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[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.

EN

[1] Text with EEA relevance

II

(Non-legislative acts)

REGULATIONS

COMMISSION IMPLEMENTING REGULATION (EU) No 27/2014

of 19 December 2013

entering a name in the register of protected designations of origin and protected geographical indications [Anglesey Sea Salt/Halen Môn (PDO)]

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) No 1151/2012 of the European Parliament and of the Council of 21 November 2012 on quality schemes for agricultural products and foodstuffs [1], and in particular Article 52(2) thereof,

Whereas:

(1) Pursuant to Article 50(2)(a) of Regulation (EU) No 1151/2012, the United Kingdom's application to register the name 'Anglesey Sea Salt/Halen Môn' was published in the *Official Journal of the European Union* [2].

(2) As no statement of opposition under Article 51 of Regulation (EU) No 1151/2012 has been received by the Commission, that name should therefore be entered in the register,

HAS ADOPTED THIS REGULATION:

Article 1

The name contained in the Annex to this Regulation is hereby entered in the register.

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, 19 December 2013.

For the Commission,
On behalf of the President,
Dacian CIOLOŞ
Member of the Commission

[1] OJ L 343, 14.12.2012, p. 1.
[2] OJ C 232, 10.8.2013, p. 17.

ANNEX

Agricultural products intended for human consumption listed in Annex I to the Treaty:

Class 1.8 other products of Annex I to the Treaty (spices, etc.)

UNITED KINGDOM

Anglesey Sea Salt/Halen Môn (PDO)

COMMISSION IMPLEMENTING REGULATION (EU) No 28/2014

of 19 December 2013

entering a name in the register of protected designations of origin and protected geographical indications [West Country Lamb (PGI)]

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) No 1151/2012 of the European Parliament and of the Council of 21 November 2012 on quality schemes for agricultural products and foodstuffs [1], and in particular Article 52(2) thereof,

Whereas:

(1) Pursuant to Article 50(2)(a) of Regulation (EU) No 1151/2012, the United Kingdom's application to register the name 'West Country Lamb' was published in the *Official Journal of the European Union* [2].

(2) As no statement of opposition under Article 51 of Regulation (EU) No 1151/2012 has been received by the Commission, that name should therefore be entered in the register,

HAS ADOPTED THIS REGULATION:

Article 1

The name contained in the Annex to this Regulation is hereby entered in the register.

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, 19 December 2013.

For the Commission,
On behalf of the President,
Dacian CIOLOȘ
Member of the Commission

[1] OJ L 343, 14.12.2012, p. 1.
[2] OJ C 231, 9.8.2013, p. 9.

ANNEX

Agricultural products intended for human consumption listed in Annex I to the Treaty:

Class 1.1. Fresh meat (and offal)

UNITED KINGDOM

West Country Lamb (PGI)

COMMISSION IMPLEMENTING REGULATION (EU) No 29/2014

of 19 December 2013

entering a name in the register of protected designations of origin and protected geographical indications [West Country Beef (PGI)]

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) No 1151/2012 of the European Parliament and of the Council of 21 November 2012 on quality schemes for agricultural products and foodstuffs [1], and in particular Article 52(2) thereof,

Whereas:

(1) Pursuant to Article 50(2)(a) of Regulation (EU) No 1151/2012, the United Kingdom's application to register the name 'West Country Beef' was published in the *Official Journal of the European Union* [2].

(2) As no statement of opposition under Article 51 of Regulation (EU) No 1151/2012 has been received by the Commission, that name should therefore be entered in the register,

HAS ADOPTED THIS REGULATION:

Article 1

The name contained in the Annex to this Regulation is hereby entered in the register.

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, 19 December 2013.

For the Commission,
On behalf of the President,
Dacian CIOLOȘ
Member of the Commission

[1] OJ L 343, 14.12.2012, p. 1.
[2] OJ C 231, 9.8.2013, p. 14.

ANNEX

Agricultural products intended for human consumption listed in Annex I to the Treaty:

Class 1.1. Fresh meat (and offal)

UNITED KINGDOM

West Country Beef (PGI)

COMMISSION IMPLEMENTING REGULATION (EU) No 30/2014

of 13 January 2014

approving non-minor amendments to the specification for a name entered in the register of protected designations of origin and protected geographical indications [Κονσερβολιά Ροβιών (Konservolia Rovion) (PDO)]

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) No 1151/2012 of the European Parliament and of the Council of 21 November 2012 on quality schemes for agricultural products and foodstuffs [1], and in particular Article 52(2) thereof,

Whereas:

(1) Pursuant to the first subparagraph of Article 53(1) of Regulation (EU) No 1151/2012, the Commission has examined Greece's application for the approval of amendments to the specification for the protected designation of origin 'Κονσερβολιά Ροβιών' (Konservolia Rovion), registered under Commission Regulation (EC) No 1263/96 [2].

(2) Since the amendments in question are not minor within the meaning of Article 53(2) of Regulation (EU) No 1151/2012, the Commission published the amendment application in the *Official Journal of the European Union* [3] as required by Article 50(2)(a) of that Regulation.

(3) As no statement of opposition under Article 51 of Regulation (EU) No 1151/2012 has been received by the Commission, the amendments to the specification should be approved,

HAS ADOPTED THIS REGULATION:

Article 1

The amendments to the specification published in the *Official Journal of the European Union* regarding the name contained in the Annex to this Regulation are hereby approved.

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, 13 January 2014.

For the Commission,
On behalf of the President,
Dacian CIOLOȘ
Member of the Commission

[1] OJ L 343, 14.12.2012, p. 1.
[2] OJ L 163, 2.7.1996, p. 19.
[3] OJ C 228, 7.8.2013, p. 30.

ANNEX

Agricultural products intended for human consumption listed in Annex I to the Treaty:

Class 1.6. Fruit, vegetables and cereals, fresh or processed

GREECE

Κονσερβολιά Ροβιών (Konservolia Rovion) (PDO)

COMMISSION REGULATION (EU) No 31/2014

of 14 January 2014

repealing Decisions 2004/301/EC, 2004/539/EC and Regulation (EU) No 388/2010

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EC) No 998/2003 of the European Parliament and of the Council of 26 May 2003 on the animal health requirements applicable to the non-commercial movement of pet animals and amending Council Directive 92/65/EEC [1], and in particular Articles 19 and 21 thereof,

Whereas:

(1) Regulation (EC) No 998/2003 lays down the animal health requirements applicable to the non-commercial movement of pet animals and the rules applying to checks on such movements. It applies to movements between Member States or from third countries of pet animals of the species listed in Annex I thereto. Dogs, cats and ferrets are listed in Parts A and B of that Annex. Regulation (EC) No 998/2003 has applied since 3 July 2004.

(2) Commission Decision 2003/803/EC of 26 November 2003 establishing a model passport for the intra-Community movements of dogs, cats and ferrets [2] lays down the model passport for the movement of pet animals of the species dogs, cats and ferrets between Member States as provided for in Article 5(1)(b) of Regulation (EC) No 998/2003.

