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Legislation

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Contents

[1] Text with EEA relevance.

EN

Acts whose titles are printed in light type are those relating to day-to-day management of agricultural matters, and are generally valid for a limited period.

The titles of all other acts are printed in bold type and preceded by an asterisk.

II

(Non-legislative acts)

REGULATIONS

COMMISSION DELEGATED REGULATION (EU) 2020/565

of 13 February 2020

correcting Delegated Regulation (EU) 2019/934 as regards transitional arrangements for the marketing of stocks of grapevine products

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) No 1308/2013 of the European Parliament and of the Council of 17 December 2013 establishing a common organisation of the markets in agricultural products and repealing Council Regulations (EEC) No 922/72, (EEC) No 234/79, (EC) No 1037/2001 and (EC) No 1234/2007 ([1]), and in particular Article 75(2) and 80(4) thereof,

Whereas:

(1) Commission Delegated Regulation (EU) 2019/934 ([2]) replaces and repeals Commission Regulation (EC) No 606/2009 ([3]). Following the publication of Delegated Regulation (EU) 2019/934, an error appearing in all language versions of the text was detected.

(2) The error concerns the transitional arrangements for the marketing of stocks of grapevine products laid down in Article 15 of Delegated Regulation (EU) 2019/934. Regulation (EC) No 606/2009 applied until 6 December 2019. Delegated Regulation (EU) 2019/934 entered into force on 27 June 2019. In order to allow operators sufficient time to adapt to the new rules, it was decided to set the date of application of that Regulation to 7 December 2019.

(3) The transitional arrangements provided for in Article 15 of Delegated Regulation (EU) 2019/934 were therefore intended to allow grapevine products produced in compliance with Regulation (EC) No 606/2009 before the date of application of Delegated Regulation (EU) 2019/934 to be placed on the market. Article 15, however, references the date of entry into force of Delegated Regulation (EU) 2019/934 instead of referring to the date of application of that Regulation. This has the unintended consequence that the grapevine products of the new harvest 2019, produced in accordance with Regulation (EC) No 606/2009, may not be marketed if they were produced on or after the date of entry into force.

(4) To allow the marketing of grapevine products produced in accordance with Regulation (EC) No 606/2009 between 27 June and 6 December 2019, the transitional arrangements laid down in Article 15 of Delegated Regulation (EU) 2019/934 should be corrected in order to cover that period.

([1]) OJ L 347, 20.12.2013, p. 671.

([2]) Commission Delegated Regulation (EU) 2019/934 of 12 March 2019 supplementing Regulation (EU) No 1308/2013 of the European Parliament and of the Council as regards wine-growing areas where the alcoholic strength may be increased, authorised oenological practices and restrictions applicable to the production and conservation of grapevine products, the minimum percentage of alcohol for by-products and their disposal, and publication of OIV files (OJ L 149, 7.6.2019, p. 1).

([3]) Commission Regulation (EC) No 606/2009 of 10 July 2009 laying down certain detailed rules for implementing Council Regulation (EC) No 479/2008 as regards the categories of grapevine products, oenological practices and the applicable restrictions (OJ L 193, 24.7.2009, p. 1).

(5) Delegated Regulation (EU) 2019/934 should therefore be corrected accordingly.

(6) The error in Delegated Regulation (EU) 2019/934 requires a correction to allow for the marketing of grapevine products produced between 27 June and 6 December 2019. For that reason, this Correcting Regulation should apply retroactively from 27 June 2019,

HAS ADOPTED THIS REGULATION:

Article 1

Article 15 of Delegated Regulation (EU) 2019/934 is replaced by the following:

'*Article 15*

Transitional arrangements

Stocks of grapevine products produced before the date of application of this Regulation in accordance with the rules in force before that date may be released for human consumption.'.

Article 2

This Regulation shall enter into force on the third day following that of its publication in the *Official Journal of the European Union*.

It shall apply from 27 June 2019.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 13 February 2020.

For the Commission
The President
Ursula VON DER LEYEN

COMMISSION DELEGATED REGULATION (EU) 2020/566

of 17 February 2020

correcting certain language versions of Delegated Regulation (EU) 2016/128 supplementing Regulation (EU) No 609/2013 of the European Parliament and of the Council as regards the specific compositional and information requirements for food for special medical purposes

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) No 609/2013 of the European Parliament and of the Council of 12 June 2013 on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control and repealing Council Directive 92/52/EEC, Commission Directives 96/8/EC, 1999/21/EC, 2006/125/EC and 2006/141/EC, Directive 2009/39/EC of the European Parliament and of the Council and Commission Regulations (EC) No 41/2009 and (EC) No 953/2009 [1], and in particular Article 11(1) thereof,

Whereas:

(1) The Estonian language version of Commission Delegated Regulation (EU) 2016/128 [2] contains errors in paragraph 5 of Article 8 as regards specific requirements for food for special medical purposes developed to satisfy the nutritional requirements of infants, and in the second paragraph of Article 11 as regards the application of the act.

(2) The Bulgarian, Estonian, Finnish, German and Romanian language versions of Delegated Regulation (EU) 2016/128 contain errors in Table 1 of Part A of Annex I as regards values for vitamins and minerals in food for special medical purposes developed to satisfy the nutritional requirements of infants.

(3) The Bulgarian, Croatian, Finnish and Swedish language versions of Delegated Regulation (EU) 2016/128 contain errors in Table 2 of Part B of Annex I as regards values for vitamins and minerals in food for special medical purposes other than that developed to satisfy the nutritional requirements of infants.

(4) The Bulgarian, Croatian, Estonian, Finnish, German, Romanian and Swedish language versions of Delegated Regulation (EU) 2016/128 should therefore be corrected accordingly. The other language versions are not affected,

HAS ADOPTED THIS REGULATION:

Article 1

(does not concern the English language)

[1] OJ L 181, 29.6.2013, p. 35.

[2] Commission Delegated Regulation (EU) 2016/128 of 25 September 2015 supplementing Regulation (EU) No 609/2013 of the European Parliament and of the Council as regards the specific compositional and information requirements for food for special medical purposes (OJ L 25, 2.2.2016, p. 30).

Article 2

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 17 February 2020.

For the Commission
The President
Ursula VON DER LEYEN

COMMISSION IMPLEMENTING REGULATION (EU) 2020/567

of 22 April 2020

amending Regulation (EC) No 1484/95 as regards fixing representative prices in the poultrymeat and egg sectors and for egg albumin

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) No 1308/2013 of the European Parliament and of the Council of 17 December 2013 establishing a common organisation of the markets in agricultural products and repealing Council Regulations (EEC) No 922/72, (EEC) No 234/79, (EC) No 1037/2001 and (EC) No 1234/2007 ([1]), and in particular Article 183(b) thereof,

Having regard to Regulation (EU) No 510/2014 of the European Parliament and of the Council of 16 April 2014 laying down the trade arrangements applicable to certain goods resulting from the processing of agricultural products and repealing Council Regulations (EC) No 1216/2009 and (EC) No 614/2009 ([2]), and in particular Article 5(6)(a) thereof,

Whereas:

(1) Commission Regulation (EC) No 1484/95 ([3]) lays down detailed rules for implementing the system of additional import duties and fixes representative prices in the poultrymeat and egg sectors and for egg albumin.

(2) Regular monitoring of the data used to determine representative prices for poultrymeat and egg products and for egg albumin shows that the representative import prices for certain products should be amended to take account of variations in price according to origin.

(3) Regulation (EC) No 1484/95 should therefore be amended accordingly.

(4) Given the need to ensure that this measure applies as soon as possible after the updated data have been made available, this Regulation should enter into force on the day of its publication,

HAS ADOPTED THIS REGULATION:

Article 1

Annex I to Regulation (EC) No 1484/95 is replaced by the text set out in the Annex to this Regulation.

Article 2

This Regulation shall enter into force on the day of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 22 April 2020.

For the Commission,
On behalf of the President,
Wolfgang BURTSCHER
Director-General
Directorate-General for Agriculture and Rural Development

([1]) OJ L 347, 20.12.2013, p. 671.
([2]) OJ L 150, 20.5.2014, p. 1.
([3]) Commission Regulation (EC) No 1484/95 of 28 June 1995 laying down detailed rules for implementing the system of additional import duties and fixing representative prices in the poultrymeat and egg sectors and for egg albumin, and repealing Regulation No 163/67/EEC (OJ L 145, 29.6.1995, p. 47).

ANNEX

'ANNEX I

CN code	Description	Representative price (EUR/100 kg)	Security under Article 3 (EUR/100 kg)	Origin [1]
0207 12 90	Fowls of the species *Gallus domesticus*, not cut in pieces, presented as "65% chickens", frozen	128,7	0	AR
0207 14 10	Fowls of the species *Gallus domesticus*, boneless cuts, frozen	212,3 195,3 269,6 220,7	26 32 9 24	AR BR CL TH
1602 32 11	Preparations of fowls of the species *Gallus domesticus*, uncooked	192,6	28	BR'

[1] Nomenclature of countries laid down by Commission Regulation (EU) No 1106/2012 of 27 November 2012 implementing Regulation (EC) No 471/2009 of the European Parliament and of the Council on Community statistics relating to external trade with non-member countries, as regards the update of the nomenclature of countries and territories (OJ L 328, 28.11.2012, p. 7).

COMMISSION IMPLEMENTING REGULATION (EU) 2020/568

of 23 April 2020

making the exportation of certain products subject to the production of an export authorisation

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) 2015/479 of the European Parliament and of the Council of 11 March 2015 on common rules for exports ([1]), and in particular Article 6 thereof,

Whereas:

(1) On 15 March 2020, the European Commission published Implementing Regulation (EU) 2020/402 ([2]) making the exportation of certain products subject to the production of an export authorisation, pursuant to Article 5 of Regulation (EU) 2015/479. That Regulation was amended by Commission Implementing Regulation (EU) 2020/426 of 19 March 2020 ([3]).

(2) Regulation (EU) 2020/402, and its amendment, apply for a limited period of 6 weeks.

(3) As the epidemiological crisis caused by the COVID-19 disease continues, the demand within the Union for personal protective equipment ('PPE'), which consists of protective masks (and surgical masks), gloves, goggles, face-shields, and overalls, remains very high and is even continuously increasing. The demand for certain types of PPE has especially led to shortages on the internal market. Given its nature and the prevailing circumstances, such type of equipment is an essential product since it is necessary to prevent the further spreading of the disease, and safeguard the health of medical staff treating infected patients.

(4) Continuous efforts are being made to help ensuring urgent and adequate provision of protective equipment throughout the EU. The production capacities of personal protective equipment have been ramped-up. The Commission finalised a joint procurement for personal protective equipment, in which 25 Member States took part. These initiatives are proving successful, and equipment is planned to be made available 2 weeks after the Member States sign the contracts with the bidders.

(5) Under the Union Civil Protection Mechanism (UCPM), the European Commission has decided to create a strategic rescEU stockpile of medical equipment such as ventilators and protective masks to help EU countries in the context of the COVID-19 pandemic. Entirely financed by the Commission via direct grants, this reserve will be hosted in one or several Member States.

(6) The Commission also set up a Clearing House, including for PPE, with the objective to coordinate efforts to match supply and demand in the EU, and facilitate an adequate functioning of the internal market.

(7) Despite these actions, and given increased needs for PPE in the Union, a gap between demand and supply within the Union still exists, in particular concerning certain types of PPE, which are vital to prevent the spreading of the disease and treat the patients.

(8) In light of these efforts to overcome the critical situation of shortage of certain types of PPE in the Union, further measures are warranted to contribute to remedying and preventing shortages of PPE.

(9) These measures, aimed at protecting health and impacting on trade, should be targeted, proportionate, transparent and temporary.

([1]) OJ L 83, 27.3.2015, p. 34.

([2]) Commission Implementing Regulation (EU) 2020/402 of 14 March 2020 making the exportation of certain products subject to the production of an export authorisation (OJ L 77 I, 15.3.2020, p. 1).

([3]) Commission Implementing Regulation (EU) 2020/426 of 19 March 2020 amending Implementing Regulation (EU) 2020/402 making the exportation of certain products subject to the production of an export authorisation (OJ L 84 I, 20.3.2020, p. 1).

(10) In a Joint Statement of 26 March the members of the European Council underlined that th**e** adoption of the decision on the authorisation for export of PPE should lead to the full and effective lifting of all forms of internal bans or restrictions.

(11) It is not the intention of the Union to restrict exports any more than absolutely necessary, and the Union also wishes to uphold the principle of international solidarity in this situation of a global pandemic. Union measures should therefore be proportionate and ensure that exports remain possible, subject to a prior authorisation. To this effect, Member States should grant export authorisations under specific circumstances, where the shipment in question poses no threat to the actual need for PPE within the Union and serves to satisfy a legitimate need for official or professional medical use in a third country. In contrast, Member States should not authorise exports that would create speculative distortion and serve stockpiling and hoarding of essential equipment by those with little or no objective need.

