ISSN 1977-0677

Official Journal of the European Union

L 320

English edition

Legislation

Volume 55

17 November 2012

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Price: EUR 4

[1] Text with EEA relevance

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EN

[1] Text with EEA relevance

II

(Non-legislative acts)

REGULATIONS

COMMISSION IMPLEMENTING REGULATION (EU) No 1076/2012

of 14 November 2012

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

THE EUROPEAN COMMISSION,

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

Having regard to Council Regulation (EC) No 510/2006 of 20 March 2006 on the protection of geographical indications and designations of origin for agricultural products and foodstuffs ([1]), and in particular the first subparagraph of Article 7(4) thereof,

Whereas:

(1) By virtue of the first subparagraph of Article 9(1) of Regulation (EC) No 510/2006 and having regard to Article 17(2) thereof, the Commission has examined Portugal's application for the approval of amendments to the specification for the protected designation of origin 'Carne Marinhoa' registered under Commission Regulation (EC) No 1107/96 ([2]).

(2) Since the amendments in question are not minor within the meaning of Article 9 of Regulation (EC) No 510/2006, the Commission published the amendment application in the *Official Journal of the European Union* ([3]), as required by the first subparagraph of Article 6(2) of that Regulation. As no statement of objection under Article 7 of Regulation (EC) No 510/2006 has been received by the Commission, the amendments 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, 14 November 2012.

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

([1]) OJ L 93, 31.3.2006, p. 12.
([2]) OJ L 148, 21.6.1996, p. 1.
([3]) OJ C 71, 9.3.2012, p. 33.

ANNEX

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

Class 1.1. Fresh meat (and offal)

PORTUGAL

Carne Marinhoa (PDO)

COMMISSION REGULATION (EU) No 1077/2012

of 16 November 2012

on a common safety method for supervision by national safety authorities after issuing a safety certificate or safety authorisation

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Directive 2004/49/EC of the European Parliament and of the Council of 29 April 2004 on safety on the Community's railways and amending Council Directive 95/18/EC on the licensing of railway undertakings and Directive 2001/14/EC on the allocation of railway infrastructure capacity and the levying of charges for the use of railway infrastructure and safety certification [1] and in particular Article 6 thereof,

Whereas:

(1) One of the purposes of Directive 2004/49/EC is to improve access to the market for rail transport services by defining common principles for the management, regulation and supervision of railway safety. Directive 2004/49/EC also provides equal treatment for all railway undertakings by applying the same safety certification requirements throughout the European Union.

(2) On 5 October 2009 the Commission issued a mandate to the European Railway Agency ('the Agency') in accordance with Directive 2004/49/EC to draw up a draft common safety method (CSM) for supervision by national safety authorities after issuing a safety certificate or a safety authorisation to railway undertakings and infrastructure managers. The Agency submitted its recommendation on the CSM to the Commission, supported by an impact assessment report, in agreement with the mandate of the Commission. This Regulation is based on the recommendation by the Agency.

(3) Commission Regulation (EU) No 1158/2010 of 9 December 2010 on a common safety method for assessing conformity with the requirements for obtaining railway safety certificates [2] provides a method for assessing conformity with requirements for obtaining safety certificates to be issued in accordance with Article 10(2)(a) and Article 10(2)(b) of Directive 2004/49/EC. That Regulation defines the criteria against which assessment by national safety authorities must be carried out, describes the procedures to follow and establishes the principles to be observed by national safety authorities during supervision as defined in that Regulation after issuing a safety certificate.

(4) Commission Regulation (EU) No 1169/2010 of 10 December 2010 on a common safety method for assessing conformity with the requirements for obtaining a railway safety authorisation [3] includes all the harmonised requirements and assessment methods by means of which national safety authorities can issue an infrastructure manager with a safety authorisation under Article 11 of Directive 2004/49/EC covering the adequacy of the safety management system in general and any network-specific authorisation. That Regulation also defines the criteria against which assessment by national safety authorities must be carried out, describes the procedures to follow and establishes the principles to be used by national safety authorities during supervision, as defined in that Regulation, after issuing a safety authorisation.

(5) After issuing a safety certificate or a safety authorisation, the national safety authority must put in place arrangements to check whether the results outlined in the application for a safety certificate or a safety authorisation are being achieved during operation and that all the necessary requirements are complied with on a continuous basis, as required by Article 16(2)(e) and Article 17(2) of Directive 2004/49/EC.

(6) To be able to perform its tasks under Article 16(2)(f) of Directive 2004/49/EC, the national safety authority also needs to judge, based on its supervision activities, the effectiveness of the safety regulatory framework. 'Supervision' means the arrangements put in place by the national safety authority to oversee safety performance after it has granted a safety certificate or safety authorisation.

(7) In undertaking supervision, the national safety authority must apply the fundamental principles of national safety authority supervision activity — proportionality, consistency, targeting, transparency, accountability and cooperation — as set out in Regulation (EU) No 1158/2010 and in Regulation (EU) No 1169/2010. However, these principles also need a framework and process to apply them in practice in the day-to-day activities of the national safety authorities. The current Regulation would provide the necessary framework and process to the national safety authorities, while improving the mutual trust in their approaches to, and decision-making during supervision activities.

[1] OJ L 164, 30.4.2004, p. 44.
[2] OJ L 326, 10.12.2010, p. 11.
[3] OJ L 327, 11.12.2010, p. 13.

(8) The measures provided for in this Regulation are in accordance with the opinion of the Committee established in accordance with Article 27(1) of Directive 2004/49/EC,

HAS ADOPTED THIS REGULATION:

Article 1

Subject matter and scope

1. This Regulation establishes a common safety method (CSM) of supervision of the safety performance after issuing a safety certificate for railway undertakings or a safety authorisation for infrastructure managers as referred to in Annex IV to Regulation (EU) No 1158/2010 and Annex III to Regulation (EU) No 1169/2010 respectively.

2. National safety authorities shall apply the common safety method to oversee compliance with the legal obligation on a railway undertaking or infrastructure manager to use a safety management system to ensure the control of all risks associated with their activities including the supply of maintenance and material and the use of contractors and, where appropriate, to check the application of Commission Regulation (EU) No 1078/2012 of 16 November 2012 on a common safety method for monitoring to be applied by railway undertakings, infrastructure managers after receiving a safety certificate or safety authorisation and by entities in charge of maintenance ([1]).

3. National safety authorities shall use this Regulation to perform their supervision activities under Article 16(2)(f) of Directive 2004/49/EC and to advise the Member States on the effectiveness of the safety regulatory framework.

Article 2

Definitions

For the purposes of this Regulation, 'supervision' has the meaning provided for by Article 2 of Regulation (EU) No 1158/2010 and Article 2 of Regulation (EU) No 1169/2010.

Article 3

Supervision strategy and plan(s)

1. The national safety authority shall develop and implement a supervision strategy and plan(s) outlining how it targets its activities and sets its priorities for supervision as set out in the Annex.

2. The national safety authority shall collect and analyse information from a variety of sources. It shall use the information collected and the outcomes of supervision for the purposes set out in Article 1.

3. The national safety authority shall regularly review the strategy and plan or plans in the light of experience, using the information collected and the outcomes of supervision.

Article 4

Techniques for conducting supervision

1. The national safety authority shall adopt techniques for supervision activities. These techniques commonly include interviews with people at various levels in an organisation, reviewing documents and records related to the safety management system and examining the safety outcomes of the management system revealed by inspections or related activities.

2. The national safety authority shall ensure that its supervision activities include checking

(a) the effectiveness of the safety management system;

(b) the effectiveness of individual or partial elements of the safety management system, including operational activities.

Article 5

Links between assessment and supervision

1. The national safety authority shall use information gathered during the assessment of a railway undertaking's or infrastructure manager's safety management system for the purposes of its supervision of the continued application of their safety management system after issuing the safety certificate or the safety authorisation.