(3) In order to facilitate the transition to the arrangements of Regulation (EC) No 998/2003, Commission Decision 2004/301/EC of 30 March 2004 derogating from Decisions 2003/803/EC and 2004/203/EC as regards the format for certificates and passports for the non-commercial movement of dogs, cats and ferrets and amending Decision 2004/203/EC [3] was adopted, in order for certificates and passports issued for pet animals prior to the date of application of Regulation (EC) No 998/2003 to continue to be used, provided they complied with certain conditions.

(4) In addition, Commission Decision 2004/539/EC of 1 July 2004 establishing a transitional measure for the implementation of Regulation (EC) No 998/2003 on the animal health requirements applicable to the non-commercial movement of pet animals [4] provides that Member States were to allow entry into their territory until 1 October 2004 of pet animals of the species listed in Annex I to Regulation (EC) No 998/2003 in conformity with national rules which were in force before 3 July 2004.

(5) Regulation (EU) No 576/2013 of the European Parliament and of the Council of 12 June 2013 on the non-commercial movement of pet animals and repealing Regulation (EC) No 998/2003 [5] repeals and replaces Regulation (EC) No 998/2003. Measures adopted to facilitate the transition to the arrangements of Regulation (EC) No 998/2003 are therefore obsolete. Decisions 2004/301/EC and 2004/539/EC should therefore be repealed.

(6) In addition, Commission Regulation (EU) No 388/2010 of 6 May 2010 implementing Regulation (EC) No 998/2003 of the European Parliament and of the Council as regards the maximum number of pet animals of certain species that may be the subject of non-commercial movement [6] was adopted in order to avoid the risk of commercial movements of dogs, cats and ferrets being fraudulently disguised as non-commercial movements, when those animals are moved into a Member State from another Member State or a third country listed in Section 2 of Part B of Annex II to Regulation (EC) No 998/2003.

[1] OJ L 146, 13.6.2003, p. 1.
[2] OJ L 312, 27.11.2003, p. 1.
[3] OJ L 98, 2.4.2004, p. 55.
[4] OJ L 237, 8.7.2004, p. 21.
[5] OJ L 178, 28.6.2013, p. 1.
[6] OJ L 114, 7.5.2010, p. 3.

(7) The provisions of Regulation (EU) No 388/2010 have been reviewed and included in Regulation (EU) No 576/2013. Regulation (EU) No 576/2013 applies from 29 December 2014. Regulation (EU) No 388/2010 therefore becomes obsolete on the date of application of Regulation (EU) No 576/2013 and should therefore be repealed with effect from that date.

(8) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health and neither the European Parliament nor the Council has opposed them,

HAS ADOPTED THIS REGULATION:

Article 1

Decisions 2004/301/EC and 2004/539/EC are repealed.

Article 2

Regulation (EU) No 388/2010 is repealed with effect from 29 December 2014.

Article 3

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, 14 January 2014.

For the Commission
The President
José Manuel BARROSO

COMMISSION REGULATION (EU) No 32/2014

of 14 January 2014

initiating a 'new exporter' review of Council Implementing Regulation (EU) No 1008/2011 imposing a definitive anti-dumping duty on imports of hand pallet trucks and their essential parts originating in the People's Republic of China as amended by Council Implementing Regulation (EU) No 372/2013, repealing the duty with regard to imports of one exporter in this country and making such imports subject to registration

THE EUROPEAN COMMISSION,

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

Having regard to Council Regulation (EC) No 1225/2009 of 30 November 2009 on protection against dumped imports from countries not members of the European Community ('the basic Regulation') [1] and in particular Article 11(4) thereof,

After having consulted the Advisory Committee in accordance with Articles 11(4) and 14(5) of the basic Regulation,

Whereas:

A. **REQUEST**

(1) The European Commission ('the Commission') has received a request for a 'new exporter' review under Article 11(4) of the basic Regulation.

(2) The request was lodged on 3 May 2013 by Ningbo Logitrans Handling Equipment Co., Ltd ('the applicant'), an exporting producer of hand pallet trucks and their essential parts in the People's Republic of China ('the country concerned').

B. **PRODUCT**

(3) The product under review is hand pallet trucks and their essential parts, i.e. chassis and hydraulics, currently falling within CN codes ex 8427 90 00 (TARIC codes 8427 90 00 11 and 8427 90 00 19) and ex 8431 20 00 (TARIC codes 8431 20 00 11 and 8431 20 00 19) and originating in the People's Republic of China.

C. **EXISTING MEASURES**

(4) The measures currently in force are a definitive anti-dumping duty imposed by Council Implementing Regulation (EU) No 1008/2011 [2] as amended by Council Implementing Regulation (EU) No 372/2013 [3], under which imports into the Union of the product under review, including the product produced by the applicant, are subject to a definitive anti-dumping duty of 70,8 %. The measures are also applicable to imports of hand pallet trucks and their essential parts consigned from Thailand whether declared as originating in Thailand or not pursuant to Council Regulation (EC) No 499/2009 [4].

D. **GROUNDS**

(5) The applicant claims that it operates under market economy conditions as defined in Article 2(7)(c) of the basic Regulation.

(6) It further claims that it did not export the product under review to the Union during the investigation period on which the anti-dumping measures were based, i.e. the period from 1 April 2003 to 31 March 2004 ('the original investigation period').

(7) Furthermore, the applicant claims that it is not related to any of the exporting producers of the product under review which are subject to the above-mentioned anti-dumping measures.

(8) The applicant further claims that it has begun exporting the product under review to the Union after the end of the original investigation period.

E. **PROCEDURE**

(9) Having examined the evidence available, the Commission concludes that there is sufficient evidence to justify the initiation of a 'new exporter' review, pursuant to Article 11(4) of the basic Regulation, with a view to determine the applicant's individual margin of dumping and, should dumping be found, the level of the duty to which its imports of the product under review into the Union shall be subject. Upon receipt of the claim for market economy treatment, it will be determined whether the applicant operates under market economy conditions as defined in Article 2(7)(c) of the basic Regulation.

[1] OJ L 343, 22.12.2009, p. 51.
[2] OJ L 268, 13.10.2011, p. 1.
[3] OJ L 112, 24.4.2013, p. 1.
[4] OJ L 151, 16.6.2009, p. 1.

(10) If it is determined that the applicant fulfils the requirements to have an individual duty established, it may be necessary to amend the rate of duty currently applicable under Article 1(2) of Implementing Regulation (EU) No 1008/2011 as amended by Implementing Regulation (EU) No 372/2013.

(a) *Questionnaires*

(11) In order to obtain information it deems necessary for its investigation, the Commission will send a questionnaire to the applicant.

(b) *Collection of information and holding of hearings*

(12) All interested parties are hereby invited to make their views known in writing and to provide supporting evidence.

(13) Union producers known to be concerned have been informed of the request for a review and have been given an opportunity to comment.

