end of financial year 2021	Total of commitments to be settled at end of financial year 2020
			Commitments	Payments	RAL	% to be settled			
			1	2	3=1-2	4=1-2/1	5	6=3+5	7
15	15 02	Instrument for Pre-accession Assistance (IPA III)	4,00	0,00	4,00	100,00%	0,80	4,80	1,22
Total Title 15			**4,00**	**0,00**	**4,00**	**100,00%**	**0,80**	**4,80**	**1,22**

TABLE 3 : BREAKDOWN OF COMMITMENTS TO BE SETTLED AT 31/12/2021 (in Mio €) for DG SANTE									
Chapter			Commitments to be settled				Commitments to be settled from financial years previous to 2020	Total of commitments to be settled at end of financial year 2021	Total of commitments to be settled at end of financial year 2020
			Commitments	Payments	RAL	% to be settled			
			1	2	3=1-2	4=1-2/1	5	6=3+5	7
20	20 01	Members, officials and temporary staff	0,39	0,23	0,16	41,08%	0,00	0,16	0,18
	20 02	Other staff and expenditure relating to persons	0,13	0,05	0,07	57,20%	0,00	0,07	0,27
	20 03	Administrative Operating expenditure	4,13	3,06	1,07	25,97%	0,00	1,07	1,03
	20 04	Information and communication technology related expenditure	0,40	0,18	0,21	54,03%	0,00	0,21	0,17
Total Title 20			**5,04**	**3,52**	**1,52**	**30,14%**	**0,00**	**1,52**	**1,65**
Total Excluding NGEU			**763,49**	**547,64**	**215,84**	**28,27%**	**124,73**	**340,57**	**434,16**

TABLE 3 : BREAKDOWN OF COMMITMENTS TO BE SETTLED AT 31/12/2021 (in Mio €) for DG SANTE									
Chapter			Commitments to be settled				Commitments to be settled from financial years previous to 2020	Total of commitments to be settled at end of financial year 2021	Total of commitments to be settled at end of financial year 2020
			Commitments	Payments	RAL	% to be settled			
			1	2	3=1-2	4=1-2/1	5	6=3+5	7
01	01 01	Support administrative expenditure of the "Research and Innovation" cluster	1,84	1,84	0,00	0,00%	0,00	0,00	0,00
Total Title 01			**1,84**	**1,84**	**0,00**	**0,00%**	**0,00**	**0,00**	**0,00**
Total NGEU Only			**1,84**	**1,84**	**0,00**	**0,00%**	**0,00**	**0,00**	**0,00**

Total for DG SANTE	**765,330108**	**549,49**	**215,84**	**28,20 %**	**124,73**	**340,57**	**434,16**

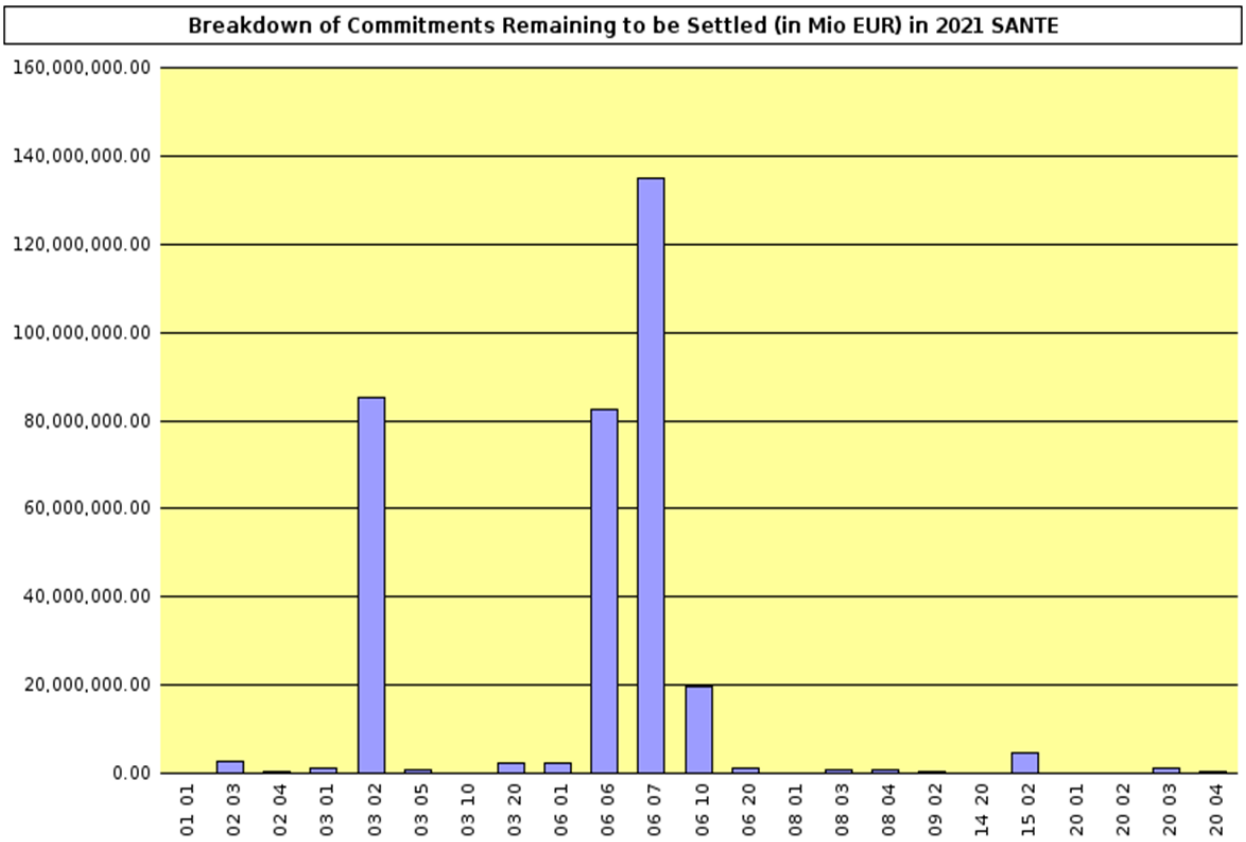

Breakdown of Commitments Remaining to be Settled (in Mio EUR) in 2021 SANTE
160,000,000.00
140,000,000.00
120,000,000.00
100,000,000.00
80,000,000.00
60,000,000.00
40,000,000.00
20,000,000.00
0.00
01 01
02 03
02 04
03 01
03 02
03 05
03 10
03 20
06 01
06 06
06 07
06 10
06 20
08 01
08 03
08 04
09 02
14 20
15 02
20 01
20 02
20 03
20 04

TABLE 4 : BALANCE SHEET for DG SANTE

BALANCE SHEET	2021	2020
A.I. NON CURRENT ASSETS	15.258.190,10	163.319.095,21
A.I.1. Intangible Assets	7.574.121,31	7.574.121,31
A.I.2. Property, Plant and Equipment	7.549.328,67	8.991.859,31
A.I.5. Non-Current Pre-Financing	134.740,12	146.753.114,59
A.II. CURRENT ASSETS	412.345.513,80	831.098.560,52
A.II.2. Current Pre-Financing	409.983.452,78	818.472.436,25
A.II.3. Curr Exch Receiv &Non-Ex Recoverables	2.359.653,12	1.015.245,07
A.II.4. Inventories	-	11.608.435,00
A.II.6. Cash and Cash Equivalents	2.407,90	2.444,20
ASSETS	**427.603.703,90**	**994.417.655,73**
P.I. NON CURRENT LIABILITIES	-	-
P.I.3. Non-Current Financial Liabilities	-	-
P.II. CURRENT LIABILITIES	- 310.250.518,06	- 338.459.277,95
P.II.2. Current Provisions	- 282.598.575,38	- 111.226.274,26
P.II.3. Current Financial Liabilities	-	- 2.056.200,99
P.II.4. Current Payables	- 10.893.216,64	- 21.650.179,11
P.II.5. Current Accrued Charges &Defrd Income	- 16.758.726,04	- 203.526.623,59
LIABILITIES	**- 310.250.518,06**	**- 338.459.277,95**
NET ASSETS (ASSETS less LIABILITIES)	**117.353.185,84**	**655.958.377,78**

P.III.2. Accumulated Surplus/Deficit	4.182.013.471,70	2.812.658.079,86

Non-allocated central (surplus)/deficit*	- 4.299.366.657,54	- 3.468.616.457,64

TOTAL DG SANTE	**0,00**	**0,00**

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

STATEMENT OF FINANCIAL PERFORMANCE	2021	2020
II.1 REVENUES	- 48.482.072,38	- 758.371.129,04
II.1.1. NON-EXCHANGE REVENUES	- 51.719.115,66	- 762.331.763,24
II.1.1.5. RECOVERY OF EXPENSES	- 25.816.042,47	- 1.762.673,04
II.1.1.7. OTHER NON-EXCHANGE REVENUES	- 25.903.073,19	- 760.569.090,20
II.1.2. EXCHANGE REVENUES	3.237.043,28	3.960.634,20
II.1.2.2. OTHER EXCHANGE REVENUE	3.237.043,28	3.960.634,20
II.2. EXPENSES	1.386.891.024,57	2.127.726.520,88
II.2. EXPENSES	1.386.891.024,57	2.127.726.520,88
II.2.10.OTHER EXPENSES	283.295.210,42	104.079.138,94
II.2.2. EXP IMPLEM BY COMMISS&EX.AGENC. (DM)	766.166.708,46	1.796.353.714,94
II.2.3. EXP IMPL BY OTH EU AGENC&BODIES (IM)	307.966.953,71	219.564.410,27
II.2.4. EXP IMPL BY 3RD CNTR & INT ORG (IM)	29.785.183,20	8.127.383,99
II.2.6. STAFF AND PENSION COSTS	- 328.295,83	- 401.620,00
II.2.8. FINANCE COSTS	5.264,61	3.492,74
STATEMENT OF FINANCIAL PERFORMANCE	**1.338.408.952,19**	**1.369.355.391,84**

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

OFF BALANCE	2021	2020
OB.1. Contingent Assets	-	-
GR for pre-financing	-	-
OB.2. Contingent Liabilities	- 29.989.330,18	- 9.673.175,08
OB.2.6. CL Other	- 29.989.330,18	- 9.673.175,08
OB.2.7. CL Legal cases OTHER	-	-
OB.3. Other Significant Disclosures	- 313.382.111,77	- 372.631.109,45
OB.3.2. Comm against app. not yet consumed	- 313.382.111,77	- 372.631.109,45
OB.4. Balancing Accounts	343.371.441,95	382.304.284,53
OB.4. Balancing Accounts	343.371.441,95	382.304.284,53
OFF BALANCE	**-**	**-**

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

Legal Times

Maximum Payment Time (Days)	Total Nbr 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
15	1	1	100,00 %	11				-	0, %
19	1	1	100,00 %	18				-	0, %
30	1343	1246	92,78 %	20,15811	97	7,22 %	37,06185567	5.358.769,88	2, %
44	1	1	100,00 %	30				-	0, %
45	38	38	100,00 %	18,55263				-	0, %
60	126	124	98,41 %	29,91129	2	1,59 %	66	114.989,40	0, %
84	1	1	100,00 %	26				-	0, %
90	50	36	72,00 %	57,75	14	28,00 %	105,8571429	5.076.719,83	17, %
91	1	1	100,00 %	35				-	0, %
94	1	1	100,00 %	35				-	0, %
212	1				1	100,00 %	218	507.855,36	100, %

Total Number of Payments	**1564**	**1450**	**92,71 %**		**114**	**7,29 %**		**11.058.334,47**	**1, %**
Average Net Payment Time	**23,78005115**			**21,9069**			**47,60526316**		
Average Gross Payment Time	**37,04603581**			**32,22**			**98,42982456**		

Suspensions

Average Report Approval Suspension	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	90	230	14,71 %	1564	230.504.677,35	27,22 %	846.889.775,81

Late Interest paid in 2021

DG	GL Account	Description	Amount (Eur)
SANTE	65010000	Interest expense on late payment of charges	0,00
SANTE	65010100	Interest on late payment of charges New FR	5 264,61
			5 264,61

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/budgweb/EN/abac/dwh/Pages/its-030-10-20_documentation.aspx).

TABLE 7 : SITUATION ON REVENUE AND INCOME in 2021 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	7=3-6
33	Other administrative revenue	865.216,52	4.709,60	869.926,12	865.216,52	4.709,60	869.926,12	-
60	Single market, innovation and digital	3.591.140,05	-	3.591.140,05	3.591.140,05	-	3.591.140,05	-
61	Cohesion, resilience and values	21.249.202,27	-	21.249.202,27	21.072.599,34	-	21.072.599,34	176.602,93
66	Other contributions and refunds	7.791.150,28	-	7.791.150,28	7.791.150,28	-	7.791.150,28	-
67	Completion for outstanding recovery orders prior to 2021	1.431.487,99	50.115,41	1.481.603,40	1.431.487,99	2.991,82	1.434.479,81	47.123,59
Total DG SANTE		**34.928.197,11**	**54.825,01**	**34.983.022,12**	**34.751.594,18**	**7.701,42**	**34.759.295,60**	**223.726,52**

TABLE 8 : RECOVERY OF PAYMENTS in 2021 for DG SANTE
(Number of Recovery Contexts and corresponding Transaction Amount)

INCOME BUDGET RECOVERY ORDERS ISSUED IN 2021	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
2015	3	63.037,50	**3**	**63.037,50**	3	63.037,50	100,00%	100,00%
2016	4	338.587,90	**4**	**338.587,90**	4	338.587,90	100,00%	100,00%
2017	4	1.113.100,87	**4**	**1.113.100,87**	4	1.113.100,87	100,00%	100,00%
2018	3	1.031.031,54	**3**	**1.031.031,54**	3	1.031.031,54	100,00%	100,00%
2019	2	1.044.802,18	**2**	**1.044.802,18**	5	1.354.758,22	40,00%	77,12%
2020					15	9.500.467,63		
2021					4	483.841,93		
No Link					3	21.043.371,52		
Sub-Total	**16**	**3.590.559,99**	**16**	**3.590.559,99**	**41**	**34.928.197,11**	**39,02%**	**10,28%**

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										
NON ELIGIBLE IN COST CLAIMS	37	20.406.127,80			**37**	**20.406.127,80**	61	65.983.181,84	60,66%	30,93%
CREDIT NOTES	23	721.548,80			**23**	**721.548,80**	84	20.529.755,90	27,38%	3,51%
Sub-Total	**60**	**21.127.676,60**			**60**	**21.127.676,60**	**145**	**86.512.937,74**	**41,38%**	**24,42%**

GRAND TOTAL	**76**	**24.718.236,59**			**76**	**24.718.236,59**	**186**	**121.441.134,85**	**40,86%**	**20,35%**

TABLE 9: AGEING BALANCE OF RECOVERY ORDERS AT 12/31/2021 for DG SANTE

	Number at 1/1/2021 1	Number at 12/31/2021	Evolution	Open Amount (Eur) at 1/1/2021 1	Open Amount (Eur) at 12/31/2021	Evolution
2011	1	1	0,00 %	47.123,59	47.123,59	0,00 %
2020	2		-100,00 %	7.701,42		-100,00 %
2021		1			176.602,93	
	3	**2**	**-33,33 %**	**54.825,01**	**223.726,52**	**308,07 %**

TABLE 10 :Recovery Order Waivers >= 60 000 € in 2021 for DG SANTE

	Waiver Central Key	Linked RO Central Key	RO Accepted Amount (Eur)	LE Account Group	Commission Decision	Comments

Total DG SANTE	

Number of RO waivers	

Justifications:

TABLE 11 : Negotiated Procedures in 2021 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	3	7.257.669,00
Annex 1 - 11.1 (c) - Extreme urgency caused by unforeseeable events not attributtable to the contracting authority	2	69.942.300,00
Total	**5**	**77.199.969,00**

The table includes only negotiated procedures for w hich the Financial Regulation foresees publication in the Annual Activity Report.

