European Commission

Annual Activity Report 2022

annexes

DG Health and Food Safety (SANTE)

Contents

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

Acting 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)
Carmen Garau
Brussels, 29 March 2023

Acting Deputy Director-General for Health responsible for Directorates B to D

"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, 30 March 2023

Deputy Director-General for Food Sustainability responsible for Directorates E to G

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

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

(e-signed)
Claire Bury
Brussels, 30 March 2023

ANNEX 2: Performance tables

General objective 1: A European Green Deal

Impact indicator: Pesticide risk

Source of data: Member States annually report data to Eurostat under Regulation (EC) No 1185/2009

Baseline (2015-2017)	Interim Milestone (2022)	Target (2024)	Latest known results (31/12/2022)
100	80	70	86 - a decrease of 14% from the baseline period

Specific objective 1.1: Ensuring food and feed safety

Related to spending programme: Single Market Programme

Result indicator 1.1.A (Animal health): Increase of the officially free areas from certain zoonoses (Infection with *Mycobacterium tuberculosis* complex (*M. bovis, M. caprae* and *M. tuberculosis*) and Infection with *Brucella abortus, B. melitensis* and *B. suis*))

Explanation: Member States implement EU approved eradication programmes aiming to reduce and eventually eliminate certain zoonoses from their territories (Infection with *Mycobacterium tuberculosis* complex (*M. bovis, M. caprae* and *M. tuberculosis*) and Infection with *Brucella abortus, B. melitensis* and *B. suis*). 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: Implementing Regulation (EU) 2021/620 designating Member States or regions thereof officially free from the above mentioned diseases.

Baseline (2019)	Interim Milestone (2022)	Target (2024)	Latest known results (Situation on 31/12/2022)
EU countries (or parts thereof) free from the above diseases	+15%	+25%	+22%

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 31/12/2022)
N/A	80%	90%	Not known for 2022, results due in Q2 2023

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 31/12/2022)
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	65% (Lately, it is taking Member States longer to fully implement corrective measures in response to DG SANTE's audit recommendations due to the combined effects of the pandemic and the pressure on resources.)

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 31/12/2022)
N/A	Positive trend	Positive trend	No legislative revisions were adopted in 2021 or 2022

Specific objective 1.1: Ensuring food and feed safety
Related to spending programme: Single Market Programme

Main outputs in 2022:

External communication actions

Output	Indicator	Target	Latest known results (Situation on 31/12/2022)
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	Media coverage in at least 15 EU countries
Social Media Sustained tweets throughout the year on the various aspects of Food and feed safety	Increase engagement on twitter	Average a minimum of 140 engagements per own tweet with #EUFoodSafety (all engagements).	Reached 142 engagements on average with posts including #EUFoodSafety

Output	Indicator	Target	Latest known results (Situation on 31/12/2022)
Website Update of related webpages	Increase in the number of visitors to the SANTE food and feed related webpages	5% increase (baseline 2021 - 5,426,127 entrances*) 5.469.396 entries/ 14.841.272 page views/10.822.378 unique page views **projection*	2022: 4.590.368 entrances / 13.200.071 page views / 9.125.137 unique page views, representing a decrease by 16%
Initiatives linked to regulatory simplification and burden reduction			
Commission Notice on the implementation of food safety management systems covering Good Hygiene Practices and procedures based on the HACCP principles, including the facilitation/flexibility of the implementation in certain food businesses (PLAN/2020/9793)	Adoption	Q2 2022	Adopted: Commission Notice C(2022)5307 of 01/09/2022
Other important outputs			
Output	**Indicator**	**Target**	**Latest known results (Situation on 31/12/2022)**
Animal health and animal diseases			
Delegated Regulation supplementing Regulation (EU) 2016/429 of the European Parliament and of Council as regards rules for the use of veterinary medicinal products for the purpose of prevention and control of category A and B diseases in terrestrial animals (PLAN/2020/6817)	Adoption	Q2 2022	Regulation adopted on 28/11/2022
Amendment to Regulation (EU) 2020/687 on disease control measures for Category A diseases (PLAN/2021/12535)	Adoption	Q1 2022	In planning; adoption foreseen for Q4 2022

Output	Indicator	Target	Latest known results (Situation on 31/12/2022)
Commission Implementing Regulation (EU) laying down rules for the application of Regulation (EU) 2016/429 of the European Parliament and of the Council with regard to registration of operators and establishments keeping terrestrial animals (PLAN/2020/7748)	Adoption	Q1 2022	Adopted: Commission Implementing Regulation 2022/1345 of 01/08/2022
Commission Implementing Regulation amending Regulation.(EU) 2018/1882 of 3 December 2018 on the application of certain disease prevention and control rules to categories of listed diseases and establishing a list of species and groups of species posing a considerable risk for the spread of those listed diseases (PLAN/2020/8808)	Adoption	Q2 2022	Adopted: Commission Implementing Regulation 2022/925 of 14/06/2022
Amendments to Implementing Regulation (EU) 2021/620 on animal health statuses in the EU	Adoption as necessary according to the epidemiological situation	In course of 2022	Amended by Commission Implementing Regulations 2022/214 and 2022/1218
Amendments to Implementing Regulation (EU) 2021/605 in relation to disease control measures on African swine fever (ASF)	Adoption as necessary according to the epidemiological situation	Q1 2022	27 amending acts adopted
Commission emergency decisions on handling evolving epidemiological situations	Adoption as necessary, according to the epidemiological situation	In course of 2022	There was no emergency situation in 2022 that triggered the need for the EU to declare a “public health emergency”. The EU was aligned with WHO’s declaration of a public health emergency of international concern for monkey pox.

Output	Indicator	Target	Latest known results (Situation on 31/12/2022)
Amendments to Implementing Regulations (EU) 2020/2235, 2020/2236 and 2021/403 on animal health and official certificates	Adoption	In course of 2022	- IR 2020/2235 amended by IRs 2022/7, 2022/36, 2022/854 and 2022/1219 - IR 2020/2236 not amended - IR 2021/403 amended by IRs 2022/37, 2022/55, 2022/250, 2022/497
Amendments to Implementing Regulation 2021/405 on the list of third countries	Adoption	In course of 2022	Amended by IRs 2022/34, 2022/363, 2022/1389
Plant health and diseases *Under the 'Plant Health Law' (PHL) Regulation 2016/2031*			
Commission Implementing Regulations on high-risk plants dossiers (PHL Art 42.4)	Adoption	The no. of adopted Regulations depends on the number of requests and on EFSA opinions	7 Implementing Regulations (2022/1942, 2022/1916, 2022/1404, 2022/1309, 2022/853, 2022/490, 2022/230) adopted
Commission Regulations on new or updated measures for quarantine pests known to occur in the Union (PHL Art 28)	Adoption	Ongoing activity for 20 pests	Reg 2022/959 of 16/6/2022 (*Thaumatotibia leucotreta* requirements Africa) Reg 2022/2095 of 28/10/2022 (*Anoplophora chinensis*) 3 containment Regulations: 2022/1629 and 2022/1630 of 21/09/2022 and 2022/1927 of 11/10/2022 4 potato pest Regulations: 2022/1192, 2022/1193, 2022/1194 and 2022/1195 of 11/7/2022
Commission Decisions on emergency measures against some specific pests (PHL Art 30.1)	Adoption according to (new) outbreak situations	In course of 2022	Reg 2022/1265 of 20/7/2022 (Rose Rosette Virus); Reg. 2022/1372 of 5/8/2022 (Meloidogyne graminicola); Reg. 2022/1941 of 13/10/2022 (prohibition list)

Output	Indicator	Target	Latest known results (Situation on 31/12/2022)
Commission Decisions with specific import requirements for trade lines where there are too many import interceptions (PHL Art 40)	Adoption according to import interception notifications from MS	In course of 2022	None
Commission Regulations with derogations from standard requirements under specific conditions (PHL Art 43)	Adoption according to requests from third countries	In course of 2022	Delegated Reg 2022/1456 of 10/6/2022 (US wood packging material)
Commission Regulations with equivalence to standard requirements (PHL Art. 44)	Adoption according to requests from third countries	In course of 2022	Reg 2022/1659 of 27/9/2022 (Import of Citrus fruit from Israel as regards Thaumatotibia leucotreta)
Evaluation of co-financing requests of Member States eradication measures	No. of co-financing requests for plant health eradication/containment dossiers (1st year outbreaks) that received co-financing	33 dossiers for 2020 measures 5-8 dossiers for 2021 measures	33 dossiers evaluated for 2020 measures dossiers for 2021 measures on-going
Market access for safe substances and products			
General plan on risk communication in the context of the implementation of the 'Transparency Regulation' 2019/1381	Preparatory work	In course of 2022	No legal deadline in the regulation; work deprioritised and postponed to 2023.
Regulatory measures on contaminants in food and feed following EFSA opinions (under Reg 315/93 on contaminants in food)	Adoption	In course of 2022	Ongoing regular activity. In 2022, MLs in food were adopted for: mercury, ochratoxin A, hydrocyanic acid, delta-9-tetrahydrocannabinol (Δ9-THC), dioxins and dioxin-like PCBs and perfluoroalkyl substances (PFAS)
Authorisations of health and nutrition claims, generic descriptors (under Reg 1924/2006 on nutrition and health claims)	Adoption	In course of 2022	No authorisations 4 refused authorisations relating to: Nutrimune, GlycoLite, Anxiofit-1 and Bi-07, Coffee C21 and MenaQ7

Output	Indicator	Target	Latest known results (Situation on 31/12/2022)
Authorisations of health claims made on foods and referring to children's development	Adoption	In course of 2022	No authorisations 3 refused authorisations relating to: Anxiofit-1, Nutrimune, Symbiosal®
Commission Regulations prohibiting, restricting or banning the use of substances other than vitamins and minerals in food (Reg 1925/2006, Art 8 procedure)	Adoption	In course of 2022	The acts adopted during 2022 are those listed below* (monacolins and catechins)
Authorisations of vitamins and mineral substances that can be added to foods and/or to food supplements or foods for specific groups (under Dir 2002/46)	Adoption	In course of 2022	Delegated Regulation of 16 December 2022 amending the Annex to Reg 609/2013 to allow the use of nicotinamide riboside chloride as a source of niacin in food for special medical purposes and total diet replacement for weight control
Commission Regulation setting minimum and maximum amounts of vitamins and minerals added to foods including food supplements (PLAN/2020/8927)	Preparatory work, including on the Impact Assessment	In course of 2022	Preparatory work progressing
Commission Regulation on the restriction of use of Monacolins under the 'Fortification' Regulation 1925/2006 (PLAN/2018/2882)	Adoption	Q1 2022	*COM Regulation 2022/860 adopted on 01/06/2022
Commission Regulation on the restriction of use of Green Tea Catechins under the 'Fortification' Regulation 1925/2006 (PLAN/2020/8914)	Adoption	Q2 2022	COM Regulation 2022/2340 of 30/11/2022
Commission Regulation on the use of Alpha Lipoic Acid under the 'Fortification' Regulation 1925/2006 [Decide reference not yet available]	Adoption	Q4 2022	Not yet in planning; due to the complexity of the matter,

Output	Indicator	Target	Latest known results (Situation on 31/12/2022)
Authorisation of novel foods under Regulation 2015/2283 on Novel Foods, including data protection (Articles 26 and 27)	Adoption	Ongoing regular activity in 2022	17 authorisations granted 60 decisions terminating the authorisation procedures adopted.
Authorisation of traditional foods from third countries (Reg 2015/2283 on Novel Foods Articles 14 to 19)	Adoption	Ongoing regular activity in 2022	1 authorisation granted 2 authorisations refused 22 decisions terminating the authorisation procedures adopted
Authorisations for new substances and new uses of already authorised substances used as food additives or food flavourings (Reg 1331/2008 Art 7)	Adoption	Ongoing regular activity in 2022	Reg 2022/1037 adopted on 29/06/2022 and 1 act pending adoption (PLAN/2022/672) 6 Regulations authorising new substances and/ or new uses (as listed below): C/2022/315 C/2022/2352 C/2022/4315 C/2022/4337 C/2022/4360 C/2022/7048
Implementing act on scientific data for the evaluation of the combination effects of chemicals for food additives (Reg 1331/2008 Art 9)	Preparatory work	End 2022	More time is needed to take into account the ongoing work, involving several Commission's services, on cumulative effects of chemicals in the context of the Chemicals strategy for sustainability and the relevant work carried out by EFSA.
Authorisations for new substances and new uses of already authorised substances used in food contact materials (Reg 1935/2004 Art 5.1)	Adoption	Ongoing regular activity in 2022	One act updating 9 and authorising 5 substances was voted favourably in the SC-PAFF; the PRAC has been launched on 29/11/2022, the scrutiny expires on 28/02/2023.

Output	Indicator	Target	Latest known results (Situation on 31/12/2022)
Authorisations (Reg 1829/2003 Arts 7.3, 19.3) and renewal-authorisations (Reg 1829/2003 Arts 11.3, 23.3) of GMO for food/feed	Adoption	Ongoing regular activity in 2022	Adoption of 6 implementing decisions to authorise new GMOs and 1 implementing decision for renewal-authorisation of GMOs.
Implementing Regulations approving/not approving or renewing/not renewing approvals of active substances (AS) for plant protection products (Different articles of Regulation 1107/2009, such as Art 20.1, Art 21.3 and Art 78.2, Art 20.1 in conjunction with Art 22.1, Art 13.2, Art 20.1a, Art 13.2 in conjunction with Art 23.5, Art 13.2c, Art 21.3 second alternative in conjunction with Art 6 and Article 78.2)	Adoption	Ongoing regular activity in 2022	25 (including also amendments of approval conditions)
Regulations establishing maximum residues levels (MRL) for pesticides (Reg 396/2005, Art 14)	Adoption	Ongoing regular activity in 2022	14 Regulations adopted in 2022 concerning 75 active substances.
Cumulative risk assessment method for pesticides residues	Development	Ongoing activity in 2022	EFSA continued with the implementation of the joint EFSA-SANTE action plan on cumulative risk assessment agreed in 2021.
Implementing acts approving/not approving or renewing/non-renewing the approval of biocidal active substances (Reg 528/2012: Art 9 – approval; Art 14 – renewal, Art 15 – cancellation/amendment of approval)	Adoption	Ongoing regular activity in 2022	4 approval regulations covering 5 active substance/product-type combinations, 5 non-approval decisions covering 8 active substance/product-type combinations 1 renewal regulation 1 implementing regulation cancelling an approval

Output	Indicator	Target	Latest known results (Situation on 31/12/2022)
Implementing Regulations granting or amending Union authorisation of biocidal products (Reg 528/2012 Art 44 – authorisation; Art 48 – amendment/cancellation)	Adoption	Ongoing regular activity in 2022	18 implementing regulations granting Union authorisation 1 implementing regulation amending a Union authorisation
Implementing Decisions on disagreements between Member States on the authorisation of biocidal products or derogation to mutual recognition (Reg 528/2012 Art 36 – disagreements; Art 37 – derogation to mutual recognition)	Adoption	Ongoing regular activity in 2022	9 implementing decisions on disagreements between Member States
Re-evaluations of authorisations, new authorisations, denial of authorisation, modifications of authorisations and renewal and non-renewal of authorisations of feed additives (Reg 2003/1831, Arts 4, 10 or 14)	Adoption	Ongoing regular activity in 2022	83 acts
Authorisations of veterinary medicinal products	Adoption	Ongoing regular activity in 2022	9 (under Reg 726/2004); 1 (under Reg 2019/6)
Setting of MRLs for substances used in veterinary medicinal products (Reg 470/2009, Art. 17)	Adoption	Ongoing regular activity in 2022	1 regulation (2022/634) adopted on 13/04/2022

Output	Indicator	Target	Latest known results (Situation on 31/12/2022)
Tertiary legislation on residues of Veterinary Medicinal Products: - Commission Delegated Regulation and Implementing Regulation on veterinary medicinal product residue monitoring plan in products of animal origin (PLAN/2021/12170 and PLAN/2017/2194) - Commission Delegated Regulation and Implementing Regulation on contaminant monitoring plan in food (PLAN/2021/11521 and PLAN/2018/3882) - Commission Delegated Regulation on import conditions for products of animal origin for the presence of contaminants, residues of veterinary medicinal products and pesticides (PLAN/2017/2208)	Adoption	Q3 2022 for DAs Q4 2022 for IAs	- DA adopted on 07/07/2022 / IA adopted on 23/09/2022 - DA adopted on 17/06/2022 / IA adopted on 17/06/2022 - DA adopted on 06/09/2022
Commission rules on safe imports, trade and related aspects (Regs 2016/2032, 2016/429, 2017/625 and 853/2004)	Adoption of Commission implementing rules	In course of 2022	144 implementing acts
Control systems, including audits, and rapid alert systems			
Delegated acts on exemptions of certain goods from checks at border control posts (Reg 2017/625, Art 48)	Adoption	In course of 2022	Reg 2022/887 of 28/03/2022 and 1 Reg pending adoption (PLAN/2022/1869)
Implementing acts on commodities to be checked at border control posts (Reg 2017/625, Art 47.2)	Adoption	In course of 2022	Reg 2022/176 of 9 February 2022 and Reg 2022/1322 of 25 July 2022
Implementing Regulations reviewing import control measures for food and feed of non-animal origin (Reg 2017/625, Art 47.2, 54.4) (Reg 178/2002 Art 53.1)	Adoption	In course of 2022	Reg 2022/913 of 30/05/2022

Output	Indicator	Target	Latest known results (Situation on 31/12/2022)
Implementing act on harmonised decisions on consignments at border control posts	Adoption	In course of 2022	Initiative abandoned following LS opinion during ISC
Delegated Regulation on import conditions of food and border control checks (PLAN/2021/11386)	Adoption	Q3 2022	Regulation 2022/887 of 28/03/2022
European Reference Laboratories	Number of laboratories funded	44	45
European Reference Centres	Number of centres funded	4	4
Controls, including audits in the area of food safety and quality, animal health, animal welfare and plant health	Approx. 175 controls, including audits completed	In the course of 2022	168 controls, including 18 analyses
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	4 plenary meetings 4 subgroup meetings;	4 plenary meetings 5 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 exchange best practices identified	Number of meetings held	3 meetings of the working group on the Sustainable Use Directive 1 meeting of the National Contact Point group on animal welfare	1 workshop on the operationalisation of One Health in context of Junior Professional Project. 2 meetings of the working group on the Sustainable Use Directive in 2022.
Assessment of planned facilities of Border Control Posts (BCPs) and inspection centres therein	Assessments carried out	Approx. 60 per year, based on figures from 2021and likely demand from the Member States	58 performed.

Output	Indicator	Target	Latest known results (Situation on 31/12/2022)
Evaluation of MS' and non-EU countries' residue monitoring plans (food of animal origin)	Number of evaluations carried out	27 Member States' plans, plus Northern Ireland; up to 50% of non-EU countries' (that are approved to export food of animal origin to the EU) plans	27 Member States, plus Northern Ireland; 63 non-EU country plans (with existing plans) and 11 new commodity applications. This is well in excess of the 50% target).
Management of lists of approved non-EU country establishments for the production of food of animal origin	Number of request managed	Based on 2021 data, ca 1000 requests for additions, modifications and deletions of establishments, resulting in around 4600 changes to the list in TRACES	In 2022 2643 lists were approved for publication in TRACES following an eligibility check. These comprised 5282 operators [formerly, establishments].
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 2022	Report on EUROPHYT (outbreaks) for 2020 and 2021 will be published in first quarter of 2023. EUROPHYT (Interceptions) has been replaced by Traces.
Plant health surveys	Member States' survey results for harmful organisms presented to Standing Committee on PAFF	In course of 2022	Survey results for 10 plant pests were presented in SCoPAFF.
Computerised systems + IT (e.g. TRACES, ADNS, EUROPHYT)			
TRACES	No of active end-users	65000	85 000
ADIS	No of active end-users	450	601
iRASFF	No of active user accounts	7211	7211
EUROPHYT (Interceptions and Outbreaks)	No of active end-users	1100	EUROPHYT (Outbreaks): 413 end users, EUROPHYT (Interceptions) has been replaced by TRACES.
AROC (Annual Reporting on Official Controls)	No of active end-users	163	134

Specific objective 1.2: Ensuring sustainable food systems the 'Farm to Fork' strategy
Related to spending programme: 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)	Interim Milestone (2022)	Target (2024)	Latest known results (Situation on 31/12/2019)
100	85 (15% decrease)	70 (30% decrease)	74 (11% decrease); compared to last known results from 2019

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 31/12/2022)
118.6 mg/PCU4	95 mg/PCU	85 mg/PCU	84.4 mg/PCU

Result indicator 1.2.C : Number of Member States that have put in place national food waste prevention strategies
Explanation: The number of Member States that have put in place integrated food waste prevention strategies and roadmap/action plan to prevent food loss and waste, based on the "Target, Measure, Act" approach 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.

Baseline (2020)	Interim Milestone (2022)	Target (2024)	Latest known results (Situation on 31/12/2022)
N/A	20	27	23 ([1])

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.

([1])*The quantification of Member States reflects the findings of the EEA report (Report No 15/2021), which states that while most Member States have implemented some measures to reduce food waste, these are relatively light and tend to focus on voluntary commitments or information provision. Moreover, while 25 Member States have reported on their food waste levels to ESTAT (2022), very few have to date applied an evidence-based approach in designing their national strategies and/or programmes.*

Source of data: Commission internal (DG SANTE)			
Baseline (2020)	**Interim Milestone (2022)**	**Target (2024)**	**Latest known results (Situation on 31/12/2022)**
81% (based on recommendations 2010-2019)	83% (based on recommendations 2010-2021)	85% (based on recommendations 2010-2023)	77% (Lately, it is taking Member States longer to fully implement corrective measures in response to DG SANTE's audit recommendations due to the combined effects of the pandemic and the pressure on resources.)
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 31/12/2022)**
N/A	Positive trend	Positive trend	1 legislative revision proposed that introduces burden reduction measures.
Main outputs in 2022:			
New policy initiatives			
Output	**Indicator**	**Target**	**Latest known results (Situation on 31/12/2022)**
Proposal for a revision of the Sustainable Use Directive for pesticides (SUD) (PLAN/2020/6975)	Adoption	Q1 2022	Proposal adopted on 22/06/2022
Proposal for a revision of the Regulation on food information to consumers (PLAN/2020/8886, PLAN/2020/9144 and PLAN/2021/11031)	Adoption	Q4 2022	Initiatives in planning; adoption date to be decided.
Preparatory work on proposal for a legislative framework for sustainable food systems including sustainability labelling (PLAN/2021/11463)	Finalisation of impact assessment	Q4 2022	Work ongoing on the impact assessment. Adoption postponed to Q3 2023.