2. The national safety authority shall also use information gathered during its supervision activities for reassessing a railway undertaking's or an infrastructure manager's safety management system prior to the renewal of a safety certificate or safety authorisation.

Article 6

Competence of the persons involved in supervision activities

The national safety authority shall have a system in place to ensure that supervision activities are undertaken by competent persons.

Article 7

Decision-making criteria

1. The national safety authority shall establish and publish decision-making criteria on how it monitors, promotes and where appropriate enforces compliance with the safety regulatory framework. These criteria shall also include non-compliance issues related to the continued application of a safety management system by a railway undertaking or infrastructure manager and to the safety regulatory framework.

([1]) See page 8 of this Official Journal.

2. The national safety authority shall adopt and publish a procedure to enable railway undertakings and infrastructure managers to submit a complaint on decisions taken during supervision activities, without prejudice to the requirement for a judicial review of those decisions.

Article 8

Coordination and cooperation

1. National safety authorities involved in the supervision of a railway undertaking operating in more than one Member State shall coordinate their approach to supervision to ensure that the safety management system of the railway undertaking is effective and covers all relevant activities. The coordination activities shall involve agreement on what information to share between national safety authorities in order to ensure a common approach to supervision of the relevant railway undertaking. It shall also include sharing information on the supervision strategy and plan or plans of the national safety authorities concerned, including any relevant outcomes, to enable a joint approach to dealing with non-compliance.

2. National safety authorities shall develop cooperation arrangements with national investigation bodies, certification bodies for entities in charge of maintenance and other competent authorities in order to share information and to coordinate their response to any failure to comply with the safety-related regulatory framework.

Article 9

Entry into force and application

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

It shall apply from 7 June 2013.

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

Done at Brussels, 16 November 2012.

For the Commission
The President
José Manuel BARROSO

ANNEX

Supervision activities

1. Setting up the supervision strategy and plan(s)

The national safety authority shall:

(a) identify areas for targeted supervision activities;

(b) develop a supervision plan or plans showing how it will give effect to the supervision strategy during the lifecycle of a valid safety certificate/safety authorisation;

(c) produce an initial estimate of resources required to give effect to the plan or plans, based on the target areas identified;

(d) allocate resources to give effect to the plan or plans;

(e) use data/information from a variety of sources as an input to the strategy and the plan or plans. Sources could include information gathered during the assessment of safety management systems, outcomes of previous supervision activities, information from authorisations to bring subsystems or vehicles into service, national investigation bodies accident reports/recommendations, other accident/incident reports or data, a railway undertaking's or an infrastructure manager's annual reports to the national safety authority, annual maintenance reports from entities in charge of maintenance, complaints from members of the public and other relevant sources.

2. Communicating the supervision strategy and plan(s)

The national safety authority shall:

(a) communicate the overall objectives of the supervision strategy and overall explanation of the plan or plans to relevant railway undertakings or infrastructure managers and, where appropriate, more widely to other stakeholders;

(b) provide relevant railway undertakings or infrastructure managers with an overall explanation on how the supervision plan or plans will be undertaken.

3. Carrying out the supervision strategy and plan(s)

The national safety authority shall:

(a) execute the plan or plans as foreseen;

(b) take proportionate action to deal with failure to comply, including issuing any urgent safety alerts when necessary;

(c) evaluate how adequately a railway undertaking or an infrastructure manager has developed and implemented an action plan or plans to remedy any non-compliance identified by the national safety authority within a specified time period.

4. Outcomes of supervision plan(s)

The national safety authority shall:

(a) share results with the relevant railway undertaking or infrastructure manager of the effectiveness of their safety management system in delivering safe performance, including identifying areas of non-compliance on the part of the infrastructure manager or railway undertaking;

(b) have an overview of the safety performance of the individual railway undertakings or infrastructure managers operating in its Member State;

(c) publish and communicate to relevant stakeholders its views on the overall safety performance in the Member State;

(d) publish and communicate to relevant stakeholders its views on the effectiveness of the safety regulatory framework.

5. Reviewing supervision activities

On the basis of experience gathered during supervision activities, the national safety authority shall at regular intervals:

(a) conduct a review of the plan or plans to check that the original targeted activity, use of data/information from a variety of sources, supervision outcomes and resource allocation are appropriate, changing priorities as necessary;

(b) make any necessary changes to the plan or plans if they are to be revised and consider the impact of the changes on the supervision strategy;

(c) contribute when necessary with its views and any proposals to its Member State to overcome any deficiencies in the safety regulatory framework.

COMMISSION REGULATION (EU) No 1078/2012

of 16 November 2012

on a common safety method for monitoring to be applied by railway undertakings, infrastructure managers after receiving a safety certificate or safety authorisation and by entities in charge of maintenance

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Directive 2004/49/EC of the European Parliament and of the Council of 29 April 2004 on safety on the Community's railways and amending Council Directive 95/18/EC on the licensing of railway undertakings and Directive 2001/14/EC on the allocation of railway infrastructure capacity and the levying of charges for the use of railway infrastructure and safety certification (Railway Safety Directive) [1], and in particular Article 6 thereof,

Whereas:

(1) The Commission should adopt the second series of common safety methods (CSM) covering at least the methods provided for in Article 6(3)(c) of Directive 2004/49/EC, on the basis of a recommendation of the European Railway Agency (the 'Agency').

(2) On 5 October 2009 the Commission issued a mandate to the Agency in accordance with Directive 2004/49/EC to draw up a draft CSM for checking conformity of operation and maintenance of structural subsystems with relevant essential requirements. This CSM should specify the methods to be used both to check that the structural sub-systems (including traffic operation and management) are operated and maintained in accordance with all essential requirements related to safety and to monitor that the sub-systems and their integration in the systems continue to fulfil their safety requirements when operated and maintained. The Agency submitted its recommendation on the CSM to the Commission, supported by an impact assessment report to address the mandate of the Commission. This Regulation is based on the recommendation by the Agency.

(3) To enable the safe integration, operation and maintenance of structural sub-systems within the railway system, and to ensure that essential requirements are met in operation, safety management systems of railway undertakings and infrastructure managers, and systems of maintenance of entities in charge of maintenance should include all necessary arrangements, including processes, procedures, technical, operational and organisational risk control measures. Consequently, monitoring the correct application and effectiveness of safety management systems of railway undertakings and infrastructure managers, as well as of systems of maintenance of entities in charge of maintenance, should cover the requirements for structural sub-systems within their operational context.

(4) This Regulation should enable the effective management of safety of the railway system during its operation and maintenance activities and, where necessary and reasonably practicable, should improve the management system.

(5) This Regulation should also enable to identify as early as possible non-compliance in applying a management system in ways that may result in accidents, incidents, near-misses or other dangerous occurrences. To manage these forms of non-compliance during operation and maintenance activities a harmonised process for monitoring activities should be used. In particular that harmonised process should be used to check the achievement of the expected outcome of the safety management systems of railway undertakings and infrastructure managers, and check the achievement of the expected outcome of the system of maintenance of the entities in charge of maintenance.

(6) The railway undertakings and infrastructure managers should monitor the correct application and the outcomes of the arrangements they have developed through their safety management system so as to operate safely, including on specific networks.

(7) This Regulation should facilitate access to the market for rail transport services through harmonisation of the monitoring process to ensure the continuous achievement of the safety performance of the railway system. In addition, this Regulation should help to create mutual trust and transparency between Member States, through a harmonised exchange of safety-related information between different actors involved within the railway sector in order to manage safety across the different interfaces of this sector and harmonised evidence from the application of the monitoring process.

(8) To report to the Commission on the effectiveness and application of this Regulation, and where applicable to make recommendations to improve it, the Agency should be able to gather relevant information from the various involved actors, including from the national safety authorities, from the certification bodies of entities in charge of maintenance of freight wagons and from other entities in charge of maintenance that do not fall under the scope of Commission Regulation (EU) No 445/2011 of 10 May 2011 on a system of certification of entities in charge of maintenance for freight wagons [2].