(14) Furthermore, the Commission may hear interested parties, provided that they make a request in writing showing that there are particular reasons why they should be heard.

(c) *Market economy treatment*

(15) If the applicant provides sufficient evidence that it operates under market economy conditions, i.e. that it meets the criteria laid down in Article 2(7)(c) of the basic Regulation, normal value will be determined in accordance with Article 2(7)(b) of the basic Regulation. For this purpose, duly substantiated claims must be submitted within the specific time limit set in Article 4 of this Regulation. The Commission will send a claim form to the applicant, as well as to the authorities of the People's Republic of China.

(d) *Selection of the market economy country*

(16) If the applicant is not granted market economy treatment, an appropriate market economy country will be used for the purpose of establishing normal value for the People's Republic of China in accordance with Article 2(7)(a) of the basic Regulation. The Commission envisages using Brazil for this purpose as was done in the investigation which led to the imposition of measures on imports from the People's Republic of China. Interested parties are invited to comment on the appropriateness of this choice within the specific time limit set in Article 4 of this Regulation.

(17) If the applicant is granted market economy treatment but reliable required data are not available in the People's Republic of China, the Commission may, if necessary, also use findings concerning the normal value established in an appropriate market-economy country, e.g. for the purpose of replacing any unreliable cost or price elements in the People's Republic of China which are needed in establishing the normal value. The Commission envisages using Brazil also for this purpose.

F. **REPEAL OF THE DUTY IN FORCE AND REGISTRATION OF IMPORTS**

(18) Pursuant to Article 11(4) of the basic Regulation, the anti-dumping duty in force should be repealed with regard to imports of the product under review which are produced and sold for export to the Union by the applicant. At the same time, such imports should be made subject to registration in accordance with Article 14(5) of the basic Regulation, in order to ensure that, should the review result in a finding of dumping in respect of the applicant, anti-dumping duties can be levied from the date of the registration of these imports. The amount of the applicant's possible future liabilities cannot be estimated at this stage of the investigation.

G. **TIME LIMITS**

(19) In the interest of sound administration, time limits should be stated within which:

— interested parties may make themselves known to the Commission, present their views in writing and submit any information to be taken into account during the investigation,

— interested parties may make a written request to be heard by the Commission,

— interested parties may comment on the appropriateness of the use of Brazil as explained in recitals 16 and 17 above,

— the applicant should submit a duly substantiated claim for market economy treatment.

(20) Attention is drawn to the fact that the exercise of most procedural rights set out in the basic Regulation depends on the party's making itself known within the time limits indicated in Article 4 of this Regulation.

H. **NON-COOPERATION**

(21) In cases in which any interested party refuses access to or does not provide the necessary information within the time limits, or significantly impedes the investigation, findings, affirmative or negative, may be made in accordance with Article 18 of the basic Regulation, on the basis of the facts available.

(22) If an interested party has supplied false or misleading information, the information shall be disregarded and use may be made of facts available.

(23) If an interested party does not cooperate or cooperates only partially and findings are therefore based on the facts available in accordance with Article 18 of the basic Regulation, the result may be less favourable to that party than if it had cooperated.

(24) Failure to give a computerised response shall not be deemed to constitute non-cooperation, provided that the interested party shows that presenting the response as requested would result in an unreasonable extra burden or unreasonable additional cost. The interested party should immediately contact the Commission.

I. **SCHEDULE OF THE INVESTIGATION**

(25) The investigation will be concluded, pursuant to Article 11(5) of the basic Regulation, within nine months of the date of the publication of this Regulation in the *Official Journal of the European Union*.

J. **PROCESSING OF PERSONAL DATA**

(26) It is noted that any personal data collected in this investigation will be treated in accordance with Regulation (EC) No 45/2001 of the European Parliament and of the Council of 18 December 2000 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data [1].

K. **HEARING OFFICER**

(27) Interested parties may request the intervention of the Hearing Officer of the Directorate-General for Trade. The Hearing Officer acts as an interface between the interested parties and the Commission investigation services. The Hearing Officer reviews requests for access to the file, disputes regarding the confidentiality of documents, requests for extension of time limits and requests by third parties to be heard. The Hearing Officer may organise a hearing with an individual interested party and mediate to ensure that the interested party's rights of defence are being fully exercised. The Hearing Officer will provide opportunities for a hearing involving parties which would allow different views to be presented and rebuttal arguments offered.

(28) A request for a hearing with the Hearing Officer should be made in writing within the specific deadlines set by the Commission in its communication with the parties. The party should specify the reasons for the request.

(29) For further information and contact details interested parties may consult the Hearing Officer's web pages on the Directorate-General for Trade's website: http://ec.europa.eu/commission_2010-2014/degucht/contact/hearing-officer/

HAS ADOPTED THIS REGULATION:

Article 1

A review of Implementing Regulation (EU) No 1008/2011 as amended by Implementing Regulation (EU) No 372/2013 is hereby initiated under Article 11(4) of Regulation (EC) No 1225/2009 in order to determine if and to what extent the imports of hand pallet trucks and their essential parts, currently falling within CN codes ex 8427 90 00 (TARIC codes 8427 90 00 11 and 8427 90 00 19) and ex 8431 20 00 (TARIC codes 8431 20 00 11 and 8431 20 00 19) and originating in the People's Republic of China, produced and sold for export to the Union by Ningbo Logitrans Handling Equipment Co., Ltd (TARIC additional code A070) should be subject to the anti-dumping duty imposed by Implementing Regulation (EU) No 1008/2011 as amended by Implementing Regulation (EU) No 372/2013 or that an individual anti-dumping duty should be imposed.

For the purpose of this Regulation, hand pallet trucks shall be trucks with wheels supporting lifting fork arms for handling pallets, designed to be manually pushed, pulled and steered, on smooth, level, hard surfaces, by a pedestrian operator using an articulated tiller. The hand pallet trucks are only designed to raise a load, by pumping the tiller, to a height sufficient for transporting and do not have any other additional functions or uses such as for example (i) to move and to lift the loads in order to place them higher or assist in storage of loads (highlifters); (ii) to stack one pallet above the other (stackers); (iii) to lift the load to a working level (scissorlifts); or (iv) to lift and to weigh the loads (weighing trucks).

Article 2

The anti-dumping duty imposed by Implementing Regulation (EU) No 1008/2011 as amended by Implementing Regulation (EU) No 372/2013 is hereby repealed with regard to the imports identified in Article 1 of the present Regulation.

[1] OJ L 8, 12.1.2001, p. 1.

Article 3

The Customs authorities shall, pursuant to Article 11(4) and Article 14(5) of Regulation (EC) No 1225/2009, take the appropriate steps to register the imports into the Union identified in Article 1 of this Regulation.

Registration shall expire nine months following the date of entry into force of this Regulation.

Article 4

1. Interested parties, if their representations are to be taken into account during the investigation, must make themselves known by contacting the Commission, present their views in writing and submit a reply to the questionnaire indicated in recital (12) of this Regulation or any information to be taken into account within 37 days from the date of entry into force of this Regulation, unless otherwise specified.