Output	Indicator	Target	Latest known results (Situation on 31/12/2022)
Preparatory work on proposal for setting EU-level targets for food waste reduction (PLAN/2021/11886)	Finalisation of impact assessment	Q4 2022	Work ongoing on the impact assessment; adoption postponed to Q2 2023 as part of a wider package with ENV amending the Waste Framework Directive.
Proposal on ceramic and vitrous food contact materials (PLAN/2018/4857)	Finalisation of impact assessment	Q4 2022	Work Ongoing; adoption of proposal now foreseen for Q1 2025. The work will be continued in parallel with the work on the revision of the FCM framework regulation with the same timing.
Preparatory work on a proposal on plants obtained by certain new genomic techniques (PLAN/2021/11456)	Finalisation of external contractor report supporting the impact assessment	Q4 2022	Work ongoing. Adoption postponed to Q2 2023.
Initiatives linked to regulatory simplification and burden reduction			
Proposal for a revision of Reg 1831/2003 on additives for use in animal nutrition (PLAN/2020/8500)	Adoption	Q2 2022	Work on the IA ongoing; finalisation postponed until 2024.
Proposal for a revision of the seeds/forest legislation (PLAN/2020/7576)	Adoption	Q4 2022	Work on the IA ongoing, but delayed due to extensive amount of work needed to prepare the impact assessment; adoption now scheduled for Q2 2023.
Proposal for a revision of the food contact materials Regulation (PLAN/2020/7637)	Finalisation of impact assessment	Q4 2022	Work on the IA ongoing; finalisation postponed to Q2 2024.
Evaluations and fitness checks			
Evaluation of Reg 1831/2003 on additives for use in animal nutrition (PLAN/2017/988) [REFIT Scoreboard 2017]	Finalisation of SWD	Q1 2022	Finalisation delayed to Q2 2023;
Fitness check of the animal welfare legislation (PLAN/2020/6933)	Finalisation of SWD	Q3 2022	SWD(2022)328 of 04/10/2022

Evaluation of the Food Contact Materials (FCM) legislation (PLAN/2016/436)	Publication of SWD	Q1 2022	Adopted on 09/06/2022
Evaluation of 2014 – 2020 food chain spending programme (PLAN/2021/10672)	Finalisation of SWD	Q4 2022	Work on the evaluation ongoing; adoption postponed to Q3 2023;
Public consultations			
Output	**Indicator**	**Target**	**Latest known results (Situation on 31/12/2022)**
Public consultation on a legislative framework for sustainable food systems (PLAN/2021/11463)	Finalisation	Q2 2022	Finalised on 21/07/2022
Public consultation on setting EU-level targets for food waste reduction (PLAN/2021/11886)	Finalisation	Q3 2022	Finalised on 24/08/2022
Public consultation on the revision of the food contact materials Regulation (PLAN/2020/7637)	Finalisation	Q2 2022	Finalised on 11/01/2023;
Public consultation on new genomic techniques (PLAN/2021/11456)	Finalisation	Q2 2022	Finalised on 22/07/2022
Public consultation on setting of nutrient profiles (PLAN/2020/9144)	Finalisation	Q2 2022	Finalised on 07/03/2022
Public consultation on revision of food information to consumers (PLAN/2020/8886)	Finalisation	Q2 2022	Finalised on 07/03/2022
Public consultation on the revision of the EU animal welfare legislation (PLAN/2021/10238)	Finalisation	Q1 2022	Finalised on 21/01/2022

External communication actions			
Output	**Indicator**	**Target**	**Latest known results (Situation on 31/12/2022)**
Press and Media Communicate on the various proposals	National print media coverage of EU's actions when proposals adopted	Media coverage by at least 25 EU countries	Media coverage of the Strategy was seen in all 27 EU countries
Farm To Fork Conference Organisation of a hybrid Conference on Farm to Fork in October 2022	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)	9 000 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)	Conference was not organised as a stand alone and was integrated as a section of DG AGRI's Agriculture OUTLOOK Conference (attended by around 15 000 people). 110 000 impressions generated on Twitter around the OUTLOOK Conference
Participation in the Paris Agriculture fair, together with DG AGRI	Visitors to the Commission stand	Maintain average daily figures achieved in 2020* Paris: 4080 visitors per day *(COVID measures will mean restrictions on the overall number of people)	3 480 visitors per day
Multimedia 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)	This campaign first went live on 05 September 2022 lasting until 18 December 2022. We have delivered 327 728 article views, (130% of the overall KPI.) and 3 931 288 Video Views, (110% of the overall KPI); a total of 4 259 016 views Survey still not done yet.

Output	Indicator	Target	Latest known results (Situation on 31/12/2022)
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	Average a minimum of 160 engagements per own tweet with #EUFarm2Fork (all engagements)	Reached 169 engagements on average with posts including #EUFarm2Fork
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 2021 baseline: 65,078 entrances*) *projection	2022: 168 823 entries/276 815 page views / 208 182 unique page views, representing a 27.6% increase. 80% positive satisfaction rate (when asked in survey)

Other important outputs			
Output	**Indicator**	**Target**	**Latest known results (Situation on 31/12/2022)**
Farm to Fork Strategy monitoring framework	Organisation of workshops with stakeholders and Member States to present indicators' selection and to gather input	Q4 2022	Work on the monitoring framework is ongoing. Workshops with stakeholders and Member States to present indicators' selection and to gather input to be organised in the first half of 2023. Delays occurred due to the complexity of the task and the wide scope of the exercise.

Output	Indicator	Target	Latest known results (Situation on 31/12/2022)
EU Code of Conduct for responsible food business and marketing practices	First assessment report Organisation of two collaborative platform meetings	Q4 2022 Q1 and Q4 2022	First draft of the mapping study on the commitments delivered mid November 2022 and presented at the collaborative platform of 29 November 2022. Final draft of the study delivered In December 2022. Two meetings with stakeholders and signatories (collaborative platform) were organised in March and November 2022.
Contribution to Commission assessment of MS' CAP National Strategic Plans	Ongoing work	In course of 2022	Contribution to the assessment of 28 CAP Strategic Plans (Belgium submitted separate Plans for Flanders and Wallonia).
Plant Protection Products and sustainable use thereof			
4 Commission Regulations on data requirements, uniform principles for evaluation and decision-making criteria for microorganisms that are active substances in plant protection products (PLAN/2020/8954, PLAN/2020/8955, PLAN/2020/8956, and PLAN/2020/9073)	Adoption	Q2 2022	Adopted on 31/08/2022: C(2022)4403 C(2022)6119 C(2022)4402 C(2022)6117
Adaptation of the Communications accompanying the data requirements for active substances and plan protection products (chemical active substances including for ED properties) (PLAN/2017/920 and PLAN/2017/921)	Adoption	Q2 2022	In planning; adoption foreseen for Q2 2023, delayed because of additional comments of Member States and stakeholders.

Output	Indicator	Target	Latest known results (Situation on 31/12/2022)
Adaptation of the Communications accompanying the data requirements for active substances and plant protection products (for microorganisms) (PLAN/2021/10493 and PLAN/2021/10492)	Adoption	Q2 2022	In planning; adoption foreseen for Q2 2023. Delay due to consultation of Member States and stakeholders.
Implementing act on record keeping of PPP use as required by Article 67 of Regulation (EC) no 1107/2009 (PLAN/2021/12099)	Adoption	Q2 2022	In planning; adoption foreseen for Q1 2023.
Implementing regulation lowering maximum residue levels (MRLs) for the two neonicotinoid substances clothianidin and thiametoxam, in order to take into account environmental concerns of global nature (decline of pollinators) (PLAN/2021/12722)	Adoption	Q2 2022	Commission Regulation (EU) 2023/334 of 2 February 2023.
Reduction in the use of antimicrobials in animals to contribute to fight AMR			
Tertiary legislation relating to Reg 2019/6 on veterinary medicinal products: - Implementing act on the format for the collection of data on antimicrobials (PLAN/2018/3984) - Implementing act on the list of antimicrobials reserved for human medicine (PLAN/2018/3966) - Delegated Act on the detailed rules on imports of animal and products of animal origin into the EU (Art. 118) (PLAN/2018/4503)	Adoption Adoption Adoption	Q1 2022 Q3 2022 Q4 2022	Reg 2022/209 adopted on 16/02/2022 Reg 2022/1255 adopted on 19/07/2022 Ongoing; adoption foreseen for Q1 2023. Progress of this delegated act was linked to the publication of Reg 2022/1255 adopted on 19/07/2022, which took longer than expected due to the extension of the objection period by the EP. Q4 2023. EMA opinion

Output	Indicator	Target	Latest known results (Situation on 31/12/2022)
- Implementing act on the list of antimicrobials that cannot be used outside the terms of their marketing authorisations, or that can be used outside the terms of their marketing authorisations subject to certain conditions (PLAN/2020/9134) - Implementing acts supplementing the DA under Art. 118 of the VMP regulation (e.g. list of third countries & amendments to the relevant certificates) [Decide reference not yet available]	Adoption Preparatory work	Q3 2022 Ongoing work in 2022	necessary to draft this act is not yet available due to the complexity of the file and its links with Reg 2022/1255 adopted on 19/07/2022. These IAs are linked to the publication of the abovementioned DA under Art 118 and further discussions with Member States.
Sustainable feeds			
Authorisations of feed additives contributing to more sustainable feed	Adoption	In course of 2022	17
Delegated act on the establishment of maximum levels of cross-contamination for antimicrobials in feed (PLAN/2021/12797)	Adoption	Q4 2022	Preparatory work still ongoing; adoption foreseen for Q1 2023.
Food loss and waste			
Operational support services for the EU Platform on Food Losses and Food Waste	Operation of EU Food Loss and Waste Prevention Hub and user activity	Ongoing regular activity in 2022	Ongoing, regular supporting activity as regards online communications, online community management and best practice sharing.

Output	Indicator	Target	Latest known results (Situation on 31/12/2022)
Meetings of the EU Platform on Food Losses and Food Waste	2 meetings held	Q1 and Q4 2022	1 online meeting held on 17/02/2022 and one hybrid meeting held on 20/10/2022
Meetings of the sub-groups of the EU Platform on Food Losses and Food Waste	10 meetings held	In course of 2022	7 meetings held (2 hybrid and 5 on-line) Action & implementation sub-group: 24/06 and 04/10/2022 Consumer food waste prevention sub-group: 08/07/2022 Date marking and food waste prevention sub-group: 05/07/2022 Food donation sub-group: 12/07 and 7-8/11/2022 (first day was a study visit at the Brussels Food Bank) Food loss and waste monitoring sub-group: 13/06/2022
Grants for Member States to improve measurement of food waste and help implement food waste prevention programmes	Signature	Q4 2022	5 grants have been signed (SE, NL, HU, IT, HR)
Grants for stakeholders to improve measurement of food waste and help implement food waste prevention in their operations and organisations	Signature	Q4 2022	Call for proposals was open between 23/06 and 20/09/2022; 24 applications received. So far 14 grants have been signed.

Output	Indicator	Target	Latest known results (Situation on 31/12/2022)
Pilot project *European Consumer Food Waste Forum (2021-2023)*	Report with the scope of the project, the framework for the evaluation of consumer food waste interventions and a protocol for the collection of information	Q4 2022	Report received from JRC on 19/05/2022, but not published yet. The evaluation framework is being tested by experts and will be updated according to results, together with the report. The ECWF received additional funding in 2022 to facilitate - through interactive online tools and other communications outputs - the uptake of the findings of the European Consumer Food Waste Forum by stakeholders engaged in consumer food waste prevention in the 27 Member States.
Animal Welfare			
Study on animal welfare labelling	Publication	Q1 2022	Published on 30/03/2022
Delegated act on animal welfare conditions on EU livestock vessels (PLAN/2020/9249)	Adoption	Q3 2022	Pending adoption foreseen for Q1 2023; The issues included in the planned legislation were more complex and articulated than expected (international and technical aspects, legal aspects...)
Food Fraud			
Food fraud fact-finding studies	No. of studies carried out	Complete series of eight fact-finding studies	Two fact-finding studies carried out; reports of the studies finalised and published; guidance document finalised and converted into a technical report.
Whistleblower platform	Development	Q4 2022	Initiative abandoned due to a lack of support by Member States, for which national solutions are already in place.

Output	Indicator	Target	Latest known results (Situation on 31/12/2022)
Support to innovation (including novel food, plant reproductive material and innovative techniques)			
Commission report regarding MS' experience with Dir 2009/41 (Art 17.3) on the contained use of genetically modified microorganisms for the period 2019-2021 (PLAN/2021/12303)	Publication	Q4 2022	Adoption foreseen for Q1 2023.
Study on the Union's situation regarding placing on the market and use of invertebrate biological control agents (PLAN/2022/450)	Publication	Q4 2022	Sent to EP and Council on 20/12/2022
Implementation of the plant reproductive material marketing Directives			
Amendment of EU equivalence Council Decision 2003/17/EC (prolongation of application and inclusion of Bolivia) (PLAN/2020/7573)		Q1 2022	COM proposal adopted on 27/01/2022
Follow notifications on temporary seed supply difficulties and preparation of derogations including seed not satisfying the requirements in respect of minimum germination	Adoption of derogatory decisions	In course of 2022	Adopted on 12 December 2022
Extension of import requirements for vegetabe propagating material	Adoption		Implementing Decis 2022/1400 on extending the period during which MS may decide on the import conditions for vegetable propagating and planting material, other than seed, from third countries.

Output	Indicator	Target	Latest known results (Situation on 31/12/2022)
Extension of import requirements for fruit propagating material			Implementing Decis 2022/1933 of 12 October 2022 on extending the derogation relating to import conditions for fruit plant propagating material and fruit plants intended for fruit production from third countries
Decisions (habilitations) updating the common catalogues of varieties of agricultural and vegetable species	Adoption	In course of 2022	24 updates published in 2022: - 2000 new varieties of agricultural species amounting in total to 23 719 - 1325 new varieties of vegetable species amounting total to 21 011
Derogations for adapted variety testing requirements for organic varieties	Adoption		Implementing Dir 2022/1647 as regards a derogation for organic varieties of agricultural plant species suitable for organic production Implementing Dir 2022/1648 as regards a derogation for organic varieties of vegetable species suitable for organic production
Food Contact Materials			
Authorisation of processes for recycling plastic food contact materials in accordance with Regulation 2022/1616, Art 19(1)	Adoption	Around 200 processes authorised in course of 2022	Adoption of approx. 200 decisions foreseen in Q1/Q2 2023 The delay is caused by the entry into force of Reg 2022/1616.
Food for Specific Groups			
Delegated act on the approval of formulae from protein hydrolysates (PLAN/2021/12214)	Adoption	Q1 2022	Reg 2022/519 adopted on 14/01/2022

Output	Indicator	Target	Latest known results (Situation on 31/12/2022)
Delegated act amending certain compositional requirements for total diet replacement for weight control	Adoption	Q3 2022	Commission Delegated Reg 2022/2182 of 30 August 2022 as regards the lipid and magnesium requirements for total diet replacement for weight control.

General objective 1: A European Green Deal

Specific objective 1.3: Increased EU influence in international fora

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 31/12/2022)
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	65%: based on sum of audits carried out in years 2018+2019+2020

Main outputs in 2022:

External communication actions

Output	Indicator	Target	Latest known results (Situation on 31/12/2022)
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 (Baseline 2021: 39 016 entries/ 74 428 page views/ 52 940 unique page views)	12,7% increase (43 993 entries / 86 617 page views / 62 502 unique page views)

Other important outputs			
Output	**Indicator**	**Target**	**Latest known results (Situation on 31/12/2022)**
Report on the application of EU health and environmental standards to imported agricultural and agri-food products (PLAN/2021/12975)	Publication	Q2 2022	Report adopted on 03/06/2022
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 2022	131 common positions
Coordinated EU position for the WOAH aquatic and terrestrial Code and Manual	Delivered	In course of 2022	51 (May 2022)
Coordinated EU Statements for the WOAH General Assembly	Delivered	In course of 2022	15 (May 2022)
Coordinated EU positions for the European and Mediterranean Plant Protection Organization (EPPO) Working Party meeting	Delivered	In course of 2022	23
Coordinated EU positions for the International Plant Protection Convention (IPPC)	Delivered	In course of 2022	47
Coordinated EU positions for the European and Mediterranean Plant Protection Organisation Council meeting	Delivered	In course of 2022	12
Coordinated EU positions in the resolutions of the Governing Body of the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA)	Delivered	In course of 2022	One position coordinated that required a Council Decision.
Input to the coordination for the Commission on Genetic Resources for Food and Agriculture	Delivered	In course of 2022	1 EU position coordinated

Output	Indicator	Target	Latest known results (Situation on 31/12/2022)
Coordinated EU positions in OECD Seed and OECD Forest schemes	Delivered	In course of 2022	No position to coordinate since 2022 was an inter-sessional year
Coordinated EU positions in the World Trade Organisation SPS	Delivered	In course of 2022	41 specific trade concerns (STCs)
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 2022	Intersessional meetings in Geneva (March 2022) and Nairobi (June 2022) and COP-15 and COP-MOP-10 in Montreal (December 2022). Main outcomes: agreed target on biosafety in the Global Biodiversity Framework; technical expert group to identify specific issues of risk assessment for consideration at the next COP-MOP; technical expert group to perform a broad horizon scanning, monitoring and assessment of synthetic biology.
Bilateral SPS 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	The SPS Chapter has been concluded in the negotiations of the new Agreements with Chile and New Zealand. Technical negotiations with Uzbekistan and Eastern and South African countries (ESA) countries were concluded. Partnership and Cooperation Agreement with Thailand, including a SPS chapter, was signed.
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 2022	IHR requirements laid down in EU certificates between the EU and South Korea for pork and poultry products. 17 EU harmonised certificates (SPS) (i.e. Canada, Moldova, Ukraine)

Output	Indicator	Target	Latest known results (Situation on 31/12/2022)
Coordinate EU position in negotiations of Agreements with non-EU countries	Delivered	In course of 2022	Coordination of EU position in negotiations of Agreements with India, Australia, New Zealand and Indonesia.
Coordinate EU position on the management of the SPS Committees of the Agreements in force	Delivered	In course of 2022	EU-Canada SPS JMC (October 2022) Coordination of EU positions on the management of the SPS Committees of the Agreements in force with Vietnam South Korea, and Singapore, Chile, Central America, Colombia-Ecuador-Peru.
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	1 AHTWG and 2 PHTWG meetings held	In course of 2022	Completed
Meeting of the EU-US Food Safety Working Group	1 yearly meeting	During 2022	Meeting postponed to 2023
Meetings of the EU-Japan Animal Health Technical Working Group: Facilitate trade and better cooperation on animal health issues with Japan	1 meeting	Q1 2022	Second AHTWG meeting held on 3-4 October 2022
Meetings of the EU-Japan mutual recognition project on animal health regionalisation. Facilitate trade and better cooperation on regionalisation approach with Japan	Monthly meetings.	In the course of 2022	Several meetings as scheduled

Output	Indicator	Target	Latest known results (Situation on 31/12/2022)
Meetings under the EU-China Memorandum of Understanding Animal Health (regionalisation project) and food safety issues. Facilitate trade and better cooperation on regionalisation approach with China	Quarterly meetings.	In course of 2022	Several meetings with GACC and MARA on animal health and food safety issues. First common meeting on regionalisation with GACC and MARA held in December 2022.
Yearly meetings of the EU-India 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 India,	1 AHTWG and 1 PHTWG meeting per year.	In course of 2022	No AHTWG or PHTWG meetings held in 2022
Meeting of the EU-India TBT SPS Technical Working: to solve TBT SPS concerns with India	1 yearly meeting	In course of 2022	Main SPS issues raised at the EU-India High-Level Meeting on Bilateral and Multilateral Issues held on 6/7 April 2022.

General objective 2: Promoting our European way of life			
Impact indicator: Healthy life years at birth **Source of data:** Eurostat (Eurostat data code: [hlth_hlye])			
Baseline (2018)	**Interim Milestone (2022)**	**Target (2024)**	**Latest known results (Situation on 31/12/2022)**
Males: 63.7 years Females: 64.2 years Total: 64.0 years	Increase	Increase	*Latest results (2020):* Males: 63.5 years Females: 64.5 years Total: 64.0 years
Specific objective 2.1: Diminishing the impact of cancer in Europe *Related to spending programme: EU4Health 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 (Situation on 31/12/2022)**
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	Latest results available from 2014*
Comment on the result available for 2022: *Baseline (2014) results are by far the most up-to-date figures available, coming as they do from CONCORD. A sustainable mechanism to obtain more timely results on survival rates is under investigation, and will be integrated in the European Cancer Information System (ECIS) when it is available.			
Result indicator: 2.1.B Ratio of Cancer Registries (CRs) and number of Member States 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 (Situation on 31/12/2022)**
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.	In 2022 a new data call to the European cancer-registries was launched to update the 2015 figures including stage at diagnosis as a new mandatory variable. As of 31/12/2022, 47 registries out of around 150 (potential) already contributed with data, which are currently undergoing validation.

Baseline (2015)	Interim Milestone (2022)	Target (2024)	Latest known results (Situation on 31/12/2022)
Number of Member States reporting cervical cancer stage at diagnosis: 20 Number of Member States reporting breast cancer stage at diagnosis: 20 Number of Member States reporting colorectal cancer stage at diagnosis: 20	All Member States reporting the information on cancer stage		

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 and related 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 (Situation on 31/12/2022)*
29%	25%	21%	25% (2020)*

*Last data are available from 2020, the next Eurobarometer scheduled for 2023

Main outputs in 2022:

New policy initiatives

Output	Indicator	Target	Latest known results (Situation on 31/12/2022)
Commission proposal to update the Council Recommendation on cancer screening (PLAN/2021/11668)	Adopted	Q3 2022	Adopted on 20/09/2022
Evaluations and fitness checks			
Evaluation of the Tobacco Products Directive and the Tobacco Advertising Directive (PLAN/2021/12253)	Launched	Q1 2022	Work on the evaluation ongoing
Public consultations			
Evaluation of the Tobacco Products Directive and the Tobacco Advertising Directive (PLAN/2021/12253)	Public consultation/Call for evidence completed	Q2 2022	Call for evidence published in May 2022

Enforcement actions			
Output	**Indicator**	**Target**	**Latest known results (Situation on 31/12/2022)**
Compliance checks finalised for 20 MS	Completed	Q4 2022	Completed; compliance checks planned for remaining MS
Structured bilateral meetings with Member States in the context of compliance assessment	Ongoing	Q4 2022	Several structured bilateral meetings took place in 2022.
External communication actions			
Press and media Communicate on the various proposals and initiatives	National print media coverage of EU's actions when proposals adopted/initiatives launched	Media coverage spanning at least 25 EU countries	EU actions under 'Europe's Beating Cancer Plan' were covered in the media in all 27 EU Member States
Social media Sustained tweets and responses throughout the year, particularly during World Cancer Day/European Week Against Cancer. The hashtag #EUCancerPlan monitored continuously. Paid promotion of tweets	Increase engagement on Twitter	Average a minimum of 175 engagements per own tweet with #EUCancerPlan (all engagements)	Reached 190 engagements on average with posts including #EUCancerPlan
Website Regular updates to relevant pages	Increase in the number of visitors to the SANTE cancer related webpages	Increase in web traffic on the cancer pages by 10% (when compared to 2021 baseline: 16,835 entrances* *projection	increase of 11,3% (23 558 entries / 51 405 page views / 40 299 unique page views for the cancer pages under / health and 8 435 entries / 14 982 page views / 13 480 unique page views for the corporate site "A cancer plan for Europe")
World Cancer Day event (hybrid)	Number of participants	Minimum 200 participants following online	1 500 viewers on Twitter livestream
Video (Marathon Man)	Number of views, embeds and downloads, completion rate	Minimum 10,000 views with minimum completion rate of 25%	Video views during 2022 (including organic and paid social media and AV Portal): 7 514 000

Screening Campaign	Number of people reached Increase in number of people going for screening	3 million citizens from target audience[2]	Campaign will be launched during 2023

Other important outputs			
Output	**Indicator**	**Target**	**Latest known results (Situation on 31/12/2022)**
Country reports on Cancer Inequalities in all EU Member States (as part of the Cancer Inequalities Registry)	Reports published	Q4 2022	Reports due to be published on 1 February 2023
EU network on Youth Cancer Survivors	Launched	2022	2 networks - OACCUs and EU-CAYAS-NET - created and working, with kick-off meetings taking place on 21 June and 26 September 2022 respectively.
Joint Action with Member States to support roll out of large-scale human papillomavirus vaccination campaigns	Operational	Q4 2022	Operational following kick-off meeting on 05 December 2022
Joint Action with Member States to establish 'National Comprehensive Cancer Centres and EU Network linking these Centres	Operational	Q4 2022	Operational following kick-off meeting on 4th November 2022
Joint Action with Member States to establish EU Networks of Expertise on Cancers and Cancer Conditions:	Operational	Q4 2022	Operational following kick-off meeting on 14th November 2022
Joint Action on Tobacco Control - 2	Operational	Q4 2022	First year of operation concluded by the annual conference in November 2022.
Joint Action with Member States strengthening eHealth, integrating telemedicine and remote monitoring in health and care systems for cancer prevention and care	Operational	Q4 2022	Operational following kick-off meeting on 20 September 2022

[2] The aim of this campaign is behavioural change rather than broad reach, which explains the conservative figure.