TABLE 12 : Summary of Procedures in 2021 for DG SANTE

Internal Procedures > € 60,000

Procedure Legal base	Number of Procedures	Amount (€)
Negotiated procedure middle value contract (Annex 1 - 14.2)	1	132.775,00
Negotiated procedure without prior publication (Annex 1 - 11.1)	6	77.479.969,00
Open procedure (FR 164 (1)(a))	3	21.449.000,00
Restricted procedure based on a call for expressions of interest - Preselection of candidates (Annex 1 - 13.3 (a))	2	255.202,73
Total	**12**	**99.316.946,73**

Additional Comments:

TABLE 13 : BUILDING CONTRACTS in 2021 for DG SANTE

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

TABLE 14 : CONTRACTS DECLARED SECRET in 2021 for DG SANTE

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

TABLE 15 : FPA duration exceeds 4 years - DG SANTE

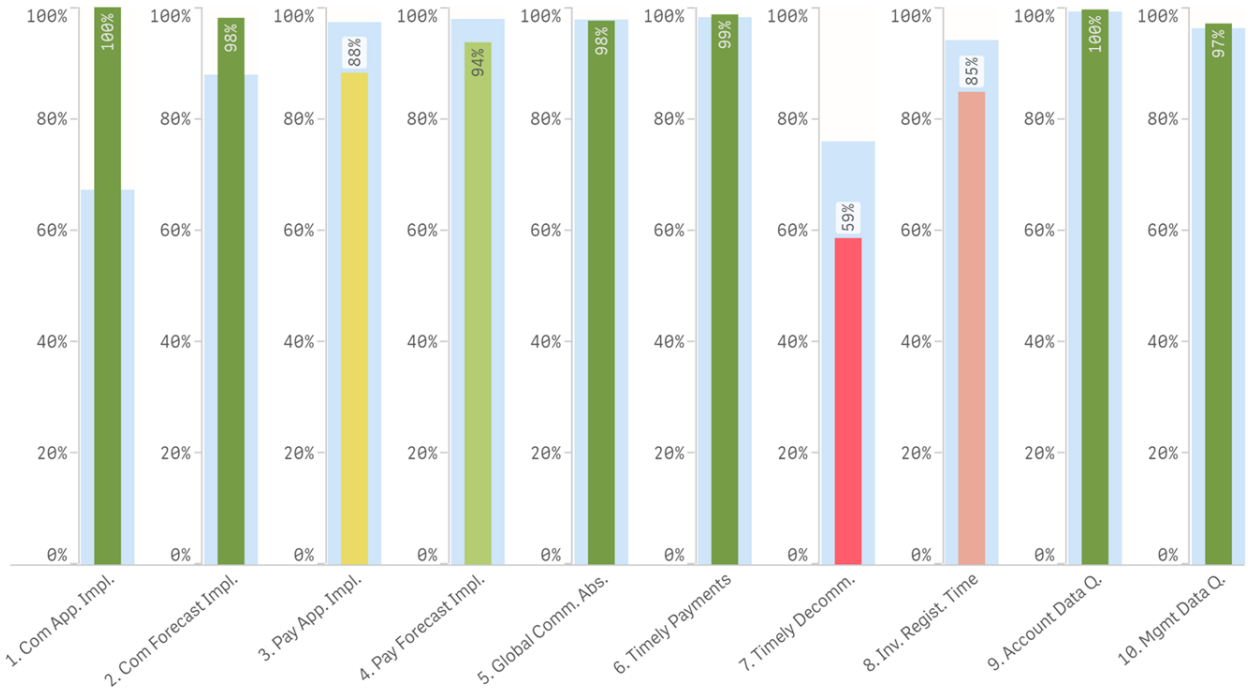
ANNEX 4 : Financial Scorecard

The Annex 4 summarises the annual result of the standard financial indicators measurement. Ten standard financial indicators are presented below, each with its objective and result for the Commission service and for the EC as a whole (for benchmarking purposes). The table below includes explanations.

Each indicator, its value (in %) for the Commission service, 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

DG SANTE Indicator Score 2021



For each indicator the light blue bar denotes the EC Score.

Indicator	Objective	Comment	SANTE Score	EC Score
1. Commitment Appropriations (CA) Implementation	Ensure efficient use of commitment appropriations expiring at the end of Financial Year		100%	67%
2. Commitment Appropriations (CA) Forecast Implementation	Ensure the cumulative alignment of the commitment implementation with the commitment forecast in a financial year		98%	88%
3. Payment Appropriations (PA) Implementation	Ensure efficient use of payment appropriations expiring at the end of Financial Year	DG SANTE received additional credits for the Emergency Support Instrument (ESI) for implementation by several DGs. As DG SANTE was in the lead, the unspent amounts remained in DG SANTE's payment budget.	88%	97%
4. Payment Appropriations (PA) Forecast Implementation	Ensure the cumulative alignment of the payment implementation with the payment forecast in a financial year		94%	98%
5. Global Commitment Absorption	Ensure efficient use of already earmarked commitment appropriations (at L1 level)		98%	98%
6. Timely Payments	Ensure efficient processing of payments within the legal deadlines	DG SANTE ensured efficient processing of payments within the legal deadlines thanks especially to electronic workflows with automatic reminders of payments due.	99%	98%
7. Timely De-commitments	Ensure efficient de-commitment of outstanding RAL at the end of commitment life cycle	In 2021, DG SANTE had to organise its de-commitments in batches due to an exceptionally high work load mainly linked to the urgent and at times quite complex transactions related to the ESI and the follow-up tasks of the late adoption of the MFF (2021-2027).	59%	76%
8. Invoice Registration Time	Monitor the accounting risk stemming from late registration of invoices in the central accounting system ABAC	In 2021, the registration of invoices lagged behind due to the exceptionally high work load as explained above. Priority was given to timely budget implementation and payments.	85%	94%
9. Accounting Data Quality	Ensure the good data quality of ABAC transactions with the focus on fields having a primary impact on the accounts		100%	99%
10. Management Data Quality	Ensure the good data quality of ABAC transactions with the focus on fields having a primary impact on the management decisions		97%	96%

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 General'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 General's 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 controls carried out in the form of financial audits (on-the-spot or remote) 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 controls carried out in the form of financial audits (on-the-spot or remote) 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

To select 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. Applicable as from 1 January 2021, the SMP – Food Safety strand is the main basis for the corresponding expenditure[12]. For actions initiated under the previous legislation[13], its provisions continue to apply until their closure. Following the transfer of budget implementation tasks to the Health and Digital Executive Agency (HaDEA) in 2021 (see annex 6.2 below), the grant management of the animal and plant disease eradication programmes of the Member States and the grants for European Reference Laboratories and Centres (EURL and EURC) are implemented by the agency. Only the management of the grant agreements with Member States and third countries at a Union border for their veterinary and plant emergency measures and grants to international organisations remained in DG SANTE.
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.

[12] Regulation (EU) 2021/690 of the European Parliament and of the Council of 28 April 2021 on the Single Market Programme (SMP) and repealing – inter alia - Regulation (EU) No 652/2014 the Common Financial Framework (CFF); 2021 work programme C(2021)3046 of 6 May 2021

[13] Common Financial Framework (CFF): Regulation (EU) No 652/2014

Grants for veterinary and phytosanitary emergency measures				
Main inherent risks	**Mitigating controls**	**Control coverage**	**Costs and benefits of controls**	**Cost-Effectiveness indicators (three E's: effectiveness, efficiency, economy)**
Stage 1 Legal base and Member States' submission of applications ***Main control objectives:*** *ensuring that the Commission finances emergency measures that are eligible and contribute towards the achievement of the policy objectives (effectiveness and best value for public money); compliance (legality & regularity); prevention of fraud (anti-fraud strategy)*				
Eligibility, selection and award criteria should be adequate to achieve the SMP objectives: avoidance of further spread of the animal diseases and plant pests and, their fast eradication	- The SMP (Regulation (EU)2021/690 sets out the eligibility, selection and award criteria; - Grants may be awarded to Member States and third countries in case of emergency measures taken as a result of confirmed occurrence of a number of listed diseases - The award criteria for the financial contribution by the Union are: a) compliance with the requirements of the relevant Union law; b) relevance of the planned activities in view of the prevention or eradication of the animal diseases and plant pests; c) activities related to prevention or eradication of plant pests during the first year after the detection of the outbreak.	The risks at stage 1 are assessed as low as the selection and attribution criteria, the submission modalities and the list of eligible programmes are set out in the legislation. No financial commitment is done at this stage.	**Cost of control**: Estimate of DG SANTE's staff costs for handling the Member States' applications **Benefits of control:** As no significant errors are to be expected, the benefits are mainly administrative in nature and thus non-quantifiable in budgetary terms	(%) Number of successfully implemented emergency measures on plant pests and animal diseases (SMP, Annex IV) ⇨ Target: 100% successfully implemented
Member States' applications should be timely, of good technical quality and include reliable estimates of the eligible costs of the emergency measures to ensure sound financial	1. Art 13 of the SMP sets out that the submission of the grant application shall be preceded by the notification to the Commission of the occurrence of the disease in accordance with Regulation (EU) 2016/429 for animal diseases and Regulation (EU) 2016/2031 for plant pests (within a certain period of time from the official confirmation of the occurrence of the disease or presence of the pest, Member States shall provide			

Grants for veterinary and phytosanitary emergency measures				
Main inherent risks	**Mitigating controls**	**Control coverage**	**Costs and benefits of controls**	**Cost-Effectiveness indicators (three E's: effectiveness, efficiency, economy)**
management	preliminary information on the ongoing and planned actions, on the estimated total eligible costs (as defined in the SMP, annex I) and on the expected date of the end of the completion of the emergency measures); 2. DG SANTE provides templates for the Member States' submissions of applications and guidelines (e.g. on the eligibility of costs); information meetings are held to explain the requirements; 3. The technical and financial parts of each application are checked by the competent operational and financial officers to ensure that the Member States' ongoing and planned emergency measures are adequate and their cost estimates reasonable; 4. The Member States send to DG SANTE on a regular basis updated information on the eligible costs of the emergency measures taken to fight the outbreak.			

Grants for veterinary and phytosanitary emergency measures				
Main inherent risks	**Mitigating controls**	**Control coverage**	**Costs and benefits of controls**	**Cost-Effectiveness indicators (three E's: effectiveness, efficiency, economy)**
Stage 2 "Contracting": approving the emergency measure and signing the grant agreement ***Main control objectives**: ensuring that the actions and funds allocation is optimal (best value for public money; effectiveness, economy, efficiency) and compliant (legality & regularity)*				
The grant agreements for emergency measures should (a) be timely, (b) include reasonable funding (c) correspond to DG BUDG template (as much as possible)	1. After a certain period of time (e.g. 4 months after the official confirmation of the occurrence of the disease or presence of the pest), the grant agreement is prepared: DG SANTE finalises its technical and financial assessment of the Member State's application and documents the results in checklists adapted to each disease; 2. The Authorising Officer responsible informs DG SANTE's management (Food Pillar) in writing on the allocation of credits per Member State and disease; 3. The Authorising Officer responsible takes the award decision defining the beneficiary and the grant amount based on the technical and financial assessment and the feedback from the Food Pillar; 4. Following ex-ante checks on administrative and legal aspects of the grant agreement, the Authorising Officer responsible approves formally in a grant agreement the Member States application and its associated funding.	1.-2. 100% of applications to be technically and financially approved prior to preparing the grant agreement 3.-4. 100% of grant agreements checked prior to approval (depth of checks depends on risk criteria)	**Cost of control:** Included in estimate of DG SANTE's staff costs for handling the Member States' applications **Benefits of control:** Compliance	- Grant agreements signed on-time. ⇨ Target: 100% on time fixed in implementing decisions [for actions initiated under the previous legislation (CFF): Commission Implementing Decision (EU) 2015/144 for veterinary emergency measures and Commission Implementing Decision (EU) 2016/159 for phytosanitary emergency measures]

Grants for veterinary and phytosanitary emergency measures				
Main inherent risks	**Mitigating controls**	**Control coverage**	**Costs and benefits of controls**	**Cost-Effectiveness indicators (three E's: effectiveness, efficiency, economy)**
Stage 3: Managing financial transactions and ex-ante controls ***Main control objectives**: ensuring that the related financial operations comply with regulatory and contractual provisions (legality & regularity); prevention of fraud (anti-fraud strategy); ensuring appropriate accounting of the operations (reliability of reporting, safeguarding of assets and information)*				
Controls should prevent that ineligible amounts are paid and ensure that derogations from the Financial Regulation as set out in the SMP are applied correctly.	1. Within a certain period of time (e.g. 6 months after the end date of the grant agreement or the confirmation of the end of the completion of the eradication and/or containment of the pest), the Member States shall submit their payment applications; 2. DG SANTE assesses the technical and financial aspects of the payment applications and documents the results in checklists adapted to each disease. Special attention is paid to the following provisions in the SMP Art. 13 (1): "emergency measures (a) shall be eligible prior to the date of submission of the grant application in accordance with Article 193(2), second subparagraph, point (b) of the Financial Regulation; (b) shall be eligible from the date of the suspected occurrence of an animal disease or the presence of a plant pest, provided that that occurrence or presence is subsequently confirmed."	1.-3. All payment applications are assessed (technical and financial checklists completed; the control depth depends on risk criteria) 4. Further to a risk assessment, a small number of programmes is subject to an in-depth financial control; 5. 100% of payments and ABAC encodings 6. 100% if conditions are fulfilled	**Cost of control:** Included in the estimate of DG SANTE's staff costs for handling the Member States' applications **Benefits of control:** - Compliance	- Files with relevance for OLAF adequately transmitted to OLAF and followed up ⇨ Target: 100% - Time between receipt of the Member States' payment application and the payment ⇨ Target: 95% payments on time (in number and in amount)

Grants for veterinary and phytosanitary emergency measures				
Main inherent risks	**Mitigating controls**	**Control coverage**	**Costs and benefits of controls**	**Cost-Effectiveness indicators (three E's: effectiveness, efficiency, economy)**
	3. Financial transactions are launched in ABAC, while paying special attention to the correct application of the following provision in the SMP: Art. 3(5): "By way of derogation from Article 111(2) of the Financial Regulation, the Commission shall make the budgetary commitment for the grant awarded for veterinary and phytosanitary emergency measures (…) after the payment applications submitted by Member States have been assessed." 4. Standard financial in-depth controls are carried out for selected files as defined in the control strategy; 5. Payments follow DG SANTE's financial circuits with financial verifications, authorisations and encodings in ABAC; they are in the scope of the Court of Auditors' annual financial audits. 6. If deemed necessary, the file is referred to OLAF (DG SANTE's SOPs apply).			

Grants for veterinary and phytosanitary emergency measures				
Main inherent risks	**Mitigating controls**	**Control coverage**	**Costs and benefits of controls**	**Cost-Effectiveness indicators (three E's: effectiveness, efficiency, economy)**
Stage 4: Financial audits (ex-ante and ex-post) ***Main control objectives**:* *a) Detect and correct any error or fraud remaining undetected after standard ex-ante controls (legality & 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);* *b) Ensuring that the (audit) results from the ex-post controls lead to effective recoveries (legality & regularity; anti-fraud strategy); ensuring appropriate accounting of the recoveries made (reliability of reporting).*				
a) Certain issues (errors or attempted fraud) cannot be detected and corrected during standard ex-ante controls; thus, **controls carried out in the form of financial audits (on-the-spot or remote)** should complement the standard desk checks.	DG SANTE's financial audit strategy aims at optimising the control impact through a risk based selection of grants to be audited either ex-ante or ex-post and a sufficient audit coverage to lower the residual error rate. 1. The financial audit work plan is drawn up annually; 2. Financial audits 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; 3. All audit reports undergo a contradictory procedure within DG SANTE and with the auditees (i.e. Member States); 4. If deemed necessary, the file is referred to OLAF (DG SANTE's SOPs on handling allegations of fraud and contacts with OLAF).	- Risk based audit sample - 20% minimum audit coverage to maximise audit correction	**Cost of control**: - Estimated staff costs for financial audits - Cost of external audit services **Benefits of control:** - Value of the financial corrections made further to the audits	- Detected correction rate (in case of ex-ante controls) and error rate (in case of ex-post controls) ⇨ Target: decreasing trend - Residual error rate by funding programme ⇨ Target: < 2% - Number of files referred to OLAF ⇨ Target: 0 - Time between audit visit and finalisation of audit report not exceeding the internal deadlines ⇨ Target: 90% on time - Implementation of the annual ex-post control work plan ⇨ Target: 100% - Percentage of audit recommendations accepted by the beneficiaries/Member States ⇨ Target: 100%
b) **Detected errors**,	1. Systematic communication and registration	1. 100% of final	**Cost of control**:	- Audit results implemented

Grants for veterinary and phytosanitary emergency measures				
Main inherent risks	**Mitigating controls**	**Control coverage**	**Costs and benefits of controls**	**Cost-Effectiveness indicators (three E's: effectiveness, efficiency, economy)**
irregularities or suspicions of fraud should be **addressed adequately and in a timely manner.**	of all audit results to management; 2. Financial and operational validation of recovery orders or additional payments following DG SANTE's financial circuit; 3. Exceptions and internal control weaknesses are reported and analysed. 4. Follow-up on audit recommendations addressed to SANTE linked to emergency measures (Court of Auditors and IAS)	control results 2. 100% financial control of recovery orders 3. 100% of financial procedures 4. 100% of accepted recommendations implemented	- Included in the estimated staff costs for handling the Member States' applications **Benefits of control:** - Amount of actually corrected errors	⇨ Target: 100% - "Time to recover" from final accepted audit report to debit note ⇨ Target: 100% on time - Ratio of corrected control weaknesses to total detected weaknesses in grant procedures ⇨ Target: 100% - Ratio of accepted audit recommendations (Court of Auditors and IAS) implemented on time ⇨ Target: 90%

6.1.2. Type of expenditure: procurement in direct management

Following the transfer of implementation tasks to the Health and Digital Executive Agency (HaDEA), public procurement in relation to the Public Health programmes as well as the procurement procedure for the initiative "Better Training for Saver Food" (BTSF) under the Single Market Programme is managed by the agency. Consequently, the number of contracts managed by DG SANTE is limited.

The majority 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.