(12) An export authorisation system should remedy or prevent a situation of a shortage of essential products within the borders of the Union. The main objective of such system would be to protect public health within the Union.

(13) The administrative modalities for these authorisations should be left to the discretion of the Member States during the time of this temporary system.

(14) Based on the principle of international solidarity, Member States should authorise exports to enable the provisions of emergency supplies in the context of humanitarian aid.

(15) Member States should positively consider granting authorisations when the exports are destined to State bodies, public bodies and other bodies governed by public law and in charge of distributing or making PPE available to the persons affected by or at risk from COVID-19 or involved in combating the COVID-19 outbreak.

(16) Authorisations should be granted only to the extent that the volume of exports is not such that it poses a threat to the availability of PPE on the market of the Member State in question or elsewhere in the Union for the purpose of meeting the objective of this Regulation. For this purpose, Member States should contact the Clearing House established by the Commission before granting such an authorisation. Member States do however not have to contact the Clearing House in the case of authorisations for emergency supplies in the context of humanitarian aid.

(17) In deciding whether to grant an export authorisation, the Member States should also take into consideration the fulfilment of a supply obligation under joint procurement or rescEU by the Union and the Member States, the support of the activities of the World Health Organization (WHO), the support of EU-level coordinated responses to crisis situations or the request for assistance by third countries or international organisations.

(18) The degree of market integration for the products concerned between parts of the customs territory of the Union and other countries or territories, whether achieved under an arrangement establishing a free-trade area or for other reasons such as geographic proximity or historic ties, should also be considered. Likewise, it would be counterproductive to disrupt closely integrated value chains and distribution networks established on the basis of those arrangements or otherwise, in particular in the case of neighbouring countries and economies.

(19) This Regulation should apply to certain types of PPE. In order to ensure coherence, the description of the types of PPE subject to this authorisation system laid down by this Regulation should be aligned with the corresponding specifications of the equipment subject to the Joint Procurement, which has identified the specific needs in the Union. The CN codes should be given for information only.

(20) The objective of the Clearing House is to ensure adequacy of the supply to meet the demand for all types of PPE on the Union market. On that basis, a need may arise to review the scope of Annex I and products covered by this Regulation. A review of the scope should be based on a continuous assessment of needs of critical equipment related to the fight against COVID-19 and their potential shortages. Special attention should be given to the products covered by the Joint Procurement as well as requested under the Union Civil Protection Mechanism such as other types of PPE, ventilators and laboratory products (test kits).

(21) The single market for medical and personal protective equipment is closely integrated beyond the boundaries of the Union, and so are its production value chains and distribution networks. This is particularly the case of the member States of the European Free Trade Association, and the Western Balkans which are engaged in a process of deep integration with the Union. Subjecting exports of certain personal protection equipment to these countries to an export authorisation requirement would be counterproductive, given the close integration of the production value chains and distribution networks, when such equipment is an essential product necessary to prevent the further spreading of the disease and safeguard the health of medical staff treating infected patients. It is therefore appropriate to exclude such countries from the scope of application of this Regulation.

(22) It is likewise appropriate to exclude from the export authorisation requirement the overseas countries and territories listed in Annex II to the Treaty, as well as the Faeroe Islands, Andorra, San Marino, the Vatican City and Gibraltar, since they have a particular dependency on the metropolitan supply chains of the Member States to which they are attached or on the supply chains of neighbouring Member States, respectively.

(23) This Regulation should apply to exports of Union goods from the customs territory of the Union. Therefore countries that form part of that customs territory need not be exempted in order to receive unrestricted shipments from within the Union. This is the case notably for the Principality of Monaco ([4]). Conversely, territories of Member States specifically excluded from the customs territory of the Union should not fall under the requirement of export authorisation and should therefore be exempted as well. This concerns the territories of Büsingen, Heligoland, Livigno, Ceuta and Melilla. Likewise, exports to the continental shelf of a Member State or the exclusive economic zone declared by a Member State pursuant to UNCLOS should be exempted from the application of this regulation.

(24) The measures provided for in this Regulation should not apply to trade between the EU Member States. Pursuant to Article 127(3) of the Withdrawal Agreement, during the transition period, the United Kingdom of Great Britain and Northern Ireland is to be considered as a Member State, and not as a third country.

(25) Some of the above-mentioned countries at present maintain export restrictions on personal protection equipment.

(26) The authorities of the countries and territories excluded from the export authorisation system should offer adequate guarantees that they will control their own exports of the products concerned, in order to avoid undermining the objective pursued by Implementing Regulation (EU) 2020/402. The Commission should closely monitor this.

(27) To avoid undermining the objective pursued by this Regulation, the authorities of the excluded countries and territories should make such exports to the Union available.

(28) To assess the situation on a regular basis, and in order to ensure transparency and consistency Member States should report their decisions to grant or reject requests for export authorisations to the Commission. The Commission should make such information publicly available on a regular basis, due account being taken of their confidential nature.

(29) Prior authorisation requirements are of an exceptional nature, should be targeted and of a limited duration. In order to ensure that the measures do not remain in place longer than is necessary, they should apply for a period of 30 days. Based on the development both in terms of the spreading of the COVID-19 disease and the adequacy between supply and demand, the Commission should review the situation on a regular basis and consider the need to shorten or extend the duration of the measures as needed.

(30) The measures provided for in this Regulation are in accordance with the opinion of the Committee established by Article 3(1) of Regulation (EU) 2015/479,

HAS ADOPTED THIS REGULATION:

Article 1

Definitions

For the purpose of this Regulation:

(1) 'export' means an export procedure within the meaning of Article 269 of Regulation (EU) No 952/2013;

(2) 'customs territory of the European Union' means the territory within the meaning of Article 4 of Regulation (EU) No 952/2013.

([4]) See Article 4(2)(a) of Regulation (EU) No 952/2013 of the European Parliament and of the Council of 9 October 2013 laying down the Union Customs Code (OJ L 269, 10.10.2013, p. 1).

Article 2

Export authorisation

1. An export authorisation established in accordance with the form set out in Annex II shall be required for the export of certain types of PPE, listed in Annex I, whether or not originating in the Union. Such authorisation is limited to Union goods ([5]), and is not required for non-Union goods. It shall be granted by the competent authorities of the Member State where the exporter is established and shall be issued in writing or by electronic means.

2. An export authorisation is required for all exports and shall be provided when the goods are declared for export and no later than at the moment of the release of the goods.

3. Without the production of a valid export authorisation, the exportation of such goods is prohibited.

4. Exports to the Republic of Albania, Andorra, Bosnia and Herzegovina, the Faeroe Islands, Gibraltar, the Republic of Iceland, Kosovo (*), the Principality of Liechtenstein, Montenegro, the Kingdom of Norway, the Republic of North Macedonia, the Republic of San Marino, Serbia, the Swiss confederation, Vatican City State as well as the overseas countries and territories listed in Annex II to the Treaty shall not be subject to the measures set out in paragraphs 1 and 2. The same applies to exports to Büsingen, Heligoland, Livigno, Ceuta and Melilla.

5. Exports to facilities located on the continental shelf of a Member State or the exclusive economic zone declared by a Member State pursuant to UNCLOS shall not be subject to the measures set out in paragraphs 1 and 2.

6. Based on the principle of solidarity, Member States shall authorise exports for use in third countries to enable the provisions of emergency supplies in the context of humanitarian aid. Member States shall process applications for export authorisations in an expedite manner, as soon as possible, but no later than 2 working days from the date on which all required information has been provided to the competent authorities.

7. Member States should positively consider granting authorisations when the exports are destined to State bodies, public bodies and other bodies governed by public law and in charge of distributing or making PPE available to the persons affected by or at risk from COVID-19 or involved in combating the COVID-19 outbreak. These authorisations should be granted only to the extent that the volume of exports is not such that it poses a threat to the availability of the PPE listed in Annex I on the market of the Member State in question or elsewhere in the Union. For this purpose, Member States shall inform the Commission before granting such an authorisation, at the following email address SG-CCH@ec.europa.eu. The Commission shall issue an opinion within 48 hours after having been informed.

Article 3

Procedural aspects

1. Where the PPE listed in Annex I is located in one or more Member States other than the one where the application for export authorisation has been made, that fact shall be indicated in the application. The competent authorities of the Member State to which the application for export authorisation has been made shall immediately consult the competent authorities of the Member State or States where the good is located and provide the relevant information. The Member State or States consulted shall make known as soon as possible, but no later than within 5 working days any objections it or they may have to the granting of such an authorisation, which shall bind the Member State in which the application has been made.

2. Member States shall process applications for export authorisations as soon as possible, but shall issue a decision no later than 5 working days from the date on which all required information has been provided to the competent authorities. Under exceptional circumstances and for duly justified reasons, that period may be extended by a further period of 5 working days.

([5]) See for excluded transactions Article 269(2) Regulation (EU) No 952/2013 of the European Parliament and of the Council of 9 October 2013 laying down the Union Customs Code (OJ L 269, 10.10.2013, p. 1) as amended.

(*) This designation is without prejudice to positions on status, and is in line with UNSCR 1244/1999 and the ICJ Opinion on the Kosovo declaration of independence.

3. In deciding whether to grant an export authorisation under this Regulation, Member States shall take into account all relevant considerations including, where appropriate, whether the export serves, inter alia:

— to fulfil supply obligations under a joint procurement procedure in accordance with Article 5 of Decision No 1082/2013/EU of the European Parliament and of the Council ([6]);

— to support the rescEU stockpiling of medical countermeasures or personal protective equipment aimed at combatting serious cross-border threats to health, as referred to in Commission Implementing Decision (EU) 2019/570 ([7]);

— to respond to the request of assistance addressed to and handled by the UCPM (Union Civil Protection Mechanism) and to support concerted support actions coordinated by the Integrated Political Crisis Response Mechanism (IPCR), the Commission or other Union institutions;

— to support the statutory activities of aid organisations abroad that enjoy protection under the Geneva Convention, provided that they do not impair the ability to work as a national aid organisation;

— to support the activities of the World Health Organization's Global Outbreak Alert & Response Network (GOARN);

— to supply foreign operations of EU Member States including, military operations, international police missions and/or civilian international peacekeeping missions;

— for the supply of Union and Member State delegations abroad.

4. Member States may take into account other elements, such as the degree of market integration for the products concerned whether or not achieved under arrangements establishing a free-trade area with the intended country of export, as well as geographic proximity.

5. In deciding whether to grant an export authorisation, the Member States shall ensure the adequacy of supply in the Union in order to meet the demand for the PPE listed in Annex I. Export authorisations may therefore be granted only where the shipment in question does not pose a threat to the availability of these goods on the market of the Member State in question or elsewhere in the Union. In order to best assess the situation, Member States shall inform the Commission at the following email address: SG-CCH@ec.europa.eu, in particular when the volume of planned exports may cause a shortage.

6. The Commission shall issue an opinion within 48 hours from the receipt of the request.

7. Member States may decide to make use of electronic documents for the purpose of processing the applications for export authorisation.

Article 4

Notifications

1. Member States shall immediately notify the Commission the authorisations granted and those refused.

2. These notifications shall contain the following elements:

(a) Name and contact details of the competent Authority,

(b) identity of the Exporter,

(c) destination country,

(d) final recipient,

(e) acceptance or refusal to grant the export authorisation,

(f) commodity code,

(g) quantity,

(h) units and description of the goods.

([6]) Decision No 1082/2013/EU of the European Parliament and of the Council of 22 October 2013 on serious cross-border threats to health and repealing Decision No 2119/98/EC (OJ L 293, 5.11.2013, p. 1).

([7]) Commission Implementing Decision (EU) 2019/570 of 8 April 2019 laying down rules for the implementation of Decision No 1313/2013/EU of the European Parliament and of the Council as regards rescEU capacities and amending Commission Implementing Decision 2014/762/EU (OJ L 99, 10.4.2019, p. 41).

The notification shall be submitted electronically at the following address:
TRADE-EXPORTAUTHORISATIONPPE@ec.europa.eu

3. The Commission shall make this information on the authorisations granted and those refused publicly available, due account being taken of the confidentiality of the data submitted.

Article 5

Review clause

The Commission shall monitor the situation and, when necessary, review expeditiously the period of application of this Regulation, and its product scope, taking into account the evolution of the epidemiological crisis caused by the COVID-19 disease and the adequacy of supply and demand in the Union market.

Article 6

Final provisions

This Regulation shall enter into force on the 26 April 2020. It shall apply for a period of 30 days.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 23 April 2020.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX I

Protective Equipment

The equipment listed in this Annex is in conformity with the provisions of Regulation (EU) 2016/425 of the European Parliament and of the Council [1] or Council Directive 93/42/EEC [2], medical device class I.