2. Interested parties may also apply to be heard by the Commission within the same 37-day time-limit.

3. A duly substantiated claim for market economy treatment must reach the Commission within 37 days of the date of the entry into force of this Regulation.

4. Parties to the investigation wanting to comment on the appropriateness of Brazil, which is envisaged as a market economy third country, must submit their comments within 10 days of the date of entry into force of this Regulation.

5. All written submissions, including the information requested in this Regulation, completed questionnaires and correspondence provided by interested parties for which confidential treatment is requested shall be labelled 'Limited' [1].

6. Interested parties providing 'Limited' information are required to furnish non-confidential summaries of it pursuant to Article 19(2) of the basic Regulation, which will be labelled 'For inspection by interested parties'. These summaries should be sufficiently detailed to permit a reasonable understanding of the substance of the information submitted in confidence. If an interested party providing confidential information does not furnish a non-confidential summary of it in the requested format and quality, such confidential information may be disregarded.

7. Interested parties are required to make all submissions and requests in electronic format (non-confidential submissions via e-mail, confidential ones on CD-R/DVD), and must indicate their name, address, e-mail address, telephone and fax numbers. However, any Powers of Attorney, signed certifications, and any updates thereof, accompanying MET claim forms or questionnaire replies must be submitted on paper, i.e. by post or by hand, at the address below. For further information concerning correspondence with the Commission, interested parties may consult the relevant web page on the website of the Directorate-General for Trade: http://ec.europa.eu/trade/tackling-unfair-trade/trade-defence

Commission address for correspondence:

European Commission
Directorate-General for Trade
Directorate H
Office: N105 08/020
1049 Bruxelles/Brussel
BELGIQUE/BELGIË

E-mail: TRADE-HPT-DUMPING@ec.europa.eu

Article 5

This Regulation shall enter into force on the 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, 14 January 2014.

For the Commission
The President
José Manuel BARROSO

[1] A 'Limited' document is a document which is considered confidential pursuant to Article 19 of Council Regulation (EC) No 1225/2009 (OJ L 343, 22.12.2009, p. 51) and Article 6 of the WTO Agreement on Implementation of Article VI of the GATT 1994 (Anti-Dumping Agreement). It is also a document protected pursuant to Article 4 of Regulation (EC) No 1049/2001 of the European Parliament and of the Council (OJ L 145, 31.5.2001, p. 43).

COMMISSION IMPLEMENTING REGULATION (EU) No 33/2014

of 14 January 2014

establishing the standard import values for determining the entry price of certain fruit and vegetables

THE EUROPEAN COMMISSION,

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

Having regard to Council Regulation (EC) No 1234/2007 of 22 October 2007 establishing a common organisation of agricultural markets and on specific provisions for certain agricultural products (Single CMO Regulation) [1],

Having regard to Commission Implementing Regulation (EU) No 543/2011 of 7 June 2011 laying down detailed rules for the application of Council Regulation (EC) No 1234/2007 in respect of the fruit and vegetables and processed fruit and vegetables sectors [2], and in particular Article 136(1) thereof,

Whereas:

(1) Implementing Regulation (EU) No 543/2011 lays down, pursuant to the outcome of the Uruguay Round multilateral trade negotiations, the criteria whereby the Commission fixes the standard values for imports from third countries, in respect of the products and periods stipulated in Annex XVI, Part A thereto.

(2) The standard import value is calculated each working day, in accordance with Article 136(1) of Implementing Regulation (EU) No 543/2011, taking into account variable daily data. Therefore this Regulation should enter into force on the day of its publication in the *Official Journal of the European Union*,

HAS ADOPTED THIS REGULATION:

Article 1

The standard import values referred to in Article 136 of Implementing Regulation (EU) No 543/2011 are fixed 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, 14 January 2014.

For the Commission,
On behalf of the President,
Jerzy PLEWA
Director-General for Agriculture and Rural Development

[1] OJ L 299, 16.11.2007, p. 1.
[2] OJ L 157, 15.6.2011, p. 1.

ANNEX

Standard import values for determining the entry price of certain fruit and vegetables

(EUR/100 kg)

CN code	Third country code (1)	Standard import value
0702 00 00	AL	78,9
	IL	182,0
	MA	80,3
	TN	93,2
	TR	141,4
	ZZ	115,2
0707 00 05	MA	158,2
	TR	139,7
	ZZ	149,0
0709 93 10	MA	63,8
	TR	113,2
	ZZ	88,5
0805 10 20	EG	60,3
	MA	64,3
	TR	75,9
	ZA	59,1
	ZZ	64,9
0805 20 10	IL	193,6
	MA	69,7
	ZZ	131,7
0805 20 30, 0805 20 50, 0805 20 70, 0805 20 90	IL	181,1
	JM	93,8
	MA	117,9
	TR	80,3
	ZZ	118,3
0805 50 10	EG	66,2
	TR	73,1
	ZZ	69,7
0808 10 80	CA	147,4
	MK	25,7
	US	164,0
	ZZ	112,4
0808 30 90	CN	65,3
	TR	161,1
	US	139,6
	ZZ	122,0

(1) Nomenclature of countries laid down by Commission Regulation (EC) No 1833/2006 (OJ L 354, 14.12.2006, p. 19). Code 'ZZ' stands for 'of other origin'.

DECISIONS

COUNCIL DECISION

of 13 January 2014

appointing a Swedish member of the European Economic and Social Committee

(2014/10/EU)

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 302 thereof,

Having regard to the proposal of the Swedish Government,

Having regard to the opinion of the European Commission,

Whereas:

(1) On 13 September 2010 the Council adopted Decision 2010/570/EU, Euratom appointing the members of the European Economic and Social Committee for the period from 21 September 2010 to 20 September 2015 [1].

(2) A member's seat on the European Economic and Social Committee has become vacant following the end of the term of office of Ms Ellen NYGREN,

HAS ADOPTED THIS DECISION:

Article 1

Ms Lise-Lotte LENBERG is hereby appointed as a member of the European Economic and Social Committee for the remainder of the current term of office, which runs until 20 September 2015.

Article 2

This Decision shall enter into force on the day of its adoption.

Done at Brussels, 13 January 2014.

For the Council
The President
D. KOURKOULAS

[1] OJ L 251, 25.9.2010, p. 8.

COMMISSION IMPLEMENTING DECISION

of 20 December 2013

correcting Annex II to Implementing Decision 2012/707/EU 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

(notified under document C(2013) 9220)

(Text with EEA relevance)

(2014/11/EU)

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 54(4) thereof,

Whereas:

(1) Verification revealed errors in Annex II to Commission Implementing Decision 2012/707/EU [2]. The flowchart included in that Annex erroneously indicated that input categories 'toxicity and other safety testing required by legislation' and 'legislative requirements' apply only to 'toxicity and other safety testing including pharmacology' and not to all other subcategories of 'regulatory use and routine production by type'. In order to clarify this issue the layout of the flowchart should be changed. To emphasise this further, the title of input category 'toxicity and other safety testing required by legislation' should be changed to 'testing by legislation'. Other minor changes to the layout of the flowchart should be introduced in order to improve clarity.