[1] OJ L 164, 30.4.2004, p. 44.

[2] OJ L 122, 11.5.2011, p. 22.

(9) The measures provided for in this Regulation are in accordance with the opinion of the Committee referred to in Article 27(1) of Directive 2004/49/EC,

HAS ADOPTED THIS REGULATION:

Article 1

Subject matter and scope

1. This Regulation establishes a common safety method (CSM) for monitoring, enabling the effective management of safety in the railway system during its operation and maintenance activities and, where appropriate, improving the management system.

2. This Regulation shall be used for the following:

(a) to check the correct application and the effectiveness of all the processes and procedures in the management system, including the technical, operational and organisational risk control measures. In case of railway undertakings and infrastructure managers, checking will include the technical, operational and organisational elements that are necessary for the issue of the certification/authorisation specified in Article 10(2)(a) and 11(1)(a) and the provisions adopted to obtain the certification/authorisation specified in Article 10(2)(b) and 11(1)(b) of Directive 2004/49/EC;

(b) to check the correct application of the management system as a whole, and if the management system achieves the expected outcomes; and

(c) to identify and implement appropriate preventive, corrective or both types of measures if any relevant instance of non-compliance to points (a) and (b) is detected.

3. This Regulation shall apply to railway undertakings, infrastructure managers after receiving a safety certificate or safety authorisation and entities in charge of maintenance.

Article 2

Definitions

For the purposes of this Regulation the definitions of Article 3 of Directive 2004/49/EC shall apply.

In addition, the following definitions shall apply:

(a) 'management system' means either the safety management systems of railway undertakings and infrastructure managers, as defined in Article 3(i) of Directive 2004/49/EC and complying with requirements laid down in Article 9 and Annex III of that Directive, or the system of maintenance of entities in charge of maintenance complying with requirements laid down in Article 14a(3) of that Directive;

(b) 'monitoring' means the arrangements put in place by railway undertakings, infrastructure managers or entities in charge of maintenance to check their management system is correctly applied and effective;

(c) 'interfaces' means interfaces as defined in Article 3(7) of Commission Regulation (EC) No 352/2009 [1].

[1] OJ L 108, 29.4.2009, p. 4.

Article 3

Monitoring process

1. Each railway undertaking, infrastructure manager and entity in charge of maintenance:

(a) shall be responsible for conducting the monitoring process set out in the Annex;

(b) shall ensure that risk control measures implemented by their contractors are also monitored in compliance with this Regulation. To this end, they shall apply the monitoring process set out in the Annex or require their contractors to apply this process through contractual arrangements.

2. The monitoring process shall contain the following activities:

(a) the definition of a strategy, priorities and plan(s) for monitoring;

(b) the collection and analysis of information;

(c) the drawing up of an action plan for instances of unacceptable non-compliance with requirements laid down in the management system;

(d) the implementation of the action plan, if such a plan is drawn up;

(e) the evaluation of the effectiveness of action plan measures, if such a plan is drawn up.

Article 4

Exchange of information between the involved actors

1. Railway undertakings, infrastructure managers and entities in charge of maintenance, including their contractors, shall ensure through contractual arrangements that any relevant safety-related information resulting from applying the monitoring process set out in the Annex is exchanged between them, to enable the other party to take any necessary corrective actions to ensure continuous achievement of the safety performance of the railway system.

2. If, through the application of the monitoring process, railway undertakings, infrastructure managers and entities in charge of maintenance identify any relevant safety risk as regards defects and construction non-conformities or malfunctions of technical equipment, including those of structural sub-systems, they shall report those risks to the other parties involved to enable them to take any necessary corrective actions to ensure continuous achievement of the safety performance of the railway system.

Article 5

Reporting

1. The infrastructure managers and railway undertakings shall report to the national safety authority on the application of this Regulation through their annual safety reports in accordance with Article 9(4) of Directive 2004/49/EC.

2. The national safety authority shall report on the application of this Regulation by the railway undertakings, infrastructure managers, and as far as it is aware of it, by the entities in charge of maintenance in accordance with Article 18 of Directive 2004/49/EC.

3. The annual maintenance report of entities in charge of maintenance of freight wagons set out in point I.7.4(k) of Annex III to Regulation (EU) No 445/2011, shall include information about the experience of entities in charge of maintenance in applying this Regulation. The Agency shall gather this information in coordination with the respective certification bodies.

4. The other entities in charge of maintenance that do not fall under the scope of Regulation (EU) No 445/2011 shall also share their experience with the Agency on the application of this Regulation. The Agency shall coordinate the sharing of experience with these entities in charge of maintenance.

5. The Agency shall collect all information on the experience of the application of this Regulation and, when necessary, shall make recommendations to the Commission with a view to improving this Regulation.

6. The national safety authorities shall support the Agency in collecting such information from railway undertakings and infrastructure managers.

7. The Agency shall submit to the Commission not later than three years after the entry into force of this Regulation a report analysing the effectiveness of the method and of the experience of railway undertakings, infrastructure managers and entities in charge of maintenance in applying this Regulation.

Article 6

Entry into force and application

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 apply from 7 June 2013.

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

Done at Brussels, 16 November 2012.

For the Commission
The President
José Manuel BARROSO

ANNEX

THE MONITORING PROCESS

1. **General**

1.1. The inputs to the monitoring process shall be all the processes and procedures contained in the management system, including technical, operational and organisational risk control measures.

1.2. The activities referred in Article 3(2) of the monitoring process are described in Sections 2 to 6.

1.3. This monitoring process is repetitive and iterative, as shown in the diagram below in the Appendix.

2. **Definition of a strategy, priorities and plan(s) for monitoring**

2.1. Based on their management system, each railway undertaking, infrastructure manager and entity in charge of maintenance shall be responsible for defining its strategy, priorities and plan(s) for monitoring.

2.2. The decision on what to prioritise shall take into account information from areas that give rise to the greatest risks and, if not monitored effectively, could lead to adverse consequences for safety. An order of priority for monitoring activities shall be set, and the time, effort and resources required shall be indicated. Prioritisation shall also take into account results from previous applications of the monitoring process.

2.3. The monitoring process shall identify as early as possible instances of non-compliance in the application of the management system that might result in accidents, incidents, near-misses or other dangerous occurrences. It shall lead to the implementation of measures to remedy such instances of non-compliance.

2.4. The monitoring strategy and plan(s) shall define either quantitative or qualitative indicators or a mixture of both that can:

(a) give early warnings of any deviation from the expected outcome, or assurance that the expected outcome is achieved as planned;

(b) give information about unwanted outcomes;

(c) support decision making.

3. **Collection and analysis of information**

3.1. The collection and analysis of information shall be carried out according to the strategy, priorities and plan(s) defined for the monitoring.

3.2. For each defined indicator referred to in point 2.4, the following shall be carried out:

(a) a collection of necessary information;

(b) an evaluation as to whether the processes, procedures, technical, operational and organisational risk control measures are correctly implemented;

(c) a check on whether the processes, procedures, technical, operational and organisational risk control measures are effective and whether they achieve the expected outcomes;

(d) an evaluation of whether the management system as a whole is correctly applied and whether it achieves the expected outcomes;

(e) an analysis and evaluation of instances of identified non-compliance with points (b), (c) and (d), as well as identification of their causes.

4. **Drawing up of an action plan**

4.1. For identified instances of non-compliance that are considered unacceptable, an action plan shall be drawn up. This shall:

(a) lead to the enforcement of correctly implemented processes, procedures, technical, operational and organisational risk control measures as specified; or

(b) improve existing processes, procedures, technical, operational and organisational risk control measures; or

(c) identify and implement additional risk control measures.