Category	Description	CN Codes
Protective spectacles and visors	— Protection against potentially infectious material, — Encircling the eyes and surroundings, — Compatible with different models of filtering facepiece (FFP) masks and facial masks, — Transparent lens, — Reusable (can be cleaned and disinfected) or single-use items, — Can seal the skin of the face.	ex 9004 90 10 ex 9004 90 90
Mouth-nose-protection equipment	— Masks for the protection of the wearer against potentially infectious material or to prevent the wearer from spreading such material, — Reusable (can be cleaned and disinfected) or single-use items, — Can include a face shield, — Whether or not equipped with a replaceable filter.	ex 6307 90 98 ex 9020 00 00
Protective garments	— Non-sterile garment (e.g. gown, suit) for the protection of the wearer against potentially infectious material or to prevent the wearer from spreading such material. — Reusable (can be clean and disinfected) or single-use items.	ex 3926 20 00 ex 4015 90 00 ex 6113 00 ex 6114 ex 6210 10 10 6210 10 92 ex 6210 10 98 ex 6210 20 00 ex 6210 30 00 ex 6210 40 00 ex 6210 50 00 ex 6211 32 10 ex 6211 32 90 ex 6211 33 10 ex 6211 33 90 ex 6211 39 00 ex 6211 42 10 ex 6211 42 90 ex 6211 43 10 ex 6211 43 90 ex 6211 49 00 ex 9020 00 00

[1] Regulation (EU) 2016/425 of the European Parliament and of the Council of 9 March 2016 on personal protective equipment and repealing Council Directive 89/686/EEC (OJ L 81, 31.3.2016, p. 51).

[2] Council Directive 93/42/EEC of 14 June 1993 concerning medical devices (OJ L 69, 12.7.1993, p. 1).

ANNEX II

Export authorisation application as referred to in Article 2

When granting export authorisations, Member States will strive to ensure the visibility of the nature of the authorisation on the form issued. This is an export authorisation valid in all Member States of the European Union until its expiry date.

<table>
<tr><td>EUROPEAN UNION</td><td colspan="3">Export of personal protective equipment (Regulation (EU) 2020/568)</td></tr>
<tr><td>1. Exporter
(EORI number if applicable)</td><td colspan="2">2. Authorisation number</td><td>3. Expiry date</td></tr>
<tr><td>4. Issuing authority</td><td>5. Destination country</td><td>6. Final recipient</td><td>6a. Does the export contribute to one of the listed considerations in Article 3 or is the export meant to enable the provisions of emergency supplies in the context of humanitarian aid as set out in Article 2(6)?</td></tr>
<tr><td>7. Commodity code</td><td rowspan="2">8. Quantity</td><td rowspan="2">9. Unit</td><td rowspan="2">10. Description of the goods</td></tr>
<tr><td>11. Location</td></tr>
<tr><td>7. Commodity code</td><td rowspan="2">8. Quantity</td><td rowspan="2">9. Unit</td><td rowspan="2">10. Description of the goods</td></tr>
<tr><td>11. Location</td></tr>
<tr><td>7. Commodity code</td><td rowspan="2">8. Quantity</td><td rowspan="2">9. Unit</td><td rowspan="2">10. Description of the goods</td></tr>
<tr><td>11. Location</td></tr>
<tr><td>7. Commodity code</td><td rowspan="2">8. Quantity</td><td rowspan="2">9. Unit</td><td rowspan="2">10. Description of the goods</td></tr>
<tr><td>11. Location</td></tr>
<tr><td colspan="4">12. Signature, place and date, stamp</td></tr>
</table>

Explanatory notes to the export authorisation form

The completion of all the boxes is mandatory except when stated otherwise.

Boxes 7 to 11 are repeated 4 times to allow requesting an authorisation for 4 different products.

Box 1	Exporter	Full name and address of the exporter for whom the authorisation is issued + EORI number if applicable.
Box 2	Authorisation number	The authorisation number is completed by the authority issuing the export authorisation and has the following format: XXyyyy999999, where XX is the 2-letter geonomenclature code ([1]) of the issuing Member State, yyyy is the 4-digit year of issuance of the authorisation, 999999 is a 6-digit number unique within XXyyyy and attributed by the issuing authority.
Box 3	Expiry date	The issuing authority can define an expiry date for the authorisation. This expiry date cannot be later than 30 days after the entry into force of this regulation. If no expiry date is defined by the issuing authority, the authorisation expires at the latest 30 days after the entry into force of this regulation.
Box 4	Issuing authority	Full name and address of the Member State authority that issued the export authorisation.
Box 5	Destination country	2-letter geonomenclature code of the country of destination of the goods for which the authorisation is issued.
Box 6	Final recipient	Full name and address of the final recipient of the goods, if known at the time of issuance + EORI number if applicable. If the final recipient is not known at the time of issuance, the field is left empty.
Box 6a	Does the export contribute to one of the listed considerations in Article 3 or is the export meant to enable the provisions of emergency supplies in the context of humanitarian aid as set out in Article 2(6)?	If the export serves one of the considerations listed in Article 3 or if the export is meant to enable the provisions of emergency supplies in the context of humanitarian aid as set out in Article 2(6), this should be indicated.
Box 7	Commodity code	The numerical code from the Harmonised System or the Combined Nomenclature ([2]) under which the goods to export are classified when the authorisation is issued.
Box 8	Quantity	The quantity of goods measured in the unit declared in box 9.
Box 9	Unit	The measurement unit in which the quantity declared in box 8 is expressed. The units to use are 'P/ST' for goods counted by number of pieces (e.g. masks).
Box 10	Description of the goods	Plain language description precise enough to allow identification the goods.
Box 11	Location	The geonomenclature code of the Member State where the goods are located. If the goods are located in the Member State of the issuing authority, this box must be left empty.
Box 12	Signature, stamp, place and date	The signature and stamp of the issuing authority. The place and the date of issuance of the authorisation.

([1]) Commission Regulation (EU) No 1106/2012 of 27 November 2012 implementing Regulation (EC) No 471/2009 of the European Parliament and of the Council on Community statistics relating to external trade with non-member countries, as regards the update of the nomenclature of countries and territories (OJ L 328, 28.11.2012, p. 7).

([2]) Council Regulation (EEC) No 2658/87 of 23 July 1987 on the tariff and statistical nomenclature and on the Common Customs Tariff (OJ L 256, 7.9.1987, p. 1).

DECISIONS

COMMISSION IMPLEMENTING DECISION (EU) 2020/569

of 16 April 2020

establishing a common format and information content for the submission of the information to be reported by Member States pursuant to Directive 2010/63/EU of the European Parliament and of the Council on the protection of animals used for scientific purposes and repealing Commission Implementing Decision 2012/707/EU

(notified under document C(2020) 2179)

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Directive 2010/63/EU of the European Parliament and of the Council of 22 September 2010 on the protection of animals used for scientific purposes ([1]), and in particular Article 43(4) and Article 54(4) thereof,

Whereas:

(1) Following the amendments provided for in Regulation (EU) 2019/1010 of the European Parliament and of the Council ([2]), Directive 2010/63/EU now requires Member States to submit non-technical project summaries of authorised projects, and any updates thereto, by electronic transfer to the Commission. In order to enable the Commission to establish and maintain a central database for those summaries and updates and to ensure that meaningful searches can be carried out on that data, a uniform presentation of those summaries and updates is needed. Therefore, templates should be established for submitting the non-technical project summaries, and any updates thereto, and Member States should be required to upload such summaries and updates to the database established by the Commission.

(2) Directive 2010/63/EU also requires Member States to submit information on the implementation of that Directive, as well as statistical information on the use of animals in procedures, by electronic transfer to the Commission.

(3) On the basis of the information submitted by the Member States on the implementation of Directive 2010/63/EU, the Commission services are to publish and regularly update a Union overview. Directive 2010/63/EU also requires the Commission services to make the statistical data submitted by the Member States and a summary report thereof publicly available on an annual basis. To enable the Commission to satisfy both of those requirements, the content of that information should be established by laying down information categories.

(4) As regards information on implementation, the information categories to be reported on should correlate with the relevant requirements of Directive 2010/63/EU. As regards statistical information, it is necessary to specify the statistical data input categories available in the searchable, open access database established by the Commission pursuant to Directive 2010/63/EU.

(5) In order to improve transparency and to reduce the administrative burden, Member States should be required to use the database established by the Commission for the purposes of submitting the information on the implementation of Directive 2010/63/EU as well as the statistical information on the use of animals in procedures.

([1]) OJ L 276, 20.10.2010, p. 33.

([2]) Regulation (EU) 2019/1010 of the European Parliament and of the Council of 5 June 2019 on the alignment of reporting obligations in the field of legislation related to the environment, and amending Regulations (EC) No 166/2006 and (EU) No 995/2010 of the European Parliament and of the Council, Directives 2002/49/EC, 2004/35/EC, 2007/2/EC, 2009/147/EC and 2010/63/EU of the European Parliament and of the Council, Council Regulations (EC) No 338/97 and (EC) No 2173/2005, and Council Directive 86/278/EEC (OJ L 170, 25.6.2019, p. 115).

(6) The content and format of the detailed information to be submitted by Member States on the methods considered to be at least as humane as those contained in Annex IV to Directive 2010/63/EU should be specified in a way that allows the list of methods for the killing of animals contained in that Annex to be kept up to date. Therefore, it is appropriate to lay down a template allowing for the submission of information on the type of method, the species concerned and the justification for granting an exemption, and to require Member States to use that template.

(7) The empowerments on which this Decision is based are closely linked as they both deal with the reporting of information by Member States under Directive 2010/63/EU. Given this substantive link, and to ensure a consistent and coherent approach, it is appropriate to adopt a single Decision establishing all requirements falling within the scope of those empowerments. It is therefore necessary to replace Commission Implementing Decision 2012/707/EU ([3]), in which the common format for the submission of the information referred to in Article 54 of Directive 2010/63/EU is laid down, by a new Implementing Decision based on both Article 43(4) and Article 54(4) of Directive 2010/63/EU. Implementing Decision 2012/707/EU should therefore be repealed.

(8) The measures provided for in this Decision are in accordance with the opinion of the Animals in Science Committee,

HAS ADOPTED THIS DECISION:

Article 1

For the purposes of the second sentence of Article 43(3) of Directive 2010/63/EU, Member States shall submit the information specified in Annex I to this Decision using the database established by the Commission in accordance with the third sentence of Article 43(4) of that Directive. The non-technical project summaries, and updates thereto, shall correspond to the templates laid down in Annex I to this Decision.

Article 2

For the purposes of Article 54(1) of Directive 2010/63/EU, Member States shall submit the information specified in Annex II to this Decision using the database established by the Commission in accordance with the first sentence of the third subparagraph of Article 54(2) of that Directive.

Article 3

For the purposes of Article 54(2) of Directive 2010/63/EU, Member States shall submit the information specified in Annex III to this Decision using the database established by the Commission in accordance with the first sentence of the third subparagraph of Article 54(2) of that Directive.

Article 4

For the purposes of Article 54(3) of Directive 2010/63/EU, Member States shall submit the information specified in Annex IV to this Decision using the template laid down in that Annex.

Article 5

Implementing Decision 2012/707/EU is repealed with effect from 17 April 2020. References to the repealed Decision shall be construed as references to this Decision and read in accordance with the correlation table in Annex V.

([3]) Commission Implementing Decision 2012/707/EU of 14 November 2012 establishing a common format for the submission of the information pursuant to Directive 2010/63/EU of the European Parliament and of the Council on the protection of animals used for scientific purposes (OJ L 320, 17.11.2012, p. 33).

Article 6

This Decision is addressed to the Member States.

Done at Brussels, 16 April 2020.

For the Commission
Virginijus SINKEVIČIUS
Member of the Commission

ANNEX I

PART A

Template for the submission of non-technical project summaries referred to in article 43(1) of directive 2010/63/EU

Title of the project	
Duration of project (in months)	
Key Words (maximum of 5) ([1])	
Purpose of project ([2]) (multiple choices possible)	— Basic research ([3]) — Translational and applied research ([3]) — Regulatory use and routine production: — Quality control (including batch safety and potency testing) — Other efficacy and tolerance testing — Toxicity and other safety testing including pharmacology — Routine production — Protection of the natural environment in the interests of the health or welfare of human beings or animals — Preservation of species — Higher education — Training — Forensic enquiries — Maintenance of colonies of genetically altered animals, not used in other procedures
Objectives and predicted benefits of the project	
Describe the objectives of the project (for example, addressing certain scientific unknowns, or scientific or clinical needs).	
What are the potential benefits likely to derive from this project? Explain how science could be advanced, or humans, animals or environment may ultimately benefit from the project. Where applicable, differentiate between short-term benefits (within the duration of the project) and long-term benefits (which may accrue after the project is finished).	
Predicted harms	
In what procedures will the animals typically be used (for example, injections, surgical procedures)? Indicate the number and duration of these procedures.	