Public Procurement				
Main inherent risks	**Mitigating controls**	**Control coverage**	**Costs and benefits of controls**	**Cost-Effectiveness indicators (three E's: effectiveness, efficiency, economy)**
Stage 1a) Programming: legal base **1b) Needs assessment and definition of needs** **1c) Selection of the offers and evaluation** ***Main control objectives:*** *ensuring sound financial management (i.e. effectiveness, efficiency and economy); compliance (legality & regularity); prevention of fraud (anti-fraud strategy)*				
a) **Needs have to be well defined** (operationally and economically) and decision to procure have to be appropriate to meet the operational objectives. Poor planning or inadequate organisation of the procurement procedure could entail delays or interruptions of services leading to an underachievement of the policy objectives.	1. For operational credits in each policy area, a detailed annual or multi-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. 2. Planned external studies are listed in a register kept by Secretariat General. 3. Each call for tenders fixes either a maximum value or a price range for the contract based on a pricing methodology. 4. The timing and organisation of a procurement procedure is supervised by the Authorising Officer responsible. 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.	1. 100% of calls for tender are covered by a Commission financing decision. 2. 100% of external studies are listed in a special register at the level of the Secretariat General. 3. All calls for tender are based on a pricing methodology (depth depending on feasibility). 4-5. All public procurements in the annual work programmes are approved by Management	**Cost of control**: - Estimated staff costs for programming and planning and execution of the procurement procedures. **Benefits of control:** - Amount of rejection of unjustified purchases or services discontinued.	- Depth of price calculation using the pricing methodology (according to template) when applicable ⇨ Target: 100% in-depth where applicable - Timely launch of procurement procedures as specified in the annual work programmes ⇨ Target: 100%
b) **If the definition of**	1. To ensure a high level of expertise in	1. Tender specifications	**Cost of control**:	- Number of open calls for tenders

Public Procurement				
Main inherent risks	**Mitigating controls**	**Control coverage**	**Costs and benefits of controls**	**Cost-Effectiveness indicators (three E's: effectiveness, efficiency, economy)**
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.	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. 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. 3. The central procurement committee (CMP) reviews the tender specifications prior to publication for certain sensitive procurements on special request of the policy Unit. 4. The tender specifications are validated by the Authorising Officer responsible who launches the publication of the tender in pre-defined means.	are drafted in the Units concerned with central support on request (depth of the support depending on needs) 2. 100% where applicable 3. Central ex-ante review of tender specifications on special request 4. 100% validation by Authorising Officer	- Estimated staff costs for drafting tender specifications **Benefits of control:** - Value of a contract, possibly at 100% if significant errors occurred - Benefit of "best value for money" is non-quantifiable as quality aspect is impossible to quantify in an objective, meaningful and reliable way.	for which no offer is received (reasons to be analysed) ⇨ Target: 0% - Number of cancellations of open tender procedures (reasons to be analysed) ⇨ Target: 0% --Timeliness of procurement procedures relative to Commission Work Programmes
c) The most economically	1. The central procurement team in the horizontal Directorate organises the	1. 100% of tender procedures are	**Cost of control**: - Estimated staff costs	- Number of valid complaints, Ombudsman cases or litigations

Public Procurement				
Main inherent risks	**Mitigating controls**	**Control coverage**	**Costs and benefits of controls**	**Cost-Effectiveness indicators (three E's: effectiveness, efficiency, economy)**
advantageous offer should be selected and the **evaluation process** should be **unbiased, fair and without error.** If procedures are not correctly followed, DG SANTE could be facing possible litigation and /or reputational damage.	opening and evaluation procedures, sees to their correct implementation and documentation; members of committees are appointed by the Authorising Officer responsible. 2. Persons involved in the formal procedures sign declarations of absence of conflict of interest. 3. Bidders are checked against exclusion and selection criteria published with the tender specifications. 4. The central procurement committee examines open call tender procedures > €139.000 (in 2021) and gives an independent opinion to the Authorising Officer responsible. 5. The Authorising Officer responsible validates the evaluation results and takes the award decision. 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.	documented; for 100% of tender procedures > €60.000 committees are formally appointed 2. 100% of evaluators 3. 100% of bidders checked 4. For 100% of open call tender procedures above the threshold the CMP gives an opinion 5. 100% validated 6. 100% when conditions are fulfilled	in the evaluation process **Benefits of control:** - Value of a contract, possibly at 100% if significant errors occurred - Benefit of "best value for money" is non-quantifiable as quality aspect is impossible to quantify in an objective, meaningful and reliable way.	received ⇨ Target: 0% - Number of cancellations of open tender procedures due to errors in evaluation process ⇨ Target: 0%

Public Procurement				
Main inherent risks	**Mitigating controls**	**Control coverage**	**Costs and benefits of controls**	**Cost-Effectiveness indicators (three E's: effectiveness, efficiency, economy)**
Stage 2: Monitoring of the implementation of the contract and financial transactions ***Main control objectives**: 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 & efficiency); ensuring that the related financial operations comply with regulatory and contractual provisions (legality & regularity); prevention of fraud (anti-fraud strategy); ensuring appropriate accounting of the operations (reliability of reporting, safeguarding of assets and information)*				
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.	1. The contract provisions follow the model contract of the Commission. 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). 3. Technical implementation reports are assessed and validated prior to initiating payments. 4. DG SANTE makes use of contractual provisions for refusing technical reports, cutting payments, termination of the contract, penalties etc. 5. Financial checks prior to payment are carried out according to DG SANTE's financial circuits with financial verifications, authorisations and encodings in ABAC. 6. If deemed necessary, the file is referred to OLAF (DG SANTE's SOPs on handling allegations and contacts with OLAF).	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); 5. 100% if conditions are fulfilled	**Cost of control**: - Estimated staff costs for monitoring and financial transactions - Mission costs for monitoring activities **Benefits of control:** - Estimated value of the financial corrections made during ex-ante controls of the final payment - Benefit of "best value for money" is non-quantifiable as quality aspect is impossible to quantify in an objective, meaningful and reliable way.	- Time-to-pay (target: maximum 30 or 60 days as applicable) ⇨ Target: 100% on time - Rate of late interest or damage payments to total value of all procurement contracts ⇨ Target: 0%

Public Procurement				
Main inherent risks	**Mitigating controls**	**Control coverage**	**Costs and benefits of controls**	**Cost-Effectiveness indicators (three E's: effectiveness, efficiency, economy)**
Stage 3: Supervisory measures ***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 & 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)*				
In some cases ex-ante controls at the desk might fail to prevent, detect and correct errors in procurement procedures or attempted fraud; **other internal controls** should be designed to prevent, detect or mitigate negative effects.	1. DG SANTE's financial audit strategy includes procurement contacts only in exceptional cases (e.g. exceptionally high amounts or other high risks); the audit work programme foresees anti-fraud measures. 2. Follow-up on audit recommendations linked to procurement (Court of Auditors and IAS) 3. Exceptions and internal control weaknesses are reported and analysed. 4. The management of sensitive functions is centralised to ensure independent analysis and judgment. 5. If deemed necessary, the file is referred to OLAF (DG SANTE's SOPs on handling allegations and contacts with OLAF).	1. Risk based audit sample (no minimum audit coverage foreseen as only on exceptional basis) 2. 100% of accepted recommendations implemented within the deadlines 3. 100% of financial procedures 4. High risk operations 5. 100% if conditions are fulfilled	**Cost of control**: - Estimated staff costs for ex-post controls, internal audits and other supervisory controls - Estimated mission costs for audits or other controls - Cost of external audit services **Benefits of control:** - Value of the financial corrections made during ex-post audits or controls	- Detected error rate ⇨ Target: decreasing trend - Ratio of accepted audit recommendations (Court of Auditors and IAS) implemented on time ⇨ Target: 100% Ratio of corrected control weaknesses to total detected weaknesses in procurement procedures ⇨ Target: 100% --Average cost per audit to average amount of audit correction ⇨ Target: > 100%

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 executive agencies 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 delegated budget implementation tasks to HaDEA

In 2021, DG SANTE managed financial operations under the following two policy areas: Public Health and Food Safety.

- About 80% of the EU4Health Programme budget for 2021 was transferred to the Health and Digital Executive Agency (HaDEA).
- About 74% of the Food chain strand of the SMP budget for 2021 was delegated to HaDEA.

DG SANTE paid subsidies to finance – partially or in full – the operating budgets of the executive agencies, CHAFEA (until its closure on 31 March 2021) and HaDEA (from 1 April 2021); the other parent DGs also pay their parts. In 2021, DG SANTE was the lead parent DG for both agencies.

The Directors of executive agencies implement the agency's operating budget as authorising officers according to the standard financial regulation applicable to executive agencies. This means that the Directors are accountable for the regularity and legality of this expenditure and are themselves subject to the discharge decision of the Parliament. HaDEA's Act of Delegation[14] 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. It 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 HaDEA encompasses both the delegated EU funds and the subsidy payments to the executive agency's operating budget as the same internal control system applies for both transactions.

[14] C(2021)948 of 12 February 2021 – Commission Decision on delegating powers to HaDEA

Budget implementation tasks delegated to executive agencies				
Main inherent risks	**Mitigating controls**	**Control coverage**	**Costs/benefits of controls**	**Cost-Effectiveness indicators (three E's: effectiveness, efficiency, economy)**
Stage 1. "Mandate of the entrusted entity": establishment, prolongation or adjustment of the delegation act of the executive agency ***Main control objectives:*** *ensuring that the legal framework for the management of the relevant funds is fully compliant and regular (legality & regularity), delegated to an appropriate entity (best value for public money, economy, efficiency), without any conflicts of interests (anti-fraud strategy)*				
The **establishment (or prolongation) of the mandate of the executive agency** 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.	The legal framework ("statute") for executive agencies is laid down by Council Regulation (EC) 58/2003. HaDEA was established by Commission Implementing Decision (EU) 2021/173 of 12 February 2021. 1. A cost-benefit study was carried out by Commission services prior to HaDEA's establishment; 2. The Member State Committee for executive agencies approved the Commission's proposals for establishing the agency; 3. DG SANTE follows the Commission's models for the decisions on establishment and task delegation to the agency; 4. DG SANTE manages the interservice consultations and publications of the Commission Decisions.	**100% in-depth** controls at each stage on DG SANTE's and DG BUDG's side **Frequency:** - Once in 2021 when the agency was established - Each time when the mandate of the agency is prolonged	**Cost of control**: 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 **Benefits of control:** The total budget amount delegated to the agency per year possibly at 100% if significant legal errors occurred	Number of legal issues a/o negative opinions during the interservice consultation ⇨ Target: 0 - Quality of the legal work not challenged by auditors or OLAF ⇨ Target: 0 - Timely adoption of all necessary legal acts for the establishment and future extensions of the agency's mandate

Budget implementation tasks delegated to executive agencies				
Main inherent risks	**Mitigating controls**	**Control coverage**	**Costs/benefits of controls**	**Cost-Effectiveness indicators (three E's: effectiveness, efficiency, economy)**
Stage 2. Readiness assessment of the executive agency's control framework towards autonomy ***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*				
The **financial and control framework deployed by the executive agency** should be fully mature to guarantee that the control objectives are met.	1. DG SANTE will carry out an ex-ante assessment of the agency's internal control system prior to granting full budget autonomy (planned for 2022). This exercise will be repeated for subsequent prolongations and amendments of the agency's mandate if this entails substantial change to the agency's control systems; 2. According to HaDEA's Act of Delegation (C(2021)948 of 12 February 2021), 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.	1. **100% in-depth** control once when the agency was set up 2. Each request for substantial change is examined in-depth **Frequency:** - Once in 2022 when the agency is expected to gain autonomy	**Cost of control:** Estimated staff costs for ex-ante assessment when agency is established **Benefits of control:** The total budget amount delegated to the agency per year possibly at 100% if significant legal errors occurred	Granting budget autonomy without significant delay ⇨ Target: Not applicable in 2021 (agency did not gain full autonomy in 2021) - Time between establishment of the agency and granting of autonomy ⇨ Target: 100% on time according to internal planning

Budget implementation tasks delegated to executive agencies				
Main inherent risks	**Mitigating controls**	**Control coverage**	**Costs/benefits of controls**	**Cost-Effectiveness indicators (three E's: effectiveness, efficiency, economy)**
Stage 3: Operations: DG SANTE's monitoring and supervision ("control *with* the executive agency") ***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*				
DG SANTE should be informed timely of **relevant management issues encountered by the executive agency**; DG SANTE should react upon notified issues timely and adequately. If not, this could reflect negatively on the Commission's reputation.	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. 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. 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; 2. A general Memorandum of Understanding (MoU) for the day-to-day co-ordination between the parent DGs and the agency was signed in December 2021; the MoU will be complemented by specific guidelines for SANTE delegated tasks (not yet finalised in 2021). 3. The Steering Committee, chaired by DG SANTE, meets at least four times a year and adopts (i) the agency's annual work programme, after approval by the Commission, and (ii) the draft	**Coverage**: 100% of the tasks delegated to the agency monitored and supervised **Depth** of control: risk based; DG SANTE has full access to the agency's internal control information, if need be **Frequency**: quarterly, annually and in day-to-day contacts as deemed necessary	**Cost of control**: - Estimated SANTE staff costs for monitoring and supervising the agency's activities - Mission costs for monitoring activities **Benefits of control:** The total budget amount delegated to the agency per year possibly at 100% if significant legal errors occurred	--Regular programme meetings between the agency and DG SANTE at operational level ⇨ Target: to be defined per delegated programme - Steering Committee meetings with adequate quorum for voting ⇨ Target: 4 times a year - 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 - Budget execution rates of the operational budget transferred to the agency and absorption rate of global commitments ⇨ Target: 99% commitments and absorption of global commitments ⇨ Target: 100% for payments - Director's mid-term report on control results and error rates endorsed by Steering

Budget implementation tasks delegated to executive agencies				
Main inherent risks	**Mitigating controls**	**Control coverage**	**Costs/benefits of controls**	**Cost-Effectiveness indicators (three E's: effectiveness, efficiency, economy)**
	administrative budget, including the establishment plan, after adoption of the general EU budget by the budgetary authority; 4. The agency reports at mid-term to the Steering Committee on the performance of its tasks; the parent DGs give feedback to the agency within four weeks from receipt of the report; 5. DG SANTE's central financial Unit reports regularly (several times a year) on the implementation of the budget delegated to the agency; 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; 7. If deemed necessary, issues are referred to OLAF (DG SANTE's SOPs on handling allegations and contacts with OLAF).			Committee within 4 weeks ⇨ Target: qualitative analysis - 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

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 lead responsible DG for ECHA is DG GROW).

- **European Centre for Disease Prevention and Control (ECDC)** located in Stockholm, Sweden[15] (Budget 2021: total sum of human resources 337; EU funding 100%: EUR 168,1 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[16] (Budget 2021: total sum of human resources 542; EU funding 100%: EUR 129,1 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[17] (Budget 2021: total sum of human resources 916; EU funding 9,9%: EUR 37,6 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 amended 2021 budget amounted to EUR 379,2 million which is to a large extent fee-financed.

[15] 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.

[16] 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.

[17] 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[18] (Budget 2021: 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 2021 budget amounted to EUR 20 million (fully fee-financed).
- **European Chemicals Agency (ECHA)** located in Helsinki[19] - relevant for DG SANTE are ECHA's biocides activities (Budget 2021 for biocides: total sum of human resources 69 for the biocides activities; EU funding: 81%: EUR 10,4 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 2021 amounted to EUR 12,8 million.

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)**
Stage 1. "Mandate of the agency": founding regulation ***Main control objectives:*** *ensuring that the legal framework for the management of the relevant funds is fully compliant and regular (legality & regularity), that the agency spends the money as intended (best value for public money, economy, efficiency), without any conflicts of interests (anti-fraud strategy)*				
The **establishment (or amendment) of the mandate of an EU agency** 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"[20] laid down by the Interinstitutional working group on EU agencies, e.g. - An impact assessment is carried out prior to establishing an EU agency and when amending its mandate;	**100% in-depth** once in establishment phase **100% in-depth** case by case if amendment or review is planned	**Cost of control**: - 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%

[18] The CPVO was created by Council Regulation (EC) No 2100/94 of 27 July 1994; OJ L 227/1 of 01/09/1994.

[19] ECHA was set up by Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2016; OJ L 396, 30.12.2006, p. 1.

[20] http://europa.eu/about-eu/agencies/overhaul/index_en.htm

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.	- 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; 1. In case of an establishment of an agency or an amendment of its founding regulation, DG SANTE manages the interservice meetings/consultations; 2. DG SANTE also manages all subsequent procedural steps (Council, Parliament, etc.) towards the adoption of the regulation by the Council and the Parliament.	**Frequency:** When amendment or review of an agency's founding regulation is planned	- Cost for external service contract for impact assessments, etc. **Benefits:** The total annual budget amount paid as subsidy to the agency's running costs possibly at 100% if significant legal errors occurred.	
Stage 2. Assessment of the agency's control framework and financial rules ***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*				
The **financial and control framework deployed by the EU agency** should be fully mature to guarantee that the control objectives are met.	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. 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 consent; DG SANTE, in co-operation with DG BUDG	**100% in-depth** per agency as need be, e.g. if amendments are to be made **Frequency:** In 2018-2019 due to the new FFR and Internal Control Framework;	**Cost of control:** Included in general estimate of SANTE's staff costs for monitoring and supervising the agency's activities **Benefits of control:** The total subsidy paid to the agency per year possibly at	- EU agencies adopting their own control framework in compliance with the Commission's framework ⇨ Target: all agencies - EU agencies adopting their own rules of independence and conflict of interest compliant with the Commission's guidelines ⇨ Target: all agencies

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)**
	consults and monitors. All SANTE agencies have adopted in 2019 Financial Regulations which are in line with the Framework Financial Regulation.[21] 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.	Annual meeting of the DG SANTE inter-agency task force on independence	100% if significant legal errors occurred	
Stage 3: Operations: DG SANTE's monitoring and supervision ("control with the EU agency") ***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*				
DG SANTE should be informed timely of **relevant management issues encountered by the EU agency;** DG SANTE should react upon notified issues timely and adequately; if not, this could reflect negatively on the Commission's	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. 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 (ii) Directors/DDG/DG. In addition, DG SANTE regularly	**Coverage**: all of the agency's activities are monitored and supervised **Depth** of control: risk based; if need be, DG SANTE has access to the agency's internal control	**Cost of control**: - Included in the general estimate of DG SANTE's staff costs for monitoring and supervising the agency's activities; - Mission costs for monitoring activities.	- Regular meetings between the agency and DG SANTE at management and technical level ⇨ Target: to be defined with each agency - Management Board meetings with DG SANTE participation ⇨ Target: depends on the agency (about 3 to 4 times

[21] 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.