4.2. The action plan shall in particular include the following information:

(a) objectives and results expected;

(b) corrective, preventive or both types of measures required;

(c) person responsible for implementing actions;

(d) dates by which actions are to be implemented;

(e) person responsible for evaluating the effectiveness of the action plan measures in accordance with Section 6;

(f) a review of the impact of the action plan on the monitoring strategy, priorities and plan(s).

4.3. For managing safety at interfaces the railway undertaking, infrastructure manager or entity in charge of maintenance shall decide, in agreement with the other actors involved, who shall be in charge of implementing the required action plan or parts of it.

5. **Implementation of the action plan**

5.1. The action plan defined in Section 4 shall be implemented so as to correct identified instances of non-compliance.

6. **Evaluation of the effectiveness of the action plan measures**

6.1. Correct implementation, appropriateness and effectiveness of measures identified in the action plan shall be checked using the same monitoring process as described in this Annex.

6.2. Evaluation of the action plan's effectiveness shall in particular include the following actions:

(a) verification of whether the action plan is correctly implemented and completed according to schedule;

(b) verification of whether the expected outcome is achieved;

(c) verification of whether in the meantime the initial conditions have changed and the risk control measures defined in the action plan are still appropriate for the given circumstances;

(d) verification of whether other risk control measures are necessary.

7. **Evidence from the application of the monitoring process**

7.1. The monitoring process shall be documented to prove it has been applied correctly. This documentation shall be made available primarily for internal assessment purposes. Upon request:

(a) railway undertakings and infrastructure managers shall make this documentation available to the national safety authority;

(b) entities in charge of maintenance shall make this documentation available to the certification body. If interfaces are managed through contracts, the entities in charge of maintenance shall make this documentation available to the respective railway undertakings and infrastructure managers.

7.2. The documentation produced under point 7.1 shall include in particular:

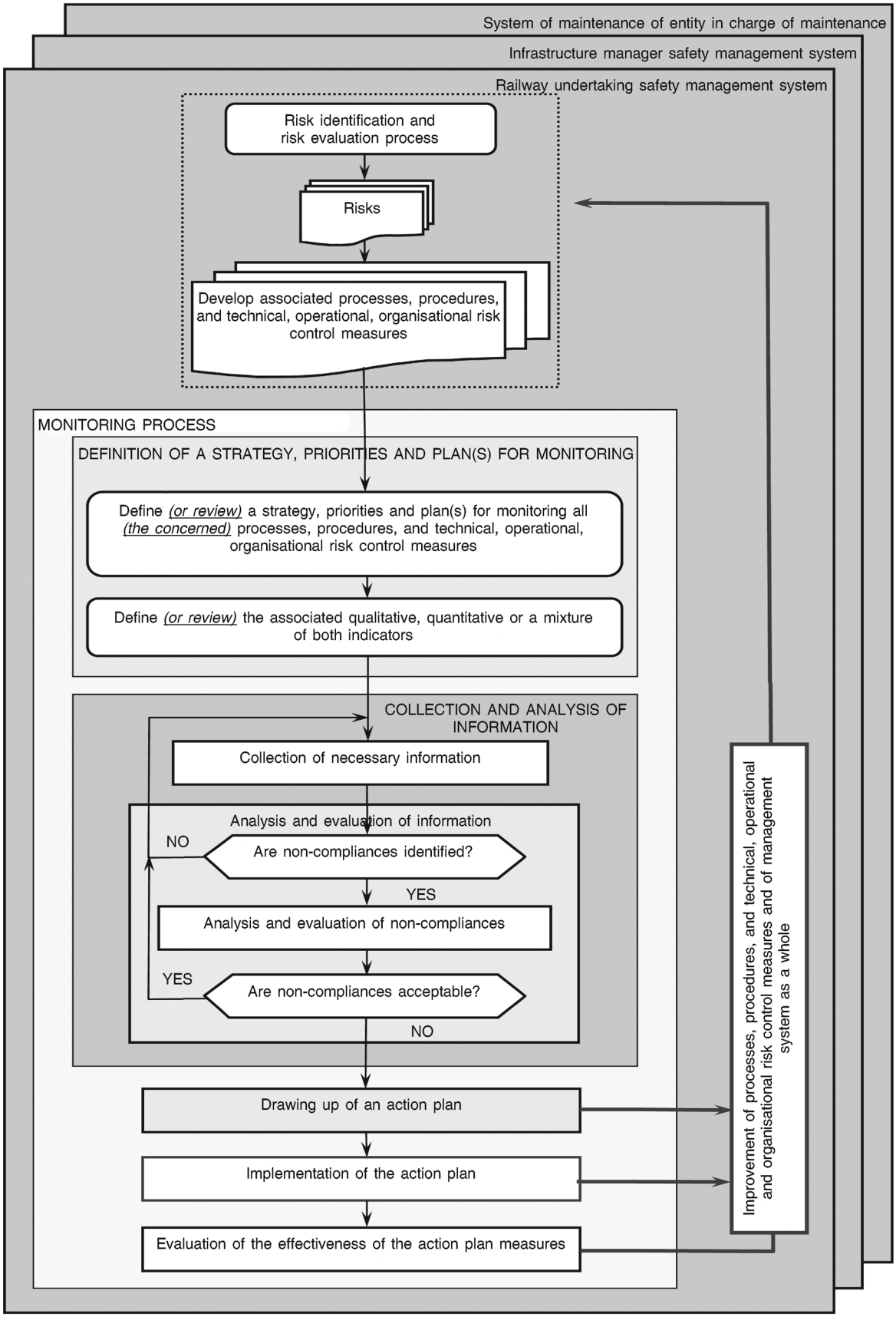
(a) a description of the organisation and staff appointed to carry out the monitoring process;

(b) the results of the different activities of the monitoring process listed in Article 3(2) and in particular the decisions made;

(c) in the case of instances of identified non-compliance that are considered unacceptable, a list of all necessary measures to be implemented to achieve the required outcome.

Appendix

Framework for the monitoring process



COMMISSION IMPLEMENTING REGULATION (EU) No 1079/2012

of 16 November 2012

laying down requirements for voice channels spacing for the single European sky

(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 552/2004 of the European Parliament and of the Council of 10 March 2004 on the interoperability of the European Air Traffic Management network (the interoperability Regulation) ([1]), and in particular Article 3(5) thereof,

Whereas:

(1) The Commission has issued a mandate to Eurocontrol in accordance with Article 8(1) of Regulation (EC) No 549/2004 of the European Parliament and of the Council of 10 March 2004 laying down the framework for the creation of the single European sky (the framework Regulation) ([2]) to develop requirements for the coordinated introduction of air-ground voice communications based on 8,33 kHz channel spacing. This Regulation is based on the resulting mandate report of 12 July 2011.

(2) The first phase of the mandate led to the adoption of Commission Regulation (EC) No 1265/2007 of 26 October 2007 laying down requirements on air-ground voice channel spacing for the single European sky ([3]) which aimed at the coordinated introduction of air-ground voice communications based on 8,33 kHz channel spacing in the airspace above Flight Level (FL) 195.

(3) Specific provisions of Regulation (EC) No 1265/2007, mainly regarding procedures, were already applicable in the airspace below FL 195.

(4) Previous conversions to 8,33 kHz channel spacing above FL 195 have reduced frequency congestion, but have not eliminated it. Many Member States find it increasingly difficult to satisfy the demand for new frequency assignments in the aeronautical mobile route service band 117,975-137 MHz ('the VHF band').

(5) The only realistic option to resolve the medium to long-term congestion problem in the VHF band is the further deployment of air-ground voice communications based on 8,33 kHz channel spacing.

(6) Inability to meet future demand for frequency assignments will delay or make impossible airspace improvements to increase capacity and will lead to increase in delays entailing significant costs.