What are the expected impacts/ adverse effects on the animals, for example pain, weight loss, inactivity/ reduced mobility, stress, abnormal behaviour, and the duration of those effects?						
What species and numbers of animals are expected to be used? What are the expected severities and the numbers of animals in each severity category (per species)?	**Species** [4]	**Estimated total numbers**	**Estimated numbers per severity**			
			Non-recovery	**Mild**	**Moderate**	**Severe**
What will happen to the animals kept alive at the end of the procedure? [5], [6]	**Estimated number to be reused**		**Estimated number to be returned to habitat/ husbandry system**		**Estimated number to be rehomed**	
Please provide reasons for the planned fate of the animals after the procedure.						
Application of the Three Rs						
1. Replacement State which non-animal alternatives are available in this field and why they cannot be used for the purposes of the project.						
2. Reduction Explain how the numbers of animals for this project were determined. Describe steps that have been taken to reduce the number of animals to be used, and principles used to design studies. Where applicable, describe practices that will be used throughout the project to minimise the number of animals used consistent with scientific objectives. Those practices may include e.g. pilot studies, computer modelling, sharing of tissue and reuse.						

3. Refinement Give examples of the specific measures (e.g., increased monitoring, post-operative care, pain management, training of animals) to be taken, in relation to the procedures, to minimise welfare costs (harms) to the animals. Describe the mechanisms to take up emerging refinement techniques during the lifetime of the project.				
Explain the choice of species and the related life stages.				
Project selected for Retrospective Assessment ([7])	Deadline	Contains severe procedures	Uses non-human primates	Other reason

([1]) Including scientific terms which may consist of more than 5 individual words and excluding species and purposes entered elsewhere in the document
([2]) To be provided via a dropdown menu
([3]) List of purposes in accordance with statistical reporting categories and sub-categories in Annex III to this Decision
([4]) Species in accordance with statistical reporting categories in Annex III to this Decision, with an additional option of 'non-specified mammal' to safeguard anonymity in exceptional cases
([5]) Species to be populated from the previous response to select from under the relevant category (proportions)
([6]) Multiple choices per species possible
([7]) Multiple choices possible; applicable to those MS where this information is required by the legislation

PART B

Template for the submission of an update to the non-technical project summary referred to in article 43(2) of directive 2010/63/EU

Title (as per Non-technical Project Summary)			
Reason for Retrospective Assessment ([1])	**Using non-human primates**	**Contains 'severe' procedures**	**Other reason**
Explain 'Other reason'			

Achievement of objectives

Explain briefly whether, and to what extent, the objectives set out in the authorised project have been achieved. Provide reasons if objectives have not been attained. Have there been any other significant findings? What benefits have resulted from the work to date, and are further benefits expected? Have the results of this project been disseminated, including where hypotheses are not proven? If so, describe how. If not, indicate how and when results are expected to be publicised.	

Harms

Species ([2])	**Total numbers of animals used**	**Numbers of animals per actual severity**			
		Non-recovery	**Mild**	**Moderate**	**Severe**

How do numbers of animals used and actual severities compare with those estimated? Where the actual numbers are higher than the estimated numbers, please provide an explanation. Where the actual numbers are lower, please provide an explanation unless that difference is a result of Reduction or Refinement?	
How does the fate of animals kept alive at the end of the study compare with the estimated fate? Please provide an explanation.	

Any elements that may contribute to further implementation of the Three Rs:

1. Replacement

With the knowledge obtained from this project, have any new approaches that could replace some or all of the use of animals in similar projects been identified/developed (including the development/validation of new *in vitro* or *in silico* techniques)?	

2. Reduction	
With the knowledge obtained from this project, could the experimental design be improved to enable any further reduction of the use of animals, and if so, how? Provide an explanation where numbers of animals used were lower than those originally estimated.	
3. Refinement	
Provide an explanation where the actual severities were lower than those originally estimated. With the new knowledge obtained from this project, are the animal models used still the most appropriate? Please specify per species/model, where appropriate. List any novel refinements introduced during the project to reduce harm to the animals or to improve their welfare. What are the potential opportunities for further refinement in the future, for example, emerging technologies, techniques, improved welfare assessment methods, earlier endpoints, housing/husbandry measures?	
4. Other	
How are the findings for further implementation of the Three Rs disseminated?	
Additional comments	

([1]) Multiple choices possible
([2]) Species in accordance with statistical reporting categories in Annex III to this Decision, with an additional option of 'non-specified mammal' to safeguard anonymity in exceptional cases

ANNEX II

INFORMATION REFERRED TO IN ARTICLE 54(1) OF DIRECTIVE 2010/63/EU

A. NATIONAL MEASURES ON THE IMPLEMENTATION OF DIRECTIVE 2010/63/EU

Provide information on changes made to national measures regarding the implementation of Directive 2010/63/EU since the previous report.

B. STRUCTURES AND FRAMEWORK

1. **Competent authorities (Article 59 of Directive 2010/63/EU)**

Explain the framework for competent authorities, including the numbers and types of authorities as well as their respective tasks, and explain the measures taken to ensure compliance with the requirements of Article 59(1) of Directive 2010/63/EU.

2. **National committee (Article 49 of Directive 2010/63/EU)**

Explain the structure and operation of the national committee, and the measures taken to ensure compliance with the requirements of Article 49 of Directive 2010/63/EU.

3. **Education and training of personnel (Article 23 of Directive 2010/63/EU)**

Provide information on the minimum requirements referred to in Article 23(3) of Directive 2010/63/EU; describe any additional educational and training requirements for staff coming from another Member State.

4. **Project evaluation and authorisation (Articles 38 and 40 of Directive 2010/63/EU)**

Explain the processes of project evaluation and authorisation, and the measures taken to ensure compliance with the requirements of Articles 38 and 40 of Directive 2010/63/EU.

C. OPERATION

1. **Projects**

1.1. *Granting of project authorisation (Articles 40 and 41 of Directive 2010/63/EU)*

1.1.1. In respect of each year, provide numbers for the following:

(a) all authorisation decisions and authorised projects;

(b) multiple generic projects, as provided for in Article 40(4) of Directive 2010/63/EU, categorised as one of the following types:

— projects to satisfy regulatory requirements;

— projects using animals for production purposes;

— projects using animals for diagnostic purposes;

(c) the authorisation decisions where the deadline of 40 days has been extended in accordance with Article 41(2) of Directive 2010/63/EU.

1.1.2. For the purposes of point (c), provide summary information, covering the five-year reporting cycle, on the reasons where the deadline of 40 days has been extended.

1.2. *Retrospective assessment, non-technical project summaries (Article 38(2)(f), Articles 39 and 43 of Directive 2010/63/EU)*

1.2.1. Explain the measures taken to ensure compliance with the requirements of Article 43(1) of Directive 2010/63/EU and indicate whether there is a requirement for non-technical project summaries to specify that a project is to undergo retrospective assessment (Article 43(2) of Directive 2010/63/EU).

1.2.2. In respect of each year, provide the number of projects authorised that are to undergo a retrospective assessment in accordance with Article 39(2) of Directive 2010/63/EU and the number of projects authorised that are to undergo a retrospective assessment under Article 38(2)(f) of that Directive. Categorise each of those projects as one of the following types:

(a) projects using non-human primates;

(b) projects involving procedures classified as 'severe';

(c) projects using non-human primates and involving procedures classified as 'severe';

(d) other projects that are to undergo a retrospective assessment.

1.2.3. Provide summary information, covering the five-year reporting cycle, on the nature of projects selected for retrospective assessment in accordance with Article 38(2)(f) of Directive 2010/63/EU that are not automatically subject to retrospective assessment in accordance with Article 39(2).

2. **Animals bred for use in procedures (Articles 10, 28 and 30 of Directive 2010/63/EU)**

2.1. Provide the species and numbers of animals that were bred and born (including by Caesarean section) for use in procedures and, having never been used in any procedures, were killed during the calendar year immediately preceding that in which the five-year report is submitted.

2.1.1. Include animals killed for organs or tissues and animals from the creation and maintenance of genetically altered (GA) animal lines, which are not covered in the annual statistics pursuant to Article 54(2) of Directive 2010/63/EU.

2.1.2. Categorise these animals as one of the following types:

(a) genetically normal animals not providing organs and/or tissues;

(b) genetically normal animals providing organs and/or tissues;

(c) GA animals providing organs and/or tissues;

(d) genetically normal animals (wild type offspring) as a result of the creation of a new GA line;

(e) animals from the maintenance of a GA line covering all GA and wild type offspring of both harmful and non-harmful phenotype.

2.1.3. The category referred to in point (a) excludes animals as a result of a creation of a new GA line and from the maintenance of a GA line, which are to be reported in the categories referred to in points (d) and (e) respectively;

2.1.4. The categories referred to in points (b) and (c) include animals as a result of creation of a new GA line and from maintenance of a GA line, when providing organs and/or tissues;

2.1.5. The categories referred to in points 2.1.2(d) and (e) exclude the following animals, which are to be reported in the annual statistics pursuant to Article 54(2) of Directive 2010/63/EU:

(a) animals that were genotyped using invasive methods;

(b) animals from a harmful phenotype line that experienced adverse effect.

2.2. Explain the measures taken to ensure compliance with the requirements of Articles 10 and 28 of Directive 2010/63/EU when sourcing non-human primates.

3. **Exemptions**

3.1. Provide summary information, covering the five-year reporting cycle, on circumstances under which exemptions were granted in accordance with Article 10(3), the second subparagraph of Article 12(1) and Article 33(3) of Directive 2010/63/EU.

3.2. Provide information for the same period on any exceptional circumstances as referred to in Article 16(2) of that Directive where the reuse of an animal was authorised after a procedure in which the suffering of that animal was assessed to have been severe.

4. **Animal welfare body (Articles 26 and 27 of Directive 2010/63/EU)**

Explain the measures taken to ensure compliance with the requirements regarding the structure and functioning of animal welfare bodies of Articles 26 and 27 of Directive 2010/63/EU.

D. PRINCIPLES OF REPLACEMENT, REDUCTION AND REFINEMENT

1. **Principle of replacement, reduction and refinement (Articles 4 and 13 and Annex VI of Directive 2010/63/EU)**

1.1. Provide information on the measures taken to ensure that the principles of (a) replacement, (b) reduction and (c) refinement are satisfactorily addressed within authorised projects in accordance with Articles 4 and 13 of Directive 2010/63/EU.

1.2. Provide information on the measures taken to ensure that the principles of (a) reduction and (b) refinement are satisfactorily addressed during housing and care in breeding and supplying establishments in accordance with Article 4 of Directive 2010/63/EU.

2. **Avoidance of duplication (Article 46 of Directive 2010/63/EU)**

Explain how duplication of procedures is avoided to comply with Article 46 of Directive 2010/63/EU.

3. **Tissue sampling of genetically altered animals (Articles 4, 30 and 38 of Directive 2010/63/EU)**

3.1. In respect of tissue sampling for the purposes of genetic characterisation carried out with and without project authorisation, provide representative information and numbers regarding species, methods and their related actual severity. That information shall be provided only for the calendar year immediately preceding that in which the five-year report is submitted.

3.2. List the criteria used to ensure that the information in point 3.1 is representative.

3.3. Provide information on efforts made to refine tissue sampling methods.

E. ENFORCEMENT

1. **Authorisation of breeders, suppliers and users (Articles 20 and 21 of Directive 2010/63/EU)**

1.1. In respect of each year, provide numbers for all active authorised breeders, suppliers and users separately.

1.2. Provide summary information, covering the five-year reporting cycle, on reasons for suspensions or withdrawals of authorisations of breeders, suppliers and users.

2. **Inspections (Article 34 of Directive 2010/63/EU)**

2.1. In respect of each year, provide numbers for inspections, broken down by announced and unannounced.

2.2. Provide summary information, covering the five-year reporting cycle, on main findings of inspections.

2.3. Explain the measures taken to ensure compliance with the requirements of Article 34(2) of Directive 2010/63/EU.

3. **Withdrawals of project authorisation (Article 44 of Directive 2010/63/EU)**

Provide summary information, covering the five-year reporting cycle, on reasons for the withdrawal of project authorisations.