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)**
reputation.	convenes meetings bringing together all Heads of its partner agencies and DG SANTE management. 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. 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. 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. 6. After adoption by the MB, the agency publishes its annual report, final accounts and report on financial management. 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).	information **Frequency**: 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	**Benefits of control:** The total subsidy paid to the agency per year possibly at 100% if significant legal errors occurred	per year) - Relevance and reliability of control data reported by the agency ⇨ Target: qualitative analysis done for the document sent to the Management Board

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)**
Stage 4: Audit and evaluation, discharge ***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*				
DG SANTE should get sufficient **information from independent sources on the EU agency's management achievements** to draw conclusions on the assurance for the subsidies paid to the agency; if not, this might reflect negatively on the Commission's reputation.	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). 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. 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. 4. Founding regulations foresee regular external evaluations of the agencies: - EMA every 10 years (ongoing in 2019); - EFSA every 6 years (last completed 2018); - ECDC every 5 years (last completed 2019). DG SANTE participates in the Steering Committee and Technical Evaluation Committee. 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.	**Coverage**: 100% of the agency's activities audited and evaluated **Depth** of control: risk based; auditors have full access to the agency's internal control information **Frequency**: - Regularly by the IAS - Annually by the Court of Auditors - Frequency of external evaluations varies with the agencies	**Cost of control**: - Included in the general estimate of SANTE's staff costs for monitoring and supervising the agency's activities **Benefits of control:** The total amount of the subsidy paid to the agency per year possibly at 100% if significant legal errors occurred	- 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 - Court of Auditors' assurance on the accounts and operating budget ⇨ Target: positive assurance ⇨ Target: all recommendations implemented - Discharge authorities grant discharge to the agency ⇨ Target: discharge granted ⇨ Target: all recommendations of the discharge authorities implemented - External evaluation concluding positively on the agency's activities

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)**
Stage 5: DG SANTE's payments of the subsidy ***Main control objectives**: 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 & regularity, sound financial management, anti-fraud strategy)*				
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.	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: - An instalment is paid in year N on request of the agency based on a cash forecast; - Prior to the subsidy payment, financial checks are carried out according to DG SANTE's financial circuits with financial verifications, authorisations and encodings in ABAC; 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); 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.	**Coverage**: 100% of DG SANTE's subsidy payments through the established financial circuits **Depth** of control: risk based **Frequency**: Administrative budget of the agency annually audited by the Court of Auditors	**Cost of control**: - Estimated staff costs for budget and finance in central financial Unit; **Benefits of control:** The total subsidy paid to the agency per year possibly at 100% if significant legal errors occurred.	- 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 - Ratio of recovery of the positive budgetary outturn of year N plus interest earned on subsidy paid in year N-1 - Files with relevance for OLAF adequately transmitted to OLAF and followed up ⇨ Target: 100% - Time-to-pay (target: maximum 30 days) ⇨ Target: 100% on time

ANNEX 7: Specific annexes related to "Financial Management"

7.1 Effectiveness of controls

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 and third countries for 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. Applicable as from 1 January 2021, the SMP[22] – Food Chain strand is the main basis for the corresponding expenditure. The SMP does not affect the continuation or modification of actions initiated under the previous legislation[23].

Table 7.1 Food and Feed Safety Grants

Commitment credits implemented by DG SANTE *(without HaDEA)*[24]	**2021 M€**	**2020 M€**	**2019 M€**
Animal disease eradication programmes (grants to Member States)	n/a*	117,2	130,6
Phytosanitary survey programmes (grants to Member States)	n/a*	12,7	32,4
Other veterinary, plant health and food safety expenditure (grants to Member States, EURL, etc.)	n/a*	3,1	19,0
Veterinary emergency fund (grants to Member States)	23,0	56,9	58,6
Phytosanitary emergency measures (grants to Member States)	3,0	0,4	5,2
Grants to international organisations	4,1	4,1	5,7
Total grants	**30,1**	**194,4**	**251,5**

n/a*: the relevant 2021 commitment credits were transferred to HaDEA

Following the transfer of budget implementation tasks to the Health and Digital Executive Agency (HaDEA) in 2021 (see annex 7.1.1.3 below), the grant management of the animal and plant disease eradication programmes of the Member States, the grants for European

[22] Regulation (EU) 2021/690 of the European Parliament and of the Council of 28 April 2021 on the Single Market Programme (SMP) and repealing – inter alia - Regulation (EU) No 652/2014 the Common Financial Framework (CFF); 2021 work programme C(2021)3046 of 6 May 2021

[23] Regulation (EU) No 652/2014 of the European Parliament and of the Council of 15 May 2014

[24] Without credits co-delegated to other DGs.

Reference Laboratories and Centres (EURL and EURC) and the grants for Member States' control plans monitoring antimicrobial resistance (AMR) are implemented by the agency.

DG SANTE still manages the grant agreements with Member States and third countries for their veterinary and plant emergency measures and grants to international organisations.

- A total of 11 applications of Member States for cost reimbursements in relation to veterinary emergency measures were handled to combat, first and foremost, African Swine Fever (EUR 10,5 million) and Avian Influenza (EUR 4,7 million). Furthermore, ten grant agreements were signed with third countries for their fight against African Swine Fever (6 files) and Lumpy Skin Disease (4 files) [25]. An additional amount of EUR 7,8 million was earmarked for ongoing animal health emergency notifications.
- Addressing the combat of organisms harmful to plants, three Member States submitted applications for emergency measures for a total amount of EUR 1,7 million. In addition, EUR 1,3 million were earmarked for ongoing files.
- In 2021, DG SANTE supported international organisations such as the OIE (World Organisation for Animal Health) for its global conferences, regional seminars, meetings, workshops and activities on animal health, animal welfare and veterinary public health, and FAO (Food and Agriculture Organisation) for the control of the Foot-and-Mouth Disease. DG SANTE also contributed to the UPOV (International Union for the Protection of New Varieties of Plants) and supported the European Food Banks Federation's capacity building.

The control process of DG SANTE's grant management pertaining to the Member States' veterinary and phytosanitary programmes is divided into four distinct stages, each with specific control objectives. The description focuses on the veterinary and phytosanitary emergency measures as they account for more than 80% of the grants in the Food and Feed policy area (see table 7.1 above).

Stage 1: Legal base and Member States' submission of applications

The SMP-Food Chain strand sets out that grants may be awarded to Member States and third countries in case of emergency measures taken as a result of a confirmed occurrence of a number of listed diseases in accordance with Regulation (EU) 2016/429 for animal diseases and Regulation (EU) 2016/2031 for plant pests. Member States provide DG SANTE with preliminary information on the ongoing and planned actions, on the estimated total eligible costs (as defined in the SMP, annex I) and on the expected completion date of the emergency measures.

At the first stage, key controls are mostly directive and preventive: application guidelines for the Member States; assessment of the technical quality and financial analysis of the application and its regular updates.

[25] The budgetary commitments of EUR 1,5 million were made on a global commitment under the 2020 budget.

The award criteria for the financial contribution are fixed in the SMP (a) compliance with the requirements of the relevant Union law; (b) relevance of the planned activities in view of the prevention or eradication of the animal diseases and plant pests; (c) activities related to prevention or eradication of plant pests during the first year after the detection of the outbreak.

Due to the late adoption of the new Multiannual Financial Framework (2021-2027) in December 2020 and the Single Market Programme (2021-2027) in April 2021, the 2021-2022 work programme for the Food Chain strand could be adopted only on 6 May 2021. Guidelines for Member States' applications and the grant agreements[26] still have to be adjusted to the new legal base. In November 2021, DG SANTE sent letters to the Chief Veterinary Officers (CVOs) and Chief Officers of Plant Health Services (COPHS) to explain the situation and inform that applications for emergency funding could be sent in early 2022. The SMP, Article 3.5, provides for the retroactive eligibility of activities and costs from 1 January 2021.

Stage 2: Approving the emergency measure and signing the grant agreement

The emergency measures for which DG SANTE awarded funding to Member States in 2021 were still based on the previous legislation[27] under which DG SANTE signed grant decisions. No budgetary commitment was done at this stage as by way of derogation from Article 111(2) of the Financial Regulation, the Commission makes the budgetary commitment for the grant awarded for veterinary and phytosanitary emergency measures after the payment applications submitted by Member States have been assessed[28].

When preparing the grant decisions, DG SANTE paid special attention to the following provisions:

- Emergency measures are eligible prior to the date of submission of the grant application in accordance with Article 193(2), second subparagraph, point (b) of the Financial Regulation[29];
- Emergency measures are eligible from the date of the suspected occurrence of an animal disease or the presence of a plant pest, provided that this occurrence or presence is subsequently confirmed.

Stage 3: Managing financial transactions and ex-ante controls

DG SANTE's assessment of the final payment applications of the Member States followed the internal control strategy for emergency files. Standard checks and in-depth controls were carried out based 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

[26] The IAS made an audit recommendation to improve the grant agreement provisions and the unit cost methodology. Actions are on-going with deadlines in mid-2022 (see Annex 8.1.2 below).

[27] Regulation (EU) No 652/2014 of the European Parliament and of the Council of 15 May 2014

[28] SMP Art. 3(5) as in previous legislation

[29] SMP Art. 13(1) as in previous legislation

ensured by the horizontal financial Unit: 2nd level control)[30]. The aim was to detect and correct errors before authorisation of a financial operation.

In addition, a risk based sample of payment applications was subject to an ex-ante financial control in the form of an audit in the Member State. Due to the COVID-19 pandemic, the audits took place remotely. The following files were selected: veterinary emergency fund and plant health emergency measures for which the request for funding exceeded EUR 2 million, other exceptionally high amounts or other high risks.

In 2021, the audit plan had to account again for the specific situation arising from the Avian Influenza and African Swine Fever crises. The audit results show an average correction rate of around 19% which is comparable to previous years; all corrections were done prior to the final payment. 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 Indicators for grants for emergency measures at control stage 3

Indicators	***Targets***	**2021**	**2020**	**2019**
Stage 3: Monitoring and financial management				
Member States' applications received and analysed	*100%* *100%*	**100%** **100%**	100% 100%	100% 100%
Number of registered **"exception reports"**	*n/a*	**0**	1	3
Instances of Article 93 FR[31]	*n/a*	**0**	0	0
Desk ex-ante 2nd-level verification: rejection rate % of amounts corrected	*< 2% in value*	**0,0%**	0,0%	0,1%
Late interest payments relative to total value of grants (in 2021 and 2020: no case; in 2019: 1 case of €443,58)	*0%*	**0,0%**	0,0%	0,0%
Ex-ante controls in the form of financial audits (on-the-spot or remote): **correction rate** *(average of all corrections)* - Veterinary emergency fund - Phytosanitary emergency fund	*n/a*	 **23,5%** **5,5%**	 17,0% -	 13,0% -

No "exception report" was submitted in 2021 pertaining to veterinary and phytosanitary emergency measures. 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.

[30] The selection of operations for the second-level verification was supported by the IT application "MUS-DICE", based on a risk analysis with a set of risk criteria.

[31] Article 93 of the FR(2018) on the financial irregularities panel

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 January 2021, the Directors' Steering Committee of DG SANTE endorsed the 2021 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 and sufficient audit coverage to lower the residual error rate. The 2021 audit plan included five ex-ante audits on emergency files and 13 ex-post audits on payments to other grants in the policy area of Food and Feed Safety.

Due to closed borders and the sanitary containment in general, the on-the–spot audits had to be replaced by remote audits.

In 2021, a total of 15 ex-post audits were completed. This corresponds to the average number of ex-post audits finalised in previous years.

The errors detected during the ex-post controls finalised in 2021 resulted in an average error rate of 0,5% (EUR 0,1 million) for the audited national programmes for animal disease eradication and monitoring mainly of the years 2017 to 2018 and European Reference Laboratories of the years 2019-2020. The situation in the files giving rise to corrections were common to a number of audited cost claims, and were due mainly to the inclusion of ineligible costs.

Ex-post control in the Food and Feed policy area	**2021**	**2020**	**2019**	**2018**	**2017**	**2016**	**2015**
Residual error rate	**0,5%**	0,8%	0,4%	1,9%	2,5% (1%)	1,1%	1,2%
Reservation	**No**	No	No	No	No	No	No

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). For one recommendation actions are still on-going to reach full effectiveness: the Animal Disease Information System (ADIS) was launched on 21 April 2021 replacing the

previous system and using the new legal basis recently adopted by the Commission[32]. The actual exchange of data between ADIS and OIE-WAHIS[33] will be further extended in 2022.

Table 7.3 Indicators for grants at control stage 4

Indicators	*Target*	2021	2020	2019
Stage 4: Ex-post controls				
Ex-post control **detected error rate** (ABB activity: Food and Feed Safety)	*n/a*	0,5%	0,9%	0,5%
Ex-post control **residual error rate** (policy area Food and Feed) (Without one exceptional file)	***< 2,0%***	0,5%	0,8%	0,4%
Amount of net financial corrections identified in year N compared with amount of transactions audited	*n/a*	0,1 M€ 21,5 M€	0,2 M€ 26,3 M€	0,2 M€ 34,2 M€
Financial corrections in year N linked to audits finalised in year N (until 31/12/year N)	*n/a*	0,0 M€ 0,0%	0,0 M€ 0%	0,0 M€ 0%
Total financial correction of detected errors by 24/03/2022	*100%*	0,0 M€ 0,0%	0,2 M€ 100%	0,2 M€ 100%

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 2021 residual error rate amounts to 0,5% in the policy area "Food and Feed Safety" as a whole. Thus, it does not exceed the materiality threshold of 2%. 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..

Against this background, DG SANTE does not consider it appropriate to make a reservation in the Director-General's 2021 declaration of assurance. To reduce the error rate, in the past few years, DG SANTE had taken a series of mitigating actions. To note that in 2021, DG SANTE delegated large parts of the implementation of the SMP-Food Chain strand to the executive agency HaDEA. Thus, future control results, including ex-post controls, of the grants for veterinary and plant health programmes and other grants transferred to HaDEA will be reported by the agency.

[32] Commission Implementing Regulation (EU) 2020/2002

[33] 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).

The benefits of the controls are mostly unquantifiable in monetary terms. The assessment of Member States' emergency measures helps ensure the measures and their funding 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. The same can be said for DG SANTE's financial audits in the Member States: 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. 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 DG SANTE's audit reports.

7.1.1.2 Procurement and ESI

The following paragraphs describe the provisions for the management of public procurement in the policy areas Food and Feed Safety[34] and Public Health[35] and the Emergency Support Instrument (ESI)[36] to fight the COVID-19 pandemic.

As in previous years, about 80% of the 2021 budget of the Health Programme were implemented by an executive agency (by CHAFEA until its closure on 31 March 2021, and from 1 April 2021 by the newly created Health and Digital Executive Agency – HaDEA. Around 20% was implemented by DG SANTE mostly using public procurement procedures.

Since the activation of the Emergency Support Instrument (ESI) in mid-April 2020, DG SANTE launched several public procurement procedures, first and foremost for Advance Purchase Agreements (APA) for vaccines against COVID-19. Having concluded six APAs in 2020[37], the Commissioner signed a seventh and an eighth APA in the second half of 2021[38]. The Commission negotiated the APAs jointly with the Member States in conformity with the requirements of the Financial Regulation. The pre-financing payments made in 2020 were cleared based on deliveries of vaccine doses made to the Member States; in 2021, first partial clearings of a total of EUR 1 231 million were made.

The grants awarded in 2021 under the ESI are not included in the description of the control processes below (or in part 7.1.1.1 above) as they were lump-sum grants to Member States to support the accessibility of tests for the delivery of the EU digital COVID-19 certificates for a total of EUR 95 million. As the ESI expired on 31 January 2022, this kind of grant will most likely not be repeated.

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[34] Regulation (EU) 2021/690 of 28 April 2021 – SMP; C(2021)3046 of 6 May 2021 – work programme 2021-2022 for the food chain strand of the SMP

[35] Regulation (EU)2021/522 of 24 March 2021 – EU4Health Programme; C(2021) 4349 of 18 June 2021 – 2021 work programme of EU4Health.Programme Statements June 2021

[36] Emergency support under Regulation (EU) 2016/369 - In mid-April 2020, the Council activated the Emergency Support Instrument (ESI) for the period 1 February 2020 to 31 January 2022.

[37] AstraZeneca, Sanofi-GSK, Janssen Pharmaceutica NV, BioNtech-Pfizer, CureVac, Moderna

[38] Novavax and Valneva

Table 7.4 Procurement DG SANTE, including ESI

Commitment credits implemented by DG SANTE *(without HaDEA)*[39]	**2021 M€**	**2020 M€**	**2019 M€**
Food and Feed Safety: DG SANTE procurement expenditure	**31,5**	33,3	18,9
Health Programmes implemented directly by DG SANTE	**64,5**	25,3	12,9
Emergency Support Instrument (ESI) procurement	**69,7**	2 696,1	-
Procurement other policy areas (operational credits mainly)	**5,0**	4,1	4,6
Building expenditure Ireland and other administrative credits	**5,0**	4,9	5,0
Total budget implemented	**175,7**	**2 763,7**	**41,4**

Joint procurement

Joint Procurements are not included in the table above as they involve only very limited amounts of the EU budget for which DG SANTE was not authorising officer by delegation in 2021. Since the outbreak of the COVID-19 pandemic in March 2020, DG SANTE has reinforced its work on joint procurement considerably. Already in 2014, a voluntary cooperation was established[40] enabling participating Member States to 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 negotiated seven framework contracts in 2020 for the supply of a range of medical countermeasures to fight the COVID-19 pandemic, five additional procedures were finalised in 2021. Together they cover, for example, personal protective equipment for healthcare workers, medical equipment to support the breathing of patients, laboratory testing and support equipment, pharmaceuticals, and medical equipment for COVID-19 vaccination, rapid antigen tests and COVID-19 therapeutics. 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.

With the establishment of the European Health Emergency preparedness and Response Authority (HERA), all Joint Procurement files were handed over to HERA from 1 January 2022.

[39] Without credits co-delegated to other DGs or transferred to HaDEA.

[40] 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

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 2021, 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 calls above the Directive threshold (currently EUR 139.000) through the e-tendering platform of the Commission. DG SANTE also uses e-submission as unique tool for the open calls and e-ordering for the automatic generation of the procurement contract.