(7) The Network Manager set up by Commission Regulation (EU) No 677/2011 of 7 July 2011 laying down detailed rules for the implementation of air traffic management (ATM) network functions and amending Regulation (EU) No 691/2010 ([4]) coordinates and harmonises the processes and procedures to enhance the efficiency of aeronautical frequency management. It also coordinates the early identification of needs and resolution of frequency problems.

(8) Harmonised frequency use in the entire European airspace under Member States responsibility for specific applications will further optimise the use of limited radio spectrum resources. Therefore the 8,33 kHz channel spacing conversion of frequencies should take into account the possible actions of the Network Manager for harmonised frequency use mainly by general aviation for air-to-air communications purposes and for specific applications related to general aviation activities.

(9) The investment made as a result of Regulation (EC) No 1265/2007 has substantially reduced the cost of deployment of 8,33 kHz channel spacing in the airspace below FL 195 for air navigation service providers and for operators flying above FL 195.

(10) The requirements for general aviation aircraft operating under visual flight rules to be equipped with radios with 8,33 kHz channel spacing capability will impose a considerable cost with limited operational benefits for those aircraft.

(11) The European Organisation for Civil Aviation Equipment (Eurocae) specification ED-23B should be considered as sufficient means of compliance with regard to the capabilities of the airborne equipment.

(12) Airborne equipment compliant with the Eurocae specification ED-23C provides improved communications characteristics. It should therefore be considered as the preferred option to ED-23B whenever possible.

(13) The arrangements for State aircraft should take into account their specific constraints with appropriate implementation dates.

([1]) OJ L 96, 31.3.2004, p. 26.
([2]) OJ L 96, 31.3.2004, p. 1.
([3]) OJ L 283, 27.10.2007, p. 25.
([4]) OJ L 185, 15.7.2011, p. 1.

(14) This Regulation should not cover military operations and training in accordance with Article 1(2) of Regulation (EC) No 549/2004.

(15) Member States which apply North Atlantic Treaty Organisation ('NATO') combined frequency requirements should maintain the 122,1 MHz frequency in 25 kHz channel spacing for the accommodation of State aircraft not equipped with radios with 8,33 kHz channel spacing capability, until a suitable alternative is found.

(16) With a view to maintaining or enhancing existing safety levels of operations, Member States should ensure that the parties concerned carry out a safety assessment including hazard identification, risk assessment and mitigation processes. Harmonised implementation of those processes to the systems covered by this Regulation necessitates the identification of specific safety requirements for all interoperability and performance requirements.

(17) In accordance with Regulation (EC) No 552/2004, implementing rules for interoperability should describe the specific conformity assessment procedures to be used to assess the conformity or suitability for use of constituents as well as the verification of systems.

(18) The level of maturity of the market for the constituents to which this Regulation applies is such that their conformity or suitability for use can be assessed through internal production control, using procedures based on Module A in Annex II to Decision No 768/2008/EC of the European Parliament and of the Council of 9 July 2008 on a common framework for the marketing of products, and repealing Council Decision 93/465/EEC [1].

(19) For reasons of clarity, Regulation (EC) No 1265/2007 should be repealed.

(20) The measures provided for in this Regulation are in accordance with the opinion of the Single Sky Committee,

HAS ADOPTED THIS REGULATION:

Article 1

Subject matter

This Regulation lays down requirements for the coordinated introduction of air-ground voice communications based on 8,33 kHz channel spacing.

Article 2

Scope

1. This Regulation shall apply to all radios operating in the 117,975-137 MHz band ('the VHF band') allocated to the aeronautical mobile route service, including systems, their constituents and associated procedures.

2. This Regulation shall apply to flight data processing systems serving air traffic control units providing services to general air traffic, their constituents and associated procedures.

3. This Regulation shall apply to all flights operating as general air traffic, within the airspace of the International Civil Aviation Organisation ('ICAO') EUR region where Member States are responsible for the provision of air traffic services in accordance with Regulation (EC) No 550/2004 of the European Parliament and of the Council [2].

4. The conversion requirements shall not apply to frequency assignments:

(a) that will remain in 25 kHz channel spacing on the following frequencies:

  (i) the emergency frequency (121,5 MHz);

  (ii) the auxiliary frequency for search and rescue operations (123,1 MHz);

  (iii) the VHF digital link (VDL) frequencies (136,725 MHz, 136,775 MHz, 136,825 MHz, 136,875 MHz, 136,925 MHz and 136,975 MHz);

  (iv) the aircraft communications addressing and reporting system (ACARS) frequencies (131,525 MHz, 131,725 MHz and 131,825 MHz);

(b) where offset carrier operation within a 25 kHz channel spacing is utilised.

5. Radios intended to operate exclusively in one or more frequency assignments that will remain in 25 kHz channel spacing shall not be required to have the 8,33 kHz channel spacing capability.

Article 3

Definitions

For the purpose of this Regulation, the definitions set out in Article 2 of Regulation (EC) No 549/2004 shall apply. The following definitions shall also apply:

(1) 'channel' means a numerical designator used in conjunction with voice communication equipment tuning, which allows unique identification of the applicable radio frequency and associated channel spacing;

(2) '8,33 kHz channel spacing' means a channel spacing where the nominal channel centre frequencies are separated in increments of 8,33 kHz;

(3) 'radio' means any installed, portable or handheld device designed to transmit and/or receive transmissions in the VHF band;

(4) 'central register' means a register where the national frequency manager registers the necessary operational, technical and administrative details for each frequency assignment in accordance with Regulation (EU) No 677/2011;

[1] OJ L 218, 13.8.2008, p. 82.

[2] OJ L 96, 31.3.2004, p. 10.

(5) '8,33 kHz conversion' means the replacement of a frequency assignment registered in the central register and using 25 kHz channel spacing by a frequency assignment using 8,33 kHz channel spacing;

(6) 'frequency assignment' means authorisation given by a Member State to use a radio frequency or radio frequency channel under specified conditions for the purpose of operating radio equipment;

(7) 'operator' means a person, organisation or enterprise engaged in or offering to engage in an aircraft operation;

(8) 'flights operated under visual flight rules' means any flights operated under visual flight rules as defined in Annex 2 to the 1944 Chicago Convention on International Civil Aviation ('the Chicago Convention');

(9) 'State aircraft' means any aircraft used by military, customs or police;

(10) 'offset carrier operation' means a case where the designated operational coverage cannot be ensured by a single ground transmitter and where, in order to minimise the interference problems, the signals from two or more ground transmitters are offset from the nominal channel centre frequency;

(11) 'aircraft radio equipment' means one or more radios located on board an aircraft and used by an authorised flight crew member during flight;

(12) 'radio upgrade' means the replacement of a radio by a radio of a different model or part number;

(13) 'designated operational coverage' means the volume of airspace in which a particular service is provided and in which the service is afforded frequency protection;

(14) 'air traffic control unit' ('ATC unit') means area control centre, approach control unit or aerodrome control tower;

(15) 'working position' means the furniture and technical equipment at which a member of the air traffic services ('ATS') staff undertakes the tasks associated with his operational responsibilities;

(16) 'radio-telephony' means a form of radio-communication primarily intended for the exchange of information in the form of speech;

(17) 'letter of agreement' means an agreement between two adjacent ATS units that specifies how their respective ATS responsibilities are to be coordinated;

(18) 'Integrated Initial Flight Plan Processing System' ('IFPS') means a system within the European Air Traffic Management Network through which a centralised flight planning processing and distribution service, dealing with the reception, validation and distribution of flight plans, is provided within the airspace covered by this Regulation;

(19) 'transport-type State aircraft' means fixed wing State aircraft that are designed for the purpose of transporting persons and/or cargo;

(20) 'airport operator' means the managing body of an airport as defined in Council Regulation (EEC) No 95/93 [1];

(21) 'operational control communication' means communication carried out by aircraft operators, which also affect air transport safety, regularity and efficiency of flights.