4. **Penalties (Article 60 of Directive 2010/63/EU)**

4.1. Provide summary information, covering the five-year reporting cycle, on the nature of the following:

(a) infringements;

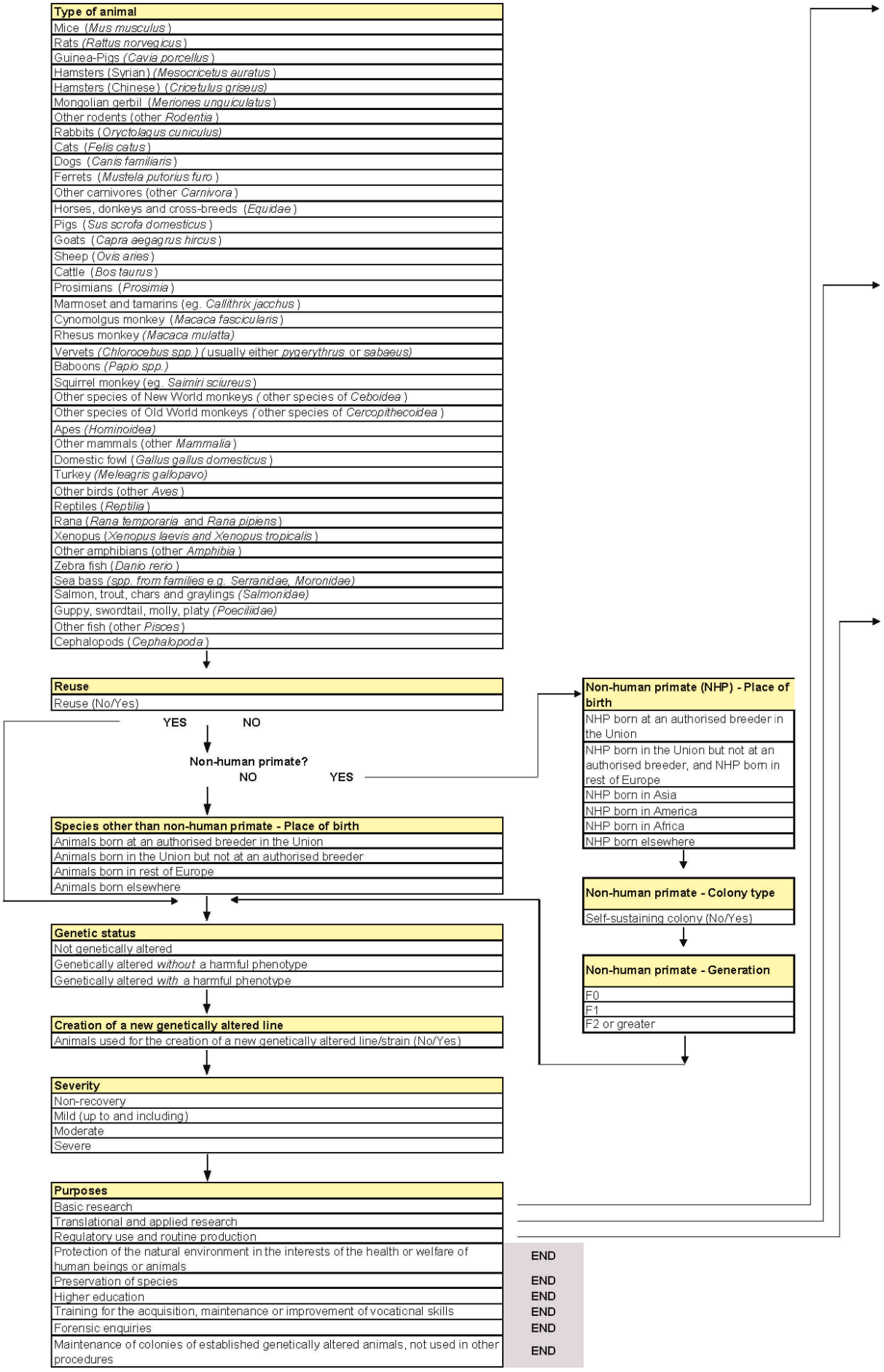
(b) administrative actions in response to infringements;

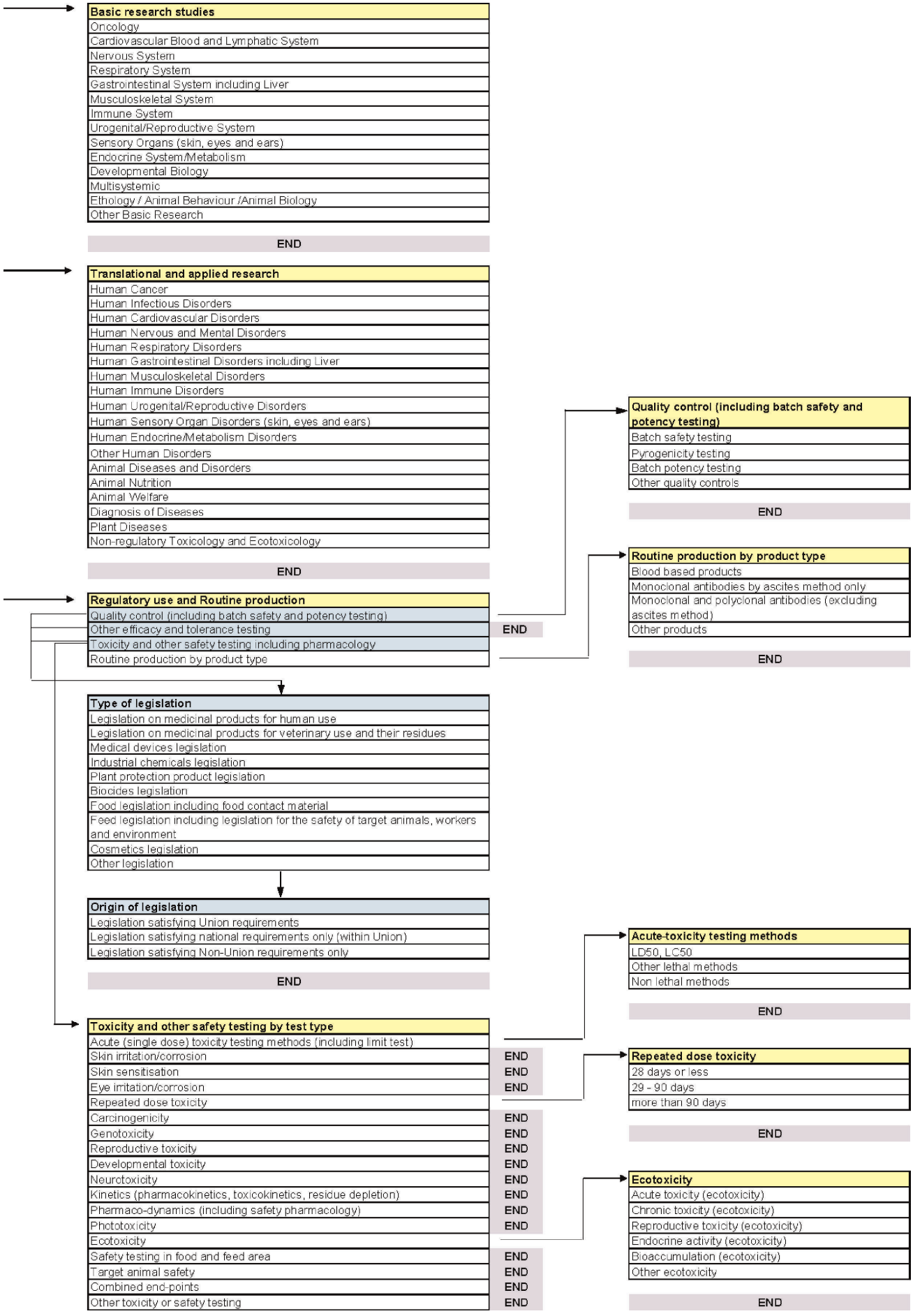
(c) legal actions in response to infringements.

ANNEX III

PART A

Flowchart of statistical data input categories under article 54(2) of directive 2010/63/EU


Type of animal
Mice (Mus musculus)
Rats (Rattus norvegicus)
Guinea-Pigs (Cavia porcellus)
Hamsters (Syrian) (Mesocricetus auratus)
Hamsters (Chinese) (Cricetulus griseus)
Mongolian gerbil (Meriones unguiculatus)
Other rodents (other Rodentia)
Rabbits (Oryctolagus cuniculus)
Cats (Felis catus)
Dogs (Canis familiaris)
Ferrets (Mustela putorius furo)
Other carnivores (other Carnivora)
Horses, donkeys and cross-breeds (Equidae)
Pigs (Sus scrofa domesticus)
Goats (Capra aegagrus hircus)
Sheep (Ovis aries)
Cattle (Bos taurus)
Prosimians (Prosimia)
Marmoset and tamarins (eg. Callithrix jacchus)
Cynomolgus monkey (Macaca fascicularis)
Rhesus monkey (Macaca mulatta)
Vervets (Chlorocebus spp.) (usually either pygerythrus or sabaeus)
Baboons (Papio spp.)
Squirrel monkey (eg. Saimiri sciureus)
Other species of New World monkeys (other species of Ceboidea)
Other species of Old World monkeys (other species of Cercopithecoidea)
Apes (Hominoidea)
Other mammals (other Mammalia)
Domestic fowl (Gallus gallus domesticus)
Turkey (Meleagris gallopavo)
Other birds (other Aves)
Reptiles (Reptilia)
Rana (Rana temporaria and Rana pipiens)
Xenopus (Xenopus laevis and Xenopus tropicalis)
Other amphibians (other Amphibia)
Zebra fish (Danio rerio)
Sea bass (spp. from families e.g. Serranidae, Moronidae)
Salmon, trout, chars and graylings (Salmonidae)
Guppy, swordtail, molly, platy (Poeciliidae)
Other fish (other Pisces)
Cephalopods (Cephalopoda)
Reuse
Reuse (No/Yes)
YES
NO
Non-human primate?
NO
YES
Non-human primate (NHP) - Place of birth
NHP born at an authorised breeder in the Union
NHP born in the Union but not at an authorised breeder, and NHP born in rest of Europe
NHP born in Asia
NHP born in America
NHP born in Africa
NHP born elsewhere
Species other than non-human primate - Place of birth
Animals born at an authorised breeder in the Union
Animals born in the Union but not at an authorised breeder
Animals born in rest of Europe
Animals born elsewhere
Non-human primate - Colony type
Self-sustaining colony (No/Yes)
Non-human primate - Generation
F0
F1
F2 or greater
Genetic status
Not genetically altered
Genetically altered without a harmful phenotype
Genetically altered with a harmful phenotype
Creation of a new genetically altered line
Animals used for the creation of a new genetically altered line/strain (No/Yes)
Severity
Non-recovery
Mild (up to and including)
Moderate
Severe
Purposes
Basic research
Translational and applied research
Regulatory use and routine production
Protection of the natural environment in the interests of the health or welfare of human beings or animals
END
Preservation of species
END
Higher education
END
Training for the acquisition, maintenance or improvement of vocational skills
END
Forensic enquiries
END
Maintenance of colonies of established genetically altered animals, not used in other procedures
END


Basic research studies
Oncology
Cardiovascular Blood and Lymphatic System
Nervous System
Respiratory System
Gastrointestinal System including Liver
Musculoskeletal System
Immune System
Urogenital/Reproductive System
Sensory Organs (skin, eyes and ears)
Endocrine System/Metabolism
Developmental Biology
Multisystemic
Ethology / Animal Behaviour /Animal Biology
Other Basic Research
END
Translational and applied research
Human Cancer
Human Infectious Disorders
Human Cardiovascular Disorders
Human Nervous and Mental Disorders
Human Respiratory Disorders
Human Gastrointestinal Disorders including Liver
Human Musculoskeletal Disorders
Human Immune Disorders
Human Urogenital/Reproductive Disorders
Human Sensory Organ Disorders (skin, eyes and ears)
Human Endocrine/Metabolism Disorders
Other Human Disorders
Animal Diseases and Disorders
Animal Nutrition
Animal Welfare
Diagnosis of Diseases
Plant Diseases
Non-regulatory Toxicology and Ecotoxicology
END
Regulatory use and Routine production
Quality control (including batch safety and potency testing)
Other efficacy and tolerance testing
Toxicity and other safety testing including pharmacology
Routine production by product type
END
Quality control (including batch safety and potency testing)
Batch safety testing
Pyrogenicity testing
Batch potency testing
Other quality controls
END
Routine production by product type
Blood based products
Monoclonal antibodies by ascites method only
Monoclonal and polyclonal antibodies (excluding ascites method)
Other products
END
Type of legislation
Legislation on medicinal products for human use
Legislation on medicinal products for veterinary use and their residues
Medical devices legislation
Industrial chemicals legislation
Plant protection product legislation
Biocides legislation
Food legislation including food contact material
Feed legislation including legislation for the safety of target animals, workers and environment
Cosmetics legislation
Other legislation
Origin of legislation
Legislation satisfying Union requirements
Legislation satisfying national requirements only (within Union)
Legislation satisfying Non-Union requirements only
END
Toxicity and other safety testing by test type
Acute (single dose) toxicity testing methods (including limit test)
Skin irritation/corrosion
Skin sensitisation
Eye irritation/corrosion
Repeated dose toxicity
Carcinogenicity
Genotoxicity
Reproductive toxicity
Developmental toxicity
Neurotoxicity
Kinetics (pharmacokinetics, toxicokinetics, residue depletion)
Pharmaco-dynamics (including safety pharmacology)
Phototoxicity
Ecotoxicity
Safety testing in food and feed area
Target animal safety
Combined end-points
Other toxicity or safety testing
END
Acute-toxicity testing methods
LD50, LC50
Other lethal methods
Non lethal methods
END
Repeated dose toxicity
28 days or less
29 - 90 days
more than 90 days
END
Ecotoxicity
Acute toxicity (ecotoxicity)
Chronic toxicity (ecotoxicity)
Reproductive toxicity (ecotoxicity)
Endocrine activity (ecotoxicity)
Bioaccumulation (ecotoxicity)
Other ecotoxicity
END

PART B

Information referred to in article 54(2) of directive 2010/63/EU

A. GENERAL PROVISIONS

1. The data shall be reported on each use of an animal.

2. When reporting data for an animal, only one option within a category shall be selected.

3. Animals killed for organs and tissues

3.1. Animals killed for organs and tissues, as well as sentinels, are excluded from the provision of annual statistical data, unless any of the following applies:

(a) the killing is performed under a project authorisation using a method not included in Annex IV to Directive 2010/63/EU;

(b) the animal has gone through a previous intervention, which has been above the threshold of minimum pain, suffering, distress and lasting harm prior to being killed;

(c) the animal is from a genetically altered animal line with an intended harmful phenotype and which has expressed the harmful phenotype before being killed for organs and tissues.