Table 7.5 Procurement contracts above EUR 60.000[41]

Type of procedure	2021		2020		2019	
	N° of contracts	Amount M€	*N° of contracts*	Amount M€	*N° of contracts*	Amount M€
Open (Financial Regulation)	***3***	**21,4**	*3*	1,8	*3*	6,8
Negotiated under extreme urgency	***2***	**70,0**	*8*	2 576,6	-	-
Negotiated without prior publication [Annex 1 - 11.1 (b)]	***3***	**7,3**	*3*	9,9	*3*	0,7
Negotiated without prior publication [Annex 1 - 11.1 (i)]	***1***	**0,3**	-	-	-	-
Negotiated middle value contract	***1***	**0,1**	*1*	0,1	*4*	0,4
Restricted	***2***	**0,2**	*1*	1,7	*3*	2,2
TOTAL	***12***	**99,3**	*16*	2 590,1	*13*	10,1

[41] Annex 3 table 12

Main open, negotiated and restricted procedures

In the health policy area, due to the COVID-19 pandemic, two negotiated procedures under extreme urgency were managed under the Emergency Support Instrument for one Advance Purchase Agreement for vaccines (EUR 69,8 million) and for the supply of antigen tests for diagnostic of COVID-19 (EUR 0,2 million); three other negotiated procedures without prior publication were finalised for a clinical patient management IT system to support the European Reference Networks (EUR 7,0 million), trainings for Member States system in relation to tobacco traceability and a subscription contract for a data base.

Through open calls for tender, DG SANTE procured services for two pilot projects, one on best practices for alternative egg production systems (EUR 0,7 million) and one on the welfare of dairy cattle (EUR 0,7 million). Furthermore, an open call led to the signature of a framework contract for services for evaluation studies, impact assessments and other related support in the policy areas Health and Food Safety (EUR 20 million).

To procure services from 2021 to 2024 related to DG SANTE's site management in Grange, Ireland, DG SANTE used two restricted procedures to firstly secure the provision of audit and inspection services (EUR 0,1 million) and secondly for the electrical infrastructure of the Grange site (EUR 0,1 million). A middle value contract was signed for the provision of air handling units for the office building in Grange (EUR 0,1 million).

In 2021, 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 2021, negotiated procedures were used in almost 60% of the limited number of cases included in table 7.5 above (7 out of 12); in 2020, it was applied in 70% of the cases. Expressed in amounts, in 2021, almost 80% of the total contract value was awarded through the negotiated procedure (in 2020, 99% and in 2019, 7%). The main reason for using negotiated procedures in 2021 and in 2020 was the purchase of medical countermeasures and vaccines to fight the COVID-19 pandemic. Another reason is that DG SANTE often needs services in specialised fields with only one or two suitable providers.

Public Procurement Committee (PPC)

Procurement procedures (open calls for tender and negotiated procedures) for contracts above the Directive threshold (EUR 139.000 in 2021) 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 2021, this voluntary additional check was applied for two files.

Table 7.6.1 Indicators for procurement (central procurement team) at stage 1

Indicators	*Targets*	2021	2020	2019
Stage 1: Assessing procurement needs and selecting the offer				
Rate of open calls for tenders for which - No offer was received (in 2021: 0 out of 4; in 2020: 0 out of 2; in 2019: 1 out of 6) - The procedure had to be cancelled (in 2021: 1; in 2020: 0; in 2019: 1)	*0%* *0%*	0% 25%	0% 0%	17% 17%
Rate of negotiated procedures[42] for which - No offer was received - The procedure had to be cancelled	*0%* *0%*	**33%** **50%**	5% 5%	0,0% 8%
Number of procurement procedures within the scope of the PPC	*n/a*	**9**	22	9
Number of procurement procedures examined by the PPC	*n/a*	**7**	5	9
% of procurement procedures examined by PPC	*100%*	**78%**	23%	100%
Ratio of positive opinions of the Public Procurement Committee	*n/a*	**90%** (1 suspended)	100%	90% (1 negative)
Public Procurement Committee opinions followed by the authorising officers responsible	*100%*	**100%**	100%	100%

One open call for tenders related to a pilot project had to be cancelled due to an administrative error in the published contract notice. The call was re-launched and awarded later during the year.

With regard to negotiated procedures, two out of six procedures were unsuccessful as no offers were received. This was mainly due to a lack of the required expertise, and the procedures were cancelled. One additional procedure had to be cancelled because the tender received was not covering all the sections of the assignment due to a lack of expertise.

In 2021, the Public Procurement Committee (PPC) provided eight opinions on procurement contracts with a total maximum value EUR 29,3 million. One opinion had to be suspended as the file was incomplete; having received additional clarifications, the PPC gave a positive opinion.

The PPC examined only 78% of the files that fell under its remit. Due to extreme urgency to conclude procurement contracts for the supply of medical countermeasures under one Joint Procurement and one Advance Purchase Agreement to secure vaccines against COVID-19, 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.

[42] 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 7.6.2 Indicators for procurement at stage 2

Indicators	*Targets*	2020	2019	2019
Stage 2: Monitoring of contract implementation and financial management				
Ex-ante rejection rate of 2nd-level verifications: no cases of financial errors	*< 2% in value*	**0,0%**	0,0%	0,0%
Late interest payments relative to total value of contracts (in 2021: one case €4.453; in 2020: no case; in 2019: 2 cases of €496,50)	*0%*	**0,0%**	0,0%	0,0%

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 2021, 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 7.6.3 Indicators for procurement at stage 3

Indicators	*Targets*	2021	2020	2019
Stage 3: Supervisory measures				
Number of registered **"exception reports"** relative to procurement procedures	*n/a*	**12**	23	3
Instances of Article 93 FR[43]	*n/a*	**0**	0	0
Ex-post control in the form of financial audits (on-the-spot or remote): detected error rate in a procurement contract	*< 2%*	**n/a**	n/a	n/a
Recovery orders of year N: (in number) in amount	*n/a*	**(2)** **0,002M€**	(0) n/a	(1) 0,5 M€
For procurement: **Ombudsman** cases or legal proceedings opened in year N	*n/a*	**2**	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 12 "exception reports" of 2021 mainly pertain to derogations from the Financial Regulation when DG SANTE launched procurement procedures prior to the adoption of the 2021 work programmes pertaining to EU4Health and the SMP (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 they were discussed at DG level and in consultation with horizontal services in the Commission.

Two Ombudsman cases are relevant for DG SANTE’s procurement procedures: in one case, the Ombudsman concluded that the Commission’s refusal to give public access to documents constituted maladministration and recommended that the Commission should reconsider its position with a view to granting significantly increased, if not full, access to the documents concerning the quality of medical masks distributed during the COVID-19 pandemic in mid-2020. Another case was closed finding no maladministration, but issuing an opinion on which kind of information could be published in relation to the team responsible for negotiating ‘advanced purchase agreements’ with pharmaceutical companies. These cases do not point to control weaknesses in DG SANTE’s access to documents handling, as they were related to highly sensitive areas where special care had to be taken to protect personal data, safeguard confidential commercial information, and prevent leaks.

[43] Article 93 of the FR(2018) on the financial irregularities panel

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 in public procurement procedures 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 cross-sub-delegations to other DGs and by the executive agency HaDEA. In addition, DG SANTE finances, partially or in full, the operating budgets of HaDEA 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).

Cross-delegations to other Authorising Officers by Delegation (AOD)

In 2021, DG SANTE cross-subdelegated EUR 119,2 million of commitment credits from the Emergency Support Instrument to DG INTPA to finance an important part of the provision and delivery of 200 million COVID-19 vaccine doses and their auxiliary material (e.g. syringes) by mid-2022. No payment credits were cross-subdelegated in 2021.

Being a Commission service itself, DG INTPA is required to implement the appropriations subject to the same rules, responsibilities and accountability arrangements as DG SANTE. The cross-subdelegation agreements signed with the DG require the authorising officer responsible to report on the use made of the delegated appropriations. In the reports sent to DG SANTE for 2021, the authorising officer of DG INTPA did not communicate any events, control results or issues which could have a material impact on assurance.

Executive Agencies

CHAFEA closed on 31 March 2021

Until 31 March 2021, the Consumers, Health, Agriculture and Food Executive Agency (CHAFEA) implemented parts of the Health Programmes and the Better Training for Safer Food measures (BTSF). DG SANTE, like the other parent DGs AGRI, GROW and JUST, paid a subsidy to CHAFEA to cover its running costs for the implementation of the tasks transferred to it.

Table 7.7 Subsidies paid by DG SANTE to CHAFEA

CHAFEA (former EAHC)	**2021** **M€**	**2020** **M€**	**2019** **M€**
Subsidy for administrative budget (SANTE share)	1,9	**5,9**	5,9
Operational budget transferred from SANTE	n/a*	**59,5**	65,6

Ad *: the budget was transferred to HaDEA (see below)

In the framework of the new Multi-annual Financial Framework (MFF 2021-2027), the Commission adopted the Commission Implementing Decision (EU) 2021/173[44]. Accordingly, the DG SANTE programmes managed by CHAFEA were transferred to the newly established European Health and Digital Executive Agency (HaDEA) as from 1 April 2021. CHAFEA was closed on 31 March 2021 and the liquidation phase is on-going to wind it up[45]. The Court of Auditors started to audit CHAFEA's accounts and transactions from January to March 2021 and will include the results in its annual report to be published in the fourth quarter of 2022. It is worth noting that since the founding of the agency, in its annual audits, the Court of Auditors has given a positive declaration of assurance to CHAFEA.

Health and Digital Executive Agency (HaDEA)

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 the agency and readiness assessment of its control framework towards autonomy

The European Health and Digital Executive Agency (HaDEA) was established from 16 February 2021 until 31 December 2028[46]. It is entrusted with the implementation of the following (parts of) Union programmes:

[44] 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.

[45] Article 3(2) of Council Regulation (EC) No 58/2003 of 19 December 2002 laying down the statute for executive agencies

[46] Commission Implementing Decision (EU) 2021/173 of 12 February 2021

Table 7.8: Union programmes delegated to HaDEA

Parent DGs	Programme
SANTE	EU4Health programme[47]
SANTE	Single Market Programme[48]: Food chain strand
RTD, CNECT	Horizon Europe: Pillar II, Cluster 1: Health
RTD, CNECT, GROW, DEFIS	Horizon Europe: Pillar II, Cluster 4: Digital, industry and space
CNECT	Digital Europe Programme
CNECT	Connecting Europe Facility: Digital

DG SANTE pays a subsidy to HaDEA to cover its running costs (administrative or operating expenditure) for the implementation of the tasks transferred to it. The other parent DGs also pay their share of the total costs to implement the transferred tasks related to their programmes.

HaDEA 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.

The use made of the subsidy is audited – inter alia – by the European Court of Auditors.

Table 7.9 Subsidies paid by DG SANTE to HaDEA

HaDEA	2021 M€
Subsidy for administrative budget (SANTE share)	**8,4**
Operational budget transferred from SANTE	**431,5**

Since its establishment in February 2021, HaDEA has well advanced in setting up its internal control framework, but could not yet reach full autonomy in 2021 as it was still awaiting the appointment of its Director. Having been nominated by the Commission on 21 January 2022, the Director of HaDEA took up her position on 16 February 2022.

[47] Regulation (EU)2021/522 of 24 March 2021 – EU4Health Programme
[48] Regulation (EU) 2021/690 of 28 April 2021 – SMP

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

According to HaDEA's Act of delegation[49], DG SANTE is the lead parent Directorate-General and has specific responsibilities in relation with the monitoring and supervision of horizontal issues in the agency, as was already the case for CHAFEA.

DG SANTE supervises the activities of the agency and carries out supporting and steering activities, in particular through the meetings of the Steering Committee, which are chaired by DG SANTE's Deputy Director-General responsible for Health. The Steering Committee is responsible for the adoption of the agency's annual work programme and administrative budget, including the establishment plan. The agency informs the Steering Committee on the achievements of its 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 HaDEA ensure the necessary co-ordination of activities.

As a key document to govern the day-to-day interactions between the agency and its parent DGs, the Memorandum of Understanding, signed on 21 December 2021, covers general provisions and modalities regarding mainly IT governance, supervision, HR, planning, reporting and evaluation. Work is ongoing to complement the general provisions by specific Memoranda of Understanding for the implementation of the programmes delegated to HaDEA.

DG SANTE follows up on the agency's consumption of both the administrative and the operational budget. In 2021, no serious control issue came to the attention of DG SANTE that would warrant a financial or reputational reservation in DG SANTE's 2021 Annual Activity Report.

- An impressive amount of work was accomplished in a very short time span from preparing the establishment on 16 February 2021 to setting up the new agency which became operational on 1 April 2021. The Steering Committee adopted a series of decisions that paved the way for the agency to reach its administrative autonomy as soon as possible. The 2021 annual work programme of HaDEA was approved by the Commission on 29 July 2021[50] and adopted by the agency's Steering Committee on 5 August 2021.

- On 1 April 2021, HaDEA started to manage the non-policy related actions in the area of public health previously under the responsibility of CHAFEA. HaDEA also got involved in the preparations for the launch of the first call for proposals under the EU4Health programme. The 2021 work programme for EU4Health was adopted on 18 June 2021[51] and the call launched on 29 July 2021.

  With regard to Food Safety, on 1 April, HaDEA took over from CHAFEA the implementation of the Better Training for Safer Food (BTSF) initiative. In addition, DG SANTE delegated to HaDEA the financial activities of the veterinary programmes,

[49] C(2021)948 of 12 February 2021 – Commission Decision on delegating powers to HaDEA
[50] C(2021)5515 of 29 July 2021 – 2021 AWP of HaDEA
[51] C(2021)4349 of 18 June 2021 – 2021 work programme of EU4Health

phytosanitary programmes, European Reference Laboratories and Centres and grants for the Member States antimicrobial resistance (AMR) monitoring previously managed by DG SANTE.

- From 1 September 2021, HaDEA is entrusted with the full management of the parts of the programmes delegated to the agency: about 80% of the EU4Health programme budget and around 74% of the funds under the Food chain strand of the Single Market Programme. HaDEA identified as its highest risk that recruitment was lagging behind the rapidly increasing need for staff managing the delegated tasks. In 2021, the agency has been running a large number of recruitment procedures in parallel, in a very short time and with a relatively small HR team.

- Although HaDEA shows an implementation rate of the 2021 operational budget of 100%, the individualisation of commitments by signing grants or procurement contracts could not yet advance due to the late adoption of the 2021 work programmes. Close co-operation with HaDEA will continue, and great care will be taken to individualise the global commitments in a timely manner in 2022.

In HaDEA's 2021 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 with regard to its implementation of the programmes EU4Health and SMP (see the agency's 2021 Annual Activity Report).

Table 7.10 Indicators of control effectiveness as regards legality and regularity

Executive agency HaDEA from 1 April 2021 (CHAFEA until 31 March 2021)	***Targets***	**2021**		**2020**	**2019**
		HaDEA	**CHAFEA***	**CHAFEA**	**CHAFEA**
Steering Committee meetings with adequate quorum for voting (info: HaDEA has 5 parent DGs)	*4*	**6**	**1**	4	4
Number of "exception reports" relative to the guidelines on the co-operation between DG SANTE and the agency	*n/a*	**0**	**0**	0	0
Budget execution rates of the operational budget transferred to the agency: commitments payments	*99%* *100%*	**100%** **100%**	**n/a**	100% 100%	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 AAR	*Yes*	**Yes**	**n/a**	Yes	Yes
Court of Auditors' assurance on the agency's accounts and implementation of the administrative budget of year N-1 without qualification	*Yes*	**n/a**	**Yes**	Yes	Yes
Discharge granted for year N-1 and discharge recommendations implemented for year N-2	*Yes*	**n/a**	**Yes**	Yes	Yes
Ratio of recovery of the positive budgetary outturn of year N to subsidy paid in year N-1	*n/a*	**n/a in 2021**	**13,9%**	6,9%	11,8%

Ad *: CHAFEA was closed down on 31 March 2021.

EU decentralised agencies

In 2021, 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[52].
  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[53].
  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[54].
  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[55].
  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[56].
  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.

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52 ECDC was established by Regulation (EC) No 851/2004 of the European Parliament and of the Council.

53 EFSA was established by Regulation (EC) No 178/2002 of the European Parliament and of the Council.

54 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.

55 CPVO was created by Council Regulation (EC) No 2100/94.

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

In addition, DG SANTE is involved in the governance of Eurofound[57] (lead partner DG is EMPL) and EMCDDA[58] (DG HOME is the lead partner DG), but does not contribute to their running costs.

Table 7.11 EU decentralised agencies – subsidies

EU decentralised agencies	*Number of staff **			EU contribution		
	2021	***2020***	***2019***	**2021 M€**	**2020 M€**	**2019 M€**
ECDC	***351***	*306*	*285*	**168,1**	62,5	59,2
EFSA	***542***	*509*	*467*	**129,1**	103,0	79,9
EMA[59]	***916***	*854*	*854*	**37,6**	58,9	35,5
CPVO[60]	***52***	*52*	*51*	**0**	n/a	n/a
ECHA-biocides[61]	***69***	*69*	*67*	**10,4**	7,2	3,1
Total	***1.930***	***1.768***	***1.724***	**345,2**	**231,6**	**177,7**

*: 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.

In 2021, the increase in DG SANTE agencies' total number of staff and subsidy payments, is most importantly due to

- ECDC's and EMA's reinforcement from the European Health Union (EHU) package[62] which extends ECDC's and EMA's mandates strengthening the EU response to health crises;
- EFSA's increase in staff and subsidy covers the additional posts and operational budget related to the increased workload and complexity of the mandate as a result of the impact of the Transparency Regulation[63];
- ECHA-biocides' budget fluctuates over the years due to the variations in fee income.

[57] 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.

[58] European Monitoring Centre for Drugs and Drug Addiction; the synergies with DG SANTE's work cover addictions and drug use associated communicable diseases.