Output	Indicator	Target	Latest known results (Situation on 31/12/2022)
Delegated as regards the withdrawal of certain exemptions in respect of heated tobacco products (PLAN/2021/12321)	Adoption	Q2 2022	Commission Delegated Directive 2022/2100 adopted on 29/26/2022
Healthier together – EU Non-Communicable Diseases Initiative	Publication	Q3 2022	Published in June 2022. Healthier together – EU non-communicable diseases initiative
Joint Action with Member States on health determinants (coordinated with Europe's Beating Cancer Plan)	Publication	Q4 2022	Proposal submission phase opened on 13 October 2022
Joint Action with Member States on cardiovascular diseases	Publication	Q4 2022	Preparatory work by Member States for the proposal.
Commission Report on the establishment of a substantial change of circumstances for heated tobacco products	Adoption	Q2 2022	Report adopted on 15/06/2022
Joint Action with Member States on diabetes	Publication	Q4 2022	Being launched
Revision of the mandate of the Steering Group on Promotion and Prevention	Completed	Q2 2022	COM Decision of 07 December 2022 setting up a COM Expert group on Public Health
Steering Group on Promotion and Prevention - 2022 cycle of selection of best practices for implementation	Completed	Q4 2022	The best practices have been selected by the MS.

General objective 2: Promoting our European way of life

Specific objective 2.2: Patients' access to safe, innovative and affordable medicines and medical devices

Related to spending programme(s): EU4Health

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)	Target (2024)	Latest known results (Situation on 31/12/2022)
7	Increase	Increase	27 (authorised in 2022)

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 supports the implementation of related legislation. The EU has been supporting Member States in conducting audits of the national system on GMP for many years to ensure high quality pharmaceutical products including Active Pharmaceutical Ingredients (APIs). This ensures increased and consistent supervision of GMP implementation in the pharma industry and contributes to the implementation of the Mutual Recognition Agreements (MRAs). 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 (2019)	Interim Milestone (2022)	Target (2024)	Latest known results (Situation on 31/12/2022)
10	20	40	7 (Due to the pandemic, it was necessary to postpone the planned audits.)

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 may 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 (Situation on 31/12/2022)
91	300	450	99

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 (2019)	Interim Milestone (2022)	Target (2024)	Latest known results (Situation on 31/12/2022)
N/A	Positive trend	Positive trend	1 proposal adopted includes burden reduction measures

Main outputs in 2022:			
Initiatives linked to regulatory simplification and burden reduction			
Output	**Indicator**	**Target**	**Latest known results (Situation on 31/12/2022)**
Proposal for the revision of the general pharmaceutical legislation (Directive 2001/83/EC and Regulation (EU) No 726/2004) (PLAN/2021/10601) and Commission Communication	Adoption	Q4 2022	Impact assessment finalised. Adoption of revision planned for 26 April 2023 together with the revision of the Regulations on orphan medicines and medicines for children
Proposal for the revision of the regulations on medicines for rare diseases ('orphan' medicines) Regulation (EC) No 141/2000 and on medicines for children Regulation (EC) No 1901/2006 (PLAN/2020/6688)	Adoption	Q4 2022	Impact assessment finalised. Adoption of revision planned for 26 April 2023 together with the revision of the general pharmaceutical legislation
Proposal to revise the EMA fees system (PLAN/2018/4193)	Adoption	Q2 2022	Adopted on 13/12/2022
Evaluations and fitness checks			
Evaluation of the general pharmaceutical legislation (back-to-back evaluation/impact assessment) (PLAN/2021/10601)	Completed	Q4 2022	Evaluation finalised together with the impact assessment Adoption of revision planned for 26 April 2023 together with the revision of the Regulations on orphan medicines and medicines for children.
Enforcement actions			
Union controls (audits) in the area of clinical trial for human medicines	4 Union controls to Member States and 2 to third countries	In the course of 2022	2 controls in MS. Union controls paused pending consultation with the legal service on their scope and depth, which has been questioned by the MS.

Output	Indicator	Target	Latest known results (Situation on 31/12/2022)
Joint assessments of conformity assessment bodies (Reg 2027/745 Art 39.4.2 and Reg 2027/746 Art 35.4.2)	90% of on-site assessments organised within 3 months following the corresponding request	In the course of 2022	5 of the 11 (45%) on-site joint assessments carried out within 14 weeks upon receipt of the preliminary assessment report. 11 of the 11 carried out on the dates indicated in the date proposed by the designated authority.
Re-assessment of notified bodies (Reg 2027/745 Art 44.10, Reg 2027/746 Art 40.10)	10 bodies which were notified in 2019	In the course of 2022	2 (of the 10) re-assessments launched. 8 re-assessments postponed, following the Commission's proposal to increase the cycle of re-assessments.
External communication actions			
Press and Media Communicate on the proposed pharmaceutical and orphan and paediatrics legislations	National print media coverage of EU's actions when proposals adopted	Media coverage by at least 25 EU Member States	Media coverage on pharma-related topics was noted in all 27 EU Member States
Multimedia campaign Ads run on a mix of social media and trusted news websites and newspapers	Number of people reached (awareness)	15 million impressions in at least 15 EU Member States [3]	Action delayed until adoption of updated pharma, orphan and paediatrics legislations in 2023.
Social Media Sustained tweets throughout the year on the pharmaceutical strategy and its implementation, including paid promotion	Increase engagement on Twitter	Average a minimum of 130 engagements per own tweet with #EUPharmaStrategy (all engagements)	Reached 132 engagements on average with posts including #EUPharmaStrategy
Website Regular updates of pharmaceutical strategy pages	Increase in the number of visitors	Resulting in increase in web traffic on the pharmaceutical strategy page by 5% (when compared to 2021 baseline: 6,383 entrances*) *projection	46% increase in web traffic (9 325 entries / 15 167 page views / 11 801 unique page views)

[3] Conservative estimate and dependent on final mix of tools and channels

Other important outputs			
Output	**Indicator**	**Target**	**Latest known results (Situation on 31/12/2022)**
Implementation of the Pharmaceutical Strategy	Ongoing implementation	In course of 2022	4
Initiative on security of supply of medicines (PLAN/2020/285)	Adoption	2022	SWD adopted and published (Q4 2022)
Work and deliverables of the cooperation on the "affordability agenda" with National Competent Authorities on Pricing and Reimbursement	Action plan	2022	Action plan finalised; actions and deliverables on track
Negotiation with the Council and Parliament of a proposal amending Regulation (EU) 2017/746 as regards transitional provisions for certain in vitro diagnostic medical devices COM(2021) 627	Political agreement	2022	Regulation 2022/112 adopted on 28/01/2022
Amendment to Commission Regulation 520/2012 on pharmacovigilance activities (PLAN/2021/12147)	Adoption	Q3 2022	In planning; reprioritisation in view of the delivery of flagship activities under the pharma strategy; adoption now foreseen for Q2 2023.
Evaluation of candidate EU Reference Laboratories infrastructure - Regulation (EU)2017/746 In Vitro Medical Devices	List of Reference Laboratories to be designated	Q4 2022	Call for applications to Member States for EURLs in 8 categories of class D devices launched in July 2022.
Transfer of the Expert Panels for medical devices and in vitro diagnostics (Medical Devices Regulation Art 106) to EMA	Transfer date	Q2 2022	Regulation (EU) 2022/123 (Art 30) adopted on 25/01/2022; transfer completed by the date of applicability on 01/03/2022.

Output	Indicator	Target	Latest known results (Situation on 31/12/2022)
Implementing act setting out common specifications for products without medical purpose - Regulation (EU) 2017/745 on Medical Devices (PLAN/2018/4271)	Adoption	Q1 2022	Implementing Regulation 2022/2346 adopted on 01/12/2022. Delay due to intense discussion with Member States in the Medical Device Coordination Group (MDCG) and in the Committee on Medical Devices to reach a final agreement on the text.
Implementing act laying down rules for the application of Reg 2017/745 on Medical Devices as regards reclassification of groups of certain active products without an intended medical purpose (PLAN/2021/10840)	Adoption	2022	Implementing Regulation (EU) 2022/2347 adopted on 01/12/2022.
Implementing act on common specifications for certain class D *in vitro* diagnostic medical devices in accordance with In Vitro Medical Devices - Reg 2017/746 (PLAN/2021/10158)	Adoption	Q1 2022	Implementing Regulation 2022/1107 adopted on 04/07/2022. Delay due discussion with Member States in the MDCG and in the Committee on Medical Devices.
Implementing acts on harmonised standards in support of Regs 2017/745 and 2017/746 on Medical Devices	Adoption	Q4 2022	4 Commission Implementing Decisions: - (EU) 2022/6 adopted on 04/01/2022 - (EU) 2022/15 adopted on 06/01/2022 - (EU) 2022/757 adopted on 11/05/2022 - (EU) 2022/729 adopted on 11/05/2022

Output	Indicator	Target	Latest known results (Situation on 31/12/2022)
Implementing acts on EU Reference Laboratories - In Vitro Medical Devices - Regulation (EU)2017/746 (PLAN/2019/5896)	Adoption	Q1 2022	2 Implementing Regulations adopted on 17/06/2022: - (EU) 2022/944 - (EU) 2022/945 One additional Implementing Regulation on designation of EU reference laboratories, foreseen for adoption in Q3 2023. Delay due to intense discussions with Member States in the MDCG and in the Committee on Medical Devices.
Preparation of an action plan to facilitate transition to Regulation 2017/745 (MDR) and Regulation 2017/746 (IVDR) and to avoid shortage of medical devices, including preparatory work for a legislative proposal to modify specific transitional provisions in the MDR and IVDR.	Endorsement by the Member States in the Medical Device Coordination Group (MDCG)	2022	Adopted as MDCG 2022-14 Position Paper in August 2022. Legislative proposal to amend the MDR and IVDR adopted on 6 January 2023.
Amendments to the Regs 2017/745 (MDR) and 2017/746 (IVDR) to change from 3 to 5 years the frequency of complete re-assessments of notified bodies, to alleviate the burden on national designating authorities and notified bodies	Adoption	2022	Commission Delegated Regs amending the MDR and the IVDR as regards the frequency of complete re-assessments of notified bodies, adopted on 01/12/2022; currently under scrutiny by the European Parliament and the Council in the Register of Delegated Acts (MDR, IVDR), until March 2023
Delegated act on Unique Device Identifier (UDI) - assignment criteria for highly individualised devices under Regulation (EU) 2017/745 on Medical Devices and In Vitro Medical Devices - Regulation (EU)2017/746 (PLAN/2021/12961)	Adoption	Q2 2022	Delay due to ongoing discussion with Member States in the MDCG; adoption now foreseen for Q4 2023.

Output	Indicator	Target	Latest known results (Situation on 31/12/2022)
Setting up of the Health Technology Assessment Coordination Group (HTA CG) as stipulated in the HTA Regulation	Group is set up designation of national authorities. Chair and co-chairs elected.	Q2 2022	First meeting on 21/06/2022 Second meeting on 28/11/2022
Setting up of the HTA Stakeholder Network as stipulated in the HTA Regulation	Launch the Call for expression of interest	Q4 2022	Call for appilcations published on 12/12/2022; .
Authorisation of new medicinal products, variations to existing marketing authorisations, including, decisions following referral procedures, periodic safety update reports, orphan designations etc.	Adoption of more than 1 200 decisions	During course 2022	1 681 decisions adopted

General objective 2: Promoting our European way of life

Specific objective 2.3: Effective response coordination of serious cross-border health threats
Related to spending programme(s):EU4Health

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 sante_aar_2021_annexes_final Page 45 of 161 implementing act

Baseline (2019)	Interim Milestone (2022)	Target (2024)	Latest known results (Situation on 31/12/2022)
24	26 (not applicable)	27 (not applicable)	N/a: indicator changed with the new Regulation; first survey will take place in 2023

Main outputs in 2022:

New policy initiatives

Output	Indicator	Target	Latest known results (Situation on 31/12/2022)
Proposal for a Council Recommendation on Antimicrobial Resistance (PLAN/2021/12503)	**Adoption**	**Q4 2022**	Finalisation of draft proposal for a Council Recommendation on AMR and accompanying Staff Working Document. Adoption planned for 26 April 2023 together with revision of EU pharmaceutical legislation.

Evaluations and fitness checks			
Output	**Indicator**	**Target**	**Latest known results (Situation on 31/12/2022)**
Evaluation of the 2018 Council Recommendation on strengthened collaboration on vaccine-preventable diseases	Launch of the evaluation	Q3 2022	Replaced by a "Study on the coherence, complementarity and continued relevance of actions in the Council Recommendation on strengthened cooperation against vaccine-preventable diseases in view of possible similar policy initiatives in the future"; kick-off meeting held on 6 January 2023.' finalisation foreseen for Q4 2023
Enforcement actions			
Review of Member States' One Health national action plans (NAPs) on AMR	Report of the review	During 2022	Overview report of MS' One Health AMR NAPs published on 17 November 2022.
Support to the national immunisation technical advisory group (NITAGs)	Timely outputs produced by the group	Contract signed in Q3 2022	Work ongoing
External communication actions			
VACCINATION			
Press and media Communicate on the various proposals and initiatives	National print media coverage of EU's actions when proposals adopted/initiatives launched	Media coverage spanning at least 25 EU countries	Media coverage spanned all 27 EU countries
Social media Sustained tweets and responses throughout the year, with a particular focus on the EIW. Paid promotion of tweets	Increase engagement on Twitter	Average a minimum of 150 engagements per own tweet with #VaccinesWork and/or #SafeVaccines (all engagements)	Reached 172 engagements on average with posts including #VaccinesWork or #SafeVaccines.
Website Regular updates to relevant pages	Increase in the number of visitors to the SANTE vaccination webpages	Increase in web traffic on the vaccination pages on ec.europa by 10% (*projected* baseline for 2021: 120 124 page views)	increase of 103% (94 065 page views on the health website + 150 934 page views on the United In Protection website, with a total of 244 999 page views

Output	Indicator	Target	Latest known results (Situation on 31/12/2022)
Maintenance and further development of the European Vaccination Information Portal (with EMA and ECDC)	Increase in the number of visitors	Increased web traffic to the EVIP by 10% (when compared to the 2021 baseline of 1,423,610 page views* **projection*	361 322 page views - a decrease due to shift in public attention.
Vaccine Misinformation Counter Initiative: Publications (teacher training module and information for teenagers)	Number of participants/link clicks/downloads	Minimum 10,000	Delayed as production still ongoing
Disinformation	Active participation in the Network Against Disinformation and its subgroup	At least one presentation to the Network during the year	Presentation given on vaccine mis/disinformation in July 2022
Campaign on COVID-19 vaccine donation (video/social media campaign in partnership with international media)	Number of people reached/impressions	25 million impressions in at least 15 EU countries	Replaced with UnitedInProtection campaign due to shift in priorities, gaining 7 398 664 website impressions, 194 400 engagement
ANTIMICROBIAL RESISTANCE			
Press and media Communicate on the Recommendation	National print media coverage of EU's actions when proposals adopted/initiatives launched	Media coverage spanning at least 25 EU countries	Media in all 27 EU Member States covered the issue of AMR.
Social media Sustained tweets and responses throughout the year	Increase engagement on Twitter	Average a minimum of 100 engagements per own tweet on AMR (all engagements)	Reached 184 engagements on average with posts including AMR or EAAD.
Website Regular updates to relevant pages	Increase in the number of visitors to the SANTE AMR webpages	Increase in web traffic on the AMR pages by 10% (when compared to 2021 baseline – 30.199entrances*) **projection*	Decrease of 39,8% (18 175 entries / 37 027 page views / 28 725 unique page views) .

Other important outputs			
Output	**Indicator**	**Target**	**Latest known results (Situation on 31/12/2022)**
Negotiation with the Parliament and Council of the proposal on the cross-border health threats regulation	Political agreement	Q1 2022	Regulation entered into force on 26/12/2022.
Negotiation with the Parliament and Council of the proposal on a revised mandate for ECDC	Political agreement	Q1 2022	Revised mandate entered into force on 26 Dec 2022
EU-level preparedness plan (linked to Cross-border health threats regulation)	Adoption	Q4 2022	The cross-border health threats regulation was only adopted in 2022 therefore the adoption of the preparedness plans are postponed to Q4/2023.
Joint Action on Antimicrobial Resistance	Operational	Q4 2022	Postponed to 2023 due to delays in the call
Output	**Indicator**	**Target**	**Latest known results (Situation on 31/12/2022)**
Future-proofing analysis of the 2017 Antimicrobial Resistance One Health Action Plan	Publication of the Staff Working Document	Q4 2022	Report finalised in December 2022; will be published at the time of the adoption of the proposal for a Council Recommendation on AMR (planned for 26 April 2023)
Progress report on the implementation of the 2017 AMR One Health Action Plan	2 publications per year	Q2 and Q4 2022	Last progress report published in March 2022. No second progress report in 2022 due to upcoming proposal for a Council Recommendation.
Joint Action on surveillance	Grant agreement signed/kick-off	Q4 2022	Kick-off meeting will take place in February 2023.
Actions on vaccination under EU4Health	Signing of service contracts	Q3 2022	3 service contracts on: 1) reducing physical obstacles to vaccination, 2) strengthening methodologies to monitor the performance of vaccination programmes, 3) strengthening the NITAGs network (AWP 2021).

INTERNATIONAL RELATIONS			
Output	**Indicator**	**Target**	**Latest known results (Situation on 31/12/2022)**
Coordinate EU position in the negotiation of the international agreement on pandemic prevention, preparedness and response and in the negotiation of the amendments to the International Health Regulations (2005)	Delivered	Throughout the year	Ensured coordinated inputs to and active participation in both ongoing negotiations under the auspices of the WHO
Coordinate EU position and implement measures to strengthen WHO and the global health security architecture	Delivered	Throughout the year	Ensured coordinated inputs to activities in relevant multilateral fora (e.g. WHO, UN, G7 and G20).
Coordinate policies developed in cooperation with other relevant actors to strengthen the role of the EU in international relations:	Number of participation in OECD health committee meetings; Contributions to WHO resolutions	Throughout the year	Ensured active participation in 2 OECD Health Committee meetings (June and December) and coordinated inputs to WHO resolutions.
Continue to work with Covax in pursuit of global vaccination targets (strengthen the multilateral approach in pursuit of global vaccination)	Number of COVID-19 vaccine doses shared with Covax as a total of total donations	Throughout the year	Covax is no longer managed by DG SANTE but by HERA
Continue to support Member States in their vaccine donation and resale efforts	Number of Member States and activities supported	Depending on timetable of the respective EU presidency	This is no longer a DG SANTE but a HERA responsibility
Bilateral relations			
Alignment with enlargement candidate countries	Negotiate health chapter with candidate countries	Throughout the year	Ongoing

Output	Indicator	Target	Latest known results (Situation on 31/12/2022)
Proximity with Neighbourhood countries; cooperation with other third countries and micro states (in line with obligations under cooperation agreements)	Number of meetings and positions delivered	Throughout the year	Formal SPS Subcommittee meetings with UA, MD and GE and several ad hoc meetings in between, in addition to communications via telephone, email etc. Formal subcommittee meetings with AM and TR. Participating to trade-related meetings led by DG TRADE as regards Armenia and Azerbaijan Participating to Custom Unions meetings with Turkiye in order to cover SPS and Public health issues
Special relations with third countries	High level Dialogue with Turkey High level Dialogue with Canada	1-2 meetings per year 1-2 meetings per year	4 meetings

General objective 2: Promoting our European way of life

Specific objective 2.4: More effective, accessible and resilient health systems

Related to spending programme(s): EU4Health

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 MS.

Source of data: DG SANTE (Unit B3) and CHAFEA and/or its follow-on entity (HADEA)

Baseline (2020)	**Interim Milestone (2022)**	**Target (2024)**	**Latest known results (Situation on 31/12/2022)**
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	Best ReMAP (Healthy Food for a Healthy Future): 19 Member States Joint action implementation: 21 Member States

Result indicator 2.4.B: 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 (2019)	**Interim Milestone (2022)**	**Target (2024)**	**Latest known results (Situation on 31/12/2022)**
N/A	Positive trend	Positive trend	2 proposals adopted include burden reduction measures

Main outputs in 2022:			
New policy initiatives			
Proposal on the European Health Data Space (PLAN/2020/8701)	Adopted	Q2 2022	COM(2022)197 adopted on 03/05/2022
Initiatives linked to regulatory simplification and burden reduction			
Proposal to revise blood, tissue and cells legislation (PLAN/2020/8495)	Adopted	Q1 2022	COM(2022)338 adopted on 14/07/2022
Evaluations and fitness checks			
Evaluation of the 3rd Health Programme (2014-2020) (PLAN/2020/9070)	Completed	Q4/2022	Ongoing; adoption foreseen for Q1 2023
Evaluation of the Cross-border Healthcare Directive (PLAN/2021/10183)	Completed	Q2 2022	COM(2022)210 adopted on 12/05/2022

External communication actions			
Output	**Indicator**	**Target**	**Latest known results (Situation on 31/12/2022)**
European Health Data Space **Press and media** Communicate on the EHDS proposal	National print media coverage of EU's actions when proposal is launched	Media coverage spanning at least 25 EU countries	EHDS triggered media coverage in all 27 EU Member States
European Health Data Space **Social media** Sustained tweets and responses throughout the year, on digital health. Paid promotion of tweets	Increase engagement on Twitter	Average a minimum of 150 engagements per own tweet with #EHDS (all engagements)	Reached 169 engagements on average with posts including #EHDS
Website Update ehealth and EHDS pages	Increase in the number of visitors to the ehealth and EHDS pages	Increase in web traffic on ALL the ehealth related webpages (including EU Health Data Space and eHealth and COVID-19) by 10% compared to 2021 baseline: 30,532 entries	2022: 156 445 entries / 264 897 page views / 202 128 unique page views, representing an increase by 412% (the inclusion of all e-health related webpages in this data extraction, namely the ones linked to COVID-19, explains this spike)
Multimedia campaigns Campaign targeting industry and healthcare providers	Number of people reached (awareness)	5 million reach	10.9 million individuals reached in the first 12 weeks [*The final figures not yet available #to be updated]*

Other important outputs				
Output		**Indicator**	**Target**	**Latest known results (Situation on 31/12/2022)**
Amendment of the Council Recommendation of 12 July 1999 on the limitation of exposure of the general public to electromagnetic fields (0 Hz to 300 GHz)		Adopted	Q4 2022	The amendment is based on the scientific Opinion of the SCHEER Committee (on radiofrequency) which has been delayed and is still ongoing. As a second opinion will be performed in 2023 on low and intermediate frequencies we will propose to wait for this before starting with the amendment with a tentative target of adoption in Q2 2024.
State of Health in the EU project	"Health at a Glance: Europe 2022" report	Published	Q4 2022	"Health at a Glance: Europe 2022" published on 05/12/2022
	Voluntary exchanges	Delivered*	Q4 2022	*3 voluntary exchanges delivered in 2022 (IRL, IT, SE). Discussions ongoing with national authorities from AT, FR, MT, PL to organise 4 additional exchanges in 2023.
Opinions of the independent expert panel on effective ways of investing in health.		Published	Q3 - Q4 2022	Opinion on antimicrobial resistance published on 17/11/2022 Opinion on long COVID published on 13/12/2022
Pact for Skills large-scale partnership on re- and upskilling of the health workforce		Launched	Q4 2022	Launch event took place on 13/12/2022
Projects to raise the capacity of Member States to implement integrated care (financed by the Third Health Programme)		Published/Launched	Q4 2022 Original targets: 'SCIROCCO Exchange' project in Q3 2021	The project "*Best Practices & Digital Strategy: Policies and best practices to prevent, control and manage NCDs across populations*", which is carried out by the OECD, has drafted 13 case studies on integrated care and has distilled a number of key findings and policy recommendations related to the transfer of best practices in integrated care. Both projects VIGOUR and SCIROCCO Exchange ended in summer 2022. They helped participating regions to upscale and to transfer best practices of integrated care. Final deliverables will be published