Article 4

Interoperability and performance requirements of radio equipment

1. Manufacturers of radios intended to operate in the VHF band, or their authorised representatives established in the Union, shall ensure that from 17 November 2013 all radios placed on the market, are 8,33 kHz channel spacing capable.

2. Air navigation service providers, operators and other users or owners of radios shall ensure that all radio equipment put into service from 17 November 2013, includes the 8,33 kHz channel spacing capability.

3. Member States shall ensure that aircraft for which the individual certificates of airworthiness or individual flight permits are first issued in the Union from 17 November 2013 and have a radio equipage requirement, are fitted with radios having the 8,33 kHz channel spacing capability.

4. Air navigation service providers, operators and other users or owners of radios shall ensure that from 17 November 2013 their radios include the 8,33 kHz channel spacing capability whenever they are subject to radio upgrades.

5. Member States shall ensure that by 31 December 2017 at the latest all radios have the 8,33 kHz channel spacing capability with the exception of ground radios operated by air navigation service providers.

6. In addition to 8,33 kHz channel spacing capability, the equipment referred to in paragraphs 1-5 shall be able to tune to 25 kHz spaced channels.

7. Users or owners of ground radios having the 8,33 kHz channel spacing capability shall ensure that the performance of these radios and the transmitter/receiver ground constituent complies with the ICAO standards specified in point 1 of Annex II.

[1] OJ L 14, 22.1.1993, p. 1.

8. Users or owners of aircraft radio equipment having the 8,33 kHz channel spacing capability shall ensure that the performance of these radios comply with the ICAO standards specified in point 2 of Annex II.

Article 5

Obligations of operators

1. An operator shall not operate an aircraft above FL 195 unless the aircraft radio equipment has the 8,33 kHz channel spacing capability.

2. From 1 January 2014 an operator shall not operate an aircraft flying under instrument flight rules in airspace class A, B or C of the Member States listed in Annex I unless the aircraft radio equipment has the 8,33 kHz channel spacing capability.

3. With regard to the carriage requirements of 8,33 kHz channel spacing radio equipment identified in paragraph 2, an operator shall not operate an aircraft flying under visual flight rules in areas operating in 8,33 kHz channel spacing unless the aircraft radio equipment has the 8,33 kHz channel spacing capability.

4. Without prejudice to Article 2(5), from 1 January 2018 an operator shall not operate an aircraft in airspace where carriage of radio is required unless the aircraft radio equipment has the 8,33 kHz channel spacing capability.

Article 6

Requirements on 8,33 kHz conversions

1. Member States shall ensure that for sectors with a lower level at or above FL 195 all voice frequency assignments are converted to 8,33 kHz channel spacing.

2. If under exceptional circumstances it is not possible to comply with paragraph 1, Member States shall communicate the reasons to the Commission.

3. Member States listed in Annex I shall implement, by 31 December 2014 at the latest, a number of new 8,33 kHz channel spacing conversions equivalent to at least 25 % of the total number of the 25 kHz frequency assignments in the central register and allocated to a specific area control centre ('ACC') in a Member State. These conversions shall not be limited to ACC frequency assignments and shall not include operational control communication frequency assignments.

4. The total number of State 25 kHz ACC frequency assignments identified in paragraph 3 shall not take into account:

(a) frequency assignments where 25 kHz offset carrier operation is utilised;

(b) frequency assignments that stay in 25 kHz as a result of a safety requirement;

(c) 25 kHz frequency assignments used to accommodate State aircraft.

5. Member States listed in Annex I shall communicate to the Commission, by 31 December 2013 at the latest, the number of conversions which can be achieved pursuant to paragraph 3.

6. If the 25 % target identified in paragraphs 3 and 4 cannot be achieved, the Member State shall provide, in its communication to the Commission, the justification for not having achieved the 25 % target and shall propose an alternative date by when those conversions shall be performed.

7. The communication to the Commission shall also identify the frequency assignments for which conversion is not feasible and shall state the reasons why the conversion is not feasible.

8. Member States listed in Annex I shall ensure that from 1 January 2015, all operational control communication frequency assignments in the central register are 8,33 kHz channel spacing frequency assignments.

9. Where, due to technical reasons, compliance with paragraph 8 can not be ensured, the Member States shall communicate to the Commission, by 31 December 2014 at the latest, the operational control communication frequency assignments which will not be converted and shall provide the justification for not making the conversions.

10. Member States shall ensure that, by 31 December 2018 at the latest, all frequency assignments are converted to 8,33 kHz channel spacing with the exception of:

(a) frequency assignments that stay in 25 kHz as a result of a safety requirement;

(b) 25 kHz frequency assignments used to accommodate State aircraft.

Article 7

Obligations of air navigation service providers

1. Air navigation service providers shall ensure that their 8,33 kHz channel spacing voice communication systems allow an operationally acceptable voice communication between controllers and pilots within the designated operational coverage.

2. Air navigation service providers shall implement the notification and initial coordination processes in their flight data processing systems in accordance with Commission Regulation (EC) No 1032/2006 [1] as follows:

(a) the information about the 8,33 kHz channel spacing capability of a flight shall be transmitted between ATC units;

[1] OJ L 186, 7.7.2006, p. 27.

(b) the information about the 8,33 kHz channel spacing capability of a flight shall be made available at the appropriate working position;

(c) the controller shall have the means to modify the information about the 8,33 kHz channel spacing capability of a flight.

Article 8

Associated procedures

1. Air navigation service providers, operators and other users of radios shall ensure that all six digits of the numerical designator are used to identify the transmitting channel in radio-telephony communications, except where both the fifth and sixth digits are zeros, in which case only the first four digits shall be used.

2. Air navigation service providers, operators and other users of radios shall ensure that their air-ground voice communication procedures are in accordance with the ICAO provisions specified in point 3 of Annex II.

3. Air navigation service providers shall ensure that the procedures applicable to aircraft equipped with radios having the 8,33 kHz channel spacing capability and to aircraft which are not equipped with such equipment are specified in the letters of agreement between ATS units.

4. All operators and agents acting on their behalf shall ensure that the letter Y is inserted in item 10 of the flight plan for aircraft equipped with radios having the 8,33 kHz channel spacing capability.

5. Operators and agents acting on their behalf shall ensure that when planning to fly in airspace requiring the carriage of radios with the 8,33 kHz channel spacing capability, the appropriate indicator is included in the flight plan for aircraft not equipped but which have been granted exemption from the mandatory carriage of equipment.

6. In the case of a change in the 8,33 kHz channel spacing capability status for a flight, the operators or the agents acting on their behalf shall send a modification message to IFPS with the appropriate indicator inserted in the relevant item.

7. The Network Manager shall ensure that IFPS processes and distributes the information on the 8,33 kHz channel spacing capability received in the flight plans.

Article 9

Arrangements for State aircraft

1. Member States shall ensure that transport-type State aircraft operating flights above FL 195 are equipped with radios having the 8,33 kHz channel spacing capability.

2. Where procurement constraints prevent compliance with paragraph 1, Member States shall ensure that transport-type State aircraft operating flights above FL 195 are equipped with radios having the 8,33 kHz channel spacing capability by 31 December 2012 at the latest.

3. Member States shall ensure that non-transport-type State aircraft operating flights above FL 195 are equipped with radios having the 8,33 kHz channel spacing capability.

4. Member States may allow non-compliance with paragraph 3 due to:

(a) compelling technical or budgetary constraints;

(b) procurement constraints.

5. When procurement constraints prevent compliance with paragraph 3, Member States shall ensure that non-transport-type State aircraft operating flights above FL 195 are equipped with radios having the 8,33 kHz channel spacing capability by 31 December 2015 at the latest.

6. Member States shall ensure that new State aircraft entering into service from 1 January 2014 are equipped with radios having the 8,33 kHz channel spacing capability.