[59] EMA's total 2021 budget amounted to EUR 379,2 million (in 2020: EUR 365,4 million; in 2019: EUR 339,9 million), mainly financed by fees. The EU contribution is a balancing grant (in 2021: 9,9%; in 2020: 16,1%; in 2019: 10,4%).

[60] CPVO does not receive any EU subsidies; its 2021 budget amounted to EUR 20,0 million (2020: EUR 20,0 million; 2019: EUR 16,4 million).

[61] 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 2021 amounted to EUR 12,8 million (in 2020: EUR 12 million; in 2019: EUR 12,7 million). The EU contribution is a balancing grant (in 2021: 81%; in 2020: 60%; in 2019: 59%.

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

[63] Regulation (EU) No 2019/1381 on the transparency and sustainability of the EU risk assessment in the food chain will enter into application on 27 March 2021

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 have been strengthened as part of the Health Union Package. DG SANTE will ensure the follow-up of the strengthened mandates of ECDC and EMA, expected to be adopted by the co-legislators in early 2022.

The latest amendment to EFSA's founding Regulation[64] dates back to June 2019. From July 2022, EFSA's Management Board will include a member from each Member State, in line with the Common Approach on decentralised agencies. 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)[65] 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. Five operational Units in DG SANTE are the primary interlocutors for the agencies. A horizontal Unit in Directorate A "Resource management and better regulation" ensures a central coordination to promote a coherent approach towards all agencies and to exchange good practices.

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[64] 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.

[65] 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.

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[66].

- **ECDC:** the latest evaluation was finalised in 2019: third external evaluation of ECDC for the years 2013-2017. In 2021, ECDC continued implementing the recommendations as approved by ECDC's Management Board.
- **EFSA:** in 2021, EFSA continued to implement the Management Board recommendations made in the framework of the third external evaluation delivered in 2018.
- **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 was finalised and delivered to the European Parliament and to the Council in August 2021[67]. 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 has been launched in 2021 and is expected to be finalised in 2022: socio-economic impact study on the benefits of the system of Community Plant Variety Rights in the EU. The study also takes into account the impact of the Green Deal and the Farm-to-Fork Strategy of the Commission.

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 29 October 2021, the Court published its "Annual report on EU agencies for the financial year 2020". The Court gave a positive declaration of assurance to all five agencies to which DG SANTE is parent (or associated).

With regard to EMA, the Court raised the following "emphasis of matter" without qualifying its positive opinion: in its final accounts, EMA discloses that the lease on the former office premises in London runs until 2039 and does not contain a break clause, but that the premises can be sublet. In July 2019, EMA reached an agreement with its landlord and has sublet its former office premises to a subtenant from July 2019 until the expiry of EMA's lease in June 2039. Since EMA remains a party to the head lease, the agency could be held

[66] 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.

[67] COM(2021) 497 of 31 August 2021

liable for the entire amount remaining payable, if the subtenant fails to meet its obligations.

Discharge

In May 2021, taking into account the Court of Auditors reports on the agencies annual accounts 2019, the European Parliament granted the four agencies which receive a subsidy from the EU budget discharge in respect of the 2019 budget implementation.

DG SANTE, within the limits of its role on the EU agencies' Management Boards and Audit Committees, if applicable[68], follows up closely the improvements to be made by the agencies in follow-up to audits, evaluations and discharge recommendations.

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 7.12 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 2021, DG SANTE cleared all pre-financing payments made to the agencies in 2020 and made the final payments of the 2020 subsidies. Thus, no reservation to DG SANTE's declaration of assurance is warranted.

Table 7.12 Indicators of control effectiveness as regards legality and regularity

EU decentralised agencies	*Targets*	2021	2020	2019
Court of Auditors' assurance 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*	**Yes** **5 out of 5**	Yes 5 out of 5	Yes 5 out of 5
Discharge granted for year N-1 and discharge recommendations implemented for year N-2	*Yes*	**Yes**	Yes	Yes
Ratio of recovery of the positive budgetary outturn of year N to subsidy paid in year N-1	*n/a*	**3,5%**	1,2%	9,7%

Conclusion on legality and regularity of subsidy payments to agencies

For the 2021 reporting year, DG INTPA and the executive agency HaDEA have reported reasonable assurance on the delegated budget managed on DG SANTE's behalf.

For all five EU agencies (EFSA, EMA, ECDC, CPVO and ECHA for its biocides activities) for which DG SANTE was responsible in 2021, the Court of Auditors gave a positive declaration of assurance for the year 2020. 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.

[68] 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.

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, HaDEA, 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. DG SANTE has developed and implemented its own anti-fraud strategy since 2013, on the basis of the methodology provided by OLAF[69]. The strategy is updated regularly. The most recent version, covering the years 2021 to 2024, was adopted by the Management Board on 8 November 2021, following the consultation of the Directors' Steering Committee and a peer review coordinated by OLAF. The strategy (2021-2024) took into consideration the new challenges experienced during the COVID-19 crisis and the results of the comprehensive fraud risk assessment exercise, conducted in May-June 2021 with relevant units in DG SANTE. The associated action plan aims to enhance fraud prevention, detection and response capacity in DG SANTE. Its implementation 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;
- Involvement in updates of the anti-fraud strategies and action plans of the Health and Digital Executive Agency (HaDEA) and the EU decentralised agencies to which DG SANTE is partner;
- Active participation in the network "Fraud Prevention and Detection" (FPD) and relevant sub-groups (including on EPPO) chaired by OLAF;
- Standing operating procedures for the handling of allegations of fraud, other irregularities and OLAF cases;

[69] 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

- Arrangements for an appropriate level of cooperation with OLAF: in 2021, the existing channels for exchanging fraud related information with OLAF were further elaborated, in the area of food fraud and EPPO co-operation; - Three awareness raising events were especially organised for DG SANTE staff:
  - ✓ On 22 February 2021, DG SANTE in co-operation with DG HR and DG DIGIT organised an information security awareness session for SANTE staff;
  - ✓ On 10 June 2021, OLAF held a remote, inter-active workshop on "Fraud prevention and detection" with special focus on procurement;;
  - ✓ On 25 January 2022, DG HR and IDOC[70] conducted a remote, interactive information session on ethics for all staff in DG SANTE.

Table 7.13 Indicators for fraud prevention and detection

Indicators	***Targets***	2021	2020	2019
Updated anti-fraud strategy and action plan (2021-2024) approved by the Management Board	*2020*	*Done 08/11/2021*	*Postponed to 2021*	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%*	**80%**	88%	92%
Awareness raising: % of financial officers reached in financial cell network meetings	*100%*	*Postponed to 2022*	*Postponed to 2021*	100%
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 2022*	*Postponed to 2021*	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 2021 were 37 permanent tasks and four new actions. Due to the difficult working conditions during the COVID-19 crisis, only about 80% of the actions were implemented and an additional 7% of the actions were launched but are still ongoing. The information and awareness raising actions that could not take place as planned will resume in 2022.

[70] Investigation and Disciplinary Office of the Commission

7.2 Efficiency and economy of controls

This section outlines the indicators used to monitor the efficiency and economy of the control systems. The main indicators monitored in 2021 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 tables below show the efficiency indicators by type of expenditure are as follows:

Table 7.14 Efficiency indicators related to grant management in the policy area Food and Feed Safety

Indicators per stage of the grant procedure	*Targets*	2021	2020	2019
Stages 1 and 2: Member States' submission of applications and signing of grant agreements				
"Time-to-inform" and "time-to-grant" (FR Art. 194(2)	*n/a*	n/a	n/a	n/a
Stage 3: Financial transactions and ex-ante controls				
Payments made on time (in number) in amount	*95%*	(74%) 86%	(95%) 95%	(92%) 90%
Average payment time	*90 days*	67 days	50 days	55 days
Stage 4: Ex-post controls and error corrections				
Timely implementation of the annual financial audit work programme (in 2021, 21 audits were planned and 19 carried out; in 2020, 18 audits planned and carried out; in 2019: 16 out of 18 audits carried out)	*100%*	90%	100%	88%
"Time to recover": average days from finalising the control to issuing the debit note (in 2021: 12 debit notes; in 2020: 10 debit notes; in 2019: no debit notes)	*n/a*	49 days	59 days	n/a

In 2021, DG SANTE's indicator of timely payments (86% of payments made on time in amount) is below DG SANTE's average of 99% in 2021 and below the target of 95%. Given the late adoption of the MFF (2021-2027), priority had to be given to the adoption of the Single Market Programme (SMP), its work programme for 2021 to 2022, and the development of the new grant agreements. Furthermore, the hand-over of a large number of files to the newly established executive agency HaDEA (see part 7.1.1.3 above) took priority over verifying cost claims. Consequently, some payment transactions could not be processed as quickly as usual. The indicator "time to recover" has however much improved.

Table 7.15 Efficiency indicators related to procurement

Indicators on control efficiency in procurement	*Targets*	2021	2020	2019
Stage 1: Rate of timely launched procurement procedures as specified in the annual work programmes	*100%*	**90%**	63%	78%
Stage 2: Average payment times	*30 days*	**22 days**	18 days	19 days
Ratio of payments made on time (in number) in amount	*95%*	(93%) 99%	(98%) 100%	(98%) 99%
Stage 3: "Time to recover": average days from information/confirmation date to issuing the debit note (in 2021: 5 cases; in 2020: none; in 2019: 1 case)	*n/a*	**11**	n/a	72

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 shows a significant improvement in comparison to previous years.

The indicator on timely payments (in number of payment transactions related to procurement procedures) is slightly below target as staff had to shift their priorities to the many urgent and at times quite complex transactions related to fighting the crisis. Payments made on time in amount are at 99% well above the target.

Table 7.16 Efficiency indicators related to agencies

Indicators on control efficiency in procurement	*Targets*	2021	2020	2019
Ratio of payments made on time (in number) in amount	*95%*	(100%) 100%	(100%) 100%	(100%) 100%
"Time to recover": average days from information/confirmation date to issuing the debit note	*n/a*	**26 days**	24 days	55 days

DG SANTE did not face any undue delays in its procedures related to the payments of the subsidies to the agencies.

Table 7.17 Economy of controls – evolution over time

Cost of controls as % of annual payments	***Targets***	**2021**		**2020**		**2019**	
		Payments M€	**Cost of controls %**	***Payments M€***	**Cost of controls %**	***Payments M€***	**Cost of controls %**
Grants in the Food Safety policy area	*1%*	***39,9***	**3,4%**	*188,8*	1,6%	*211,9*	1,5%
Public procurement and other grants (including ESI)	*< 7%*	***450,2***	**1,3%**	*2 565,5*	0,2%	*36,5*	6,9%
Subsidy payments to agencies	*< 1%*	***362,8***	**0,3%**	*238,8*	0,4%	*187,5*	0,5%
Total		***852,9***	**1,0%**	*2 993,1*	0,3%	*435,9*	1,6%

Conclusion on cost effectiveness of controls related to grants in the policy area Food and Fed Safety

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.

In 2021, payments made in the policy area Food and Feed Safety have decreased substantially in comparison to previous years further to the transfer of important parts of the budget to the executive agency HaDEA (see part 7.1.1.3 above). Given that DG SANTE keeps only the files relative to the funding of Member States' veterinary and plant emergency measures and IT expenditure, the "historical" target of 1% of costs in relation to the payments made is no longer adequate. The main cost-drivers in managing the funding of emergency measures are the diversity and complexity of the files in both technical and financial aspects. As the increase of the indicator in 2021 is mainly due to the reduced amount of payments, DG SANTE believes that the cost of control is reasonable. Therefore, DG SANTE reached a positive conclusion as to the relative efficiency of the controls of these grants to Member States and will maintain the main elements of its control strategy in this regard. However, a new target for the costs of control will be defined and efforts will continue to simplify financial management and thus reduce the cost of controls by broadening the use of lump-sums, ceilings and unit-costs.

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. However, the low ratios in 2020 and 2021 were due to a few high volume procurement procedures relative to the ESI funds. For the usual type, number and size of contracts related to DG SANTE's spending programmes in the Health and Food Safety policy areas (i.e. excluding the procedures under the ESI), 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.

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 7.18 Overview of DG SANTE's estimated cost of controls at Commission (EC) level *(the absolute values are presented in million EUR)*

SANTE Relevant Control System (RCS) / Other as defined in Annex 6 of the AAR	**Ex ante controls [1]** (a) EC total costs	(b) Related payments made	(c) Ratio (%) *(a)/(b)*	**Ex post controls [2]** (d) EC total costs	(e) Total value verified and/or audited	(f) Ratio (%) *(d)/(e)*	**Total** (g) EC total estimated cost of controls *(g)+(d)*	(h) Ratio (%)** *(g)/(b)*
Grants in the Food and Feed Safety policy area	1.153.882,93 €	39.974.212,94 €	2,89%	196.206,32 €	17.907.388,05 €	1,10%	1.350.089,25 €	3,38%
Public procurement and other grants (including ESI)	5.688.693,69 €	450.214.846,75 €	1,26%	- €	- €	0,00%	5.688.693,69 €	1,26%
Subsidy payments to agencies (indirect management)	1.163.718,25 €	362.796.355,49 €	0,32%	- €	- €	0,00%	1.163.718,25 €	0,32%
OVERALL total estimated cost of control at EC level for expenditure	**8.006.294,87 €**	**852.985.415,18 €**	**0,94%**	**196.206,32 €**	**17.907.388,05 €**	**1,10%**	**8.202.501,19 €**	**0,96%**

[1] All payments made 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, but no overhead rate;

[2] The total value verified and/or audited represents the EU contribution audited during ex-post control missions actually carried out in 2021 by DG SANTE own staff and external audit services.

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: 2021 DAS

In October 2021, the Court published its annual report (2020 DAS) on the implementation of the 2020 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 special reports on performance audits in DG SANTE

In 2021, the Court of Auditors did not finalise a performance audit in which recommendations were addressed to DG SANTE.

In June 2021, the Court started an audit on the Advance Purchase Agreements (APA) for vaccines. DG SANTE is in the lead of this audit co-operating closely with associated DGs, the Secretariat General and DG BUDG. The Court's indicative timing foresees the audit report to be finalised in the summer of 2022.

The main audit question is whether the EU's COVID-19 vaccine procurement was effective. The audit will examine whether (i) the EU set up an appropriate framework for the vaccine procurement process; (ii) the Commission followed an effective APA negotiation strategy; (iii) the Commission followed up on the implementation of the APAs.

DG SANTE is fully co-operating with the auditors. A meeting between the Member of the Court and Commissioner Kyriakides took place on 9 September 2021.

8.1.2 Internal Audit Service of the Commission (IAS)

IAS limited conclusion on 2021 and DG SANTE's follow-up

The IAS contributed to DG SANTE's Annual Activity Report for 2021 by submitting a "limited conclusion on the state of internal control" in mid-February 2022. Based on the audit work performed in the period 2019 to 2021, 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) 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:

<u>Recommendation 1 on the staffing of activities</u>

- 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 taken several actions to address its recruitments needs and to reduce Directorate F's policy work during the Management Plan exercises for 2021 and 2022. It has to be noted that the DG's strategic priorities and, subsequently, the overall DG staff allocation was severely impacted by the COVID-19 pandemic. In order to meet these challenges, senior management took a number of strategic decisions that affected all Directorates. Directorate F was attributed an extended role on policy work in several areas (including a number of policy initiatives in the Health Pillar and in the Farm-to-Fork strategy) and contributed to these highest EU priorities with the redeployment of some posts. Any human resource strategy will have to be coherent with the new HR strategy of the Commission which is not yet available. The COVID-19 pandemic has caused delays of more than a year.

  Given the recent developments in the staffing activities and the strategic decisions taken on Directorate F's role, DG SANTE believes that the risks of not being able to deliver on Directorate F's objectives and control obligations, as pointed out by the auditors, has decreased substantially.

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.
- The actions had to be postponed from early 2020 due to the cancellation of audits and exceptional working arrangements during the COVID-19 pandemic as much of the data would not have been useful. In 2021, a pilot project of time recording was launched and ran over several months. Having analysed its outcomes, Directorate F found that the following new reporting arrangement was the most useful and efficient: each Head of Unit provides a weekly report on the main activities, outputs, progress against plans and forward views for the coming week. This reporting mechanism has been launched in February 2022 and will be reviewed continuously. On this basis, DG SANTE is confident that the risk identified by the IAS auditors has been reduced significantly.

(2) 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 to address the audit recommendations are well under way. Most importantly, in early 2020, DG SANTE and JRC signed an administrative arrangement which includes the objective to improve the unit cost methodology and inform Member States well in advance of the financial impact of any change in the methodology. The whole project runs for three years until February 2023 and has already delivered positive results.

  Some recommendations of the IAS have been handed over to HaDEA as important parts of the budget of the SMP-Food Chain strand have been delegated to HaDEA from 1 September 2021. The recommendations are not rated “critical” or “very important”. The actions still to be implemented by DG SANTE pertain to the veterinary and phytosanitary emergency measures. The implementation is behind target, as in 2021 priority had to be given to the adoption of the Single Market Programme (SMP), its work programme for 2021 to 2022, the development of the new grant agreements and the hand-over to HaDEA.

8.1.3 DG SANTE's follow-up on the Court’s audits

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.

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).

In 2021, DG SANTE monitored the implementation of the recommendations of eight 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. The open

action was related to the merge of two IT systems for Animal Disease Notification, ADNS and OIE-WAHIS[71] into the Animal Disease Information System (ADIS).

In April 2021, ADIS became operational and replaced the Commission's previous IT tool ADNS. It is aligned with the global OIE-WAHIS in terms of data structure and data dictionary. Two more modules in ADIS are expected to become operational in 2022 (Union reporting and two-way interoperability with OIE-WAHIS).