(2) Changes made to the flowchart should be mirrored in the second part of Annex II to Implementing Decision 2012/707/EU, containing the detailed instructions.

(3) Implementing Decision 2012/707/EU should therefore be corrected accordingly.

(4) The measures provided for in this Decision are in accordance with the opinion of the Committee established under Article 56(1) of Directive 2010/63/EU,

HAS ADOPTED THIS DECISION:

Article 1

Annex II to Implementing Decision 2012/707/EU shall be replaced by the Annex to this Decision.

Article 2

This Decision is addressed to the Member States.

Done at Brussels, 20 December 2013.

For the Commission

Janez POTOČNIK

Member of the Commission

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

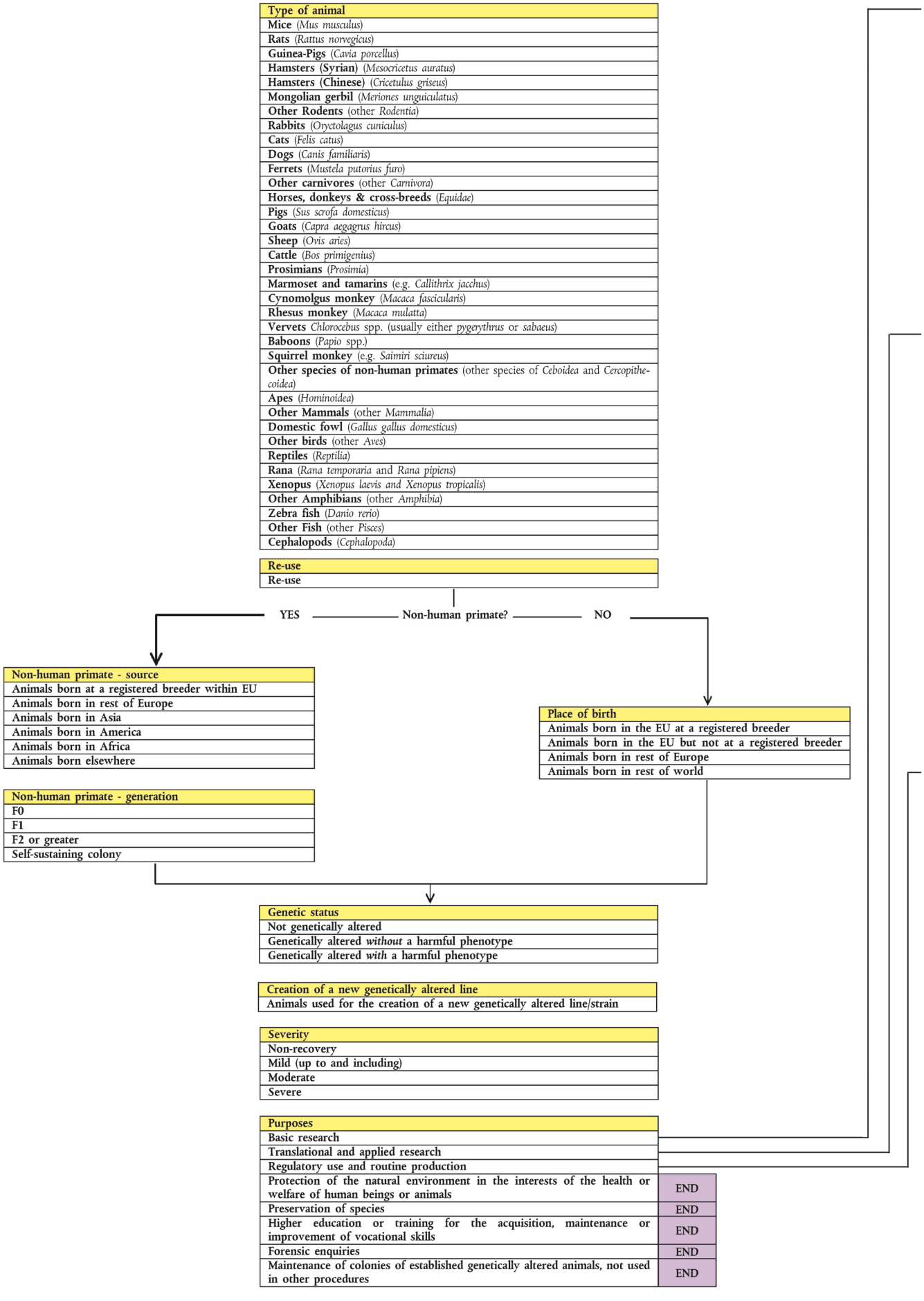
[2] Commission Implementing Decision 2012/707/EU of 14 November 2012 establishing a common format for the submission of the information pursuant to Directive 2010/63/EU of the European Parliament and of the Council on the protection of laboratory animals used for scientific purposes (OJ L 320, 17.11.2012,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