7. Member States shall ensure that from 1 January 2014, whenever the radios installed on-board the State aircraft are subject to radio upgrades, the new radios have the 8,33 kHz channel spacing capability.

8. Member States shall ensure that all State aircraft are equipped with radios having the 8,33 kHz channel spacing capability by 31 December 2018 at the latest.

9. Without prejudice to national procedures for the communication of information on State aircraft, Member States shall communicate to the Commission by 30 June 2018 at the latest the list of State aircraft that cannot be equipped with radios having the 8,33 kHz channel spacing capability in accordance with paragraph 8 due to:

(a) compelling technical or budgetary constraints;

(b) procurement constraints.

10. Where procurement constraints prevent compliance with paragraph 8, Member States shall also provide to the Commission by 30 June 2018 at the latest the date by which the aircraft concerned will be equipped with radios having the 8,33 kHz channel spacing capability. That date shall not be later than 31 December 2020.

11. Paragraph 8 shall not apply in respect of State aircraft that will be withdrawn from operational service by 31 December 2025.

12. Air traffic service providers shall ensure that State aircraft not equipped with radios having the 8,33 kHz channel spacing capability can be accommodated, provided that they can be safely handled within the capacity limits of the air traffic management system on UHF or 25 kHz frequency assignments.

13. Member States shall publish procedures for the handling of State aircraft which are not equipped with radios having the 8,33 kHz channel spacing capability in their national aeronautical information publications.

14. Air traffic service providers shall communicate to the Member State that has designated them on an annual basis, their plans for the handling of State aircraft which are not equipped with radios having the 8,33 kHz channel spacing capability, taking into account the capacity limits associated with the procedures referred to in paragraph 13.

Article 10

Safety requirements

Member States shall take the necessary measures to ensure that any changes to the existing systems referred to in Article 2(1) or the introduction of new systems, are preceded by a safety assessment, including hazard identification, risk assessment and mitigation, conducted by the parties concerned. During this safety assessment, the requirements specified in Annex III shall be taken into consideration as a minimum.

Article 11

Conformity or suitability for use of constituents

1. Before issuing an EC declaration of conformity or suitability for use pursuant to Article 5 of Regulation (EC) No 552/2004, manufacturers of constituents of the systems referred to in Article 2(1) of this Regulation shall assess the conformity or suitability for use of these constituents in compliance with the requirements set out in Annex IV, Part A, to this Regulation.

2. Where a certificate issued in accordance with Regulation (EC) No 216/2008 of the European Parliament and of the Council [1] applies to constituents, it shall be considered as an EC declaration of conformity or suitability for use if it includes a demonstration of compliance with the applicable interoperability, performance and safety requirements of this Regulation.

Article 12

Verification of systems

1. Air navigation service providers which can demonstrate or have demonstrated to their national supervisory authority that they fulfil the conditions set out in Annex V shall conduct a verification of the systems referred to in Article 2(1) in compliance with the requirements set out in Annex IV, Part C.

2. Air navigation service providers which cannot demonstrate that they fulfil the conditions set out in Annex V shall subcontract to a notified body a verification of the systems referred to in Article 2(1). The verification shall be conducted in compliance with the requirements set out in Annex IV, Part D.

3. Where a certificate issued in accordance with Regulation (EC) No 216/2008 applies to systems, it shall be considered as an EC declaration of verification if it includes a demonstration of compliance with the applicable interoperability, performance and safety requirements of this Regulation.

Article 13

Additional requirements

1. Member States shall ensure that all relevant stakeholders are made duly aware of the requirements laid down in this Regulation and that they are adequately trained for their job functions.

2. The Network Manager shall ensure that the personnel operating the IFPS involved in flight planning are made duly aware of the requirements laid down in this Regulation and that they are adequately trained for their job functions.

3. Air navigation service providers shall:

(a) develop and maintain operations manuals containing the necessary instructions and information to enable all their relevant personnel to apply this Regulation;

(b) ensure that the manuals referred to in point (a) are accessible and kept up to date and that their update and distribution are subject to appropriate quality and documentation management;

(c) ensure that the working methods and operating procedures comply with this Regulation.

4. The Network Manager shall ensure that the centralised flight planning processing and distribution service:

(a) develops and maintains operations manuals containing the necessary instructions and information to enable all relevant personnel to apply this Regulation;

(b) ensures that the manuals referred to in point (a) are accessible and kept up to date and that their update and distribution are subject to appropriate quality and documentation management;

(c) ensures that its working methods and operating procedures comply with this Regulation.

5. Operators shall ensure that the personnel operating radio equipment are made duly aware of this Regulation, that they are adequately trained to use this equipment and that instructions are available in the cockpit where feasible.

6. Member States shall take the necessary measures to ensure compliance with this Regulation including the publication of relevant information in the national aeronautical information publications.

[1] OJ L 79, 19.3.2008, p. 1.

Article 14

Exemptions

1. In the framework of the first paragraph of Article 4 of Commission Regulation (EC) No 730/2006 [1], Member States may issue temporary derogations from airborne carriage obligations laid down in Article 5(1) of this Regulation for flights operated under visual flight rules.

2. Member States may take local measures granting exemptions from the compliance with Articles 4(5), 5(4) and 6(10) for cases having limited impact on the network.

3. Member States taking the local measures referred to in paragraph 2, shall provide the Commission with detailed information justifying the need for exemptions at the latest: one year before the dates identified in Articles 4(5), 5(4) and 6(10).

4. Within six months from receipt of detailed information from the Member States pursuant to paragraph 3 and after consultation with the Network Manager, the Commission may review any exemption granted pursuant to paragraph 2 if the impact on the network is not limited.

Article 15

Repeal

Regulation (EC) No 1265/2007 is repealed.

Article 16

Entry into force

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, 16 November 2012.

For the Commission
The President
José Manuel BARROSO

[1] OJ L 128, 16.5.2006, p. 3.

ANNEX I

Member States referred to in Articles 5 and 6

The Member States referred to in Articles 5(2), 6(3), 6(5) and 6(8) are the following:

— Germany,

— Ireland,

— France,

— Italy,

— Luxembourg,

— Hungary,

— Netherlands,

— Austria,

— United Kingdom.

ANNEX II

ICAO provisions referred to in Articles 4 and 8

1. Chapter 2 'Aeronautical Mobile Service', Section 2.1 'Air-ground VHF communication system characteristics' and Section 2.2 'System characteristics of the ground installations' of Annex 10 to the Chicago Convention, Volume III, Part 2 (Second Edition — July 2007 incorporating Amendment No 85).

2. Chapter 2 'Aeronautical Mobile Service', Section 2.1 'Air-ground VHF communication system characteristics', Section 2.3.1 'Transmitting function' and Section 2.3.2 'Receiving function' excluding Subsection 2.3.2.8 'VDL — Interference Immunity Performance' of Annex 10 to the Chicago Convention, Volume III, Part 2 (Second Edition — July 2007 incorporating Amendment No 85).

3. Section 12.3.1.4 '8,33 kHz channel spacing' of ICAO PANS-ATM Doc. 4444 (15th Edition – 2007 incorporating Amendment No 2).

ANNEX III

Requirements referred to in Article 10, to be taken into consideration during the safety assessment

1. The interoperability and performance requirements set out in Articles 4(6), 4(7), 4(8), 7(1) and 7(2) shall be taken into consideration during the safety assessment.

2. The associated procedures requirements set out in Article 8 shall be taken into consideration during the safety assessment.

3. The State aircraft arrangements set out in Article 9(13) and (14) shall be taken into consideration during the safety assessment.

4. The requirements supporting compliance set out in Article 13(1), (2), (5) and (6) shall be taken into consideration during the safety assessment.

5. Member States shall ensure that when a frequency assignment is to be converted to 8,33 kHz channel spacing, the new frequency assignment is tested for a trial period of an appropriate duration, during which time safe operation is verified, prior to registration in the central register.