Output	Indicator	Target	Latest known results (Situation on 31/12/2022)
		'VIGOUR' project in Q1 2022 Q3 2023	soon. JADECARE is ongoing and well on track.
Projects to raise the capacity of Member States to implement primary care (financed by EU4Health)	Launched	Q4 2022	Grant agreement signed for the Joint Action CIRCE-JA to transfer best practices in primary care. The Joint Action will kick-off in Q1 2023.
Projects to raise the capacity of Member States to efficiently plan and forecast health workforce needs.	Launched	Q4-2022	Grant agreement signed for the Joint Action HEROES - JA on health workforce planning and forecasting The Joint Action will kick-off in Q1 2023.
Periodic technical evaluation of European Reference Networks and all their members after 5 years	Launched	Q4 2022	Evaluation launched on 9/11/2022 Duration 11 months.
Support for Member States onboarding to MyHealth@EU	15 Member States in routine operations at MyHealth@EU	Q4 2022	11 Member States in routine operations at MyHealth@EU by end-2022. In addition, 15 other Member States + Norway and Iceland already received grants from CEF and/or EU4Health to support their onboarding to MyHealth@EU in the upcoming period and by 2025/2026 at the latest.
Two meetings of the plenary of the eHealth Network Regular (e.g. weekly or bi-weekly) meetings of the eHealth Network	Organised	Q4 2022	Two physical meetings of the eHealth Network plenary organised in 2022 (June and November). In addition, 189 online meetings and 4 additional physical meetings of the eHealth Network ("Coordinated actions" meetings) and its subgroups were organised in 2022.
Study assessing the HPP	Launched	Q2 2022	Launched in September 2022

ANNEX 3: Draft annual accounts and financial reports

AAR 2022 Version 3

Annex 3 Financial Reports - DG SANTE - Financial Year 2022

Additional comments

TABLE 1: OUTTURN ON COMMITMENT APPROPRIATIONS IN 2022 (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	17,98	16,83	93,60 %
Total Title 01			**17,98**	**16,83**	**93,60 %**
Title 02 European Strategic Investments					
02	02 01	Support administrative expenditure of the "European Strategic Investments" cluster	7,38	7,38	100,00 %
	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			**7,38**	**7,38**	**100,00 %**
Title 03 Single Market					
03	03 01	Support administrative expenditure of the 'Single Market' cluster	2,47	2,47	100,00 %
	03 02	Single Market Programme	139,54	138,34	99,14 %
	03 05	Cooperation in the field of customs (Customs)	1,25	1,03	82,73 %
	03 10	Decentralised agencies	8,34	7,30	87,54 %
	03 20	Pilot projects, preparatory actions, prerogatives and other actions	0,25	0,25	100,00 %
Total Title 03			**151,85**	**149,40**	**98,38 %**
Title 06 Recovery and Resilience					
06	06 01	Support administrative expenditure of the 'Recovery and Resilience' cluster	13,50	13,49	99,96 %
	06 06	EU4Health Programme	100,43	100,22	99,79 %
	06 07	Emergency support within the Union	6,74	0,00	0,00 %
	06 10	Decentralised agencies	326,56	299,37	91,67 %
	06 20	Pilot projects, preparatory actions, prerogatives and other actions	0,00	0,00	0,00 %
Total Title 06			**447,22**	**413,08**	**92,37 %**
Title 08 Agriculture and Maritime Policy					
08	08 03	European Agricultural Fund for Rural Development (EAFRD)	0,62	0,62	100,00 %
	08 04	European Maritime, Fisheries and Aquaculture Fund (EMFAF)	0,33	0,33	100,00 %
Total Title 08			**0,95**	**0,95**	**100,00 %**
Title 09 Environment and Climate Action					
09	09 02	Programme for the Environment and Climate Action (LIFE)	0,16	0,16	100,00 %
Total Title 09			**0,16**	**0,16**	**100,00 %**
Title 14 External Action					
14	14 20	Pilot projects, preparatory actions, prerogatives and other actions	0,38	0,38	100,00 %
Total Title 14			**0,38**	**0,38**	**100,00 %**
Title 15 Pre-accession Assistance					
15	15 02	Instrument for Pre-accession Assistance (IPA III)	0,00	0,00	0,00 %
Total Title 15			**0,00**	**0,00**	**0,00 %**
Title 20 Administrative expenditure of the European Commission					
20	20 01	Members, officials and temporary staff	0,48	0,40	83,53 %
	20 02	Other staff and expenditure relating to persons	0,06	0,05	81,88 %
	20 03	Administrative Operating expenditure	2,69	2,46	91,45 %
	20 04	Information and communication technology related expenditure	0,42	0,42	100,00 %
Total Title 20			**3,64**	**3,32**	**91,24 %**
Total Excluding NGEU			**629,55**	**591,48**	**93,95 %**
Title 01 Research and Innovation					
01	01 01	Support administrative expenditure of the "Research and Innovation" cluster	14,65	3,94	26,92 %
Total Title 01			**14,65**	**3,94**	**26,92 %**
Total NGEU Only			**14,65**	**3,94**	**26,92 %**
Total DG SANTE			**644,20**	**595,43**	**92,43 %**

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

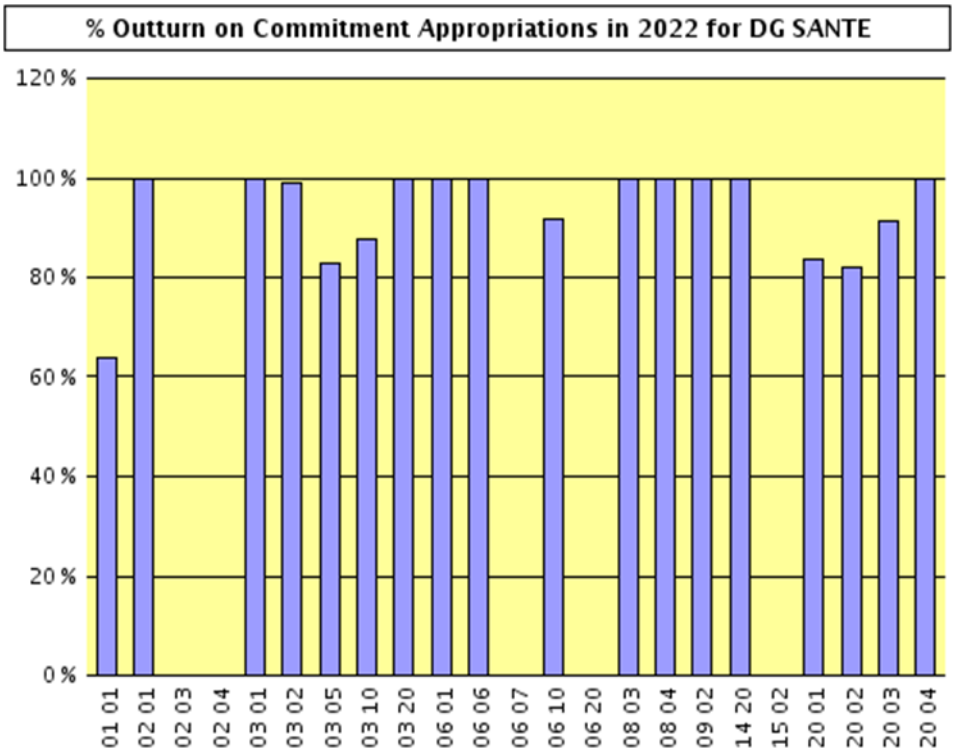
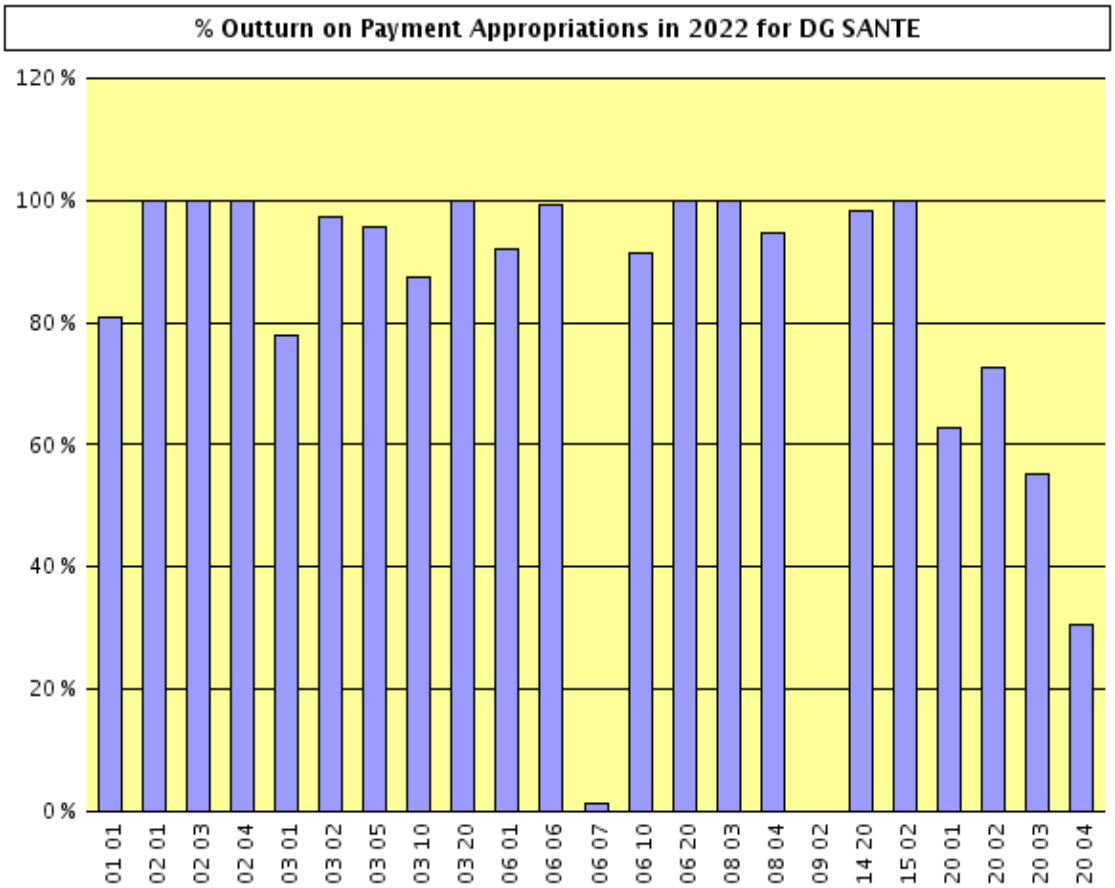

% Outturn on Commitment Appropriations in 2022 for DG SANTE
120 %
100 %
80 %
60 %
40 %
20 %
0 %
01 01
02 01
02 03
02 04
03 01
03 02
03 05
03 10
03 20
06 01
06 06
06 07
06 10
06 20
08 03
08 04
09 02
14 20
15 02
20 01
20 02
20 03
20 04

TABLE 2: OUTTURN ON PAYMENT APPROPRIATIONS in 2022 (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	17,98	16,83	93,60 %
Total Title 01			**17,98**	**16,83**	**93,60%**
Title 02 European Strategic Investments					
02	02 01	Support administrative expenditure of the "European Strategic Investments" cluster	7,38	7,38	100,00 %
	02 03	Connecting Europe Facility (CEF)	1,69	1,69	100,00 %
	02 04	Digital Europe programme	0,18	0,18	100,00 %
Total Title 02			**9,25**	**9,25**	**100,00%**
Title 03 Single Market					
03	03 01	Support administrative expenditure of the 'Single Market' cluster	3,72	2,90	77,92 %
	03 02	Single Market Programme	72,69	70,70	97,25 %
	03 05	Cooperation in the field of customs (Customs)	0,44	0,42	95,77 %
	03 10	Decentralised agencies	8,34	7,30	87,54 %
	03 20	Pilot projects, preparatory actions, prerogatives and other actions	0,63	0,63	100,00 %
Total Title 03			**85,83**	**81,95**	**95,48%**
Title 06 Recovery and Resilience					
06	06 01	Support administrative expenditure of the 'Recovery and Resilience' cluster	15,74	14,48	91,98 %
	06 06	EU4Health Programme	50,59	50,22	99,28 %
	06 07	Emergency support within the Union	6,82	0,09	1,27 %
	06 10	Decentralised agencies	311,49	284,30	91,27 %
	06 20	Pilot projects, preparatory actions, prerogatives and other actions	0,78	0,78	100,00 %
Total Title 06			**385,42**	**349,86**	**90,78%**
Title 08 Agriculture and Maritime Policy					
08	08 03	European Agricultural Fund for Rural Development (EAFRD)	0,31	0,31	100,00 %
	08 04	European Maritime, Fisheries and Aquaculture Fund (EMFAF)	0,45	0,43	94,62 %
Total Title 08			**0,76**	**0,73**	**96,80%**
Title 09 Environment and Climate Action					
09	09 02	Programme for the Environment and Climate Action (LIFE)	0,00	0,00	0,00 %
Total Title 09			**0,00**	**0,00**	**0,00%**
Title 14 External Action					
14	14 20	Pilot projects, preparatory actions, prerogatives and other actions	0,38	0,37	98,17 %
Total Title 14			**0,38**	**0,37**	**98,17%**
Title 15 Pre-accession Assistance					
15	15 02	Instrument for Pre-accession Assistance (IPA III)	1,48	1,48	100,00 %
Total Title 15			**1,48**	**1,48**	**100,00%**
Title 20 Administrative expenditure of the European Commission					
20	20 01	Members, officials and temporary staff	0,64	0,40	62,73 %
	20 02	Other staff and expenditure relating to persons	0,13	0,09	72,75 %
	20 03	Administrative Operating expenditure	3,76	2,07	55,11 %
	20 04	Information and communication technology related expenditure	0,63	0,19	30,67 %
Total Title 20			**5,16**	**2,76**	**53,51%**
Total Excluding NGEU			**506,24**	**463,23**	**91,50%**
Title 01 Research and Innovation					
01	01 01	Support administrative expenditure of the "Research and Innovation" cluster	7,68	3,94	51,39 %
Total Title 01			**7,68**	**3,94**	**51,39%**
Total NGEU Only			**7,68**	**3,94**	**51,39%**
Total DG SANTE			**513,92**	**467,18**	**90,90 %**

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


% Outturn on Payment Appropriations in 2022 for DG SANTE
120 %
100 %
80 %
60 %
40 %
20 %
0 %
01 01
02 01
02 03
02 04
03 01
03 02
03 05
03 10
03 20
06 01
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06 20
08 03
08 04
09 02
14 20
15 02
20 01
20 02
20 03
20 04

TABLE 3 : BREAKDOWN OF COMMITMENTS TO BE SETTLED AT 31/12/2022 (in Mio €) for DG SANTE									
Chapter			Commitments to be settled				Commitments to be settled from financial years previous to 2021	Total of commitments to be settled at end of financial year 2022	Total of commitments to be settled at end of financial year 2021
			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	16,83	16,83	0,00	0,00%	0,00	0,00	0,00
Total Title 01			**16,83**	**16,83**	**0,00**	**0,00%**	**0,00**	**0,00**	**0,00**

TABLE 3 : BREAKDOWN OF COMMITMENTS TO BE SETTLED AT 31/12/2022 (in Mio €) for DG SANTE									
Chapter			Commitments to be settled				Commitments to be settled from financial years previous to 2021	Total of commitments to be settled at end of financial year 2022	Total of commitments to be settled at end of financial year 2021
			Commitments	Payments	RAL	% to be settled			
			1	2	3=1-2	4=1-2/1	5	6=3+5	7
02	02 01	Support administrative expenditure of the "European Strategic Investments" cluster	7,38	7,38	0,00	0,00%	0,00	0,00	0,00
	02 03	Connecting Europe Facility (CEF)	0,00	0,00	0,00	0,00%	0,83	0,83	2,70
	02 04	Digital Europe programme	0,00	0,00	0,00	0,00%	0,04	0,04	0,22
Total Title 02			**7,38**	**7,38**	**0,00**	**0,00%**	**0,87**	**0,87**	**2,93**

TABLE 3 : BREAKDOWN OF COMMITMENTS TO BE SETTLED AT 31/12/2022 (in Mio €) for DG SANTE									
Chapter			Commitments to be settled				Commitments to be settled from financial years previous to 2021	Total of commitments to be settled at end of financial year 2022	Total of commitments to be settled at end of financial year 2021
			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	2,47	1,84	0,64	25,71%	0,00	0,64	1,25
	03 02	Single Market Programme	138,34	37,15	101,18	73,14%	72,25	173,44	92,37
	03 05	Cooperation in the field of customs (Customs)	1,03	0,00	1,03	100,00%	0,21	1,25	0,64
	03 10	Decentralised agencies	7,30	7,30	0,00	0,00%	0,00	0,00	0,00
	03 20	Pilot projects, preparatory actions, prerogatives and other actions	0,25	0,00	0,25	100,00%	1,51	1,76	2,14
Total Title 03			**149,40**	**46,29**	**103,10**	**69,01%**	**73,98**	**177,08**	**96,39**

TABLE 3 : BREAKDOWN OF COMMITMENTS TO BE SETTLED AT 31/12/2022 (in Mio €) for DG SANTE									
Chapter			Commitments to be settled				Commitments to be settled from financial years previous to 2021	Total of commitments to be settled at end of financial year 2022	Total of commitments to be settled at end of financial year 2021
			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	13,49	12,64	0,85	6,33%	0,00	0,85	2,25
	06 06	EU4Health Programme	100,22	20,94	79,28	79,11%	60,78	140,06	82,32
	06 07	Emergency support within the Union	0,00	0,00	0,00	0,00%	1,82	1,82	15,81
	06 10	Decentralised agencies	299,37	284,30	15,07	5,03%	19,59	34,66	19,59
	06 20	Pilot projects, preparatory actions, prerogatives and other actions	0,00	0,00	0,00	0,00%	0,22	0,22	1,26
Total Title 06			**413,08**	**317,87**	**95,20**	**23,05%**	**82,41**	**177,61**	**121,23**

TABLE 3 : BREAKDOWN OF COMMITMENTS TO BE SETTLED AT 31/12/2022 (in Mio €) for DG SANTE									
Chapter			Commitments to be settled				Commitments to be settled from financial years previous to 2021	Total of commitments to be settled at end of financial year 2022	Total of commitments to be settled at end of financial year 2021
			Commitments	Payments	RAL	% to be settled			
			1	2	3=1-2	4=1-2/1	5	6=3+5	7
08	08 03	European Agricultural Fund for Rural Development (EAFRD)	0,62	0,00	0,62	100,00%	0,30	0,92	0,79
	08 04	European Maritime, Fisheries and Aquaculture Fund (EMFAF)	0,33	0,01	0,32	98,41%	0,18	0,51	0,65
Total Title 08			**0,95**	**0,01**	**0,94**	**99,45%**	**0,48**	**1,43**	**1,44**

TABLE 3 : BREAKDOWN OF COMMITMENTS TO BE SETTLED AT 31/12/2022 (in Mio €) for DG SANTE									
Chapter			Commitments to be settled				Commitments to be settled from financial years previous to 2021	Total of commitments to be settled at end of financial year 2022	Total of commitments to be settled at end of financial year 2021
			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)	0,16	0,00	0,16	100,00%	0,17	0,33	0,21
Total Title 09			**0,16**	**0,00**	**0,16**	**100,00%**	**0,17**	**0,33**	**0,21**

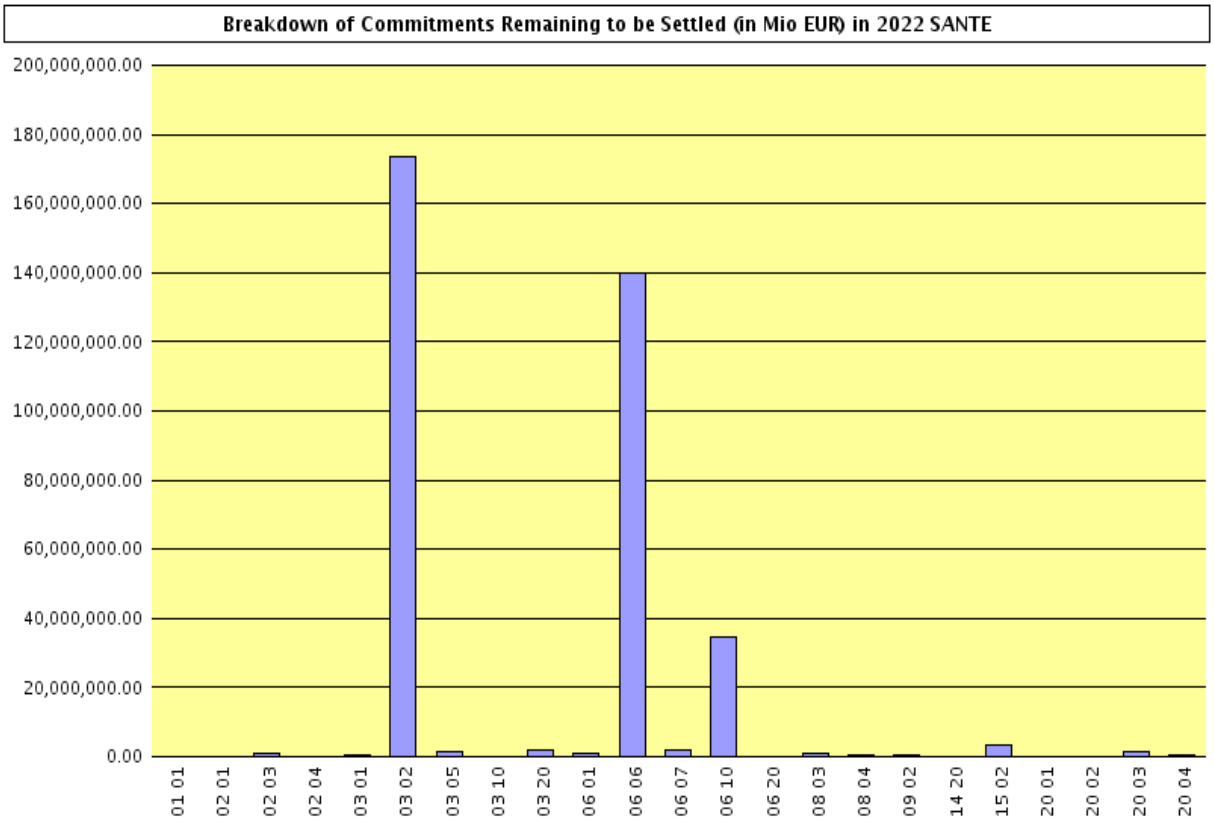
TABLE 3 : BREAKDOWN OF COMMITMENTS TO BE SETTLED AT 31/12/2022 (in Mio €) for DG SANTE									
Chapter			Commitments to be settled				Commitments to be settled from financial years previous to 2021	Total of commitments to be settled at end of financial year 2022	Total of commitments to be settled at end of financial year 2021
			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	0,38	0,37	0,01	1,83%	0,00	0,01	0,05
Total Title 14			**0,38**	**0,37**	**0,01**	**1,83%**	**0,00**	**0,01**	**0,05**

TABLE 3 : BREAKDOWN OF COMMITMENTS TO BE SETTLED AT 31/12/2022 (in Mio €) for DG SANTE									
Chapter			Commitments to be settled				Commitments to be settled from financial years previous to 2021	Total of commitments to be settled at end of financial year 2022	Total of commitments to be settled at end of financial year 2021
			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)	0,00	0,00	0,00	0,00%	3,32	3,32	4,80
Total Title 15			**0,00**	**0,00**	**0,00**	**0,00%**	**3,32**	**3,32**	**4,80**

TABLE 3 : BREAKDOWN OF COMMITMENTS TO BE SETTLED AT 31/12/2022 (in Mio €) for DG SANTE									
Chapter			Commitments to be settled				Commitments to be settled from financial years previous to 2021	Total of commitments to be settled at end of financial year 2022	Total of commitments to be settled at end of financial year 2021
			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	0,40	0,25	0,15	36,56%	0,00	0,15	0,16
	20 02	Other staff and expenditure relating to persons	0,05	0,04	0,01	14,74%	0,00	0,01	0,07
	20 03	Administrative Operating expenditure	2,46	1,20	1,26	51,30%	0,00	1,26	1,07
	20 04	Information and communication technology related expenditure	0,42	0,03	0,39	92,82%	0,00	0,39	0,21
Total Title 20			**3,32**	**1,52**	**1,80**	**54,23%**	**0,00**	**1,80**	**1,52**
Total Excluding NGEU			**591,48**	**390,27**	**201,22**	**34,02%**	**161,23**	**362,45**	**228,57**