3.2. Other animals killed for organs and tissues (those not reported in the annual statistics) are reported as part of the five-year implementation report in line with Annex II to this Decision.

4. Animals that are bred and killed without being used in a procedure

4.1. Animals that are bred and killed without being used in a procedure shall not be included in the annual statistical data apart from the following animals:

(a) genetically altered animals with an intended and exhibited harmful phenotype;

(b) those animals that have been genotyped (genetic characterisation/tissue sampling) using an invasive method, which was not carried out for the purposes of identification/marking of the animal.

4.2. For the purposes of point 4.1(b), an invasive method shall be a method which may cause the animal pain, suffering, distress or lasting harm equivalent to, or higher than, that caused by the introduction of a needle in accordance with good veterinary practice.

4.3. The animals that are bred and killed without being used in a procedure shall be reported in accordance with Annex II of this Decision as part of the five-year implementation report.

5. Genetically normal animals born during the creation of a new genetic line shall be excluded from the provision of annual statistical data and shall instead be reported as part of the five-year implementation report in line with Annex II of this Decision, unless such animals have been genotyped using an invasive method.

6. Larval forms of animals shall be included once they become capable of independent feeding.

7. Foetal and embryonic forms of mammalian species shall be excluded from the provision of annual statistical data. Only animals that are born, including by Caesarean section, and live are to be counted. When studies involve both mother and offspring, the mother shall be reported when she has been subject to a procedure above the threshold of minimum pain, suffering, distress and lasting harm. Offspring shall be reported when they are an integral part of the procedure.

8. Where the use of an animal in a procedure results in severe pain, suffering or distress that is long-lasting and cannot be ameliorated, whether pre-authorised or not, the animal shall be reported under the 'severe' category. Commentary shall be inserted in the Member State narrative pursuant to Section C of this Annex covering the species, numbers, whether prior exemption was authorised, the details of the use and the reasons why 'severe' classification was exceeded.

9. Data relating to animals used in a procedure shall be reported for the year in which that procedure ends. In the case of studies running across two calendar years, all of the animals may be accounted for together in the year in which the last procedure ends if this exemption to annual reporting is authorised by the competent authority. For projects running longer than two calendar years, data on animals shall be reported for the year the animal is killed or dies.

10. Where the 'Other' categories are used, an entry shall be made in the narratives to provide a further breakdown of the content of 'Other'.

11. Genetically altered animals

11.1. For the purposes of statistical reporting, 'genetically altered animals' refer to either of the following:

(a) genetically modified (such as transgenic, knock-out and other forms of genetic alteration) and induced mutant animals (irrespective of the type of mutation);

(b) animals with spontaneous deleterious mutations maintained for research for that specific genotype.

11.2. Genetically altered animals shall be reported in any of the following cases:

(a) when used for the creation of a new line;

(b) when used for the maintenance of an established line with an intended and exhibited harmful phenotype (see section B.10.7);

(c) when used in procedures other than maintenance of a line.

11.3. All animals carrying the genetic alteration shall be reported during the creation of a new line. In addition, those used for superovulation, vasectomy, embryo implantation shall be reported (these may or may not be genetically altered themselves).

11.4. Genetically normal animals (wild type offspring) produced as a result of creation of a new genetically altered line shall not be reported in annual statistics, unless the animal has been genotyped (genetic characterisation/tissue sampling) using an invasive method which was not carried out for the purposes of identification/marking of the animal. Genetically normal animals (wild type offspring) not reported in annual statistics are covered in the five-year implementation report as described in Annex II.

11.5. In the category 'Purposes' as set out in Part A of this Annex, the animals used for the creation of a new genetically altered line shall be reported in the respective category for which the line is being created (generally expected to be 'basic research' or 'translational and applied research').

11.6. A new strain or line of genetically altered animals is considered to be 'established' where transmission of the genetic alteration is stable, which will be a minimum of two generations, and a welfare assessment has been completed.

11.7. The welfare assessment will determine if the newly created line is expected to have an intended harmful phenotype and, if this is the case, the animals from this point onwards shall be reported under category 'Maintenance of colonies of established genetically altered animals, not used in other procedures' – or, if appropriate, in the other procedures they are being used for. Such animals include, amongst others, those that require a specific bio-secure environment (for example, special housing arrangements to protect animals that are particularly sensitive to infection as a consequence of the gene alteration) or additional care beyond that required for conventional animals to maintain their health and well-being.

11.8. If the welfare assessment concludes that the line is not expected to have a harmful phenotype, its breeding falls outside the scope of a procedure and no longer needs to be reported. Such animals include, amongst others, inducible and cre-lox lines, which require an active intervention for the harmful phenotype to be expressed.

11.9. 'Maintenance of colonies of established genetically altered animals, not used in other procedures'

11.9.1. This category contains the animals required for the maintenance of colonies of genetically altered animals of established lines with an intended harmful phenotype and which have exhibited pain, suffering, distress or lasting harm as a consequence of the harmful genotype. The intended purpose for which the line is being maintained is not recorded.

11.9.2. This category also includes genetically altered animals during maintenance of an established line, irrespective of whether the line is of intended non-harmful or harmful phenotype, that have been subject to invasive genotyping (genetic characterisation/tissue sampling). See section B.10.7.

11.10. All genetically altered animals which are used in other procedures (not for the creation or maintenance of a genetically altered line) shall be reported under their respective purposes (the same way as any non-genetically altered animal). These animals may or may not exhibit a harmful phenotype.

11.11. Genetically altered animals, expressing a harmful phenotype, and killed for their organs and tissues, shall be reported under the respective primary purposes for which the organs/tissues were used.

B. DATA INPUT CATEGORIES

The sections below follow the order of the categories and related headings in the flow chart laid down in Part A.

1. **Type of animal**

Mice (*Mus musculus*)
Rats *(Rattus norvegicus*)
Guinea-Pigs *(Cavia porcellus*)
Hamsters (Syrian) *(Mesocricetus auratus*)
Hamsters (Chinese) (*Cricetulus griseus)*
Mongolian gerbil (*Meriones unguiculatus*)
Other rodents (other *Rodentia*)
Rabbits (*Oryctolagus cuniculus)*
Cats (*Felis catus*)
Dogs (*Canis familiaris*)
Ferrets (*Mustela putorius furo*)
Other carnivores (other *Carnivora*)
Horses, donkeys and cross-breeds (*Equidae*)
Pigs (*Sus scrofa domesticus*)
Goats (*Capra aegagrus hircus*)
Sheep (*Ovis aries*)
Cattle (*Bos taurus*)
Prosimians (*Prosimia*)
Marmoset and tamarins (eg. *Callithrix jacchus*)
Cynomolgus monkey (*Macaca fascicularis*)
Rhesus monkey *(Macaca mulatta)*
Vervets *(Chlorocebus spp.)* (usually either *pygerythrus* or *sabaeus)*
Baboons *(Papio spp.)*
Squirrel monkey (eg. *Saimiri sciureus*)
Other species of New World monkeys (other species of *Ceboidea*)
Other species of Old World monkeys (other species of *Cercopithecoidea*)
Apes *(Hominoidea)*
Other mammals (other *Mammalia*)

Domestic fowl (*Gallus gallus domesticus*)
Turkey *(Meleagris gallopavo)*
Other birds (other *Aves*)
Reptiles (*Reptilia*)
Rana (*Rana temporaria* and *Rana pipiens*)
Xenopus (*Xenopus laevis and Xenopus tropicalis*)
Other amphibians (other *Amphibia*)
Zebra fish (*Danio rerio*)
Sea bass *(spp*. from families e.g. *Serranidae, Moronidae)*
Salmon, trout, chars and graylings *(Salmonidae)*
Guppy, swordtail, molly, platy *(Poeciliidae)*
Other fish (other *Pisces*)
Cephalopods (*Cephalopoda*)

1.1. Fish shall be reported from the stage of independent feeding when the gut is open end to end and the fish would normally take food.

1.2. The time at which fish feed independently is different for each species and in many cases dependent on the temperature at which they are kept. Temperature should be set to maintain optimal welfare, as determined by the person responsible for the welfare and care of the animals and for species specific information in coordination with the designated veterinarian. Zebrafish larvae, which are kept at approximately + 28 °C shall be reported 5 days post fertilisation.

1.3. Due to the small size of some fish and cephalopod species, the count may be done on the basis of estimation.

1.4. All cephalopod species shall be reported under the heading 'cephalopod' from the stage at which the animal becomes capable of independent feeding, that is to say immediately after hatching.

2. **Reuse**

Reuse (No/Yes)

2.1. General

2.1.1. Each use of the animal shall be reported at the end of each procedure.

2.1.2. Information on the place of birth and for non-human primates also the generation and information on whether the animal was obtained from a self-sustaining colony shall only be reported for naïve animals, that is to say animals used for the first time. For reused animals, this information is therefore not recorded.

2.1.3. Any subsequent categories shall show the number of uses of animals in procedures. These numbers cannot be cross referenced with the total numbers of naïve animals.

2.1.4. The actual suffering of the animal in the procedure shall be reported. In some cases this could be influenced by a previous use. However, the severity will not always increase in a subsequent use and in some cases may even decrease as a result (habituation). Therefore, the actual severity to be reported shall always be determined on a case-by-case basis taking account of any impact from previous uses.

2.2. Reuse versus continued use

For the purposes of determining whether there is a 'reuse', the following shall apply:

2.2.1. A single use is the use of one animal for a single scientific/experimental/educational/training purpose. A single use extends from the time when the first technique is applied to the animal until the completion of data collection, observations or achievement of educational objective. This is usually a single experiment, test or training of a technique.

2.2.2. A single use may contain a number of steps (techniques) all necessarily related to achieve a single outcome and which require the use of the same animal.

2.2.3. Examples of preparation for the purposes of continued use include:

(a) surgical techniques (such as cannulation, implantation of telemetry, ovariectomy, castration, hypophysectomy);

(b) non-surgical techniques (such as feeding modified diets, induction of diabetes, induction of transgene expression);

(c) breeding of genetically altered animals of harmful phenotype;

(d) genetic characterisation using an invasive method (which was not carried out for the purposes of identification/marking of the animal) and where an animal of that genotype is required for the next step.

2.2.4. When the prepared animal is used in the procedure intended for it, the entire procedure, including any preparation (regardless of the location this has taken place) is reported at the end taking into account the severity associated with the preparation. For example, for the breeding of a genetically altered animal and its end use, the reporting shall take into account the severity associated with all the steps (for example, the effect of the phenotype, if expressed; genetic characterisation, if performed; and end use).

2.2.5. The use of an animal is only reported once at the end of the complete procedure including where the preparatory steps described in point 2.2.3 and the end use have been carried out under separate projects.

2.2.6. Where a prepared animal is not subsequently used for a scientific purpose, the establishment in which the animal is killed shall report the preparation as an independent use in the statistics as per the intended purpose, provided that the preparation of the animal has been above the threshold of minimum pain, suffering, distress and lasting harm. However, if this preparation concerns maintenance of a genetically altered animal line, the criteria by which animals are reported are provided for in section B.10.7.

2.2.7. If the animal has been genotyped (genetic characterisation/tissue sampling) as part of a routine verification in a genetically altered breeding colony of an established line to confirm that the genotype has not varied from the intended genetic background and that animal is later used in another procedure, not requiring that particular genotype, that use is considered reuse and all such uses shall be reported separately in the statistics, that is to say:

(a) first use under 'maintenance of the established genetically altered line' with the severity related to the actual severity experienced by the animal as the result of the invasive genotyping, and

(b) as reuse under the specific purpose the animal is used for.

3. **Species other than non-human primate – Place of birth**

Animals born at an authorised breeder in the Union
Animals born in the Union but not at an authorised breeder
Animals born in rest of Europe
Animals born in elsewhere

3.1. Origin is based on the place of birth, that is to say 'born in' and not according to where the animal is supplied from.

3.2. 'Animals born at an authorised breeder in the Union' refers to animals born at breeders authorised and registered under Article 20 of Directive 2010/63/EU.

3.3. 'Animals born in the Union' but not at an authorised breeder includes, amongst others, wild animals, farm animals (unless the breeder is authorised under Article 20 of Directive 2010/63/EU), as well as any exemptions granted under Article 10(3) of Directive 2010/63/EU.