(2) 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. Having implemented two recommendations in 2020, the last open recommendation is being addressed by the work to prevent labelling practices that generate food waste. The following milestones have already been achieved or are ongoing:

To support food business operators, in 2020, the Commission, with the support of EFSA, adopted guidance on food safety management systems for food retail activities, including food donations. Furthermore, on proposal of the Commission, EU food hygiene rules have been amended in 2021 to lay down certain requirements to promote and facilitate food donation, whilst guaranteeing its safety for consumers[72].

To support food business operators in adopting more consistent date marking practices based on food safety, the European Commission requested scientific advice from EFSA. Concerning the prevention of labelling practices that generate food waste, the Commission started exploring options for more effective use and understanding of date marking ('use by', 'best before'). As part of the Farm to Fork Strategy, the Commission will propose, by the end 2022, revising EU rules on date marking. To inform this legislative proposal, the Commission carried out an impact assessment with public consultations from 13 December 2021 to 7 March 2022

[71] 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).

[72] Commission Regulation 2021/382 amending the Annexes to Regulation No 852/2004 and Commission Delegated Regulation (EU) 2021/1374 of 12.4.2021 amending Annex III to Regulation (EC) No 853/2004 of the European Parliament and of the Council on specific hygiene requirements for food of animal origin

and other targeted consultations. In addition, the Commission launched at the end of March 2021, consumer behavioural research to identify new ways of expressing date marking that meet consumers' information needs whilst avoiding unnecessary food waste linked to the misunderstanding and misuse of date marking. In 2021, an inventory and review of evidence on consumer behaviour regarding date marking and food waste was carried out as well as stakeholder interviews and consumer focus groups. Following this qualitative research, policy options have been further refined in view of testing these (in all EU official languages) through quantitative consumer research (online surveys to be carried out in 27 Member States in 2022). Research findings, expected by March 2022, will help inform the development of the legislative proposal.

(3) 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[73] 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) On the basis of the evaluation results, to consider the need for a new strategy, with a possible review of the legislation;
(v) Define baseline and target indicators to measure Member States' degree of compliance.

[73] European Commission's online platform for sanitary and phytosanitary certification required for the importation of animals, animal products, food and feed of non-animal origin and plants into the European Union, and the intra-EU trade and EU exports of animals and certain animal products

In mid-2021, the Court of Auditors carried out a follow-up audit and concluded that three recommendations were implemented without undue delay as DG SANTE strengthened its arrangements for a faster escalation of audit recommendations, modified Member States' access rights to the IT system TRACES and provided trainings 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 System.

In addition, the Commission published the evaluation of the animal welfare strategy (2012-2015)[74] in March 2021. The results were used for reviewing the animal welfare acquis as well as other Commission initiatives in the area of Animal Welfare. Based on the preliminary Fitness Check findings, an Inception Impact Assessment for future legislation was published for feedback until 24 August 2021. The Public Consultation was open from 15 October 2021 until 21 January 2022. Furthermore a stakeholders' conference "EU Animal welfare today & tomorrow" was held on 9 December 2021 allowing for an exchange of views both on the fitness of current provisions and on the future policy choices. Plans are to finalise the Impact Assessment studies by late 2022 and to submit a legislative proposal by Q4 2023.

The last recommendation has been implemented partially with the adoption of the new standard model form for Member States' annual reports in the framework of the Multi-annual National Control Plans; the new template was used for the first time in 2021 when Member States reported on their controls carried out in 2020, including on animal welfare on farm and during transport. DG SANTE's analysis of non-compliances in animal welfare on farm that Member States have provided so far proved to be insufficient to support identifying common baselines and targets. In addition, the different methodologies that the Member States use for obtaining results (e.g. risk-based controls, targeted, ones, random ones) hinders the identification of common baselines and targets. Solving the many problems that DG SANTE became aware of takes much more time than initially planned.

(4) 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:

[74] Staff Working Document (SWD(2021)76) published on 31 March 2021

(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;
(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 first 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 second recommendation has been implemented partially in 2020 mainly with the REFIT evaluation regarding the pesticides legislation[75]. Important milestones have been achieved in 2021 as follows: firstly, the evaluation of the Food Contact Materials legislation has been finalised in late 2021 and the publication of the Staff Working Document is expected in April 2022; the work on the Impact Assessment for the revision of this legislation has been launched. Secondly, the combined evaluation roadmap/inception impact assessment of the revision of the Feed Additives Legislation was launched on 14 December 2020 for open public consultation until June 2021. The summary report was published on 10 October 2021. The impact assessment is expected to be finalised with the Staff Working Document to be treated in the Regulatory Scrutiny Board of 6 April 2022. The Commission adoption of the proposal is scheduled for mid-June 2022.

With regard to the third recommendation, to facilitate consistent application of EU food law, the Commission gave Member States further guidance on the application of enforcement measures. Consultations with Member States on the working document serving as a basis to establish the methodology for the monitoring of food additives and flavourings were completed in November 2020. This was followed by an ad hoc workshop organised by the Netherlands in February 2021, to discuss in particular practical aspects of the implementation of the monitoring. With a view to finalising the draft common methodology, the Commission still needs to consult EFSA and other stakeholders. Against the background of the COVID-19 pandemic, other top priorities of DG SANTE and the critical staff situation in 2021, the completion of this work will not be achieved before late 2022.

[75] Report to Council and Parliament was adopted on 20 May 2020

(5) **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. The five open recommendations have target dates until 2025 and important milestones have already been achieved:

To provide more support for National Contact Points (NCP), in January 2020 the Commission published the full Toolbox for Cross-Border Healthcare completed with translations. Its use by the NCPs is being addressed as part of the Commission's evaluation of the Cross-border Healthcare Directive (Directive 2011/24/EU). Feedback on the toolbox was planned to be discussed in the meeting of the Cross-Border Healthcare (CBHC) expert group in November 2020. However, the Expert Group meeting on 26 November 2020 had to focus on COVID-19 cooperation and evaluation. Plans are now to wait for the finalisation of the Directive's evaluation in the second quarter of 2022 and organise the NCP capacity-building workshop in the second half of 2022 to address actions arising from the evaluation conclusions.

To better prepare for cross border exchanges of health data, DG SANTE is monitoring and reporting the results achieved through the governance structures of the eHealth Digital Service Infrastructure (eHDSI). Member States adopted the new eHDSI Monitoring and Reporting Framework, which will enable gathering more detailed and qualitative Key Performance Indicators (KPI)[76]. 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. In the meantime, an infrastructure study was launched to explore the different options for the MyHealth@EU infrastructure, including services for healthcare providers and citizens. The monitoring of the eHealth Strategy and the eHealth Action Plan was combined with the evaluation of Article 14 of the cross-border healthcare directive. The Staff Working Document is expected to be adopted together with the European Health Data Space (EHDS) legal proposal in mid-2022.

[76] Information on KPIs is published quarterly; Monitoring Framework

The Commission supports and coordinates meetings of the European Reference Networks (ERN) Board of the Member States and ERN Coordinators Group (ERN CG) and five thematic ERN working groups to facilitate exchanges and decisions on strategic issues and to address challenges faced by the ERNs. The Statement of the ERN Board of the Member States on ERN Integration into national healthcare systems was adopted by the ERN's Board of Member States at its meeting on 25 June 2019[77] and has been translated in all EU languages.[78] Together with the Statement, an annex with a list of prioritised potential actions was adopted by the Board[79]. A working group on ERN integration has been set up and has worked on the implementation of the principles set out in the 2019 Board's statement. On the basis of the 2019 Board's statement and the activities of the ERN working group on integration a new Joint Action on ERN integration into the Member States' healthcare systems is included in the 2022 Work Programme of the EU4Health Programme.

The Board of Member States also accepted the Statement of the ERN Board of Member States on ERNs & industry on 25 June 2019. Based on this Statement, good practices and examples of cooperation with the industry are being exchanged and discussed in regular meetings of the ERN working group on Legal, Ethical and Stakeholders issues. Pilot projects to further explore structural cooperation of ERNs with the industry are being identified as well as good practices and exchange examples of cooperation with the industry.

A proposal for an integrated quality improvement system (AMEQUIS) of the ERNs has been developed by the Commission with support from an external service provider. It was presented to the ERN-CG, the ERN Board of Member States and all other related experts in January 2022

A number of projects funded by the Commission have been implemented to support ERNs in their activities, in particular the programme for the development of ERN Clinical Practice Guidelines and other Decision Support Tools (launched in 2021), ERN professional mobility programme (launched in 2021), ERN Virtual Academy for eTraining and eLearning programs (included in the 2022 Work Programme under the EU4Health Programme). The creation of rare disease registries by all existing 24 ERNs has been supported by the Commission from the Third Health Programme.

As regards funding for the European Reference Networks (ERNs), the EU4Health Programme, adopted in March 2021, includes – most importantly – support for strengthening and scaling up networking through the ERNs. The ERNs are beneficiaries of direct grants and the level of eligible costs will increase up to 100% of the grant value (compared to the current 60%). The launch of the new direct grants for all 24 existing networks is foreseen in March 2022.

[77] https://ec.europa.eu/health/sites/health/files/ern/docs/integration_healthcaresystems_en.pdf.

[78] https://ec.europa.eu/health/ern/board_member_states_en

[79] https://ec.europa.eu/health/sites/health/files/ern/docs/integration_healthcaresystems_annex_en.pdf

In the medium-term (as of 2023), the grants under the EU4Health Programme are expected to integrate support currently provided by different funding instruments (grants for ERN coordination, grants for ERN registries and grants for ERN IT related activities currently supported by funds of the Connecting Europe Facility).

(6) 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; promote the results of the JAMRAI and OECD projects;
(ii) Promote prudent use of veterinary antimicrobials and better surveillance of AMR;
(iii) Strengthen strategies for boosting AMR research in the EU.

All actions are on-going with target dates until early 2023. Important milestones have already been achieved. To implement the first recommendation a serious of actions have been taken, for example, in 2021,

- Funding opportunities such as the EU4Health programme, European Structural and Investment Funds (ESIF), InvestEU and the Technical Support Instrument (TSI) were presented to Member States at the WHO-EC workshop on 16-17 June 2021 and at a meeting dedicated to AMR national action plans on 7 July 2021.
- On 19 February 2021, DG SANTE provided 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 January 2022, preliminary screening of national recovery and resilience plans for the Recovery and Resilience Facility revealed AMR related measures for eight Member States.
- As a parallel process, the Commission negotiates with each Member State its investment plans to be financed by European Structural and Investment Funds (new partnership agreements and operational programmes) in the programming period 2021-2027 and will be able to screen for preliminary AMR investment plans by the second quarter 2022.
- In 2021, Expert Panel on effective ways of investing in health has been requested to deliver an opinion on managing antimicrobial resistance across the health system. The opinion is expected to be finalisation in July 2022.
- The final report of JAMRAI has been submitted at the end of June 2021; it will be taken into consideration for any future joint action. The OECD project has been prolonged, also due to COVID-19. The final deliverable (report) is expected in the summer 2022.

The outcome indicators recommended by ECDC, EMA and EFSA were analysed. Member States and WHO discussed the overall progress at the WHO-EC workshop on 16-17 June 2021. The joint scientific opinion was presented at the One Health Network meeting of 25-26 January 2022 It will be one of the elements feeding into the preparation of the AMR proposal for Council Recommendation planned by the end of 2022.On 30 March 2021, the Commission published its Roadmap on the revision of the pharmaceutical legislation. One of the objectives of the review is to consider the creation of specific incentives to promote the development of new classes of antimicrobials in combination with rules aiming to promote their prudent use and measures aligning use to patient needs, such as reduction of package sizes. Since the publication of the Roadmap, the Commission has conducted consultation activities in particular an online public consultation that ended in December 2021.

With regard to the second recommendation, i.e. to promote prudent use of veterinary antimicrobials, 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 Member States' data collection, the Commission plans to sign multi-annual grant agreements with Member States under the Single Market Programme (SMP).

To implement the third recommendation on strengthening strategies for boosting AMR research, as part of the Pharmaceutical Strategy for Europe initiative, a joint meeting of the EU Directors for Pharmaceutical Policy & Pharmaceutical Committee was organised under the Slovenian presidency on 8-9 July 2021. On the agenda were discussion on innovation, access and availability of antimicrobials in the EU. The conclusions from the meeting informed further work under the Pharmaceutical Strategy.

The impact assessment for the revision of the two regulations on medicines for children and rare diseases has been initiated. It was decided to focus the revision on the specific needs of the two subpopulations. Needs deriving from market failure, like the lack of development of new antimicrobial agents, will be assessed in the framework of the revision of the general pharmaceutical framework which is taking place in parallel and in close collaboration with the revision of the Regulations on medicines for children and rare diseases.

(7) 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:

(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.

Several milestones were already implemented during 2020 and 2021, with a slight delay due to the COVID-19 outbreak.

Through a dedicated SUD webpage, the Commission continues to support, encourage and facilitate the exchange of information between Member States on SUD implementation, including implementation of IPM general principles and, in particular, existing general and crop-specific IPM Guidelines. An EU-funded IPM project Farmers Toolbox - IPM | (agrilpm.eu) aims at developing an IPM toolbox for farmers across the EU which is planned to be launched at a conference in September 2022 with wide dissemination and use thereafter.

Following the SUD (Sustainable Use Directive) Working Group meeting in November 2020, the Commission held a meeting with experts from selected Member States in March 2021 to discuss potential solutions that could be implemented across the EU. Further discussions with all Member States took place at the SUD Working Group meetings on 14-15 April 2021 and 23-24 June 2021. In parallel, Member States provided two rounds of written feedback. The insights from this work will feed into the ongoing revision of the SUD.

In 2021; the Commission has moved swiftly ahead with the evaluation and impact assessment of the SUD. This will pave the way for the adoption of the Commission's legislative proposal to revise the SUD in 2022.

In total, 12 Member States have been audited to assess their implementation of SUD in the 2018-2021 period. Two additional audits on SUD were included in the Audit Programme 2022 published in mid-December 2021.

In the "Farm to Fork Strategy" of May 2020, targets are established for reducing the use and risk of chemical Plant Protection Products (PPPs) and the use of the more hazardous PPPs. The Commission published progress towards the two "Farm to Fork" pesticide targets in May 2021 for the EU 27 and for all Member States that agreed to have their trends published[80].

On 10 August 2021, the Commission published updated Harmonised Risk Indicators for the period 2011-2019[81].

[80] Farm to Fork Targets - Progress

[81] Harmonised Risk Indicators for 2011-2019

(8) Protection of wild pollinators in the EU: Commission initiatives have not borne fruit (Special Report 2020/15 published in July 2020)

The Court assessed the extent to which the Commission's framework for wild pollinators helped to stop the decline in their number and diversity, and whether the Commission used biodiversity conservation measures, and measures available in the common agricultural policy and the pesticide legislation to address the need to protect wild pollinators.

The Court concluded that overall the Commission had not taken a consistent approach to the protection of wild pollinators in the EU. 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
- 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 are used.

On 9 August 2021, the Commission requested EFSA to continue the work on the review of the Bee Guidance document on the basis of the supported specific protection goal for honeybees and to support risk managers in the setting of a specific protection goal for bumble bees and solitary bees. On 15 November 2021, EFSA held an information session to explain how the protection goal for honeybees will be translated into decision making criteria for the lower tiers.

On 23 November 2021, the Commission organised two separate sessions to inform Member States and stakeholders on the available evidence for bumblebees and solitary bees. During these information sessions, EFSA presented the data available which will be compiled in a supporting document (under finalisation) to support risk managers in setting specific protection goals for solitary bees and bumble bees.

EFSA published its technical reports on the evaluations of the emergency authorisations[82] for the use of certain neonicotinoids in sugar beet on 18 November 2021. EFSA presented the results to the Member States in the Standing Committee on Plants, Animals, Food and Feed – Section Phytopharmaceuticals Legislation at its meeting on 1-2 December 2021.

The Commission is currently reflecting on the next steps.

[82] See https://www.efsa.europa.eu/en/news/neonicotinoids-efsa-assesses-emergency-uses-sugar-beet-202021

8.2 Assessment of the effectiveness of internal control systems

8.2.1 Changes in DG SANTE's control environment

In 2021, the following major changes to DG SANTE's control environment took place:

- In the fourth quarter 2021, the outgoing Deputy Director-General (DDG1) handed over all tasks and responsibilities to the acting Deputy Director-General. In his declaration, he provided reasonable assurance that the resources assigned to the activities under his responsibilities 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.

- Starting from 1 April 2021, the newly established European Health and Digital Executive Agency (HaDEA) took over the management of the non-policy related actions in the area of public health previously under the responsibility of CHAFEA. With regard to Food and Feed Safety, on 1 April, HaDEA took over from CHAFEA the implementation of the Better Training for Safer Food (BTSF) initiative. In addition, DG SANTE delegated to HaDEA the budget implementation of the veterinary programmes, phytosanitary programmes, European Reference Laboratories and Centres and Member States' antimicrobial resistance (AMR) monitoring. DG SANTE provided HaDEA with Standard Operating Procedures and guidelines in relation to the technical and financial management of veterinary and phytosanitary programmes. The IT system for the submission of veterinary programmes developed by DG SANTE is used by HaDEA; training sessions have been provided to test compatibility. No specific issues have been encountered. The delegation of tasks to HaDEA necessitated several organisational changes in DG SANTE at Unit level.

- In September 2021, the Commission decided to set up the "European Health Emergency Preparedness and Response Authority" (HERA)[83] as a Commission service reporting directly to Commissioner Kyriakides. From 1 October 2021, HERA has taken over responsibility for some of the tasks previously assigned to DG SANTE: as the Emergency Support Instrument (ESI) contributes to HERA's mission to improve preparedness and response to serious cross-border threats in the area of medical countermeasures, DG SANTE handed over to HERA all budget implementation tasks related to the ESI as from 1 January 2022. In particular, HERA is responsible for managing the processes and structures aimed at improving the availability of medical countermeasures in the Union. The Head of HERA was appointed in December 2021, and the Authority is expected to be fully operational from the beginning of 2022.