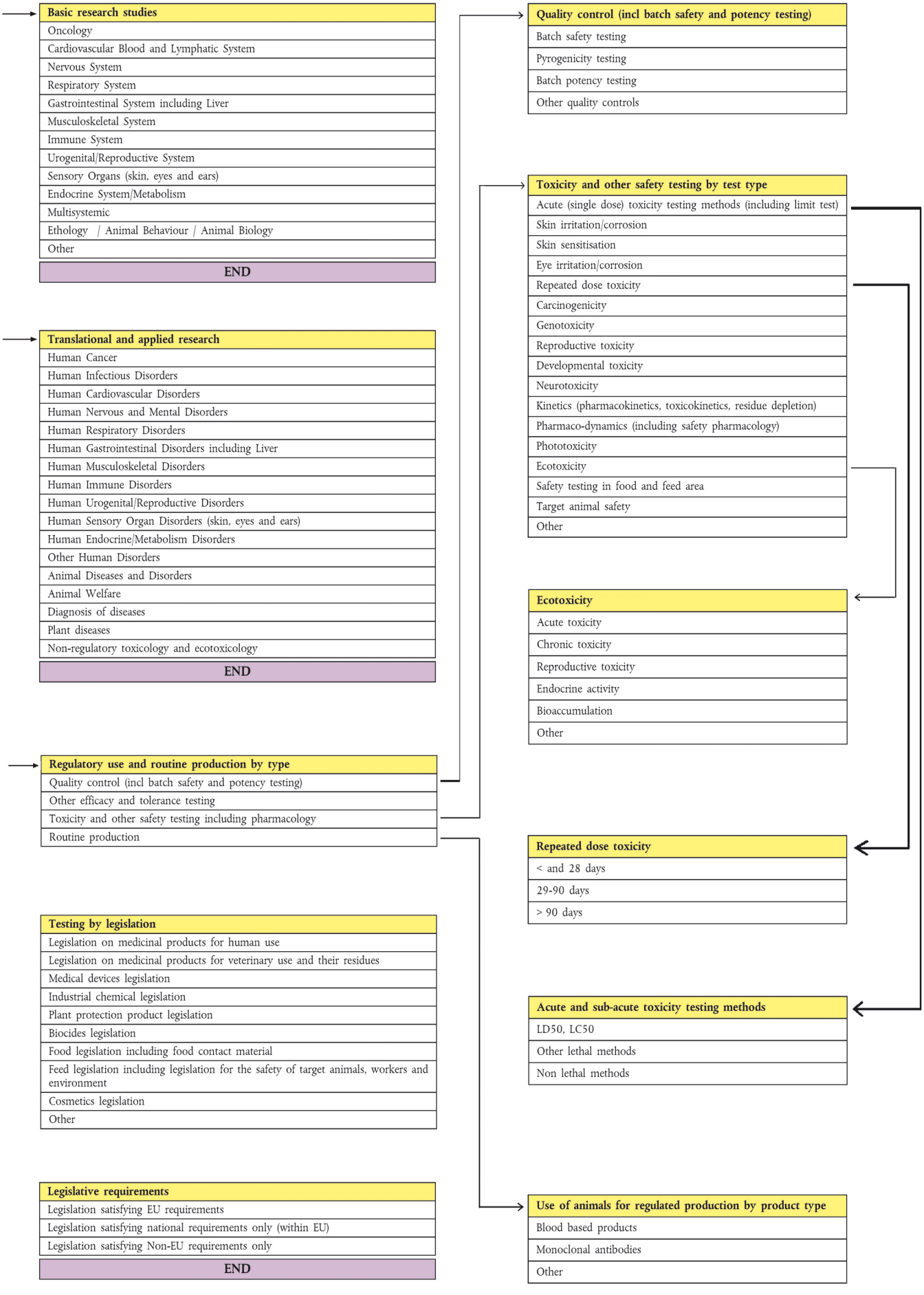
ANNEX

'ANNEX II

PART A

FLOWCHART OF STATISTICAL DATA INPUT CATEGORIES UNDER ARTICLE 54(2)


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 & cross-breeds (Equidae)
Pigs (Sus scrofa domesticus)
Goats (Capra aegagrus hircus)
Sheep (Ovis aries)
Cattle (Bos primigenius)
Prosimians (Prosimia)
Marmoset and tamarins (e.g. Callithrix jacchus)
Cynomolgus monkey (Macaca fascicularis)
Rhesus monkey (Macaca mulatta)
Vervets Chlorocebus spp. (usually either pygerythrus or sabaeus)
Baboons (Papio spp.)
Squirrel monkey (e.g. Saimiri sciureus)
Other species of non-human primates (other species of Ceboidea and Cercopithecoidea)
Apes (Hominoidea)
Other Mammals (other Mammalia)
Domestic fowl (Gallus gallus domesticus)
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)
Other Fish (other Pisces)
Cephalopods (Cephalopoda)
Re-use
Re-use
YES
Non-human primate?
NO
Non-human primate - source
Animals born at a registered breeder within EU
Animals born in rest of Europe
Animals born in Asia
Animals born in America
Animals born in Africa
Animals born elsewhere
Place of birth
Animals born in the EU at a registered breeder
Animals born in the EU but not at a registered breeder
Animals born in rest of Europe
Animals born in rest of world
Non-human primate - generation
F0
F1
F2 or greater
Self-sustaining colony
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
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 or 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
Multisystemic
Ethology / Animal Behaviour / Animal Biology
Other
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 Welfare
Diagnosis of diseases
Plant diseases
Non-regulatory toxicology and ecotoxicology
END
Regulatory use and routine production by type
Quality control (incl batch safety and potency testing)
Other efficacy and tolerance testing
Toxicity and other safety testing including pharmacology
Routine production
Testing by legislation
Legislation on medicinal products for human use
Legislation on medicinal products for veterinary use and their residues
Medical devices legislation
Industrial chemical 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
Legislative requirements
Legislation satisfying EU requirements
Legislation satisfying national requirements only (within EU)
Legislation satisfying Non-EU requirements only
END
Quality control (incl batch safety and potency testing)
Batch safety testing
Pyrogenicity testing
Batch potency testing
Other quality controls
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
Other
Ecotoxicity
Acute toxicity
Chronic toxicity
Reproductive toxicity
Endocrine activity
Bioaccumulation
Other
Repeated dose toxicity
< and 28 days
29-90 days
> 90 days
Acute and sub-acute toxicity testing methods
LD50, LC50
Other lethal methods
Non lethal methods
Use of animals for regulated production by product type
Blood based products
Monoclonal antibodies
Other

PART B

DETAILED INSTRUCTIONS FOR THE PROVISION OF STATISTICAL DATA ON THE USE OF ANIMALS FOR SCIENTIFIC PURPOSES UNDER ARTICLE 54(2)

REPORTING FORMAT FOR THE SUBMISSION OF THE INFORMATION REFERRED TO IN ARTICLE 54(2) OF DIRECTIVE 2010/63/EU

1. The data should be entered on each use of an animal.

2. When entering data for an animal, only one option *within* a category can be selected.

3. Animals killed for organs and tissues, as well as sentinels, are excluded from the provision of statistical data, unless the killing is performed under a project authorisation using a method not included in Annex IV or where the animal has gone through a previous intervention, prior to being killed, and which has been above the threshold of minimum pain, suffering, distress and lasting harm.

4. Surplus animals that are killed are not included in the statistical data apart from genetically altered animals with intended and exhibited harmful phenotype.

5. Larval forms of animals are to be counted once they become capable of independent feeding.

6. Foetal and embryonic forms of mammalian species are not counted; only animals that are born, including by Caesarean section, and live, are to be counted.

7. Whenever the "severe" classification is exceeded, whether pre-authorised or not, these animals and their use are to be reported normally like any other use, and under the "severe" category. Commentary should be added in the "Member State" narrative section covering the species, numbers, whether prior exemption was authorised, the details of the use and the reasons why "severe" classification was exceeded.

8. The data are to be reported for the year that the procedure ends. In case of studies running across 2 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 2 calendar years, animals are reported on the year they are killed or die.

9. The use of "other" category requires a compulsory entry in the narratives to provide further details.

A. GENETICALLY ALTERED ANIMALS

1. For the purposes of statistical reporting, "genetically altered animals" include genetically modified (transgenic, knock-out and other forms of genetic alteration) and naturally occurring or induced mutant animals.

2. Genetically altered animals are reported either:

(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; or

(c) when used in other (scientific) procedures (i.e. not for creation or for the maintenance of a line).

3. All animals *carrying the genetic alteration* should be reported during the creation of a new line. In addition, those used for superovulation, vasectomy, embryo implantation should equally be reported (these may or may not be genetically altered themselves). Genetically normal animals (wild type offspring) produced as a result of creation of a new genetically altered line should not be reported.