TABLE 3 : BREAKDOWN OF COMMITMENTS TO BE SETTLED AT 31/12/2022 (in Mio €) for DG SANTE									
Chapter			Commitments to be settled				Commitments to be settled from financial years previous to 2021	Total of commitments to be settled at end of financial year 2022	Total of commitments to be settled at end of financial year 2021
			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	3,94	3,94	0,00	0,00%	0,00	0,00	0,00
Total Title 01			**3,94**	**3,94**	**0,00**	**0,00%**	**0,00**	**0,00**	**0,00**
Total NGEU Only			**3,94**	**3,94**	**0,00**	**0,00%**	**0,00**	**0,00**	**0,00**

Total for DG SANTE	**595,43**	**394,21**	**201,22**	**33,79 %**	**161,23**	**362,45**	**228,57**


Breakdown of Commitments Remaining to be Settled (in Mio EUR) in 2022 SANTE
200,000,000.00
180,000,000.00
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 01
02 03
02 04
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14 20
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20 02
20 03
20 04

TABLE 4 : BALANCE SHEET for DG SANTE		
BALANCE SHEET	**2022**	**2021**
A.I. NON CURRENT ASSETS	20.772.134,56	15.258.190,10
A.I.1. Intangible Assets	13.313.502,71	7.574.121,31
A.I.2. Property, Plant and Equipment	6.115.127,54	7.549.328,67
A.I.5. Non-Current Pre-Financing	1.343.504,31	134.740,12
A.II. CURRENT ASSETS	101.788.965,82	412.345.513,80
A.II.2. Current Pre-Financing	81.575.387,64	409.983.452,78
A.II.3. Curr Exch Receiv &Non-Ex Recoverables	6.327.372,57	2.359.653,12
A.II.4. Inventories	13.884.000,00	0,00
A.II.6. Cash and Cash Equivalents	2.205,61	2.407,90
ASSETS	**122.561.100,38**	**427.603.703,90**
P.I. NON CURRENT LIABILITIES	0,00	0,00
P.I.3. Non-Current Financial Liabilities	0,00	0,00
P.II. CURRENT LIABILITIES	-597.808.347,26	-310.250.518,06
P.II.2. Current Provisions	-493.533.126,77	-282.598.575,38
P.II.3. Current Financial Liabilities	0,00	0,00
P.II.4. Current Payables	-21.259.056,52	-10.893.216,64
P.II.5. Current Accrued Charges &Defrd Income	-83.016.163,97	-16.758.726,04
LIABILITIES	**-597.808.347,26**	**-310.250.518,06**
NET ASSETS (ASSETS less LIABILITIES)	**-475.247.246,88**	**117.353.185,84**
P.III.2. Accumulated Surplus/Deficit	5.520.422.423,89	4182013472
Non-allocated central (surplus)/deficit*	-5.045.175.177,01	-4.299.366.657,54
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	2022	2021
II.1 REVENUES	-244.642.197,62	-48.482.072,38
II.1.1. NON-EXCHANGE REVENUES	-254.817.410,35	-51.719.115,66
II.1.1.5. RECOVERY OF EXPENSES	-12.178.190,96	-25.816.042,47
II.1.1.7. OTHER NON-EXCHANGE REVENUES	-242.639.219,39	-25.903.073,19
II.1.2. EXCHANGE REVENUES	10.175.212,73	3.237.043,28
II.1.2.2. OTHER EXCHANGE REVENUE	10.175.212,73	3.237.043,28
II.2. EXPENSES	1.265.219.073,80	1.386.891.024,57
II.2. EXPENSES	1.265.219.073,80	1.386.891.024,57
II.2.10.OTHER EXPENSES	568.522.151,61	283.295.210,42
II.2.2. EXP IMPLEM BY COMMISS&EX.AGENC. (DM)	425.765.941,23	766.166.708,46
II.2.3. EXP IMPL BY OTH EU AGENC&BODIES (IM)	261.816.723,19	307.966.953,71
II.2.4. EXP IMPL BY 3RD CNTR & INT ORG (IM)	9.494.597,87	29.785.183,20
II.2.6. STAFF AND PENSION COSTS	-382.475,94	-328.295,83
II.2.8. FINANCE COSTS	2.135,84	5.264,61
STATEMENT OF FINANCIAL PERFORMANCE	**1.020.576.876,18**	**1.338.408.952,19**

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	2022	2021
OB.1. Contingent Assets	480.732,26	0,00
GR for pre-financing	480.732,26	0,00
OB.2. Contingent Liabilities	-36.463.787,72	-29.989.330,18
OB.2.6. CL Other	-36.463.787,72	-29.989.330,18
OB.2.7. CL Legal cases OTHER	0,00	0,00
OB.3. Other Significant Disclosures	-258.777.338,65	-313.382.111,77
OB.3.2. Comm against app. not yet consumed	-258.777.338,65	-313.382.111,77
OB.4. Balancing Accounts	294.760.394,11	343.371.441,95
OB.4. Balancing Accounts	294.760.394,11	343.371.441,95
OFF BALANCE	**0,00**	**0,00**

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
30	1.561	1.513	96,93 %	17,89	48	3,07 %	41,33	1.656.322,17	2, %
45	72	71	98,61 %	19,79	1	1,39 %	58,00	444.756,53	0, %
48	1	1	100,00 %	35,00				0,00	0, %
60	101	96	95,05 %	30,55	5	4,95 %	79,20	410.418,15	3, %
87	1	1	100,00 %	11,00				0,00	0, %
89	1	1	100,00 %	8,00				0,00	0, %
90	31	21	67,74 %	47,67	10	32,26 %	238,60	11.106.223,88	29, %

Total Number of Payments	**1.768**	**1.704**	**96,38 %**		**64**	**3,62 %**		**13617720,73**	**3, %**
Average Net Payment Time	**21,09106335**			**19,05**			**75,38**		
Average Gross Payment Time	**27,69626697**			**22,40669**			**168,5313**		

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	60	196	11,09 %	1.768	54.948.927,50	11,79 %	466.031.165,15

Late Interest paid in 2022

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	2.135,84
			2.135,84

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 2022 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	1.332.825,88	0,00	1.332.825,88	1.332.825,88	0,00	1.332.825,88	0,00
60	Single market, innovation and digital	1.203.499,98	0,00	1.203.499,98	1.203.499,98	0,00	1.203.499,98	0,00
61	Cohesion, resilience and values	16.175.036,12	176.602,93	16.351.639,05	6.745.138,12	176.602,93	6.921.741,05	9.429.898,00
66	Other contributions and refunds	28.229.297,82	0,00	28.229.297,82	28.229.297,82	0,00	28.229.297,82	0,00
67	Completion for outstanding recovery orders prior to 2021	0,00	47.123,59	47.123,59	0,00	0,00	0,00	47.123,59
Total DG SANTE		**46.940.659,80**	**223.726,52**	**47.164.386,32**	**37.510.761,80**	**176.602,93**	**37.687.364,73**	**9.477.021,59**

TABLE 8 : FINANCIAL IMPACT OF EX-ANTE AND EX-POST CONTROLS in 2022 for DG SANTE

EX-ANTE CONTROLS	Irregularity	Total undue payments recovered
NON ELIGIBLE IN COST CLAIMS	1.070.617,30	**1.070.617,30**
CREDIT NOTES	1.005.430,64	**1.005.430,64**
RECOVERY ORDERS ON PRE-FINANCING	51.512,80	**51.512,80**
Sub-Total	**2.127.560,74**	**2.127.560,74**

EX-POST CONTROLS	Irregularity	Total undue payments recovered
INCOME LINES IN INVOICES		
RECOVERY ORDERS OTHER THAN ON PRE-FINANCING	752.216,34	**752.216,34**
Sub-Total	752.216,34	**752.216,34**
GRAND TOTAL (EX-ANTE + EX-POST)	**2.879.777,08**	**2.879.777,08**

TABLE 9: AGEING BALANCE OF RECOVERY ORDERS AT 12/31/2022 for DG SANTE

	Number at 1/1/2021 1	Number at 12/31/2022	Evolution	Open Amount (Eur) at 1/1/2021 1	Open Amount (Eur) at 12/31/2022	Evolution
2011		1			47.123,59	
2022		2			9.429.898,00	
		3			**9.477.021,59**	

TABLE 10 :Recovery Order Waivers >= 60 000 € in 2022 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	

There are no waivers below 60 000 €

Justifications:

TABLE 11 : Negotiated Procedures in 2022 for DG SANTE

Internal Procedures > € 60,000

Negotiated Procedure Legal base	Number of Procedures	Amount (€)
Annex 1 - 11.1 (a) - Follow-up of an open/restricted procedure where no (or no suitable) tenders/requests to participate have been submitted	1	68.250,00
Annex 1 - 11.1 (b) - Artistic/technical reasons or exclusive rights or technical monopoly/captive market	2	545.936,75
Total	**3**	**614.186,75**

TABLE 12 : Summary of Procedures in 2022 for DG SANTE

Internal Procedures > € 60,000

Procedure Legal base	Number of Procedures	Amount (€)
Negotiated procedure middle value contract (Annex 1 - 14.2)	5	571.820,21
Negotiated procedure without prior publication (Annex 1 - 11.1)	3	614.186,75
Open procedure (FR 164 (1)(a))	4	15.554.300,00
Total	**12**	**16.740.306,96**

Additional Comments:

TABLE 13 : BUILDING CONTRACTS in 2022 for DG SANTE

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

TABLE 14 : CONTRACTS DECLARED SECRET in 2022 for DG SANTE

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

TABLE 15 : FPA duration exceeds 4 years - DG SANTE

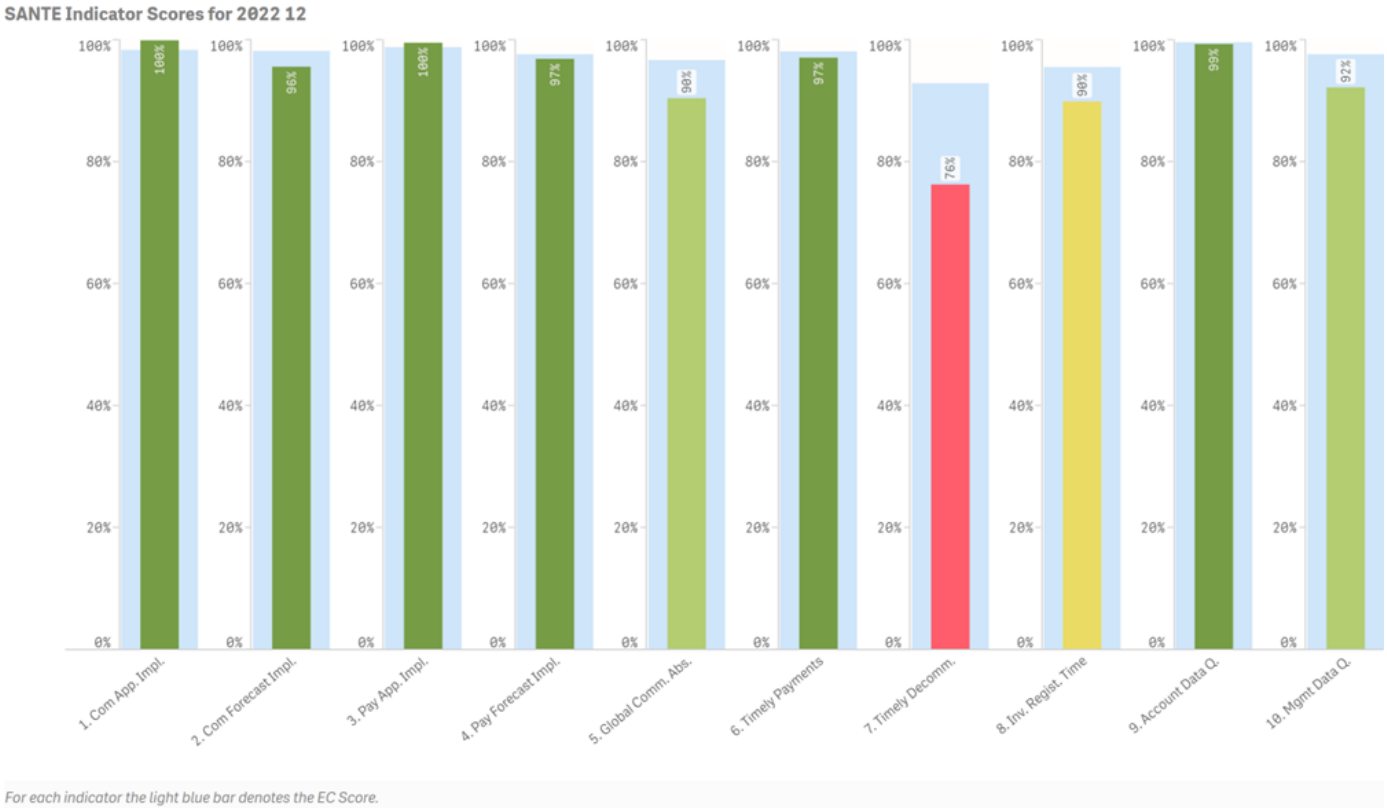
TABLE 16 : Commitments co-delegation type 3 in 2022 for DG SANTE

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 2022

Indicator	Objective	Comment	SANTE Score	EC Score
1. Commitment Appropriations Implementation	Ensure efficient use of commitment appropriations expiring at the end of Financial Year		100%	98%
2. Commitment Forecast Implementation	Ensure the cumulative alignment of the commitment implementation with the commitment forecast in a financial year		96%	98%
3. Payment Appropriations Implementation	Ensure efficient use of payment appropriations expiring at the end of Financial Year		100%	99%
4. Payment Forecast Implementation	Ensure the cumulative alignment of the payment implementation with the payment forecast in a financial year		97%	98%
5. Global Commitment Absorption	Ensure efficient use of already earmarked commitment appropriations (at L1 level)	*The core amounts to 96% taking into account the impact of the global commitments that were split in 2022.*	96%	97%
6. Timely Payments	Ensure efficient processing of payments within the legal deadlines		97%	98%
7. Timely Decommitments	Ensure efficient decommitment of outstanding RAL at the end of commitment life cycle	*In 2022, DG SANTE organised its de-commitments in batches which is more efficient; priority was given to implement the very high number of complex files and to catch up the delay in the adoption of the MFF (2021-2027).*	76%	93%
8. Invoice Registration Time	Monitor the accounting risk stemming from late registration of invoices in the central accounting system ABAC	*In 2022, the registration of invoices lagged slightly behind due to the exceptionally high work load as explained above. Priority was given to timely budget implementation and timely payments.*	90%	95%
9. Accounting Data Quality	Ensure the good data quality of ABAC transactions with the focus on fields having a primary impact on the accounts		99%	100%
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		92%	98%

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 Safety 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[4]. For actions initiated under the previous legislation[5], 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.

[4] 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

[5] 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 - Implementation of the annual ex-post control work plan ⇨ Target: 100% - Percentage of audit recommendations accepted by the beneficiaries/Member States ⇨ Target: 100%

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)**
b) **Detected errors**, irregularities or suspicions of fraud should be **addressed adequately and in a timely manner.**	1. Systematic communication and registration 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)	1. 100% of final control results 2. 100% financial control of recovery orders 3. 100% of financial procedures 4. 100% of accepted recommendations implemented	**Cost of control**: - Included in the estimated staff costs for handling the Member States' applications **Benefits of control:** - Amount of actually corrected errors	- Audit results implemented ⇨ Target: 100% - "Time to recover" from final accepted audit report to debit note ⇨ Target: 100% on time - 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%

Public Procurement				
Main inherent risks	**Mitigating controls**	**Control coverage**	**Costs and benefits of controls**	**Cost-Effectiveness indicators (three E's: effectiveness, efficiency, economy)**
b) **If the definition of tender specifications**, exclusion, selection and award criteria are poor, or if the publication of a tender is insufficient, the best possible bids might not be received.	1. To ensure a high level of expertise in drafting the tender specifications, DG SANTE competent staff of the policy Units write the specifications with the support of the central procurement team in the horizontal Directorate. 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.	1. Tender specifications 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	**Cost of control**: - 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.	- Number of open calls for tenders 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

Public Procurement				
Main inherent risks	**Mitigating controls**	**Control coverage**	**Costs and benefits of controls**	**Cost-Effectiveness indicators (three E's: effectiveness, efficiency, economy)**
c) The most economically 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.	1. The central procurement team in the horizontal Directorate organises the opening and evaluation procedures, sees to their correct implementation and documentation; members of committees are appointed by the Authorising Officer responsible. 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.	1. 100% of tender procedures are 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	**Cost of control**: - Estimated staff costs 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.	- Number of valid complaints, Ombudsman cases or litigations 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 2022, DG SANTE managed financial operations under the following two policy areas: Public Health and Food Safety.

- About 82% of the EU4Health Programme budget for 2022 was transferred to the Health and Digital Executive Agency (HaDEA).
- About 55% of the Food chain strand of the SMP budget for 2022 was implemented by HaDEA.

DG SANTE paid subsidies to finance – partially or in full – the operating budget of HaDEA; the other parent DGs also pay their parts. In 2022, 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[6] 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.

[6] 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. All parent DGs agreed on an ex-ante assessment of the agency's internal control system prior to granting full budget autonomy. 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 is complemented by specific guidelines for SANTE delegated tasks. 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).

For detailed information on the agencies, see Annex 13.

- ❑ European Centre for Disease Prevention and Control (ECDC)
- ❑ European Food Safety Authority (EFSA)
- ❑ European Medicines Agency (EMA)
- ❑ Community Plant Variety Office (CPVO)
- ❑ European Chemicals Agency (ECHA)

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	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"[7] laid down by the Interinstitutional working group on EU agencies, e.g. - An impact assessment is carried out prior to establishing	**100% in-depth** once in establishment phase **100% in-depth** case by case if amendment or	**Cost of control**: - Estimated SANTE staff costs involved in establishing an EU agency or the review or amendment of its	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%

[7] 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)**
agency's management of the EU funds paid by DG SANTE to subsidise its running costs.	an EU agency and when amending its mandate; - 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.	review is planned **Frequency:** When amendment or review of an agency's founding regulation is planned	founding regulation - 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.	**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	**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	- 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

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)**
	Deviations from the FFR need the Commission's prior consent; DG SANTE, in co-operation with DG BUDG consults and monitors. All SANTE agencies have adopted in 2019 Financial Regulations which are in line with the Framework Financial Regulation.[8] 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.	Control Framework; Annual meeting of the DG SANTE inter-agency task force on independence	paid to the agency per year possibly at 100% if significant legal errors occurred	⇨ Target: all agencies
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	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	**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	**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	- 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

[8] 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)**
negatively on the Commission's reputation.	(i) operational and financial Units and (ii) Directors/DDG/DG. In addition, DG SANTE regularly 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).	agency's internal control 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	monitoring activities. **Benefits of control:** The total subsidy paid to the agency per year possibly at 100% if significant legal errors occurred	⇨ Target: depends on the agency (about 3 to 4 times 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 (last completed in 2021); - 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 Safety

In the policy area Food 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[9] – 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[10].

Table 7.1 Food Safety Grants

Payment credits implemented by DG SANTE *(without HaDEA)*[11]	**2022 M€**	**2021 M€**
Veterinary emergency fund (grants to Member States)	**32,1**	20,8
Phytosanitary emergency measures (grants to Member States)	**11,2**	1,8
Grants to international organisations (mostly indirect management; see under 7.1.1.3 and annex 11)	**4,6**	4,1
Total grants	**47,9**	**26,7**

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 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 such as the UPPOV (International Union for the Protection of New Varieties of Plants), FAO

[9] Regulation (EU) 2021/690 of the European Parliament and of the Council of 28/04/2021 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 06/05/2021 and 2022 work programme C(2022)724 of 17/02/2022 last amended by C(2022)9176 of 07/12/2022.

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

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

(Food and Agriculture Organization) and OIE (Office International des Epizooties or World Organisation for Animal Health).

- A total of 14 applications of Member States for cost reimbursements in relation to veterinary emergency measures were handled to combat, first and foremost, Avian Influenza (EUR 27,2 million) and African Swine Fever (EUR 3,9 million). In addition, seven payment files were treated according to grant agreements signed with third countries for their fight against African Swine Fever (4 files) and Lumpy Skin Disease (3 files).
- Addressing the combat of organisms harmful to plants, nine Member States submitted applications for emergency measures for which DG SANTE signed grant agreements in 2022 and made pre-financing payments of a total amount of EUR 9,1 million. Furthermore, seven grants of previous years were closed with final payments of EUR 2,1 million.
- In 2022, 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 and for the platform for actions against AMR. DG SANTE also contributed to the UPOV (International Union for the Protection of New Varieties of Plants) and supported the 2022 international plant health conference in the UK.

The control process of DG SANTE's grant management pertaining to the Member States' emergency measures 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 90% of the grants in the Food Safety policy area (see table 7.1 above). As unforeseeable developments in emergency situations entail a relatively high uncertainty of whether or not a measure is eligible, DG SANTE focusses its control efforts on ex-ante checks, i.e. before the final payment.

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

The SMP-Food Chain strand provides for the award of grants 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.

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.

In addition, the SMP, Article 13, provides for derogations from the principle of non-retroactivity pursuant to Article 193 of the Financial Regulation as follows:

- 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[12];
- 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 2: Approving the emergency measure and signing the grant agreement

In 2022, DG SANTE evaluated nine grant applications for phytosanitary emergency measures that Member States had taken in 2020. Having taken the award decision, the authorising officer by sub-delegation signed the corresponding grant agreements. For the first time, Member States co-signed the agreement. The grant agreements were adapted[13] to the novelties of the Single Market Programme (SMP 2021-2027) and further to an audit recommendation made by the IAS to improve certain grant agreement provisions.

The signed grant agreements were not preceded by a budgetary commitment by way of derogation from Article 111(2) of the Financial Regulation: according to the SMP, Article 4(5), 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.

The preparation of grant agreements for animal health emergency measures implemented by the Member States in 2021 and 2022 had to be postponed to early 2023 due to the lack of EU budget to cover the exceptionally high costs to combat first and foremost Avian Influenza with an estimated co-financing need of more than EUR 400 million for measures Member States had taken in 2021 and 2022, but also African Swine Fever with an estimated EUR 100 million for co-financing. To re-allocate the necessary funds to the emergency measures within the SMP-Food Chain strand, the future co-financing rates for veterinary and phytosanitary programmes were decreased by 60% starting from 2023 programmes onwards. The work programme 2023-2024 of the SMP Food chain strand was amended accordingly[14].

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

[13] The IAS made an audit recommendation to improve the grant agreement provisions and the unit cost methodology. The action plan has been implemented by late 2022 (see Annex 8.1.2 below).

[14] C(2023)1133 of 20/02/2023

Stage 3: Managing financial transactions and ex-ante controls

Following the signature of the nine grant agreements for phytosanitary emergency measures, DG SANTE made pre-financing payments of a total of EUR 9,1 million which corresponded to about 70% of the co-financing amount.

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: centralised financial cell with operational verification in the policy Units and authorising officer by sub-delegation for commitments and payments at the level of the Deputy Director-General for Food Sustainability. 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. Audits took place on the spot as well as remotely. Almost 90% of all final payments were preceded by a financial audit. The audit results in 2022 show a weighted average correction rate of around 7%. 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***	**2022**	**2021**
Stage 3: Monitoring and financial management			
Member States' applications received and analysed	*100%*	100%	100%
Number of registered **"exception reports"** related to veterinary and phytosanitary emergency measures	*n/a*	0	0
Instances of Article 93 FR[15]	*n/a*	0	0
Late interest payments relative to total value of grants (since 2020 no more case)	*0%*	0,0%	0,0%
Ex-ante controls in the form of financial audits **Audit coverage**	*80%*	88%	80%
Ex-ante controls in the form of financial audits **Average corrections** - Veterinary emergency fund - Phytosanitary emergency fund	*n/a*	28,4% 4,1%	23,5% 5,5%

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

No “exception report” was submitted in 2022 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.