[83] Commission decision (C(2021) 6712 of 16.9.2021 establishing the Health Emergency Preparedness and Response Authority

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".

In 2021, the COVID-19 pandemic still required a large share of teleworking for all staff, the business continuity measures put in place in 2020 continued to apply and ensured full service of all critical and essential functions without interruption. The Business Continuity Management Sub-group met regularly 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.

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 2022 and was endorsed by the Management Board in its meeting on 28 March 2022. 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. DG HR launched its staff survey in late October 2021; DG SANTE carried out a complementary staff survey in January 2022;

(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. These relate to the following 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 9 on "change management" and ICP 10 on control activities.

- ICP 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 2021, 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 and 9: The results of the 2021 DG HR staff survey – in comparison to the 2018 DG HR staff survey – point to an improvement of senior management's guidance on "missions, objectives and tasks". Despite this positive trend, more is needed to ensure clarity of vision, purpose and means. Furthermore, the results of the DG HR staff survey show that a large majority of participants perceived that change is not well managed in DG SANTE. After DG SANTE's re-organisation and changes in top management in 2020[84], 2021 was the first year to implement the new MFF 2021-2027. This necessitated further adaptations to DG SANTE's organisation due to the delegation of tasks to the new Health and Digital Executive Agency (HaDEA), and the hand-over of tasks to the newly created European Health Emergency Preparedness and Response Authority (HERA).

- ICPs 10: 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, and (ii) the time reporting and performance monitoring in DG SANTE's Directorate "Health and food audits and analysis". All issues are addressed already partially.

[84] In the second half of 2020, DG SANTE welcomed a new Director-General, two new Deputy Directors-General and two new Directors.

(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 2021, the most important exceptions were the following:

- Several urgent procurement procedures were launched prior to the adoption of the 2021 work programmes for the EU4Health Programme and for the Single Market Programme which took place in mid-2021 rather than in late 2020. Several actions could not be further delayed as they were linked to DG SANTE's legal obligations (scientific committees, etc.), political commitments or indispensable for the continuity of services.

- 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.
  - DG SANTE amended the Commission model contract 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 two procedures[85] so that award decisions could be taken immediately after the finalisation of the evaluations.

- DG SANTE also applied a number of derogations to a Joint Procurement procedure for a framework contract for the supply of medical countermeasures. The derogations were brought to the attention of the participating Member States and met their approval. They concern most importantly a deviation from the minimum requirements in the tender specifications setting forth that the contract may not enter into force before a (conditional) marketing authorisation is obtained. The derogation allows countries participating in this joint procurement to purchase and use the new Covid-19 therapeutic as soon as possible, including, if they so wish, on the basis of a national authorisation to temporarily distribute the product.

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.

[85] One Advance Purchase Agreement and one Joint Procurement procedure

(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 or IDOC report was addressed to DG SANTE. In 2021, the Ombudsman issued an opinion in one case and a recommendation in another case, but they do no point to serious control weaknesses in DG SANTE (see parts 7.1.1.2 and 8.1.1 above for more detail).
- The audit observations of the IAS rated "very important" and open in 2021 are related to 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 even if two audit recommendation are open since more than a year due to the COVID-19 pandemic and its impact on DG SANTE’s audit activity (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. In one case, the IAS pointed to two long outstanding audit recommendations, but in DG SANTE’s point of view the delays are not undue as they were caused by the COVID-19 pandemic and its impact on DG SANTE’s audit activity.

(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 2021, 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 Directors' 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 Director-General discussed the 2021 report with the Commissioner in November 2021.

In 2021, no major event impacting the Director-General's declaration of assurance occurred.

ANNEX 9: Specific annexes related to "Control results" and "Assurance: Reservations"

Table 9 Estimated risk at payment and closure

DG SANTE (1)	'Payments made' (2021; MEUR) (2)	Minus new prefinancing (in 2021; MEUR) (3)	Plus cleared prefinancing (in 2021; MEUR) (4)	'Relevant expenditure' (for 2021; MEUR) (5)	Detected error rate or equivalent estimates (6)	Estimated risk at payment (2021; MEUR) (7)	Adjusted Average Recoveries and Corrections (*adjusted* ARC; %) (8)	estimated future corrections [and deductions] (for 2021;MEUR) (9)	estimated risk at Closure (2021;MEUR) (10)
Food Safety (mainly grants to Member States)	39,97	- 13,83	3,25	29,40	0,51% - 0,51%	0,15 - 0,15	0,43% - 0,43%	0,13 - 0,13	0,02 - 0,02
Health expenditure (EU4H and ESI; mainly procurement)	357,06	- 192,43	48,28	212,91	0,00% - 2,00%	0,00 - 4,26	0,00% - 0,00%	0,00 - 0,00	0,00 - 4,26
Emergency Support Instrument (lump sums and deliveries)	93,15	- 66,71	1 293,47	1 319,91	0,00% - 0,50%	0,00 - 6,60	0,00% - 0,00%	0,00 - 0,00	0,00 - 6,60
Subsidies to EU decentralised agencies	336,20	- 336,20	219,59	219,59	0,00% - 0,50%	0,00 - 1,10	0,00% - 0,00%	0,00 - 0,00	0,00 - 1,10
Total without contribution to EA's operating budget	**826,39**	**- 609,16**	**1 564,60**	**1 781,82**		**0,15 - 12,10**	**0,01% 0,01%**	**0,13 - 0,13**	**0,02 - 11,98**
					Overall risk at payment in %	**0,01% - 0,68%** *(7) / (5)*		**Overall risk at closure in %**	**0,00% - 0,67%** *(10) / (5)*
CHAFEA	0,70	0,00	12,69	13,39	0,00% - 0,50%	0,00 - 0,07	0,00% - 0,00%	0,00 - 0,00	0,00 - 0,07
HADEA	25,90	- 28,71	0,00	- 2,81	0,00% - 0,50%	0,00 - - 0,01	0,00% - 0,00%	0,00 - 0,00	0,00 - - 0,01
Sub-total contributions (if more than one)	26,60	- 28,71	12,69	10,58		0,00 0,05		0,00 0,00	0,00 0,05
Total DG (with contributions to EAs)	**852,99**	**- 637,87**	**1 577,29**	**1 792,40**					

Notes to the table

- For projects implemented through cross sub-delegated budget lines, the pre-financings amounts from 2021 appear in the payment implementation of the 'delegator' entity (as the paying authorising DG), whilst the pre-financing and clearing are reported by the 'delegated' entity. The split reporting (budgetary and accounting) is regularized in the next year AAR, when the cross sub-delegations become co-delegations of type II.
- To column (1) Type of expenditure differentiated for DG SANTE's relevant portfolio segments
- To column (2) Payments made or equivalent, e.g. expenditure registered in the Commission's accounting system, accepted expenditure or cleared pre-financing. This means after the preventive (ex-ante) control measures have already been implemented earlier in the cycle. In all cases of co-delegations (Internal Rules Article 3), "payments made" are covered by the delegated DGs. For cross-subdelegations (Internal Rules Article 12), they remain with the delegating DGs.
- To column (3) New pre-financing actually paid by the department itself during the financial year (i.e. excluding any pre-financing received as a transfer from another department). "Pre-financing" is covered as in the context of note 2.5.1 to the Commission annual accounts (i.e. excluding "Other advances to Member States" (note 2.5.2) which is covered on a purely payment-made basis). "Pre-financing paid/cleared" are always covered by the delegated DGs, even for cross-subdelegations.
- To column (4) Pre-financing actually cleared during the financial year (i.e. their 'delta' in the financial year 'actuals', not their 'cut-off' based estimated 'consumption').
- To column (5) For the purpose of equivalence with the European Court of Auditors' scope of the EC funds with potential exposure to legality & regularity errors, the Commission's concept of "relevant expenditure" includes the payments made, subtracts the new pre-financing paid out, and adds the previous pre-financing actually cleared during the financial year. This is a separate and 'hybrid' concept, intentionally combining elements from the budgetary accounting and from the general ledger accounting.
- To column (6) In order to calculate the weighted Average Error Rate (AER) for the total relevant expenditure in the reporting year, (i) the detected error rates in ex-post financial audits have been used for grants to Member States in the policy area Food and Feed Safety; (ii) a conservative estimate of 2% was used for expenditure based on public procurement for which in general no

financial audits are carried out; (iii) for low-risk types of expenditure, where there are indications that the equivalent error rate might be close to 'zero' (e.g. administrative expenditure, operating subsidies to agencies, lump-sum grants and clearings based on deliveries), DG SANTE used a conservative estimate of 0,5%.

- To column (8) Even though to some extent based on the 7 years historic average of recoveries and financial corrections (ARC), which is the best available indication of the corrective capacity of the ex-post control systems implemented by DG SANTE over the past years, the DG adjusted this historic average from 1,65% to 0,13%. This figure only includes recoveries and corrections based on ex-post controls while the historic average also includes differences between the registered cost-claim/invoice and the actual payments made that are not corrections stemming from ex-post controls.
- To column (9) Any ex-ante elements, one-off events, (partially) cancelled or waived recovery orders, and other factors from the past years that would no longer be relevant for current programmes (e.g. higher ex-post corrections of previously higher errors in earlier generations of grant programmes, current programmes with entirely ex-ante control systems) would be adjusted in order to come to the best and most conservative estimate of the ex-post future corrections to be applied to the reporting year's relevant expenditure for the current programmes.

ANNEX 10: 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[86]		
	At 31/12/2021	At 31/12/2020	At 31/12/2019
Administrators	**435**	**427**	**432**
Assistants and secretaries	**203**	**200**	**208**
Contractual agents	**91**	**99**	**97**
National experts	**45**	**43**	**35**
Total	**774**	**770**	**772**

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			
Main outputs in 2021:			
Output	**Indicator**	**Target**	**Results 2021**
Updated organisation chart to ensure alignment with the new MFF and COVID lessons learned action plans	Validation by the College	1/07/2021 at the latest	The COVID-19 crisis continued to dominate DG SANTE work in 2021. The revision of the DG SANTE organisation chart has been postponed.
Recruitment of new female middle managers	Number of appointments validated	2 by end 2021	5 were recruited in 2021 of which 3 in the new executive agency HaDEA
Dedicated training and development initiative targeting potential future managers	Actions implemented	31/12/2021	Coaching sessions were organised for 3 Deputy Heads of Unit and 2 Team Leaders to prepare for applying to management positions
DG SANTE staff engagement index	DG SANTE staff engagement index	>= 70%	2021 Staff index: SANTE 76%, Commission average 72%

[86] 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.

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			
Main outputs in 2021:			
Output	**Indicator**	**Target**	**Results 2021**
			2020 Staff index: SANTE: 72%, Commission average 69% 2018 Staff index: SANTE 69%, Commission average 69%
Organisation of a dedicated selection for temporary agents for Grange (auditors)	Selection launched	01/09/2021	Postponed awaiting the outcome of the DG SANTE competition for AD specialists.
Competition for AD Staff in the area of health and food safety.	Competition launched	31/12/2021	Published on 20 May 2021 in the Official Journal (C193A)

Digital transformation

In 2021, the key digital transformation initiatives and consideration of digital elements in policymaking were the following:

- The first phase of SANTE's flagship initiative facilitating electronic submission of applications for authorisation of different domains within the food chain (ESFC) went live in March 2021. This common user centric solution embodies SANTE's quest to digital improving the way we work and fully supports being open and transparent by implementing the EU transparency regulation. The resulting solution has transformed the way submissions are made, digitalising previous paper processes, aligning with the once only principle ensuring that data is shared electronically with stakeholders including with citizens and industry (applicants), National Competent Authorities within Member States, the European Food Safety Agency and the Commission. The solution helped transform and harmonise a number of business processes, enabling the rationalisation of SANTE's IT portfolio and providing a common model facilitating data driven evidence based policymaking. Additional phases of the project continue to be implemented further building on the success of the solid foundations already built.

- EUDAMED-MDR also launched its actors, devices and certificates modules in September 2021, this version of the system goes beyond the existing EUDAMED2 system by implementing the once only principle and ensuring a digital by default workflow relying on industry to provide data, reducing the burden on Member States who previously performed this role.

- In the TRACES system, the old system was shut down by end of 2021, allowing TRACES/NT to manage all kinds of imports and related documents. Launch of the project to implement eSealing through the corporate EUSign service. The collaboration

with the different participating DGs is followed by a common governance and steering allowing to better align efforts and ensure adequate prioritisation and delivery.

- Through the Health Policy Agencies Collaboration initiative, SANTE launched a project in 2021, looking at mapping the digital landscape across HPAC members to help further steer our strategy and identify synergies where common solutions could be deployed. The first phase of this project will be completed in May 2022 and will help to provide the input to start further HPAC projects looking at CRM and common data lakes to avoid working in silos, bring about efficiencies and foster a more collaborative approach to supplying digital solutions across the HPAC horizon.

- Following the corporate decision on IT legacy and Coldfusion technologies DG SANTE has put in place concrete plans to decommission old technologies and systems or absorb them in more modern solutions. This process should complete by the end of 2022.

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

Main outputs in 2021:

Output	Indicator	Target	Results 2021
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.	65% by Q4 2021[87]	68%
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	45% by Q4 2021	100% (All now use M365)
The corporate data inventory includes well managed SANTE key data assets	Percentage of SANTE key data assets for which corporate principles for data governance have been implemented	50% by Q4 2021	20% *(no information collected on progress of this indicator)*
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	68% of the units responded *(followed by an update of 84% of all data assets, the addition of 1 new data asset and the removal of 2 data assets)*
Data strategy elaborated in response to the DG's needs	Data strategy adopted by	Adoption in Q1	Proposed as a common IT and Data strategy to be

[87] Minor change since 2019. The target achievement will increase as of the following year, as the digital strategy and modernisation plans will start to realise also retiring older systems.

Output	Indicator	Target	Results 2021
and priorities	Management Board	2021	established in 2022
Work plan 2021	Work plan 2021 adopted by Management Board	Adoption in Q1 2021	Adopted on 08/02/2021
Increase in awareness of staff on data protection compliance	Percentage of staff attending awareness raising activities	100% Commission newcomers and 20% rest of the staff	- 90 % of the managers - 70% of the newcomers attended the trainings (estimation due to the pandemic and the teleworking situation; outstanding newcomers will be included in trainings during 2022).

Sound environmental management

Objective: DG 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			
Main results and outputs in 2021:			
Corporate EMAS Indicator 1a, Total energy consumption of buildings (MWh/p or kW/m^2) **Corporate Target 2014-2020: -5,2%**			
Output	**Indicator**	**Target**	**Results 2021**
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.	2. actions 85% of staff informed	Address all SANTE Grange staff	Due to the pandemic some initiatives were delayed. However staff continue to be informed through regular newsletter and display boards signage and newsletters.
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).	85% of staff informed	Address all DG/service staff Reduce energy consumption by 0.85% *(compared with the previous year)*	The overall trend in energy consumption is on target.

Corporate EMAS Indicator 1d, Water consumption (m3/p or L/m²) **Corporate Target 2014-2020: -5,4% and -4,8%**			
Output	**Indicator**	**Target**	**Results 2021**
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.	2 actions 85% of staff informed	Address all Grange staff Reduction of 0.85% *(compared with the previous year)*	The water reduction targets were not met due to necessity to carry out extensive flushing for technical reasons.
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).	85% of staff informed	Address all Grange staff	The information campaign relied on noticeboards displays and newsletters to staff
Corporate EMAS Indicator 1e Office paper consumption (Tonnes/person or Sheets/person/day) **Corporate Target 2014-2020: -34%**			
Output	**Indicator**	**Target**	**Results 2021**
Promote staff awareness actions about optimal office paper use in line with the EMAS corporate action on resource efficiency during March.	1. action 85% of staff informed	Address all DG/service staff	Due to the fact that staff were still teleworking this was not carried out. However all our systems are now paperless,
Raise awareness about DG/service's office paper use and communicate observed trends to staff), based verified data from Commission's Environmental Statement.	85% of staff informed	Address all DG/service staff Reduce paper consumption by 0.85% *(compared with the previous year)*	The trends are communicated by notice board display.
Reducing CO2, equivalent CO2 and other atmospheric emissions			
Corporate EMAS Indicator 2 - Reducing emissions, (actions with non-numeric indicators)			
Output	**Indicator**	**Target**	**Results 2021**
Increase in use of Video Conference (VC) meeting rooms in the SANTE Grange, in collaboration with DG SCIC.	5% increase of VC meeting rooms/sessions	Increase use by 5% *(compared with the previous year)*	Due to the pandemic almost all audits with few exceptions were carried out by VC. This is exceptional and not comparable with normal years

ANNEX 11: Implementation through national or international public-sector bodies and bodies governed by private law with a public sector mission (not applicable)

ANNEX 12: EAMR of the Union Delegations (not applicable)

ANNEX 13: Decentralised agencies

EU decentralised agencies	Policy area concerned	*Number of staff * 2021*	EU contribution 2021 M€
ECDC – European Centre for Disease Prevention and Control	Public Health	***351***	**168,1**
EFSA – European Food Safety Authority	Public Health and Food Safety	***542***	**129,1**
EMA[88] – European Medicines Agency	Public Health	***916***	**37,6**
CPVO[89] – Community Plant Variety Office	Food Safety	***52***	**0**
ECHA-biocides[90] – European Chemicals Agency	Food Safety	***69***	**10,4**
Total		***1.930***	**345,2**

*: 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.

More information is included in Annexes 6.2 and 7.1.1.3.

[88] EMA's total 2021 budget amounted to EUR 379,2 million, mainly financed by fees. The EU contribution is a balancing grant (in 2021: 9,9%).

[89] CPVO does not receive any EU subsidies; its 2021 budget amounted to EUR 20,0 million.

[90] 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 2021 amounted to EUR 12,8 million. The EU contribution is a balancing grant (in 2021: 81%)