4. In the category "Purposes", the animals used for the *creation* of a new genetically altered line should be reported under "basic research" or "translational and applied research" in the *respective category the line is being created for*.

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

6. 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. 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.

7. "**Maintenance of colonies of established genetically altered animals, not used in other procedures**" 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 for is not recorded.

8. **All genetically altered animals which are used in other procedures** (not for the creation or maintenance of a genetically altered line) should 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.

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

B. DATA CATEGORIES

The sections below follow the order of the categories and related headings in the flow chart.

1. **Type of animal**

(i) All cephalopod species are to be reported under heading cephalopod from the stage at which the animal becomes capable of independent feeding, i.e. immediately post-hatching for octopus and squid; and around 7 days after hatching for cuttlefish.

(ii) Fish should be counted from the stage of being capable of independent feeding onward. Zebrafish kept in optimal breeding conditions (approximately + 28 °C) should be counted 5 days post fertilisation.

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

2. **Reuse**

(i) Each use of the animal should be reported at the end of each procedure.

(ii) The statistics will present the **number of naïve animals only in connection with their species and place of birth**. For reused animals, their "place of birth" is therefore not recorded.

(iii) Any **subsequent categories** will show the **number of uses of animals in procedures**. Thus these numbers cannot be cross referenced with the total numbers of naïve animals.

(iv) The number of animals that are reused cannot be deduced from the data due to the fact that some animals may be reused more than once.

(v) The actual suffering of the animal in the procedure should 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 even decrease as a result (habituation). Therefore there should be no attempt to automatically add up the severities from its previous uses. This should always be judged on a case-by-case basis.

Reuse versus continued use

A procedure means a 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.

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

The end user will report **the entire procedure** including any preparation (regardless of the location this has taken place) and take into account the severity associated with the preparation.

Examples of preparation include surgical procedures (such as cannulation, implantation of telemetry, ovariectomy, castration, hypophysectomy, etc.) and non-surgical (such as feeding modified diets, induction of diabetes, etc.). The same applies to the breeding of genetically altered animals, i.e. when the animal is used in its intended procedure, the end user will report the entire procedure taking into account the severity associated with the phenotype. See section on genetically altered animals for more details.

Should, for exceptional reasons, a prepared animal not be used for a scientific purpose, the establishment having prepared the animal should report the details of the preparation as an independent procedure in the statistics as per the intended purpose, provided the preparation of the animal has been above the threshold of minimum pain, suffering, distress and lasting harm.

3. **Place of birth**

Animals born in the EU at a registered breeder
Animals born in the EU but not at a registered breeder
Animals born in rest of Europe
Animals born in rest of world

(i) Origin is based on the place of birth, i.e. "born in" and not according to where the animal is supplied from.

(ii) Animals born in the EU at a registered breeder covers animals born at breeders as authorised and registered under Article 20 of Directive 2010/63/EU.

(iii) Animals born in the EU but not at a registered breeder includes animals born outside a registered breeder such as wild animals, farm animals (unless the breeder is authorised and registered), as well as any exemptions granted under Article 10(3) of Directive 2010/63/EU.

(iv) Animals born in rest of Europe and Animals born in rest of world groups together all animals regardless of whether they have been bred in registered breeding establishments, other establishments and includes animals that have been captured in the wild.

4. **Non-human primate — source**

Animals born at a registered breeder within EU
Animals born in rest of Europe
Animals born in Asia
Animals born in America
Animals born in Africa
Animals born elsewhere

For the purposes of this reporting:

(i) Animals born in rest of Europe is to include animals born in Turkey, Russia and Israel.

(ii) Animals born in Asia is to include animals born in China.

(iii) Animals born in America is to include animals born in the North, Central and South America.

(iv) Animals born in Africa is to include animals born in Mauritius.

(v) Animals born elsewhere is to include animals born in Australasia.

The origins of animals recorded under Animals born elsewhere are to be detailed to the competent authority with the data submission.

5. **Non-human primate — generation**

F0
F1
F2 or greater
Self-sustaining colony

(i) As long as the colony is not self-sustained, animals born in that colony should be reported under F0, F1, F2 or greater according to their generation derived from the maternal line.

(ii) Once the whole colony is self-sustained, all animals born in that colony should be reported under Self-sustaining colony regardless of their generation derived from the maternal line.

6. **Genetic status**

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

(i) Not genetically altered covers all animals that have not been genetically altered, including genetically normal parent animals used for the creation of a new genetically altered animal line/strain.

(ii) Genetically altered without a harmful phenotype includes animals used for the **creation of a new line**, carrying the genetic alteration but exhibiting no harmful phenotype and genetically altered animals **used** in other procedures (not for creation or maintenance) but exhibiting no harmful phenotype.

(iii) Genetically altered with a harmful phenotype includes:

(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; and

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

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

Animals used for the creation of a new genetically altered line/strain

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".

8. **Severity**

(i) **Non-recovery** — Animals which have undergone a procedure that has been performed entirely under general anaesthesia from which the animal has not recovered consciousness shall be reported as non-recovery.

(ii) **Mild (up to and including)** — Animals which have undergone a procedure as a result of which the animals have experienced up to, and including, short-term mild pain, suffering or distress, as well as when there has been no significant impairment of the well-being or general condition of the animals shall be reported as Mild. NB: This should also include any 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.

(iii) **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 have caused moderate impairment of the well-being or general condition of the animals shall be reported as Moderate.

(iv) **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.

(v) If the "severe" classification is exceeded, whether pre-authorised or not, these animals and their use are to be reported under Severe. Commentary should be added in the "Member State" narrative section covering the species, numbers, whether prior exemption was authorised, the details of the use and the reasons why "severe" classification was exceeded.

9. **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 or 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

(i) Basic research

Basic research includes 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 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.

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*** (e.g. developmental biology, immunology) should be recorded *according to the purpose* they are being created for. In addition they should be reported in "Creation of a new genetic line — Animals used for the creation of a new genetically altered line/strain".

All animals carrying the genetic alteration should 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 should exclude non-genetically altered (wild type) offspring.

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

(ii) Translational and applied research

Translational and applied research includes animals used for purposes as described in Article 5(b) and (c) excluding any regulatory use of animals.

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.

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 translational or applied research*** (e.g. cancer research, vaccine development) should be recorded *according to the purpose* they are being created for. In addition, they should be reported in "Creation of a new genetic line — Animals used for the creation of a new genetically altered line/strain".

All animals carrying the genetic alteration should 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 should exclude non-genetically altered (wild type) offspring.

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

(iii) Regulatory use and routine production by type

Use of animals in procedures carried out with a view to satisfying legal requirements for producing, placing and maintaining products/substances on the market, including safety and risk assessment for food and feed. This includes tests carried out on products/substances for which no regulatory submission is ultimately made if those tests would have been included in a regulatory submission had a regulatory submission occurred (i.e. tests performed on those products/substances that fail to reach the end of the development process).