3.4. 'Animals born in the rest of Europe' includes, amongst others, animals born in Switzerland, Turkey, Russia and Israel, and groups together all animals, irrespective of whether they have been bred in registered breeding establishments or other establishments, and includes, amongst others, animals that have been captured in the wild.

3.5. 'Animals born elsewhere' groups together all animals, irrespective of whether they have been bred in registered breeding establishments or other establishments, and includes, amongst others, animals that have been captured in the wild.

4. **Non-human primate (NHP) – Place of birth**

NHP born at an authorised breeder in the Union
NHP born in the Union but not at an authorised breeder, and NHP born in rest of Europe
NHP born in Asia
NHP born in America
NHP born in Africa
NHP born elsewhere

4.1. Origin is based on the place of birth, that is to say 'born in' and not the place where the animal is supplied from.

4.2. 'NHP born at an authorised breeder in the Union' (and Norway) refers to NHP born at breeders as authorised and registered under Article 20 of Directive 2010/63/EU.

4.3. 'NHP born in the Union but not at an authorised breeder, and NHP born in rest of Europe' includes, amongst others, animals born in Switzerland, Turkey, Russia and Israel.

4.4. 'NHP born in Asia' includes, amongst others animals born in China.

4.5. 'NHP born in America' refers to animals born in the North, Central and South America.

4.6. 'NHP born in Africa' includes also animals born in Mauritius.

4.7. 'NHP born elsewhere' includes also animals born in Australasia. The origins of NHP born elsewhere shall be reported.

5. **Non-human primate – Colony type**

Self-sustaining colony (No/Yes)

'Self-sustaining colony' covers non-human primates obtained from colonies in which animals are bred only within the colony or sourced from other self-sustaining colonies but not taken from the wild, and where the animals are kept in a way that ensures that they are accustomed to humans.

6. **Non-human primate – Generation**

F0
F1
F2 or greater

6.1. 'F0' refers to animals that are captured from the wild.

6.2. 'F1' refers to animals that are born in captivity to one, or two parents, that were captured from the wild.

6.3. 'F2 or greater' refers to animals that are born in captivity to parents both of which were themselves born in captivity.

7. **Genetic status**

Not genetically altered
Genetically altered *without* a harmful phenotype
Genetically altered *with* a harmful phenotype

7.1. 'Not genetically altered' refers to all animals that have not been genetically altered, including also genetically normal parent animals used for the creation of a new genetically altered animal line/strain.

7.2. 'Genetically altered without a harmful phenotype' refers to

(a) animals used for the creation of a new line, carrying the genetic alteration but exhibiting no harmful phenotype;

(b) genetically altered animals used in other procedures (not for creation or maintenance) but exhibiting no harmful phenotype.

7.3. 'Genetically altered with a harmful phenotype' refers to

(a) animals used for the creation of a new line and exhibiting a harmful phenotype;

(b) those used for maintaining an established line with an intended harmful phenotype and exhibiting a harmful phenotype;

(c) genetically altered animals used in other procedures (not for creation or maintenance) and exhibiting a harmful phenotype.

8. **Creation of a new genetically altered line**

Animals used for the creation of a new genetically altered line/strain (No/Yes)

Animals used for the creation of a new genetically altered line/strain identifies animals which are used for the creation of a new genetically altered line/strain, separating from other animals used for the purposes of 'basic research' or 'translational and applied research'. This includes the crossing of different lines to create a new genetically altered line where the phenotype of the new line cannot be determined prospectively as non-harmful.

9. **Severity**

Non-recovery
Mild (up to and including)
Moderate
Severe

9.1. Actual severity shall be reported for each animal individually by reference to the most severe effects experienced by that animal during the course of the entire procedure. Those effects can occur during any of the steps (not necessarily the last) of a multi-step procedure. Actual severity may be higher or lower than the classification predicted prospectively. Cumulative suffering shall also be considered when assigning actual severity.

9.2. Severity categories

9.2.1. **Non-recovery** – Animals, which have undergone a procedure that has been performed entirely under general anaesthesia and from which the animals have not recovered consciousness shall be reported as 'Non-recovery'. This also includes the situation where animals have failed to recover consciousness from anaesthesia during the first step of a planned recovery procedure.

9.2.2. **Mild (up to and including)** – Animals, which have undergone a procedure as a result of which the animals have experienced short-term mild pain, suffering or distress shall be reported as 'Mild' This includes situations where there has been no significant impairment of the well-being or general condition of the animals.

This category shall also include animals used in an authorised project, but which have ultimately not been observed to have experienced a level of pain, suffering, distress or lasting harm equivalent to that caused by the introduction of a needle in accordance with good veterinary practice with the exception of animals required for the maintenance of colonies of genetically altered animals of established lines with an intended harmful phenotype and which have not exhibited pain, suffering, distress or lasting harm as a consequence of the harmful genotype.

9.2.3. **Moderate** – Animals, which have undergone a procedure as a result of which the animals have experienced short-term moderate pain, suffering or distress, or long-lasting mild pain, suffering or distress as well as procedures that cause moderate impairment of the well-being or general condition of the animals, shall be reported as 'Moderate'.

9.2.4. **Severe** – Animals, which have undergone a procedure as a result of which the animals have experienced severe pain, suffering or distress, or long-lasting moderate pain, suffering or distress as well as procedures that have caused severe impairment of the well-being or general condition of the animals shall be reported as 'Severe'.

9.2.5. If the 'Severe' classification is exceeded, whether pre-authorised or not, these animals and their use are to be reported as 'Severe'. Commentary shall be added in the 'Member State' narrative in section C of this Annex. In such cases, the following shall be reported: species, numbers, whether prior exemption was authorised, details of the use and reasons why the 'Severe' classification was exceeded.

9.3. Animals found dead

9.3.1. With respect to animals that are found dead, severity shall be determined by reference to whether the death is the result of factors related to the procedure that the animal was undergoing. If not related (such as in the case of death due to deficiencies in equipment or environmental controls; inappropriate husbandry practices; unrelated disease and infections), the actual reported severity shall reflect the most severe effects experienced by that animal during the course of the procedure (excluding the experience preceding the death).

9.3.2. If the death is related to the procedure, the actual reported severity shall be 'severe' unless an informed decision can be made that the severity can be assigned a lesser category.

9.4. Capture and transport of animals taken from the wild

The actual severity shall only relate to the effects of the scientific procedure carried out on that animal. Capture and transport (unless these are the specific, or a component of the, objective of the scientific procedures) shall therefore not be taken into account in the reporting of actual severity, including if the animal dies during capture or transport.

10. **Purposes**

Basic research
Translational and applied research
Regulatory use and routine production
Protection of the natural environment in the interests of the health or welfare of human beings or animals
Preservation of species
Higher education
Training for the acquisition, maintenance or improvement of vocational skills
Forensic enquiries
Maintenance of colonies of established genetically altered animals, not used in other procedures

10.1. Basic research

10.1.1. 'Basic research' refers to studies of a fundamental nature including physiology; studies that are designed to add knowledge about normal and abnormal structure, functioning and behaviour of living organisms and environment, this includes also fundamental studies in toxicology. Investigation and analysis focused on a better or fuller understanding of a subject, phenomenon, or a basic law of nature instead of on a specific practical application of the results.

10.1.2. The animals used for the creation of a new genetically altered animal line (including crossing of two lines) intended to be used for the purposes of basic research (for example, developmental biology, immunology) shall be reported according to the purpose category they are being created for. In addition, they are reported in 'Creation of a new genetic line – Animals used for the creation of a new genetically altered line/strain'.

10.1.3. All animals carrying the genetic alteration shall be reported during the creation of a new line. Also animals used in creation, such as for superovulation, vasectomy and embryo implantation, are reported here. The reporting shall exclude non-genetically altered (wild type) offspring, unless that animal has been genotyped (genetic characterisation/tissue sampling) using an invasive method, which was not carried out for the purposes of identification/marking of the animal.

10.1.4. A new strain or line of genetically altered animals is considered to be 'established' where transmission of the genetic alteration is stable, which will be a minimum of two generations, and a welfare assessment has been completed.

10.2. Translational and applied research

10.2.1. 'Translational and applied research' refer to animals used for purposes as described in Article 5(b) and (c) excluding any regulatory use of animals (see point 10.3. below).

10.2.2. This also includes discovery toxicology and investigations to prepare for the regulatory submission and method development. This does not include studies required for regulatory submissions.

10.2.3. The animals used for the creation of a new genetically altered animal line intended to be used for the purposes of translational or applied research (for example, cancer research, vaccine development) shall be recorded according to the purpose they are being created for. In addition, they shall be reported in 'Creation of a new genetic line – Animals used for the creation of a new genetically altered line/strain'.

10.2.4. All animals carrying the genetic alteration shall be reported during the creation of a new line. Also animals used in creation, such as for superovulation, vasectomy and embryo implantation shall be reported here. The reporting shall exclude non-genetically altered (wild type) offspring.

10.2.5. A new strain or line of genetically altered animals is considered to be 'established' where transmission of the genetic alteration is stable, which will be a minimum of two generations, and a welfare assessment has been completed.

10.3. Regulatory use and Routine production

10.3.1. 'Regulatory use' covers the use of animals in procedures with a view to satisfying regulatory requirements, that is to say for producing, placing and maintaining products/substances on the market, including safety and risk assessment for food and feed.

10.3.2. This includes tests carried out in respect of products/substances for which a regulatory submission was foreseen but ultimately not made, for instance because they were deemed unsuitable for the market by the developer and thus fail to reach the end of the development process.

10.3.3. 'Routine production' includes animals used in the manufacturing process of products such as antibodies and blood based products, for example, animals used in the manufacturing of serum-based medicinal products shall be included within this category.

10.3.4. Efficacy testing during the development of new medicinal products is excluded and shall be reported under category 'Translational and applied research'.

10.4. Protection of the natural environment in the interests of the health or welfare of human beings or animals

10.4.1. This refers to studies aimed at investigating and understanding phenomena such as environmental pollution, loss of biodiversity, and epidemiology studies in wild animals.

10.4.2. This excludes any regulatory use of animals for ecotoxicology purposes.

10.5. Higher education

This refers to animals used for delivering theoretical knowledge within a higher education programme.

10.6. Training for the acquisition, maintenance or improvement of vocational skills

This refers to animals used for training to acquire and maintain practical vocational skills, such as animals used in the training of medical doctors.

10.7. Maintenance of colonies of established genetically altered animals, not used in other procedures

10.7.1. This contains animals required for the maintenance of colonies of genetically altered animals of established lines with an intended harmful phenotype and which have exhibited pain, suffering, distress or lasting harm as a consequence of the harmful genotype. The intended purpose which the line is being bred for is not recorded.

10.7.2. This category also includes genetically altered animals during maintenance of an established line, irrespective of whether the line is of non-harmful or harmful phenotype, and either of the following applies:

(a) the genotype has been *confirmed using an invasive method,* which was not carried out for the purposes of identification/marking of the animal, and the animal is killed without further use;

(b) the animals are of *unsuitable genotype, confirmed using an invasive method,* which was not carried out for the purposes of identification/marking of the animal.

10.7.3. This category also includes re-derivation where it is done solely for scientific purposes (that is to say not to benefit health/welfare of colony) during maintenance of an established line, and animals used for embryo transfer and vasectomy.

10.7.4. This excludes all animals needed for the creation of a new genetically altered line and those used in other procedures (that is to say other than creation/maintenance).

11. **Basic research studies**

Oncology
Cardiovascular Blood and Lymphatic System
Nervous System
Respiratory System
Gastrointestinal System including Liver
Musculoskeletal System
Immune System
Urogenital/Reproductive System
Sensory Organs (skin, eyes and ears)
Endocrine System/Metabolism
Developmental Biology
Multisystemic
Ethology/Animal Behaviour/Animal Biology
Other Basic Research

11.1. Oncology

Any research studying oncology shall be included here regardless of the target system.

11.2. Nervous system

This category includes, amongst others, neuroscience, peripheral or central nervous system, psychology.

11.3. Musculoskeletal System

This category includes, amongst others, dentistry.

11.4. Sensory Organs (skin, eyes and ears)

Studies on nose shall be reported under 'Respiratory System' and those on tongue under 'Gastrointestinal System including Liver'.

11.5. Developmental Biology covers studies of changes associated with an organism from embryogenesis (when not carried out as part of reproductive toxicity study), to growth, aging and death, and includes, amongst others, cell differentiation, tissue differentiation and organogenesis.

11.6. Multisystemic

This shall only include research where more than one system is the primary interest, such as on some infectious diseases, and excluding oncology.

11.7. 'Ethology/Animal Behaviour/Animal Biology' category covers both animals in the wild and in captivity with the primary goal of learning more about that specific species.

11.8. Other Basic Research

11.8.1. Research that is not related to an organ/system listed above or is not organ/system specific.

11.8.2. Particular attention needs to be paid before using category 'other' to ensure that none of the pre-defined categories could be used.