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 financial audits either on-the-spot in the Member States or carried out remotely. In principle, these audits take place either prior to the final payment (ex-ante) or after the final payment (ex-post). The aim is to provide reasonable assurance on the legality and regularity of expenditure on an annual basis.

Ex-post financial audits are carried out on a sample basis after the final payment has been made. The audit samples are taken based on 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).

Member States’ animal disease eradication programmes, plant pest survey programmes, European Reference Laboratories and other grants to Member States in the policy area Food Safety were transferred in 2021 to the Health and Digital Executive Agency (HaDEA) for implementation, including ex-post controls. In 2022, DG SANTE continued carrying out ex-post controls only on payments for grants it made as authorising officer by sub-delegation under the 2014-2020 Food and Feed programme[16]. In 2022, DG SANTE did not make any payments anymore for grants under the 2014-2020 Food and Feed programme.

Since 2013, the results of financial audits did not warrant a reservation in DG SANTE’s Annual Activity Report. The weighted average detected error rate for grants in the previous financial framework 2014 to 2020 amounted to 1,8% and the estimated overall risk at closure amounted to 0,8%. Both values are below the threshold of 2%.

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

Table 7.3 Error rates stemming from ex-post controls in the policy areas Food Safety

DG SANTE ex-post controls in the Food Safety policy area	AAR 2022	AAR 2021	AAR 2020	AAR 2019	AAR 2018	AAR 2017	AAR 2016	AAR 2015
Detected error rate	5,2%	0,5%	0,9%	0,5%	2,0%	2,7% (1%)	1,3%	1,7%
Residual error rate (after corrections)	N/A*	0,5%	0,8%	0,4%	1,9%	2,5% (1%)	1,1%	1,2%
Reservation	No	No	No	No	No	No	No	No

Ad *: as the type of grant, in which the errors were found, was transferred from DG SANTE to HaDEA in 2021 and – most importantly – does no longer apply the system of incurred costs but changed largely to lump-sums, the errors found in the ex-post audits of payments made in previous years cannot be extended to other non-audited payments made in 2022. Thus, no residual error rate is calculated. For the calculation of the overall risk at closure, a conservative estimated error rate of 2% is applied.

In 2022, a total of 9 ex-post audits were completed on animal disease eradication programmes of 2018 and 2019. This is about 50% less than the average number of completed audits in the past seven years due to the phasing-out process of ex-post controls on eradication programmes further to the transfer of budget implementation tasks to HaDEA. The audited amount of EUR 8,2 million represents a sample size covering only a fifth of the amount audited in the last seven years (2015 to 2021). In this relatively small sample, DG SANTE detected an exceptionally high error rate of 5,2% with overpayments amounting to EUR 0,4 million. They were mainly due to reporting errors in Member States cost claims relating to programmes not yet covered by the use of unit costs. DG SANTE believes that the error rate detected in 2022 cannot be extrapolated given that DG SANTE has made no more payments for this type of grant since late 2021 and the eligibility rules for eradication programmes have changed under the Multiannual Financial Framework (2021 to 2027), with the introduction of lump-sums covering – for the first time – also the cost category in which the errors were found.

The only grants in the Food Safety policy area that remain with DG SANTE are related to Member State's veterinary and phytosanitary emergency measures. They are subject to extensive ex-ante controls, including ex-ante on-the-spot audits: almost 90% of the final payments made in 2022 were based on audits. Therefore, the ex-post error rate is estimated conservatively at 2%. If, in the next few years, sufficient information becomes available on an ex-post control error rate for this kind of grant, DG SANTE will revise this estimate.

Against this background, DG SANTE does not consider it appropriate to make a reservation in the Director-General's 2022 declaration of assurance.

Table 7.3 Indicators for grants at control stage 4

Indicators	*Target*	2022	2021	2020
Stage 4: Ex-post controls				
Ex-post control **detected error rate** (policy area Food Safety)	*n/a*	5,2%	0,5%	0,9%
Ex-post control **residual error rate** (policy area Food Safety) (Without one exceptional file)	***< 2,0%***	n/a	0,5%	0,8%
Estimated error rate as no ex-post error rate is available	***< 2,0%***	2%		
Amount of net financial corrections identified in year N compared with amount of transactions audited	*n/a*	0,4 M€ 8,1 M€	0,1 M€ 21,5 M€	0,2 M€ 26,3 M€
Financial corrections in year N linked to audits finalised in year N (until 31/12/year N)	*n/a*	0,1 M€ 30,0%	0,0 M€ 0,0%	0,0 M€ 0%
Total financial correction of detected errors by mid-March 2023	*100%*	0,1 M€ 30,0%	N/A*	0,2 M€ 100%

Ad *: Files transferred to HaDEA

7.1.1.2 Procurement

The following paragraphs describe the provisions for the management of public procurement in the policy areas Food and Feed Safety[17] and Public Health[18] within the remit of DG SANTE.

As in previous years, about 65% of the 2022 payment budget of the EU4Health Programme was implemented by the Health and Digital Executive Agency (HaDEA). Around 35 % was implemented by DG SANTE mainly through contribution agreements with international organisations under indirect management and public procurement procedures (e.g. specific contracts on framework contracts for IT services, communication, evaluation and impact assessments and administrative arrangements with JRC.

[17] 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

[18] Regulation (EU)2021/522 of 24 March 2021 – EU4Health Programme; C(2022) 5436 final of 25 July 2022– 2022 work programme of EU4Health. Programme Statements June 2022

Table 7.4 Procurement DG SANTE, including ESI

Commitment credits implemented by DG SANTE *(without HaDEA)* [19]	**2022 M€**	**2021 M€**
Food and Feed Safety: DG SANTE procurement expenditure	**25,1**	31,5
Food and Feed Safety: SANTE – TAXUD charge-back IT	**0,3**	-
Health Programmes implemented directly by DG SANTE	**31,9**	64,5
Emergency Support Instrument (ESI) Procurement	**0,1**	69,7
Procurement other policy areas (operational credits mainly)	**4,1**	5,0
Building expenditure Ireland and other administrative credits	**2,8**	5,0
Total budget implemented	**64,3**	175,7

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 2022, 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 140.000) 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.

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

Table 7.5 Procurement contracts above EUR 60.000[20]

Type of procedure	2022		2021		2020	
	N° of contracts	Amount M€	*N° of contracts*	Amount M€	*N° of contracts*	Amount M€
Open (Financial Regulation)	***4***	***15,6***	*3*	21,4	*3*	1,8
Negotiated under extreme urgency	**-**	**-**	*2*	70,0	*8*	2 576,6
Negotiated without prior publication [Annex 1 - 11.1 (b)]	***1***	**0,4**	*3*	7,3	*3*	9,9
Negotiated without prior publication [Annex 1 - 11.1 (i)]	***1***	**0,1**	*1*	0,3	-	-
Negotiated middle value contract	***5***	**0,6**	*1*	0,1	*1*	0,1
Restricted	**-**	**-**	*2*	0,2	*1*	1,7
TOTAL	***11***	***16,7***	*12*	99,3	*16*	2 590,1

Main open, negotiated and restricted procedures

Through open calls for tender, DG SANTE signed a framework contract for IT services for a clinical patient management systems for the European Reference Network (ERN) (EUR 10 million) and procured an online testing tools for eHealth services (EUR 0,4 million). DG SANTE also engaged in the purchase, storage and delivery of live attenuated vaccines against Classical Swine Fever (EUR 1,2 million) and procured services for capacity building of plant health services in Western Balkans (EUR 4 million).

Negotiated procedures were applied for a study on consumer understanding of Front-of-Pack nutrition labelling (EUR 0,1 million), for the state of vaccine confidence in the EU (EUR 0,5 million) and for an educational book series to strengthen youth vaccine confidence in the EU (EUR 0,1 million). To procure technical consultancy and legal services, as well as tree planting for DG SANTE's site management in Grange, Ireland, DG SANTE applied three negotiated procedures of middle value contracts (EUR 0,3 million). A negotiated procedure without prior publication was signed for heating oil for the office building in Grange (EUR 0,1 million).

In 2022, as in previous years, DG SANTE made extensive use of framework contracts concluded by itself or by other DGs (mainly DGs DIGIT and COMM). In addition to the more than 100 specific contracts, DG SANTE awards every year a rather low number of contracts following an open, restricted or negotiated procedure (table 7.5 above).

The share of different procedures thus fluctuates significantly from year to year: while in 2022, about 7% of the total contract value was awarded through the negotiated procedure, it was almost 80% in 2021. Expressed in number of transactions, in 64% of the limited number of cases included in table 7.5 above, the negotiated procedure was applied (7 out of 11 in 2022; 7 out of 12 in 2021);

[20] Annex 3 table 12

The main reason for using negotiated procedures in 2022 was that DG SANTE often needs services in specialised fields with only one or two suitable providers, especially for site management of the office building in Grange, Ireland. Another reason is the demand driven purchase of vaccines and antigens for animal diseases in which DG SANTE often faces situations such as monopoly or extreme urgency due to unforeseen events.

Public Procurement Committee (PPC)

Procurement procedures (open calls for tender and negotiated procedures) for contracts above the Directive threshold (EUR 140.000 in 2022) 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.

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

Indicators	***Targets***	**2022**	**2021**
Stage 1: Assessing procurement needs and selecting the offer			
Rate of open calls for tenders for which - No offer was received (in 2022: 0 out of 5; in 2021: 0 out of 4) - The procedure had to be cancelled (in 2022: 1; in 2021: 1)	*0%* *0%*	**0%** **25%**	0% 25%
Rate of negotiated procedures[21] for which - No offer was received - The procedure had to be cancelled	*0%* *0%*	**0%** **25%**	33% 50%
Number of procurement procedures within the scope of the PPC	*n/a*	**4**	9
Number of procurement procedures examined by the PPC	*n/a*	**4**	7
% of procurement procedures examined by PPC	*100%*	**100%**	78%
Ratio of positive opinions of the Public Procurement Committee	*n/a*	**100%**	90% (1 suspended)
Public Procurement Committee opinions followed by the authorising officers responsible	*100%*	**100%**	100%

In 2022, the Public Procurement Committee (PPC) provided four positive opinions on procurement contracts with a total maximum value EUR 15,7 million.

[21] 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 provide for a first-level verification of each financial transaction by the responsible financial Unit. Checks are done at the desk prior to the authorisation of the transaction (ex-ante).

Table 7.6.2 Indicators for procurement at stage 2

Indicators	*Targets*	2022	2021
Stage 2: Monitoring of contract implementation ar financial management			
Late interest payments relative to total value of contracts (in 2022: 5 cases for a total of €2 135; 2021: one case €4 453)	*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 2022, 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*	2022	2021
Stage 3: Supervisory measures			
Number of registered **"exception reports"** relative to procurement procedures	*n/a*	**7**	12
Instances of Article 93 FR[22]	*n/a*	**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
Recovery orders of year N: (in number) in amount	*n/a*	**(2)** **0,7M€**	(2) 0,002M€
For procurement: **Ombudsman** cases or legal proceedings opened in year N	*n/a*	0	2

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 brought to the attention of the Director-General. The 7 "exception reports" of 2022 mainly pertain to derogations from the Financial Regulation when DG SANTE launched procurement procedures prior to the adoption of the 2022 SMP work programme due to urgency, an a-posteriori commitment when extending a service contract, a case of inadequate handling of a so-called “very low value” purchase. DG SANTE assesses that these derogations have no bearing on the Director-General’s declaration of assurance as they did not point to weaknesses in the internal control procedures.

DG SANTE issued in 2022 two recovery orders related to public procurement for a total amount of EUR 0,7 million, mainly for the buy-back of antigens under an existing contract.

In 2022, no Ombudsman case relevant for DG SANTE’s procurement procedures was opened.

7.1.1.3 Budget implementation tasks entrusted to other services and entities

DG SANTE has entrusted parts of its budget for implementation in direct management by cross-sub-delegations to other DGs and by the executive agency HaDEA. In addition, DG SANTE contributes to the operating budget of HaDEA.

In direct managemnet, DG SANTE finances, partially or in full, the operating budgets of a number of EU decentralised agencies and signed contribution agreements with international organisations.

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).

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

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

In 2022, DG SANTE cross-subdelegated EUR 0,1 million of commitment and payment credits to DG RTD for their share of evaluation services related to an executive agency and EUR 0,1 million of commitment credits to DG COMP from the SMP Food chain strand for IT services.

Being a Commission services themselves, DGs COMP and RTD are required to implement the appropriations subject to the same rules, responsibilities and accountability arrangements as DG SANTE. The cross-subdelegation agreements signed with the DGs require the authorising officer responsible to report on the use made of the delegated appropriations. In the reports sent to DG SANTE for 2022, the authorising officers of DGs COMP and RTD did not communicate any events, control results or issues which could have a material impact on assurance.

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[23]. It is entrusted with the implementation of the following (parts of) Union programmes:

Table 7.8: Union programmes delegated to HaDEA

Parent DGs	Programme
SANTE and HERA	EU4Health programme[24]
SANTE	Single Market Programme[25]: 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

[23] Commission Implementing Decision (EU) 2021/173 of 12 February 2021
[24] Regulation (EU)2021/522 of 24 March 2021 – EU4Health Programme
[25] Regulation (EU) 2021/690 of 28 April 2021 – SMP

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	2022 M€	2021 M€
Subsidy payments for administrative budget (SANTE share)	**13,9**	8,4
Operational budget transferred from SANTE to HaDEA		
➢ Payments made under EU4Health	**98,7**	34,3
➢ Payments made under the SMP	**137,7**	117,4

Since its establishment in February 2021, HaDEA set up its internal control framework and reached full autonomy with the appointment of its Director nominated by the Commission on 21 January 2022, with effect from 16 February 2022.

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

According to HaDEA's Act of delegation[26], 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 (MoU), signed on 21 December 2021,

[26] C(2021)948 of 12 February 2021 – Commission Decision on delegating powers to HaDEA, amended by C(2021) 9343 of 14 December 2021

covers general provisions and modalities regarding mainly IT governance, supervision, HR, planning, reporting and evaluation. In addition, DG SANTE and HaDEA signed the specific Memorandum of Understanding for the implementation of the EU4Health programme on 13 December 2022 and the Memorandum of Understanding for the SMP Food chain strand on 16 February 2023.

DG SANTE follows up on the agency's consumption of both the administrative and the operational budget. In 2022, no serious control issue came to the attention of DG SANTE that would warrant a financial or reputational reservation in DG SANTE's Annual Activity Report.

In HaDEA's 2022 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 2022 Annual Activity Report.

Table 7.10 Indicators of control effectiveness as regards legality and regularity

Executive agency HaDEA	***Targets***	**2022**	**2021**
Steering Committee meetings with adequate quorum for voting (info: HaDEA has 6 parent DGs)	*4*	**4**	6
Number of "exception reports" relative to the MoUs on the co-operation between DG SANTE and the agency	*n/a*	**0**	0
Budget execution rates of the operational budget transferred to the agency: commitments payments	*99%* *100%*	**99,7%** **99,8%**	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**	Yes
Court of Auditors' assurance on the agency's accounts and implementation of the administrative budget of year N-1 without qualification	*Yes*	**Yes**	**n/a***
Discharge granted for year N-1 and discharge recommendations implemented for year N-2	*Yes*	**Yes**	**n/a***
Ratio of recovery of the positive budgetary outturn of year N to subsidy paid in year N-1	*n/a*	**3,2%**	**n/a***

Ad *: HaDEA was set up in February 2021.

EU decentralised agencies

In 2022, DG SANTE was responsible for the following five EU agencies.

- ❑ European Centre for Disease Prevention and Control (ECDC)
- ❑ European Food Safety Authority (EFSA)
- ❑ European Medicines Agency (EMA)
- ❑ Community Plant Variety Office (CPVO)
- ❑ European Chemicals Agency for its biocides activities (ECHA-biocides)

While CPVO is fully fee-financed, 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). For detailed information on the agencies, see Annex 13.

Table 7.11 EU decentralised agencies – subsidies in 2022

EU decentralised agencies	Policy area concerned	*Number of staff **	EU contribution M€
ECDC – European Centre for Disease Prevention and Control	Public Health	***350***	**99,9**
EFSA – European Food Safety Authority	Public Health and Food Safety	***587***	**134,7**
EMA[27] – European Medicines Agency	Public Health	***915***	**49,7**
CPVO[28] – Community Plant Variety Office	Food Safety	***55***	**0**
ECHA-biocides[29] – European Chemicals Agency	Food Safety	***69***	**7,3**
Total		***1.930***	**291,6**

*: 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.

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

[27] EMA's total 2022 budget for payments amounted to EUR 417,5 million, mainly financed by fees. The EU contribution is a balancing grant (in 2022: 12%).

[28] CPVO does not receive any EU subsidies; its 2022 payment budget amounted to EUR 20,4 million.

[29] 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 2022 amounted to EUR 11,9 million in payments. The EU contribution is a balancing grant (in 2022: 61%)

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, namely the mandates of ECDC[30] and EMA[31].

The latest amendment to EFSA's founding Regulation[32] dates back to June 2019. From July 2022, EFSA's Management Board includes a member from each Member State, in line with the Common Approach on decentralised agencies.

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

In December 2018, the Commission adopted a revised Framework Financial Regulation (FFR)[33] 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 annual Opinions on the 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 strategies, adopted by the respective Management Boards, and updated them 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 R "Policy and administrative support " ensures a central coordination to promote a coherent approach towards all agencies and to exchange good practices.

[30] Regulation (EU)2022/2370 of 23 November 2022

[31] The Regulation is expected to be adopted by the co-legislators in early 2023.

[32] 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.

[33] 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[34].

- **ECDC:** the latest evaluation was finalised in 2019: third external evaluation of ECDC for the years 2013-2017. In 2022, ECDC continued implementing the recommendations as approved by ECDC's Management Board.
- **EFSA:** in 2022, EFSA continued to implement the Management Board recommendations made in the framework of the third external evaluation delivered in 2018.
- **EMA:** the latest evaluation of the Agency's operation was published on 31 August 2021 and is available in the form of a Report from the Commission to the European Parliament and the Council on the experience acquired with the procedures for authorising and supervising medicinal products for human use, in accordance with the requirements set out in the EU legislation on medicinal products for human use[35]. 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 organised regularly (at least every six years) an evaluation of its activities. In 2022, a socio-economic impact study on the benefits of the system of Community Plant Variety Rights in the EU was finalised.

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 27 October 2022, the Court published its "Annual report on EU agencies for the financial year 2021". 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 included a disclosure on the lease of the EMA's former premises in London. The lease runs until 2039 and does not contain a so-called break clause, but the premises can be sublet or assigned subject to the landlord's consent. In July 2019, the EMA reached an agreement with its landlord, and has sublet its former premises to a subtenant with effect from July 2019. The term of the sublease lasts until the EMA's lease expires in June 2039. Since the EMA remains a party to the head lease, it could be held liable for the entire amount remaining payable under the contractual

[34] 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.

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

obligations of the head lease if the subtenant fails to meet its obligations. On 31 December 2021, the total estimated outstanding rent associated service charges and landlord insurance to be paid by the EMA up to the end of the lease term was EUR 383 million

Discharge

In May 2022, taking into account the Court of Auditors reports on the agencies annual accounts 2020, the European Parliament granted the four agencies which receive a subsidy from the EU budget discharge in respect of the 2020 budget implementation.

DG SANTE, within the limits of its role on the EU agencies' Management Boards and Audit Committees, if applicable[36], 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 2022, DG SANTE cleared all pre-financing payments made to the agencies in 2021 and made the final payments of the 2021 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*	2022	2021
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
Discharge granted for year N-1 and discharge recommendations implemented for year N-2	*Yes*	**Yes**	Yes
Ratio of recovery of the positive budgetary outturn of year N to subsidy paid in year N-1	*n/a*	**9,7%**	3,5%

Indirect management - contribution agreements

Implementing actions of the 2021 and 2022 work programmes of the EU4Health programme and the SMP, in 2022, DG SANTE concluded contribution agreements with international organisations and made pre-financing payments of EUR 22,7 million (Annex 11). The organisations were all pillar assessed, i.e. they demonstrated a level of financial management and protection of the EU financial interest equivalent to that of the

[36] 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.

Commission. This is verified by an ex-ante assessment ("pillar assessment") of the entity, carried out by the Commission. DG SANTE does not conduct own pillar assessments itself but relies on assessments conducted by other DGs.

Pillars are the broad areas covered by this assessment. According to the Financial Regulation (2018) and the pillar assessment methodology adopted on 17 April 2019, these are:

- Basic pillars (compulsory): (1) internal control, (2) accounting, (3) independent external audit;
- Operational pillars (optional): (4) grants (including certain aspects from the discontinued sub-delegation pillar), (5) procurement, (6) financial instruments and budgetary guarantees;
- New pillars (compulsory): (7) exclusion from access to funding, (8) publication of information on recipients, (9) protection of personal data.

DG SANTE also concluded contribution agreements with EU decentralised agencies with the European Medicines Agency (EMA) for a pilot of electronic product information (ePI) and with the European Centre for Disease Prevention and Control (ECDC) for the reinforcement of the vaccination information portal.

Programme	EU decentralised agency	2022 Payments in M€	2022 Commitments M€
EU4Health	EMA	0,75	1,50
	ECDC	0,80	1,00
Total		**1,55**	**2,50**

DG SANTE used the corporate template of contribution agreements. Payment requests and related reports submitted by the organisations are verified and approved by DG SANTE staff (ex ante controls).

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, based on the methodology provided by OLAF[37]. 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

[37] 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

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: most actions implemented in 2022, but the meeting of SANTE's inter-agencies task force had to be postponed to 2023;
- 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;
- Throughout 2022, 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 put on SANTE intranet;
- Arrangements for an appropriate level of cooperation with OLAF: in 2022, the existing channels for exchanging fraud related information with OLAF were further elaborated, in the area of food fraud and EPPO co-operation;
- Two awareness raising events were especially organised for DG SANTE staff:
  - ✓ On 25 January 2022, DG HR and IDOC[38] conducted a remote, interactive information session on ethics for all staff in DG SANTE;
  - ✓ In the period February-June 2022, all staff in DG SANTE had the opportunity to enrol in one of the four remote trainings on "How to work with lobby and stakeholders in policymaking".

Table 7.7 Indicators for fraud prevention and detection

Indicators	*Targets*	2022	2021
Annual implementation rate of awareness activities	*>90%*	**80%**	*100%*
% of implementation of actions planned in the anti-fraud strategy	*100%*	**75%**	80%
Annual meeting of the SANTE inter-agencies task force on independence: once per year with participants and contributions from all 5 EU agencies for which DG SANTE is parent DG	*100% (all 5 agencies)*	*Postponed to 2023*	*Postponed to 2022*
Updated list of "red flags" for procurement and grants- communicated to relevant staff	*By the end 2022*	*Postponed to 2023*	n/a
Participation in all FPDnet meetings	*Yes*	**Yes**	Yes
Arrangement of an appropriate level of cooperation with OLAF- meeting at Director level	*At least 1 meeting per year*	*Postponed to 2023*	n/a

[38] Investigation and Disciplinary Office of the Commission

Relevant for the monitoring in 2022 were 45 permanent tasks and 18 new actions. Due to a re-prioritisation during the COVID-19 pandemic, only about 75% of the actions were implemented in 2022 and an additional 13% of the actions were launched but are still ongoing. Considering the reorganisation from October 2022, several actions had to be postponed to 2023. The information and awareness raising actions that could not take place as planned will resume in 2023.