This also includes animals used in the manufacturing process of products if that manufacturing process requires regulatory approval (e.g. animals used in the manufacturing serum-based medicinal products should be included within this category).

The efficacy testing during the development of new medicinal products is excluded and should be reported under category "Translational and applied research".

(iv) Protection of the natural environment in the interests of the health or welfare of human beings or animals

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

This excludes any regulatory use of animals for ecotoxicology purposes.

(v) Higher education or training for the acquisition, maintenance or improvement of vocational skills

This includes training to acquire and maintain practical competence in techniques as required under Article 23(2).

(vi) Maintenance of colonies of established genetically altered animals, not used in other procedures

This contains the number of 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 bred for is not recorded.

This excludes all animals needed for the *creation* of a new genetically altered line and those used *in other procedures* (other than creation/breeding).

10. **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
Multisystemic
Ethology/Animal Behaviour/Animal Biology
Other

(i) Oncology

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

(ii) Nervous system

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

(iii) Sensory Organs (skin eyes and ears)

Studies on nose should be reported under "Respiratory System" and those on tongue should be reported under "Gastrointestinal System including Liver"

(iv) Multisystemic

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

(v) 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.

(vi) Other

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

(vii) Remarks

Animals used for the production and maintenance of infectious agents, vectors and neoplasms, animals used for other biological material and animals used for the production of polyclonal antibodies for the purposes of translational/applied research, but excluding production of monoclonal antibodies by ascites method (which is covered under category "Regulatory use and routine production by type") should be reported in the respective fields of categories "Basic research studies" or "Translational and applied research". The purpose of studies needs to be carefully established, because any listings under the two categories could apply and only the main purpose shall be reported.

11. **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 Welfare
Diagnosis of diseases
Plant diseases
Non-regulatory toxicology and ecotoxicology

(i) Any applied research studying *human cancer* and *human infectious disorders* should be included regardless of the target system.

(ii) Any regulatory use of animals is to be excluded such as regulatory carcinogenicity studies.

(iii) Studies on disorders of the nose should be reported under "Human Respiratory Disorders" and those of the tongue should be reported under "Human Gastrointestinal Disorders including Liver".

(iv) Diagnosis of diseases includes animals used in direct diagnosis of diseases such as rabies, botulism, but excluding those covered under regulatory use.

(v) Non-regulatory toxicology covers 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)).

(vi) Animal welfare should include studies as per Article 5(b)(iii) of Directive 2010/63/EU.

(vii) Remarks

Animals used for the production and maintenance of infectious agents, vectors and neoplasms, animals used for other biological material and animals used for the production of polyclonal antibodies for the purposes of translational/applied research, but excluding production of monoclonal antibodies by ascites method (which is covered under category "Regulatory use and routine production by type") should be reported in the respective fields of categories "Basic research studies" or "Translational and applied research". The purpose of studies needs to be carefully established, because any listings under the two categories could apply and only the main purpose shall be reported.

12. **Regulatory use and routine production**

(i) Use of animals in procedures carried out with a view to satisfying legal requirements for producing, placing and maintaining products/substances on the market, including safety and risk assessment for food and feed.

(ii) This includes tests carried out on products/substances for which no regulatory submission is made (i.e. tests performed on those products/substances (for which a regulatory submission was foreseen) that are ultimately deemed unsuitable for the market by the developer, and thus fail to reach the end of the development process).

(iii) This category also includes animals used in the manufacturing process of products if that manufacturing process requires regulatory approval (e.g. animals used in the manufacturing of serum-based medicinal products should be included within this category).

13. **Regulatory use and routine production by type**

Quality control (incl. batch safety and potency testing)
Other efficacy and tolerance testing
Toxicity and other safety testing including pharmacology
Routine production

(i) Efficacy testing during the development of new medicinal product is excluded and should be reported under category "Translational and Applied research".

(ii) Quality control includes 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 pyrogenicity testing.

(iii) 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.

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

(v) Routine production covers the production of monoclonal antibodies (by ascites) and blood products including polyclonal antisera by established methods. This excludes immunisation of animals for hybridoma production which should be captured under basic or applied research under the appropriate category.

14. **Testing by 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

(i) The legislative requirement should be entered as per the *intended primary* use.

(ii) Water quality; if concerning e.g. tap water to be reported under food legislation.

15. **Legislative requirements**

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

(i) This category allows identification of the level of harmonisation between different legislative requirements. The determining factor is not *who* requests the test to be carried out but which legislation is satisfied, giving priority to the widest level of harmonisation.

(ii) Where national legislation is derived from EU legislation, only Legislation satisfying EU requirements is to be chosen.

(iii) Legislation satisfying EU requirements also includes any international requirement which at the same time satisfies EU requirements (such as testing to ICH, VICH, OECD guidelines, European Pharmacopoeia monographs).

(iv) Legislation satisfying national requirements only (within EU) is to be chosen only when the test is carried out to satisfy the requirements of one or more Member State; not necessarily the one in which the work is being carried out. However, there is no equivalent requirement in the EU.

(v) Legislation satisfying Non-EU requirements only is to be chosen when there is no equivalent requirement to carry out the test to satisfy EU requirements.

16. **Quality control (incl. batch safety and potency testing)**

Batch safety testing
Pyrogenicity testing
Batch potency testing
Other quality controls

Batch safety testing excludes pyrogenicity testing. These are reported under a separate category Pyrogenicity testing.

17. **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
Other

(i) Immunotoxicology studies should be covered under Repeated dose toxicity.

(ii) Kinetics (pharmacokinetics, toxicokinetics, residue depletion) if toxicokinetics is performed as part of the regulatory repeat dose toxicity study, it should be reported under repeated dose toxicity.

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

(iv) Target animal safety this is testing to ensure a product for a specific animal can be used safely on that species (excluding batch safety testing which is covered under quality control).

18. **Acute and subacute toxicity testing methods**

LD50, LC50
Other lethal methods
Non-lethal methods

19. **Repeated dose toxicity**

< and 28 days
29-90 days
> 90 days

20. **Use of animals for regulated production by product type**

Blood based products
Monoclonal antibodies
Other

21. **Ecotoxicity**

Acute toxicity
Chronic toxicity
Reproductive toxicity
Endocrine activity
Bioaccumulation
Other

C. MEMBER STATE NARRATIVE

1. General information on any changes in trends observed since the previous reporting period.

2. Information on significant increase or decrease in use animals in any of the specific areas and analysis of the reasons thereof.

3. Information on any changes in trends in actual severities and analysis of the reasons thereof.

4. Particular efforts to promote the principle of replacement, reduction and refinement and its impacts on statistics if any.

5. Further breakdown on the use of "other" categories if a significant proportion of animal use is reported under this category.

6. Details on cases where the "severe" classification is exceeded, whether pre-authorised or not, covering the species, numbers, whether prior exemption was authorised, the details of the use and the reasons why "severe" classification was exceeded.'

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