11.9. Remarks

11.9.1. Animals used for the production and maintenance of infectious agents, vectors (for example, arthropod feeding) and neoplasms, animals used for other biological material and animals used for the production of antibodies for the purposes of research, but excluding the growth of hybridoma cells by ascites method in the production of monoclonal antibodies (which is covered under category 'Regulatory use and Routine production by product type'), shall be reported in the respective categories under 'Basic research' studies.

11.9.2. Where more than one category applies to the purpose of the animal use, only the main purpose shall be reported.

12. **Translational and applied research**

Human Cancer
Human Infectious Disorders
Human Cardiovascular Disorders
Human Nervous and Mental Disorders
Human Respiratory Disorders
Human Gastrointestinal Disorders including Liver
Human Musculoskeletal Disorders
Human Immune Disorders
Human Urogenital/Reproductive Disorders
Human Sensory Organ Disorders (skin, eyes and ears)
Human Endocrine/Metabolism Disorders
Other Human Disorders
Animal Diseases and Disorders
Animal Nutrition
Animal Welfare
Diagnosis of Diseases
Plant Diseases
Non-regulatory Toxicology and Ecotoxicology

12.1. Any applied research on human cancer shall be included in category 'Human cancer' regardless of the target system.

12.2. Any applied research on human infectious disorders shall be included in 'Human Infectious Disorders' regardless of the target system.

12.3. Any regulatory use of animals, such as regulatory carcinogenicity studies, shall be excluded from category 'Translational and applied research' and reported under category 'Regulatory use and routine production'.

12.4. Studies on disorders of the nose shall be reported under 'Human Respiratory Disorders' and those of the tongue shall be reported under 'Human Gastrointestinal Disorders including Liver'.

12.5. Particular attention shall be paid before using category 'Other Human Disorders' to ensure that none of the pre-defined categories should be used instead.

12.6. 'Diagnosis of Diseases' includes, amongst others, animals used in direct diagnosis of diseases such as rabies, botulism, but excluding those covered under regulatory use.

12.7. 'Non-regulatory Toxicology and Ecotoxicology' refers to discovery toxicology and investigations to prepare for the regulatory submission and method development. This category does not include studies required for regulatory submissions (preliminary studies, MTD (Maximum Tolerated Dose)). Dose-range-finding (DRF) studies, when carried out with a view to satisfying legislative requirements, are also excluded and covered in 'Regulatory use and routine production' under 'Other efficacy and tolerance testing'.

12.8. 'Animal welfare' refers to studies as per Article 5(b)(iii) of Directive 2010/63/EU.

12.9. Remarks

12.9.1. Animals used for the production and maintenance of infectious agents, vectors (for example, arthropod feeding) and neoplasms, animals used for other biological material and animals used for the production of antibodies for the purposes of translational and applied research, but excluding the growth of hybridoma cells by ascites method in the production of monoclonal antibodies (which is covered under category 'Regulatory use and routine production by type') shall be reported in the respective categories under 'Translational and applied research'.

12.9.2. Where more than one category applies to the purpose of the animal use, only the main purpose shall be reported.

13. **Regulatory use and Routine production**

Quality control (including batch safety and potency testing)
Other efficacy and tolerance testing
Toxicity and other safety testing including pharmacology
Routine production by product type

13.1. Efficacy testing during the development of new medicinal product is excluded and shall be reported under category 'Translational and Applied research'.

13.2. Quality control refers to animals used in the testing of purity, stability, efficacy, potency and other quality control parameters of the final product and its constituents and any controls carried out during the manufacturing process for registration purposes, to satisfy any other national or international regulatory requirements or to satisfy the in-house policy of the manufacturer. This includes, amongst others, pyrogenicity testing.

13.3. Other efficacy and tolerance testing

Efficacy testing of biocides and pesticides is covered under this category as well as the tolerance testing of additives in animal nutrition. This covers also dose-range-finding studies when carried out with a view to satisfying legislative requirements.

13.4. Toxicity and other safety testing (including safety evaluation of products and devices for human medicine and dentistry and veterinary medicine)

13.4.1. This covers studies carried out on any product or substance to determine its potential to cause any dangerous or undesirable effects in humans or animals as a result of its intended or abnormal use, manufacture or as a potential or actual contaminant in the environment.

13.4.2. Where studies involve both mother and offspring, the mother shall be reported if she has been subject to a procedure above the threshold of minimum pain, suffering, distress and lasting harm. Offspring shall be reported if they are an integral part of the procedure such as in the case of end-points for reproduction.

13.5. Routine production by product type

13.5.1. This covers the production of antibodies and blood products by established methods. This excludes immunisation of animals for subsequent hybridoma production carried out for the purposes of basic or applied and translational research within a given project, which shall be captured under basic or applied research under the appropriate category.

13.5.2. The use of animals for antibody production for commercial purposes, including immunisation for the subsequent hybridoma production, shall be reported under 'Routine production'/'Monoclonal and polyclonal antibodies (excluding ascites method)'. All use of the ascites method for the culture of monoclonal antibodies shall be reported under 'Routine production'/'Monoclonal antibodies by ascites method only'.

14. **Quality control (including batch safety and potency testing)**

Batch safety testing
Pyrogenicity testing
Batch potency testing
Other quality controls

Batch safety testing excludes pyrogenicity testing which shall be reported separately under 'Pyrogenicity testing'.

15. **Toxicity and other safety testing by test type**

Acute (single dose) toxicity testing methods (including limit test)
Skin irritation/corrosion
Skin sensitisation
Eye irritation/corrosion
Repeated dose toxicity
Carcinogenicity
Genotoxicity
Reproductive toxicity
Developmental toxicity
Neurotoxicity
Kinetics (pharmacokinetics, toxicokinetics, residue depletion)
Pharmaco-dynamics (including safety pharmacology)
Phototoxicity
Ecotoxicity
Safety testing in food and feed area
Target animal safety
Combined end-points
Other toxicity or safety testing

15.1. 'Repeated dose toxicity' includes also immunotoxicological studies.

15.2. 'Reproductive toxicity' includes, amongst others, extended one-generation reproductive toxicity studies, also when including cohorts for developmental neuro- and immunotoxicity.

15.3. 'Developmental toxicity' includes also developmental neurotoxicity studies. Extended one-generation reproductive toxicity studies including cohort for developmental neurotoxicity shall be reported under reproductive toxicity.

15.4. 'Neurotoxicity' includes, amongst others, acute delayed effects (for example, delayed neurotoxicity of organophosphorus substances following acute exposure) and repeated dose studies for the purposes of neurotoxicity, but excludes developmental neurotoxicity. Extended one-generation reproductive toxicity studies including cohort for developmental neurotoxicity shall be reported under reproductive toxicity.

15.5. 'Kinetics' refers to pharmacokinetics, toxicokinetics and residue depletion. However, if testing for toxicokinetics is performed as part of the regulatory repeated dose toxicity study, it shall be reported under repeated dose toxicity.

15.6. 'Safety testing in the food and feed area' includes also testing of drinking water (including target animal safety testing).

15.7. 'Target animal safety' testing ensures that a product for a specific animal can be used safely on that species (excluding batch safety testing which is covered under quality control).

15.8. 'Combined end-points' include, amongst others, combination of carcinogenicity and chronic toxicity study, screening studies combining reproductive toxicity and repeated dose toxicity.

16. **Acute toxicity testing methods**

LD50, LC50
Other lethal methods
Non-lethal methods

16.1. The sub-category shall be reported on the basis of the type of method used and not on the basis of the level of severity experienced by the animal as a result of that method.

16.2. 'LD50, LC50' refer only to test methods that provide a point estimate for LD50/LC50 such as OECD test guidelines 203, 403 and 425.

16.3. 'Other lethal methods' refers to those methods that categorise substances in a class, that is to say, methods involving assignment of a range in which LD50 would fall, such as fixed dose methods and acute toxic class methods. It is likely that a number of deaths will occur but not as many as those expected in LD50-type methods.

17. **Repeated dose toxicity**

28 days or less
29 – 90 days
more than 90 days

18. **Ecotoxicity**

Acute toxicity (ecotoxicity)
Chronic toxicity (ecotoxicity)
Reproductive toxicity (ecotoxicity)
Endocrine activity (ecotoxicity)
Bioaccumulation (ecotoxicity)
Other ecotoxicity

18.1. Ecotoxicity refers to toxicity relating to the aquatic and terrestrial environment.

18.2. Ecotoxicity studies addressing short-term toxicity to determine LC/LD50 shall be reported under 'acute toxicity (ecotoxicity)'.

18.3. Ecotoxicity studies addressing long-term toxicity, for example, early life cycle test or full life cycle tests, shall be reported under 'chronic toxicity (ecotoxicity)'.

18.4. Ecotoxicity studies carried out to primarily assess endocrine properties of substances and addressing, for example, amphibian metamorphosis, development and growth, fish sexual development and reproduction, shall be reported under 'endocrine activity (ecotoxicity)'.

19. **Type of legislation**

Legislation on medicinal products for human use
Legislation on medicinal products for veterinary use and their residues
Medical devices legislation
Industrial chemicals legislation
Plant protection product legislation
Biocides legislation
Food legislation including food contact material
Feed legislation including legislation for the safety of target animals, workers and environment
Cosmetics legislation
Other legislation

19.1. The type of legislation shall not be reported for animals whose use falls within the category 'Routine production'.

19.2. The type of legislation shall be reported by reference to the intended primary use.

19.3. Testing of the quality of water, other than waste water, shall be reported under 'Food legislation'. Quality testing of waste water shall be reported under 'Other legislation'.

20. **Origin of legislation**

Legislation satisfying Union requirements
Legislation satisfying national requirements only (within Union)
Legislation satisfying Non-Union requirements only

20.1. The origin of legislation shall not be reported for animals whose use falls within the category 'Routine production'.

20.2. The use shall be reported in reference to the region for which the test is being carried out, not where it is carried out.

20.3. Where national legislation is derived from Union legislation, the use shall be reported under 'Legislation satisfying Union requirements'.

20.4. 'Legislation satisfying Union requirements' also includes any international requirement, which at the same time satisfies Union requirements (such as testing to ICH ([1]), VICH ([2]), OECD guidelines, European Pharmacopoeia monographs).

20.5. Where the test is carried out to satisfy the legislation of one or more Member States (not necessarily the one in which the test is being carried out), and the requirement is not derived from Union law, the use shall be reported under 'Legislation satisfying national requirements only (within Union)'.

20.6. Legislation satisfying Non-Union requirements is to be chosen only where there is no equivalent requirement to carry out the test to satisfy Union legislation.

21. **Routine production by product type**

Blood based products
Monoclonal antibodies by ascites method only
Monoclonal and polyclonal antibodies (excluding ascites method)
Other products

21.1. Routine production by product type covers the production of antibodies and blood products using established methods. This excludes immunisation of animals for subsequent hybridoma production when carried out for the purposes of basic or applied research within a given project. That immunisation shall be captured under basic or applied research under the appropriate category.

21.2. All use of the ascites method for the culture of monoclonal antibodies shall be reported under 'Monoclonal antibodies by ascites method only'.

21.3. The use of animals for antibody production for commercial purposes, including immunisation for the subsequent hybridoma production, shall be reported under 'Monoclonal and polyclonal antibodies (excluding ascites method)'.

C. MEMBER STATE NARRATIVE

1. Member States shall provide a narrative on the statistical data. That narrative shall contain the following:

(a) general information on any changes in trends observed since the previous reporting period;

([1]) The International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use
([2]) The International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products

(b) information on significant increase or decrease in use of animals in any of the specific areas and analysis of the reasons thereof;

(c) information on any changes in trends in actual severities and analysis of the reasons thereof;

(d) information on particular efforts to promote the principle of replacement, reduction and refinement and its impacts on statistics if any;

(e) further breakdown on the use of 'other' categories if a significant proportion of animal use is reported under this category;

(f) information on the uses of animals in categories where a method or testing strategy for obtaining the results sought, not entailing the use of live animals, is recognised under the legislation of the Union;

(g) details on cases where the 'severe' classification is exceeded, whether pre-authorised or not.

2. For the purposes of point 1(g), the following shall be reported:

(a) species;

(b) numbers of animals;

(c) whether exceeding the 'severe' classification was pre-authorised or not;

(d) details of the use;

(e) reasons why the 'severe' classification was exceeded.

ANNEX IV

TEMPLATE FOR THE SUBMISSION OF THE INFORMATION REFERRED TO IN ARTICLE 54(3) OF DIRECTIVE 2010/63/EU

Member State: Year:

Type of method	Species	Justification

ANNEX V

CORRELATION TABLE

Implementing Decision 2012/707/EU	This Decision
Article 1	Article 2
Article 2	Article 3
Article 3	Article 4
Article 4	Article 6
ANNEX I	ANNEX II
ANNEX II	ANNEX III
ANNEX III	ANNEX IV

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