DG SANTE contributed to the Commission anti-fraud strategy (CAFS) and currently co-operates with OLAF on the revision of the CAFS Action Plan, by suggesting new actions relevant to DG SANTE's activity, and through DG SANTE's active participation in the Fraud Prevention and Detection Network and the sub-group of correspondents for EPPO (European Public Prosecution Office). In 2022, DG SANTE participated in OLAF's actions feeding into the evaluation of the 2019 CAFS Action Plan and communicated to OLAF the identified fraud risks for the Commission's corporate fraud risk exercise. In February 2023, DG SANTE was invited for a bilateral meeting with OLAF on the revision of the CAFS Action Plan.

In September 2022, the Director General of DG SANTE appointed a new central contact point for OLAF responsible for the co-operation with OLAF in respect of both investigative and fraud prevention matters.

In 2022, DG SANTE became aware of one allegation of fraud which is under investigation by OLAF.

7.2 Economy of controls

The main economy indicators monitored in 2022 focussed on the resources employed for internal control activities. They 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 without including an overhead rate. They are based - where possible – on estimates made in the 2022 Unit Management Plans of October 2021 approved by the Director-General.

Table 7.14 Overview of DG SANTE's estimated cost of controls at Commission level
(the absolute values are presented in EUR)

SANTE	Ex ante controls***			Ex post controls			Total	
	(a)	(b)	(c)	(d)	(e)	(f)	(g)	(h)
Relevant Control System (RCS) / Other as defined in Annex 6 of the AAR*	EC total costs	related payments Made	Ratio (%)** *(a)/(b)*	EC total costs	total value verified and/or audited	Ratio (%) *(d)/(e)*	EC total estimated cost of controls *(a)+(d)*	Ratio (%)** *(g)/(b)*
Grants in the Food Safety policy area	1.242.629,89 €	47.852.050,51 €	2,60%	247.382,61 €	8.188.891,52 €	3,02%	1.490.012,50 €	3,11%
Public procurement and other grants (including indirect management)	3.183.000,08 €	85.681.636,15 €	3,71%	- €	- €	0,00%	3.183.000,08 €	3,71%
Subsidy payments to agencies (indirect management)	1.473.721,00 €	333.614.456,18 €	0,44%	- €	- €	0,00%	1.473.721,00 €	0,44%
OVERALL total estimated cost of control at EC level for expenditure	**5.899.350,97 €**	**467.148.142,84 €**	**1,26%**	**247.382,61 €**	**8.188.891,52 €**	**3,02%**	**6.146.733,58 €**	**1,32%**

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

Every year the Court audits the revenue and expenditure sides of the EU budget and provides its opinion on the extent to which the annual accounts are reliable and income and spending comply with the rules and regulations. In the first nine months of 2022, the Court finalised its fieldwork on the 2021 Annual Report (2021 DAS) and published its final report on the implementation of the EU budget for the 2021 financial year on 13 October 2022.

The structure of the Court's 2021 report is adapted to the budget headings of the Multi-annual Financial Framework (MFF) 2021-2027. DG SANTE is part of the policy chapter 5 "Cohesion, resilience and values". In its report, the Court did not raise a finding on DG SANTE and did not report any error rate in DG SANTE's financial transactions. The Court's recommendation to improve the control of the implementation of the Advance Purchase Agreements for COVID-19 vaccines is addressed to HERA further to the transfer of these files from DG SANTE to HERA.

B. Court's special reports on performance audits in DG SANTE

In 2022, the Court of Auditors finalised three performance audits in which DG SANTE was actively involved: 1) free movement in the EU during the COVID-19 pandemic (SR 2022/13); 2) tools facilitating travel within the EU during the COVID-19 pandemic (SR 2023/01); 3) EU COVID-19 vaccine procurement (SR 2022/19).

In addition, in December 2022 and January 2023 the Court has issued the draft Clearing Letters for three follow-up audits for which DG SANTE was in the lead on the following performance audits of previous years: i) cross-border healthcare access (SR 2019/07); ii) AMR– anti-microbial resistance (SR 21/2019); iii) food safety- chemicals (SR 02/2019).

B.1. Audit on free movement in the EU during the COVID-19 pandemic (SR 2022/13)

The Court's aim was to assess whether the Commission had taken effective action to protect the right of free movement of persons during the COVID-19 pandemic. The report covered the Commission's scrutiny of internal Schengen border controls, related travel restrictions and coordination efforts at EU level.

The Court's special report on free movement in the EU during the COVID-19 pandemic was published on 13 June 2022. It examined the Commission's supervision of the internal Schengen border controls and travel restrictions imposed by the Member States during the COVID-19 pandemic, as well as the efforts undertaken at EU level to coordinate these restrictions until the end of June 2021. The report emphasised that while the Commission monitored the free movement restrictions imposed by the Member States, the limitations of the legal framework hindered its supervisory role. The Court acknowledged that the Commission launched important initiatives to coordinate measures affecting freedom of movement. DG SANTE was associated to the audit, and no recommendation was directly addressed to DG SANTE.

DG SANTE was fully co-operating with the auditors throughout the Court's audits, DG ensuring the full transparency and access to supporting evidence.

B.2. Audit on tools facilitating travel within the EU during the COVID-19 pandemic (SR 2023/01)

The audit complemented the Court's special report (SR 2022/13) on free movement in the EU during the COVID-19 pandemic and assessed whether the Commission had developed effective tools to facilitate travel within the EU during the COVID-19 crisis. The Court aimed to identify examples of good practice and areas for improvement in the way the Commission develops IT tools to facilitate free movement during health crises.

The audit report, published on 11 January 2023, concluded that, despite its limited competence in public health policy, the Commission moved fast to propose suitable technological solutions to facilitate travel. DG SANTE is in the lead to implement two recommendations: (i) to address the reasons for the low uptake of EU digital passenger locator forms; (ii) to make the EU tools, which were used to facilitate cross border contact tracing during crises, easier for EU citizens to access. DG SANTE welcomed the recommendations and will draft an action plan to ensure their timely implementation as per indicated target implementation dates in the Court's report.

B.3. Audit on EU COVID-19 vaccine procurement (SR 2022/19)

On 12 September 2022, the Court published the special report on EU COVID-19 vaccine procurement. The Court assessed whether the Commission and Member States procured COVID-19 vaccines up to the end of 2021 effectively. The Court examined the framework the EU set up, its negotiation strategy and how the Commission followed up contract implementation.

The Court's report covered actions taken in the period July 2021- June 2022 and acknowledged that the centralised system for vaccine procurement succeeded in creating a broad and diversified portfolio of vaccine candidates and in procuring sufficient doses of COVID-19 vaccines. The Commission is now drawing on this experience and the lessons learned during the COVID-19 pandemic in its work to set up a strong European Health Union and improve the joint EU crisis preparedness and management.

The Court made two recommendations: (i) to create pandemic procurement guidelines on the basis of lessons learnt; (ii) to stress-test the EU's medical countermeasures procurement approach. The implementation of Court's recommendations is followed-up by DG HERA, further to the transfer of the related files from DG SANTE to HERA.

B.4. Follow-up audits on four previous performance audits

In 2022, the Court conducted four follow-up audits on special reports dating back to 2019:

A. EU actions for cross-border healthcare: significant ambitions but improved management required (SR 2019/07);
B. Addressing antimicrobial resistance: progress in the animal sector, but this health threat remains a challenge for the EU (SR 21/2019);
C. Chemical hazards in our food: EU food safety policy protects us but faces challenges (SR 02/2019);
D. The control system for organic products has improved, but some challenges remain (SR 2019/04).

The purpose of these audits was to examine the progress made to implement the audit recommendations. Generally, the conclusions of the Court are positive. Nevertheless, considering the unprecedented COVID-19 crisis, some of the Commission's actions had to be postponed or are delayed due to key priorities in the fight against the pandemic. More information is included in part 8.1.3 below.

B.5. The Court is currently carrying out a review on animal transport

In January 2022, the Court has initiated a review on transport of live animals in the EU. DG SANTE is in the lead and DG AGRI is associated to the review. The Court aimed to address the Parliament's (ANIT) suggestions to look into certain aspects of animal transport and to examine the impact of EU rules on the transport of live animals. The Commission has received the draft report for a written feedback on the Court's findings by the end of February 2023. The Court intends to publish the report by April 2023.

8.1.2 Internal Audit Service of the Commission (IAS)

IAS limited conclusion on 2022 and DG SANTE's follow-up

The IAS contributed to DG SANTE's Annual Activity Report for 2022 by submitting a "limited conclusion on the state of internal control" on 14 February 2023. Based on the audit work performed in the period 2018 to 2022, the IAS points to three 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. The three recommendations pertain to the internal audit on the Commission actions against food fraud in DGs SANTE and AGRI and OLAF for which the audit report was finalised on 30 January 2023.

IAS audit on food fraud

The objective of the audit was to assess the adequacy of the design, and the efficiency and effectiveness of the processes put in place by the audited services to prevent, detect food fraud and coordinate actions against food fraud. The main conclusion of the IAS is that DG SANTE and DG AGRI have overall put in place adequate processes to prevent and detect food fraud and coordinate actions against food fraud. The IAS also points to three areas in which weaknesses could affect the efficiency and effectiveness of these processes. DGs SANTE and AGRI accepted all audit recommendations and drafted an action plan (i) to lay down in writing certain aspects of the allocation of tasks between DG AGRI and DG SANTE as regards organic food products; (ii) to enhance the screening of notifications and monitoring of detected potential issues in Member States control Systems; (iii) to improve the functionalities of the current IT systems.

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 new Director in charge of Risk Management and Internal Control (RMIC), appointed in September 2022, 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 2022, 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 to

(i) Improve the exchange of epidemiological information between Member States;

(ii) Possibly update the existing indicators to provide better information on veterinary control activities and the cost-effectiveness of programmes;

(iii) Include the wildlife aspect in the veterinary programmes more systematically, when relevant;

(iv) 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[39] 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. The training and feedback session with Member States took place on 13-14 December 2022. The tool continues to be enhanced; most importantly, two more modules in ADIS are expected to become operational in September 2023 (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[40].

[39] 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).

[40] 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

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 has looked at possible options to review current rules on date marking, based also on consultations with citizens, stakeholders and targeted surveys with Member States, businesses, SMEs and consumer/health organisations, and on consumer behavioural research. This will address the ECA recommendation to assess the need to intervene to prevent labelling practices that generate food waste.

(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 (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[41] 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.

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,

[41] 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

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)[42] 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. On 4 October 2022, the Commission published its Staff Working Document[43] on the outcome of the Fitness Check. Due to the complexity of the matters and the multitude of stakeholders concerned, the Impact Assessment studies are expected to be finalised by March 2023, and the legislative proposal to be submitted by September 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 (for example, risk-based controls, targeted, ones, random ones) hinders the identification of common baselines and targets. DG SANTE published in mid-March 2022 an overview report on Animal Welfare indicators at farm level detailing the various challenges and difficulties in establishing a system of animal welfare indicators[44].

Solving the many problems that DG SANTE became aware of takes much more time than initially planned. DG SANTE has asked EFSA to propose animal-welfare indicators and is leading subgroups with Member States to discuss them. The intention is to include such indicators in the revised Animal Welfare legislation as indicated in the inception impact assessment.

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

[43] SWD(2022) 328 final

[44] https://ec.europa.eu/food/audits-analysis/overview_reports/details.cfm?rep_id=147

(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 three topics:

(i) Assess potential changes to the legislation governing chemical hazards in the light of the capacity to apply it consistently and further encourage complementarity, so that Member State public authorities can rely more extensively on checks carried out by the private sector;
(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 Court's first recommendation is considered fully implemented by the Commission through the REFIT exercise and the Farm to Fork Strategy. 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 recommendation calls for continuous supervision and measures, therefore DG SANTE provided the Court with detailed information on two examples (Feed Additives and Food Contact Materials).

The second recommendation has been implemented with the REFIT evaluation regarding the pesticides legislation[45]. The Commission continues to act according to the principles laid down in Regulation (EC) No 396/2005 and grants import tolerances in case EFSA have assessed the proposed maximum reside levels (MRLs) based on Good Agricultural Practices of a third country and found them to be safe for consumers. In addition, a first draft Regulation implementing the new policy announced in the European Green Deal and more specifically the Farm to Fork Strategy on imported food in relation to pesticides residues was published on 15 February 2023[46]. The Regulation lowers the MRLs for the two neonicotinoid substances that are known to contribute significantly to the decline of pollinator populations.

[45] Report to Council and Parliament was adopted on 20 May 2020
[46] Commission Regulation (EU) 2023/334: http://data.europa.eu/eli/reg/2023/334/oj.

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. A Commission Recommendation on the common methodology for the monitoring of food additives and food flavourings was prepared in 2022 and endorsed by the Standing Committee on "Plants, Animals, Food and Feed" on 27 February 2023. With regard to contaminants, the applicable legislation allows Member States to enforce the rules properly and no additional specific guidance document is needed at this stage. In 2022, the Commission started working with Member States on principles for enforcement action for a specific group of very toxic chemical substances, aiming at guiding them to act in a harmonised way, including regarding recalls. The completion of this work will not be achieved before late 2023.

(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 was addressed as part of the Commission's evaluation of the Cross-border Healthcare Directive (Directive 2011/24/EU). The Commission Staff Working document was finalised in May 2022.[47] In 2022, the toolbox was supplemented by a compilation of links to prior authorisation lists of

[47] SWD(2022)131 final of 3 May 2022 (link https://health.ec.europa.eu/system/files/2022-05/ehealth_ehds_2022ia_4_en.pdf)

Member States and guiding principles on information provision on prior authorisation systems. The Annex to the third Commission report on the operation of the Cross-border Healthcare Directive contains a continuous follow-up action plan concerning promoting and monitoring the implementation of the guiding principles and the multi-lingual Manual for Patients. The NCPs were encouraged to publish the above tools on their websites during the NCPs' sub-group meeting on 28 September 2022. A supporting knowledge and capacity building workshop with NCPs to improve information to patients took place in Luxembourg on 8 and 9 February 2023, providing the possibility to exchange good practices on shortcomings identified in the evaluation report.

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)[48]. 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 above mentioned evaluation also looked at Article 14 of the Cross-border Healthcare Directive was evaluated and at the exchange of cross border health data. The results of the evaluation fed into the European Health Data Space proposal (EHDS) and are underpinning preparatory work for the EHDS. The services of MyHealth@EU will expand to most Member States, and Norway and Iceland in the years ahead. The services will also be expanded to include lab results, medical images and hospital discharge reports. At the end of 2022, a Pilot was launched to enable Patient access to their translated data.

The Commission coordinates and supports 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[49] and has been translated in all EU languages.[50] The Board also adopted an annex with a list of prioritised potential actions[51]. A working group on ERN integration into national healthcare systems has been set up and has worked on the implementation of the principles set out in the 2019 Board's statement. A new Joint Action on ERN integration into the Member States' healthcare systems was included in the 2022 Work Programme of the EU4Health Programme. The action will start in the second half of 2023. The total budget of the Joint Action is

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

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

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

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

EUR 18,6 million, with the EC providing almost EUR 15 million and 20% of funding coming from national budgets.

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. Following approval of the evaluation method of the ERNs by the Commission (AMEQUIS), in September 2022, the assessment of the ERNs started, expected to be completed by August 2023.

Three meetings of the ERN working group on Knowledge Generation were organised between January and July 2022. Based on the guidance received by ERN Coordinators Group and the Board of the Member States, the working group discussed a strategy for launching a policy awareness campaign to tackle the educational needs of future physicians on Rare and Complex Diseases. The ERN Virtual Academy is part of the existing corporate platform (EU Academy, managed by the JRC), allowing the ERNs to use the platform for their e-learning and e-training needs. The platform will be open for all the networks in 2023, after a pilot period with a reduced number of ERNs.

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 Commission is working towards simplifying the process of financing of the European Reference Networks. Regulation (EU) 2021/522 setting out the EU4Health Programme for 2021-2027 provides for the possibility of direct non-competitive grants to the ERNs without calls for proposals and of financing eligible costs up to 100%. The 2022 work programme has provided direct grants to ERNs to support coordinating centres of the 24 ERNs and direct grants to the portal for rare diseases and orphan drugs (Orphanet).

(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.

Important milestones achieved before 2022 have been reported in the 2021 Annual Activity Report of DG SANTE. The ongoing actions have target dates until early 2023.

To implement the first recommendation a set of actions have been taken in 2022:

- In January 2022, DG SANTE launched a screening of investments in AMR in national Recovery and Resilience Plans, and identified AMR related measures for eight Member States;
- In February 2022, a temporary subgroup of the AMR One Health Network composed of the 27 Member States' representatives and led by France was set-up and tasked to formulate suggestions to the European Commission for AMR actions. The subgroup delivered its report in September 2022[52];
- The review of the National Action Plans has been completed in June 2022 and the final overview report was published in November 2022 on the occasion of the European Antibiotic Awareness Day[53];
- A Health Security Committee (HSC) plenary took place on 4-5 October 2022, providing a complete update on the latest policy developments around AMR, including all on-going funding actions (grants and procurement);
- The OECD project has been prolonged, due to the COVID-19 pandemic. Preliminary results were presented at an OECD meeting that took place on 30 November 2022 and OECD has to present until May 2023 the final report;
- Regular updates on the progress made related to the actions set out in the 2017 One Health Action Plan against AMR. The last update was published in May 2022[54];
- The analysis of JAMRAI is the final stage, and the new proposal for JAMRAI 2 was submitted to the Health and Digital Executive Agency on 15 February 2023 by the consortium;
- The proposal for a Council Recommendation on AMR is planned to be adopted together with the proposal to revise the EU pharmaceutical legislation in April 2023, including recommendations for the Member States and the Commission in the environmental, animal health and human health sectors;
- The Regulation (EU) 2022/2371 of the European Parliament and of the Council of European Union on serious cross-border threats to health and repealing Decision No 1082/2013/EU was adopted on 23 November 2022 and entered into force in December 2022.

52 https://health.ec.europa.eu/latest-updates/final-report-subgroup-established-under-eu-amr-one-health-network-formulate-suggestions-amr-actions-2022-09-05_en

53 https://health.ec.europa.eu/latest-updates/overview-report-member-states-one-health-national-action-plans-against-antimicrobial-resistance-2022-11-17_en

54 https://ec.europa.eu/health/sites/default/files/antimicrobial_resistance/docs/amr_2018-2022_actionplan_progressreport_en.pdf

With regard to the second recommendation, the Commission grants Member States financial support for data collection and reporting of data on sales and use of antimicrobials in animals. Out of 18 Member States who asked for funding, grant agreements with 16 Member States were signed by mid-March 2023.

To implement the third recommendation on strengthening strategies for boosting AMR research, the proposal to revise the EU pharmaceutical legislation (to be adopted in the first quarter of 2023) considers the creation of a transferable regulatory data protection voucher, which would allow the developer of a novel antimicrobial that addresses AMR to benefit from additional data protection on a product in their portfolio or sell the voucher to another company to use. It effectively would be a market entry reward for the developers with a value of up to hundreds of million euros, if co-legislators support the proposed incentive.

The Commission has included in the 2023 EU4Health work programme an action to support innovation and access to antimicrobials through the establishment of a network of public bodies supporting HERA in the implementation of the chosen option(s) for pull incentives.

(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 Integrated Pest Management (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 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.

The Commission held meetings with experts from selected Member States in 2020 and 2021 to discuss potential solutions that could be implemented across the EU. In parallel, Member States provided two rounds of written feedback, which fed into the preparation of the Commission proposal for the revision of the SUD adopted in

June 2022.[55] The proposal is currently being discussed by the co-legislators. The proposal provides for establishment of two new indicators measuring the achievement of the 50% legally binding reduction targets at EU and Member States level set in the proposal and provides for improvement of existing (HRI II) and development of future harmonised risk indicators.

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. Several sessions of training on IPM under the "Better Training for Saver Food" initiative were organised in 2022 aiming at helping Member States competent authorities to develop IPM crop-specific checklists for inspection purpose.

The EU-funded IPM toolbox project Farmers Toolbox - IPM | (agrilpm.eu) was concluded in November 2022 and assessed the potential of currently available IPM implementing approaches aiming at reducing dependency on pesticide use. The database developed during the project contains approximately 1300 examples of specific IPM practices and 273 "crop-specific guidelines" developed by national authorities.

Statistics on agricultural inputs and outputs (SAIO) was adopted by the end of 2022.

Improved data on pesticide use is expected to become available in 2028 and will allow to improving current risk indicators and develop better indicators in the future as appropriate.

The EEA, EFSA and JRC are providing assistance in developing additional Harmonised Risk Indicators.

(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

[55] https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12413-Pesticides-sustainable-use-updated-EU-rules-_en

(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 define the specific protection goals for wild pollinators.

In 2022, the following actions to address the Court's recommendations have been completed:

- On 17 February 2022, the Commission organised a workshop with risk assessors and risk managers from Member States to further discuss the specific protection goals for wild bees. The discussion continued in the Standing Committee on Plants, Animals, Food and Feed – section phytopharmaceuticals;
- On 21 June 2022, in the light of the information provided by EFSA in the supporting document and the discussion in the Standing Committee, the Commission requested EFSA to finalise the review of the guidance document based on an undefined threshold approach for both bumblebees and solitary bees in the absence of sufficiently robust evidence;
- On 18 July 2022, EFSA launched a public consultation on a draft update of the Bee Guidance document which ended on 3 October 2022 (1500 comments were received);
- On 5 October 2022, EFSA and the Commission held a workshop with Member States and stakeholders to discuss their comments on this draft. EFSA is now in the process to finalise the updated guidance document;
- On 19 December 2022, the Commission sent a follow-up mandate to EFSA to assess the justifications for emergency authorisations for the use of certain neonicotinoids in sugar beet during the 2022 growing season. The mandate includes as well a request to develop new fit-for-purpose protocols to assess such justifications. On 19 January 2023, the European Court of Justice published its judgement for case C-162/21 which made it clear that Member States can no longer grant emergency authorisations for the neonicotinoids banned for outdoor use. The Commission has therefore withdrawn the above-mentioned mandate to EFSA for the assessment of the justifications for emergency authorisations for the use of neonicotinoids on sugar beet seeds. The existing guidance on emergency authorisations will be updated to reflect the judgement once the discussions with Member States and within the Commission will have been completed.

The Commission foresees the full implementation of the Court's recommendations by the end of 2023.

8.2 Assessment of the effectiveness of internal control systems

8.2.1 Changes in DG SANTE's control environment

In 2022, the following major changes to DG SANTE's control environment took place:

- Further to the 2021 transfer of budget implementation tasks to the European Health and Digital Executive Agency and of tasks related to the EU's health emergency response and preparedness to the "European Health Emergency Preparedness and Response Authority" (HERA[56]), DG SANTE engaged in a reorganisation process, aiming at rebalancing the resources allocated to the different policies, Directorates and Units. The new SANTE organisation chart was adopted by the Commission on 17 June 2022 and entered into force on 1 October 2022 after transition periods for the transfer of files and change of DG SANTE's geographical sites for the Units concerned. Following the reorganisation, five acting Directors and one acting Deputy Director-General are currently ensuring the business continuity. The recruitment procedures for the Directors were launched in late 2022.

- On 30 June 2022, the Director responsible for "Resource management and better regulation" retired, ensuring a smooth handover of files and tasks to the acting Director. In September 2022, the acting Director was appointed as Director in charge of Risk Management and Internal Control (RMIC).

- The new Multi-Annual Financial Framework (2021-2027) entailed a substantial change to the arrangements for the delegation of DG SANTE's financial programmes. In 2021, HaDEA became responsible for the implementation of large parts of the EU4Health programme and the Food Chain strand of the Single Market Programme. DG SANTE still manages some procurement procedures, grants to international organisations, as well as grants with Member States and third countries for their veterinary and phytosanitary emergency measures. The control processes already in place were adapted were necessary, but a comprehensive review of DG SANTE's internal control strategy had to be postponed to 2023 given the reorganisation process in 2022.

- The Emergency Support Instrument (ESI) expired on 31 January 2022 and was not reactivated. On 28 July 2022, the Commission provided a report to the Council and the Parliament on the implementation of the implementation of the ESI[57]. In 2022, DG SANTE cleared the pre-financing payments made in 2020 and 2021 for Advance Purchase Agreements for COVID-19 vaccines, based on the value of vaccine doses delivered to the Member States. No more payments will be made and no pre-

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

[57] Regulation (EU) 2020/521 on activating emergency support to finance necessary expenditure to address the COVID-19 pandemic

financing remains open after 31 December 2022. Following the handover of files, the monitoring of the APAs' implementation is ensured by HERA.

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".

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 2023 and was endorsed by the Management Board in its meeting on 27 March 2023. The following four elements underpin 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 survey organised by DG HR and the internal staff survey of DG SANTE to get a better insight into the effectiveness of selected control principles. As DG HR did not carry out a general staff survey in 2022, DG SANTE prepared an internal staff survey and launched it in mid-January 2023;

(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 (if available): 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

DG SANTE embedded continuous monitoring measures in its internal control system to ensure its effectiveness. 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 12 on control policies and procedures.

- ICP 1 and 4: In 2022, 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. The results of the 2022 DG SANTE’s staff survey – in comparison to the 2021 results – point to a slight improvement of the internal control principle related to staff allocation. However, indicators are still below DG SANTE’s targets.

- ICP 6: The results of the 2022 DG SANTE survey indicate a positive trend since 2018 of staff’s perception of senior management’s guidance on “missions, objectives and tasks”. As the indicator is still below target, more actions are needed to ensure clarity of objectives, purpose and means at DG level.

- ICP 9: Following the reorganisation in October 2022, the results of DG SANTE’s internal staff survey show an improvement in the perception of SANTE’s management of change. Reflecting on the reorganisation process as a whole, the majority of the survey participants replied that they have been informed how the changes will affect their teams and their work and that they could adapt to the change quickly. Considering that the reorganisation took place only in the last quarter of 2022, it is too early to draw further conclusions, for example, on how the reorganisation affects DG SANTE’s achievements of policy objectives, in particular the ‘One Health’ agenda.

- ICP 12: With regard to control policies and procedures, DG SANTE’s current internal control strategy was adopted by the Management Board in December 2017 and needs to be adapted formally to the new Multi-annual Financial Framework (2021-2027), the externalisation of budget implementation tasks to HaDEA, and the organisational changes in DG SANTE in October 2022. The revision of the control strategy is planned to be finalised in 2023.

(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 2022, the most important exceptions were the following:

- An urgent procurement procedure was launched prior to the adoption of the 2022 work programme for the Food Chain strand of the Single Market Programme. The action could not be further delayed due to its importance for DG SANTE's political commitments.

- In one case, DG SANTE made an a-posteriori commitment when extending a service contract.

- Inadequate handling of a so-called "very low value" purchase: in one case just exceeding the threshold of a thousand euro, procedural steps were omitted to be able to keep an important deadline.

In each case, the underlying causes behind the exceptions and weaknesses were analysed and drawn to the attention of the Director-General. Management assessed that, overall, the existing controls are sufficient and that the procedures in place function well.

(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 2022, none of the Ombudsman cases was linked to procurement or grant procedures in DG SANTE.

- The audit recommendations of the IAS rated "very important" and open in 2022 are related to the internal audit on European Commission actions against food fraud that was finalised in January 2023 and for which DG SANTE drafted an action plan in close co-operation with DG AGRI. The main actions to address the weaknesses identified in the audit are already ongoing. DG SANTE believes that the mitigating measures it has in place do not put the effectiveness of DG SANTE's internal control system into question (see part 8.1.2 above for more detail on the audits and DG SANTE's actions).

- DG SANTE's centralised function to follow up on audit recommendations ensures a timely management of and reporting on the implementation of audit recommendations. In 2022, the IAS closed three very important recommendations that were long overdue. The delays were caused by the key priorities set during COVID-19 pandemic and their impact on other activities.

(d) Results of the internal desk review

- The financial verifying agents, 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 2022, 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

The risk identification and assessment process is an essential management activity and an important part of the DG SANTE's internal control process. It 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 annual Management Plan (MP).

The risk assessment exercise for the MP 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. In 2022, the monitoring of the implementation of the action plan addressing DG SANTE's critical risks was carried out in September/October, in parallel with the risk identification exercise for the year 2023. Actions to address the Unit risks, which are not included in SANTE's critical risks, are organised at the level of the Units.

In 2022, 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 (2022;MEUR) -2	minus new prefinancing [plus retentions made] (in 2022;MEUR) -3	plus cleared prefinancing [minus retentions released and -4	Relevant expenditure (for 2022;MEUR) -5	Detected error rate or equivalent estimates -6	Estimated risk at payment (2022;MEUR) -7	Adjusted Average Recoveries and -8	Estimated future corrections [and -9	Estimated risk at Closure (2022;MEUR) -10
Food Safety (Grants to Member States)	43,33	- 9,10	35,94	70,17	2,00%	1,40	0,74%	0,52	0,89
Contribution agreements and other grants with International organisations (mainly indirect management)	25,39	- 24,80	0,61	1,20	2,00%	0,02	0,00%	0,00	0,02
Procurement in Health and Food Safety	64,84	- 1,67	1,52	64,69	2,00%	1,29	0,00%	0,00	1,29
Emergency Support Instrument (lump sums and deliveries)	0,00	0,00	549,37	549,37	0,50%	2,75	0,00%	0,00	2,75
Subsidies to EU decentralised agencies	291,60	- 291,60	307,97	307,97	0,50%	1,54	0,00%	0,00	1,54
Total without contribution to EA's operating budget	**425,16**	**- 327,17**	**895,41**	**993,40**		**7,01**	**0,05%**	**0,52**	**6,49**
					Overall risk at payment in %	**0,71%** *(7) / (5)*		**Overall risk at closure in %**	**0,65%** *(10) / (5)*
HADEA	42,01	- 42,01	24,57	24,57	0,50%	0,12	0,00%	0,00	0,12
Sub-total contributions (if more than one)	42,01	- 42,01	24,57	24,57		0,12		0,00	0,12
Total DG (with contributions to EAs)	**467,18**	**- 369,18**	**919,97**	**1 017,97**					

Notes to the table

- To column (1) Relevant Control Systems differentiated per relevant portfolio segments and at a level which is lower than the total
- 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 reported by the Delegated departments. For Cross-Sub-Delegations (Internal Rules Article 12), the reporting remains with the Delegating departments.
- To column (3) New pre-financing actually paid by DG SANTE during the financial year (i.e. excluding any pre-financing received as a transfer from another department).
- 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' (ECA) scope of the EC funds with potential exposure to legality & regularity (see the ECA's Annual Report methodological annex 1.1), our concept of "relevant expenditure" includes the payments made, subtracts the new pre-financing paid out, and adds the 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 this column, DG SANTE discloses equivalent estimates to the detected error rates as follows (i) a conservative estimate of 2% was used for expenditure based on grants to Member States, for which extensive ex-ante controls are in place, and grants to international organisations, but results on ex-post error rates are not yet available; (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 (7) The estimated risk at payment is calculated by multiplying he error rate (column 6) with the relevant expenditure (column 5).
- To column (8) The adjusted average recovery and corrections percentage is based on the 7-year historic Average of Recoveries and financial Corrections (ARC), which is the best available indication of the corrective measures DG SANTE applied over the past years as a result of ex-post controls. In accordance with the control strategy, no ex-post audits took place on procurement contracts in either policy area as these were mostly fixed price contracts; in addition, no ex-post audits took place on the subsidies paid to agencies as they are cleared based the annual audit results of the European Court of Auditors. Thus, the future corrections are prudently estimated at 0%. This corresponds to the average amount of the implemented corrections over the past 3 years (2020-2022).

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	Total staff[58]		
	At 31/12/2022	At 31/12/2021	At 31/12/2020
Administrators	**446**	**444**	**427**
Assistants and secretaries	**195**	**203**	**200**
Contractual agents	**93**	**91**	**101**
National experts	**57**	**51**	**43**
Total	**791**	**789**	**771**

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 2022:			
Output	**Indicator**	**Target**	**Results 2022**
Recruitment of new female middle managers	Number of appointments validated	2 appointments validated by end 2022	2 appointments of female HoU were made 49% of HoU are women (17 out of 35)
Back to the office events at DIR and Unit level	All actions implemented	31/12/2022	10 team events took place
DG SANTE staff engagement index	DG SANTE staff engagement index as communicated by DG HR	Above Commission average	2022 Staff index: SANTE 76%, Commission average 72% 2021 Staff index: SANTE 76%, Commission average 72% 2020 Staff index: SANTE: 72%, Commission average 69%

[58] The Human Resource data rely on the snapshot of Commission personnel 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 2022:			
Output	**Indicator**	**Target**	**Results 2022**
DG SANTE Local HR Strategy 2022-2025	Selection launched	01/07/2022	The Commission HR strategy and action plan were validated by end 2022. DG SANTE will invest in implementing the action instead of developing its own plan.

Digital transformation

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 2022:			
Output	**Indicator**	**Target**	**Results 2022**
Implementation of the corporate principles for data governance for DG SANTE key data assets	Percentage of implementation of the corporate principles for data governance for DG SANTE's key data assets[59]	50%	50%
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.	75%	65% *(Results slightly lower, as considerable effort had to be spent on modernisation and phase-out of legacy systems during 2022)*
The interim corporate data catalogue reflects the current key data assets of DG SANTE, improving transparency, sharing and reuse of Data across the EC	Percentage of SANTE key data assets reviewed and included in the interim solution	100%	100% *(of key data assets reviewed, update of the contact points after restructuring pending technical solution in the data catalogue itself)*
Setting up and implementing a digital and data strategy board to review and endorse actions	Annual IT MP replaced by an all-encompassing digital and data annual plan to address both individual and horizontal needs	-Board to meet twice per year - Annual plan due Q4 2022	- Board met 4 times in 2022 - Digital and Data masterplan finalised in Q4 2022
Increase staff awareness in cyber-security threats	Percentage of staff completing DG SANTE's cyber-aware security	100% (Newcomers)	100% (Newcomers)

[59] Follow-up indicator from SANTE's multi-annual strategic plan 2020-2024.

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 2022:			
Output	**Indicator**	**Target**	**Results 2022**
	education training programme on top of the DIGIT programme	20% (All staff)	45% (All staff, participating in different campaigns)
Increase in the number of data sets made available by the open data portal	Number of public solutions published via open data portal	15	16 *(+1 compared to 2021)*
More accessible IT solutions	Number of solutions migrated to e-UI and accessibility tests	5	5 *(Solutions using e-UI)*
Increase in awareness of staff on data protection compliance[60]	Percentage of staff attending awareness raising activities	100% (Newcomers) 20% (All staff)	100% (Newcomers) 20% (All staff)

Working towards the 'Next Generation Digital Commission' and addressing technical debt, DG SANTE contributed to the corporate modernisation exercise to understand the business and technical capabilities for the whole SANTE IT portfolio. The results of which were used to help steer SANTE's own rationalisation strategy by tightening follow-up of migrations and upgrades, decommissioning old technologies and creating transition plans to streamline and modernise our solutions portfolio.

This year considerable effort has been placed on auditing our cybersecurity position and taking action where necessary to improve the security of our systems and data.

In parallel, SANTE has started a journey to change the sourcing model used to source and deliver IT projects, reducing the reliance on traditional Time and Means contracts and moving towards a more delivery, results-based approach. 150 consultants were moved to the new DIGIT TM-II framework-contract in 2022, whilst a third of the total IT budget is now dedicated to service/delivery based contracts. Such contracts aim at reducing the administrative burden placed on officials and allowing our technical staff to concentrate on delivery for our DG.

DG SANTE also launched an AI task force in 2022, aimed at identifying business use cases where innovative technologies using artificial intelligence and machine learning could reduce the burden on staff and bring about efficiencies and cost savings through automation, and assistance during various mundane day-to-day tasks.

[60] Follow-up indicator from SANTE's multi-annual strategic plan 2020-2024.

At the same time in 2022, we also put in place services in the cloud, deliver, host and operate modern IT solutions. These services can ensure continuous operation of systems, adequate cybersecurity and more cost and time efficient evolution of our systems. This infrastructure will be used to migrate existing systems but also host the new SANTE IT systems. All new Digital transformation is a multi-year process and SANTE will continue its endeavours to help identify synergies and bring value to our business.

Major projects key accomplishments

- MDR-EUDAMED has delivered updates for the modules "Vigilance", "Market Surveillance" and "Clinical Investigations" in the playground environment for testing and feedback by stakeholders. The majority of other modules is almost complete.
- Work has started end of 2022 for the new ERN CPMS to develop a new more user focused, open-source solution, expected to be launched in 2024 for the replacement of the current ERN-CPMS.
- Two new services have been developed for MyHealth@EU (EHDSI): e-dispensation and Original Clinical Documents to complement the existing e-prescription and patient summary services available to Member States. MyHealth@EU offers 20 services and is used in 11 Member States.
- For HealthData@EU (EHDS2), the focus in 2022 has been on setting up this pilot project to deliver central services necessary to support sharing of health data by a consortium of stakeholders (including SANTE's partner decentralised Agencies)
- Major enhancement in TRACES for providing digitalisation of the certification process, revolutionising the way both EU and non-EU authorities stamp documents and certificates: eliminating paper workflows (integration using EUSign). Launch in March of the "Animal Disease" module (TRACES-ADIS) to replace existing ADNS solution.
- Introduction of Security enhancements and improvements to improve the stability of RASFF. At the same time, the analysis of the business needs and requirements have been prepared to launch a project to replace the current system.
- The e-submission in the food chain module in FIP has been updated to 1) support applications for GMO parts B and C, Traditional foods from third countries and emergency authorisations for plant protection products; 2) implement new processes to support requests for information for novel foods for both SANTE and EFSA; 3) provide functionalities to fully manage process surrounding confidential documents; 4) Provide access to Member States national competent authorities and SANTE to view confidentiality decisions made by EFSA.
- Working with DG COMP on IMSA to use the CASE@EC corporate solution to replace the aging MISDOC solution.
- Consolidation of modules that form the EUROPHYT portal to have a streamlined governance structure, an improved security as well as an updated and rationalised infrastructure resources.

Sound environmental management

Objective: DG SANTE takes account of its environmental impact in their actions and actively promotes measures to reduce the related day-to-day impact of the administration and its work, with the support their respective EMAS Correspondents/EMAS Site Coordinators.			
Main results and outputs in 2022:			
Corporate EMAS Indicator 1a, Total energy consumption of buildings (MWh/p or kW/m^2)			
Output	**Indicator**	**Target**	**Results 2022**
Staff awareness actions to reduce energy use in the framework of EMAS corporate campaigns and/or awareness actions about DG's total energy consumption in collaboration with OIB/OIL[61] where appropriate.	Number of staff awareness actions	3 actions	Due to internal reorganisation of Directorate F in 2022, the number of staff awareness actions was limited to three awareness raising emails: one during EU Green Week, one during the European Week for Waste Reduction; and one informing staff of EMAS-related training.
	% of staff informed/participated	85%	100% of SANTE staff on site informed
Participation in the end of the year energy saving action, by closing down DG's buildings during the Christmas and New Year's holiday period	B232, F101. GRAN will operate at the minimum level	66% of DG buildings participating	GRAN building participated in the end-of-year closure of the buildings campaign. In addition, GRAN building closed during the week immediately before and after the Christmas holiday period (19-22 December 2022 and 3-6 January 2023). Furthermore, the management decided to close a section of the GRAN building (approx. 25%) for the winter 2022-2023 to reduce energy and resource consumption.

[61] See OIB – Environmental Building Performances for Brussels and OIL- Environmental Building Profiles for Luxembourg.

Corporate EMAS Indicator 1d, Water consumption (m3/p or L/m²)			
Output	**Indicator**	**Target**	**Results 2022**
Staff awareness actions to reduce water use (for example ensuring that staff use the technical services hotline 22 to report leaks) in the framework of EMAS corporate campaigns and/or awareness raising actions about DG's water consumption in collaboration with OIB/OIL where appropriate.	Number of staff awareness actions to reduce water use	3 actions	In GRAN, staff was made aware about the need to achieve resource efficiencies as part of the seasonal closure of a section of GRAN building referred to above. This process included communication with all staff to explain the rationale for the decision and ensure staff buy-in in the process.
Corporate EMAS Indicator 1e Office paper consumption (Tonnes/person or Sheets/person/day)			
Output	**Indicator**	**Target**	**Results 2022**
Paperless working methods at DG level (such as paperless working: e-signatories, financial circuits, collaborative working tools) and staff awareness actions to reduce office paper use in the framework of EMAS corporate campaigns and/or raise awareness about DG's office paper use in collaboration with OIB/OIL where appropriate.	Number of staff awareness actions to reduce office paper use	1 action	In GRAN, as staff embraces new paperless working methods and the hybrid working patter, paper consumption on site decreases. Staff was made aware about the need to achieve resource efficiencies as part of the seasonal closure of a section of GRAN building referred to above. This process included communication with all staff to explain the rationale for the decision and ensure staff buy-in in the process.
	Paper consumption	Reduce (in line with Commission target for 2022)	In GRAN: 27.15% reduction in 2022 as compared to 2021
Reducing CO2, equivalent CO2 and other atmospheric emissions			
Corporate EMAS Indicator 2 - Reducing emissions, (actions with non-numeric indicators)			
Output	**Indicator**	**Target**	**Results 2022**
Staff awareness actions on reducing GHG emissions (such as actions on sustainable commuting during EU Mobility week and VeloWalk corporate events) and/or raise staff awareness on sustainable commuting in collaboration with OIB or OIL (e.g. availability of bike parking facilities, lockers and showers, promote the reduction of parking	% of staff informed/ participated	85%	In GRAN, no awareness raising actions specific to sustainable commuting took place; however, Facilities Management is taking steps to equip the site with EV charging points to improve the sustainability of staff commuting patterns.

spaces' use amongst staff).			
Gradual increased use (and number of) VC [23] meeting rooms for meetings with stakeholders (avoiding business trips) in the DG, in collaboration with DG SCIC, OIB and OIL.	% of use of VC meeting rooms (number of VC meeting rooms has substantially increased in 2021 with 9 additional rooms in Brussels and 5 in Grange. With the return to work greater use of these facilities will be possible)	Increase (depending on the return to the office)	Since 2021, all meeting rooms in GRAN are VC equipped and provide ample capacity for staff wishing to conduct meetings in virtual or hybrid mode.
Promoting green public procurement (GPP)			
Corporate EMAS Indicator 4- Promoting green public procurement (GPP)			
Output	**Indicator**	**Target**	**Results 2022**
Gradual introduction of GPP criteria in contracts and starting to monitor the process	Number of contracts relevant for GPP criteria	3 new contracts in 2022	Due to resource constraints and reorganisation of Directorate F in Grange, the procurement procedures referred to in the indicator were rescheduled for 2023.
Supporting biodiversity			
Corporate EMAS Indicator 5- Supporting biodiversity			
Output	**Indicator**	**Target**	**Results 2022**
Staff awareness actions on supporting biodiversity (for example for urban sites, sponsor the creation and maintenance of urban gardens, insect hotels and green roofs within EC-premises with the support of volunteers)	Number of staff awareness actions on supporting biodiversity	1 action	In GRAN, no awareness raising actions promoting biodiversity took place in 2022; however, a procurement procedure related to a biodiversity (tree-planting) project was completed. The project will be implemented in 2023.

ANNEX 11: Implementation through national or international public-sector bodies and bodies governed by private law with a public sector mission

DG SANTE signed contribution agreements with international organisations on the topics listed below. The organisations have been chosen in accordance with the EU4Health Regulation (EU) 2021/522, Articles 7(1) and 13(1) point (b), and the SMP Regulation (EU) 2021/690, Articles 4(6) and 6(1). They are the eligible legal entities to implement the actions described in the contribution agreements.

- IFRC (International Federation of Red Cross and Red Crescent Societies): EU4Health action: "mental health and psychosocial support for displaced people coming from Ukraine".
- OECD (Organization for Economic Cooperation and Development): EU4Health actions: "EU Health System Resilience Testing and Support Programme"; "State of Health in the EU (4th cycle)"; "establishment of a Cancer Inequalities Registry to map disparities and inequalities between Member States and regions"; "collection and support for the implementation of innovative best practices and research results on non-communicable diseases".
- WHO (World Health Organization): EU4Health actions: "supporting Member States in improving access to healthcare and effectiveness of health coverage"; "addressing alcohol-related harm"; "contribution to the Cancer Inequalities Registry to monitor national cancer control policies".
- EDQM (European Directorate for the quality of medicines of the Council of Europe): EU4Health action: "Improving the quality, safety and availability of Substances of Human Origin, disseminating best practices, implementing Union standards and tackling new challenges".
- FAO (Food and Agriculture Organization): SMP-Food Chain strand actions "control of the foot-and-mouth disease (EUFMD) - year 4 (2022)"; "multi-stakeholder Partnership Platform for action against AMR"; "International Plant Health Conference (IPHC) on 21-23 September 2022 in United Kingdom".

Table 11 Contribution agreements with international organisations

Programme	Organisations	2022 Payments in M€	2022 Commitments M€
EU4Health	IFRC	13,4	28,4
	WHO	2,8	11,0
	OECD	2,0	4,8
	EDQM	1,0	3,0
SMP	FAO	3,5	3,6
Total		**22,7**	**50,8**

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

ANNEX 13: Decentralised agencies

DG SANTE is responsible for five EU 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[62] (Budget 2022: total sum of human resources 350; EU funding 100%: EUR 99,9 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[63] (Budget 2022: total sum of human resources 587; EU funding 100%: EUR 134,7 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[64] (Budget 2022: total sum of human resources 915; EU funding 12%: EUR 49,7 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 2022 budget amounted to EUR 417,5 million which is to a large extent fee-financed.
- **Community Plant Variety Office (CPVO)** in Angers, France[65] (Budget 2022: total sum of human resources 55; EU funding 0%: EUR 0 million)

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[62] 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), amended by Regulation (EU)2022/2370 of 23 November 2022 (OJ L 314/1, 06.12.2022)

[63] 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) amended by Regulation (EU) 2019/1381 of the European Parliament and of the Council of 20 June 2019 on the transparency and sustainability of the EU risk assessment in the food chain

[64] 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.

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

CPVO supports the innovative patenting of new plant varieties throughout the EU; it decides on applications for Community plant variety rights based on a formal examination and a technical examination of the candidate variety. CPVO does not receive any EU subsidies; its 2022 budget amounted to EUR 20,4 million (fully fee-financed).

- **European Chemicals Agency (ECHA)** located in Helsinki[66] - relevant for DG SANTE are ECHA's biocides activities (Budget 2022 for biocides: total sum of human resources 69 for the biocides activities; EU funding: 61%: EUR 7,3 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 2022 amounted to EUR 11,9 million.

DG SANTE pays annual subsidies from the EU budget to four agencies as follows. CPVO is fully fee-financed. More information is included in Annexes 6.2 and 7.1.1.3.

EU decentralised agencies	**Policy area concerned**	***Number of staff ****	**EU contribution 2022 M€**	
		2022	**Administrative budget**	**Operational budget****
ECDC – European Centre for Disease Prevention and Control	Public Health	***350***	**99,9**	**0,80**
EFSA – European Food Safety Authority	Public Health and Food Safety	***587***	**134,7**	**-**
EMA[67] – European Medicines Agency	Public Health	***915***	**49,7**	**0,75**
CPVO[68] – Community Plant Variety Office	Food Safety	***55***	**0**	**-**
ECHA-biocides[69] – European Chemicals Agency	Food Safety	***69***	**7,3**	**-**
Total		***1.930***	**291,6**	**1,55**

*: 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.

**: Contribution agreements (see Annex 7, point 7.1.1.3 above)

[66] 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.

[67] EMA's total 2022 budget for payments amounted to EUR 417,5 million, mainly financed by fees. The EU contribution is a balancing grant (in 2022: 12%).

[68] CPVO does not receive any EU subsidies; its 2022 payment budget amounted to EUR 20,4 million.

[69] 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 2022 amounted to EUR 11,9 million in payments. The EU contribution is a balancing grant (in 2022: 61%)

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

[70] 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.

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