6. Member States shall ensure that conversions to 8,33 kHz channel spacing are made considering the ICAO guidance material on frequency planning criteria as described in Part II — 'VHF Air-Ground Communications Frequency Assignment Planning Criteria' of the EUR Frequency Management Manual — ICAO EUR Doc. 011.

7. Air navigation service providers shall ensure that procedures for handling non-8,33 kHz equipped aircraft operating in airspace requiring the carriage of radios with the 8,33 kHz channel spacing capability are published and applied as appropriate.

8. Air navigation service providers and/or airport operators shall ensure that procedures for handling non-8,33 kHz equipped vehicles through airport areas using 8,33 kHz channel spacing are published and applied as appropriate.

9. Member States which convert frequency assignments to 8,33 kHz channel spacing in any part of their airspace shall:

   (a) ensure that operators of aircraft operating in such airspace are informed that these aircraft must be equipped with radios having the 8,33 kHz channel spacing capability;

   (b) ensure that appropriate training is provided to flight crew members that use 25 kHz radios in airspace where the carriage of radios having the 8,33 kHz channel spacing capability is required, as specified in Article 2(5);

   (c) perform a local safety assessment prior to the conversion that takes into account all the traffic expected to cross that airspace and the potential issues arising from the voice communication system in operation in all surrounding airspace.

ANNEX IV

PART A

Requirements for the assessment of the conformity or suitability for use of constituents referred to in Article 11

1. The verification activities shall demonstrate the conformity of constituents or their suitability for use in accordance with the performance requirements of this Regulation whilst these constituents are in operation in the test environment.

2. The application by the manufacturer of the module described in Part B shall be considered as an appropriate conformity assessment procedure to ensure and declare the compliance of constituents. Equivalent or more stringent procedures are also authorised.

PART B

Internal production control module

1. This module describes the procedure whereby the manufacturer or his authorised representative established within the Union who carries out the obligations laid down in point 2, ensures, and declares that the constituents concerned satisfy the requirements of this Regulation. The manufacturer or his authorised representative established within the Union must draw up a written declaration of conformity or suitability for use in accordance with point 3 of Annex III to Regulation (EC) No 552/2004.

2. The manufacturer must establish the technical documentation described in point 4. He or his authorised representative established within the Union must keep the documentation at the disposal of the relevant national supervisory authorities for inspection purposes and at the disposal of the air navigation service providers that integrate these constituents in their systems, for a period ending at least 10 years after the last constituent has been manufactured. The manufacturer or his authorised representative established within the Union shall inform the Member States where and how the above technical documentation is available.

3. Where the manufacturer is not established within the Union, he shall designate the person(s) who place(s) the constituents on the Union market. These person(s) shall inform the Member States where and how the technical documentation can be made available.

4. Technical documentation must demonstrate the conformity of the constituents with the requirements of this Regulation. It must, as far as relevant for the assessment, cover the design, manufacture and operation of the constituents.

5. The manufacturer or his authorised representative must keep a copy of the declaration of conformity or suitability for use with the technical documentation.

PART C

Requirements for the verification of systems referred to in Article 12(1)

1. The verification of systems identified in Article 2(1) shall demonstrate the conformity of these systems with the interoperability, performance and safety requirements of this Regulation in an assessment environment that reflects the operational context of these systems. In particular:

   — the verification of communication systems shall demonstrate that 8,33 kHz channel spacing is in use for voice communications in accordance with Article 4 and that the performance of the 8,33 kHz voice communication systems complies with Article 4(7),

   — the verification of systems for flight data processing shall demonstrate that the functionality described in Article 7(2) is properly implemented.

2. The verification of systems identified in Article 2(1) shall be conducted in accordance with appropriate and recognised testing practices.

3. Test tools used for the verification of systems identified in Article 2(1) shall have appropriate functionalities.

4. The verification of systems identified in Article 2(1) shall produce the elements of the technical file required by point 3 of Annex IV to Regulation (EC) No 552/2004 including the following elements:

   — description of the implementation,

   — the report of inspections and tests achieved before putting the system into service.

5. The air navigation service provider shall manage the verification activities and shall in particular:

   — determine the appropriate operational and technical assessment environment reflecting the operational environment,

   — verify that the test plan describes the integration of systems identified in Article 2(1) in an operational and technical assessment environment,

— verify that the test plan provides full coverage of the applicable interoperability, performance and safety requirements of this Regulation,

— ensure the consistency and quality of the technical documentation and the test plan,

— plan the test organisation, staff, installation and configuration of the test platform,

— perform the inspections and tests as specified in the test plan,

— write the report presenting the results of inspections and tests.

6. The air navigation service provider shall ensure that the systems identified in Article 2(1) operated in an operational assessment environment meet the interoperability, performance and safety requirements of this Regulation.

7. Upon satisfying completion of verification of compliance, air navigation service providers shall draw up the EC declaration of verification of system and submit it to the national supervisory authority together with the technical file as required by Article 6 of Regulation (EC) No 552/2004.

PART D

Requirements for the verification of systems referred to in Article 12(2)

1. The verification of systems identified in Article 2(1) shall demonstrate the conformity of these systems with the interoperability, performance and safety requirements of this Regulation in an assessment environment that reflects the operational context of these systems. In particular:

— the verification of communication systems shall demonstrate that 8,33 kHz channel spacing is in use for voice communications in accordance with Article 4 and that the performance of the 8,33 kHz voice communication systems complies with Article 4(7),

— the verification of systems for flight data processing shall demonstrate that the functionality described in Article 7(2) is properly implemented.

2. The verification of systems identified in Article 2(1) shall be conducted in accordance with appropriate and recognised testing practices.

3. Test tools used for the verification of systems identified in Article 2(1) shall have appropriate functionalities.

4. The verification of systems identified in Article 2(1) shall produce the elements of the technical file required by point 3 of Annex IV to Regulation (EC) No 552/2004 including the following elements:

— description of the implementation,

— the report of inspections and tests achieved before putting the system into service.

5. The air navigation service provider shall determine the appropriate operational and technical assessment environment reflecting the operational environment and shall have verification activities performed by a notified body.

6. The notified body shall manage the verification activities and shall in particular:

— verify that the test plan describes the integration of systems identified in Article 2(1) in an operational and technical assessment environment,

— verify that the test plan provides full coverage of the applicable interoperability, performance and safety requirements of this Regulation,

— ensure the consistency and quality of the technical documentation and the test plan,

— plan the test organisation, staff, installation and configuration of the test platform,

— perform the inspections and tests as specified in the test plan,

— write the report presenting the results of inspections and tests.

7. The notified body shall ensure that the systems identified in Article 2(1) operated in an operational assessment environment meet the interoperability, performance and safety requirements of this Regulation.

8. Upon satisfying completion of verification tasks, the notified body shall draw up a certificate of conformity in relation to the tasks it carried out.

9. Then, the air navigation service provider shall draw up the EC declaration of verification of system and submit it to the national supervisory authority together with the technical file as required by Article 6 of Regulation (EC) No 552/2004.

ANNEX V

Conditions referred to in Article 12

1. The air navigation service provider must have in place reporting methods within the organisation which ensure and demonstrate impartiality and independence of judgement in relation to the verification activities.

2. The air navigation service provider must ensure that the personnel involved in verification processes carry out the checks with the greatest possible professional integrity and the greatest possible technical competence and are free of any pressure and incentive, in particular of a financial type, which could affect their judgement or the results of their checks, in particular from persons or groups of persons affected by the results of the checks.

3. The air navigation service provider must ensure that the personnel involved in verification processes have access to the equipment that enables them to properly perform the required checks.

4. The air navigation service provider must ensure that the personnel involved in verification processes have sound technical and vocational training, satisfactory knowledge of the requirements of the verifications they have to carry out, adequate experience of such operations and the ability required to draw up the declarations, records and reports to demonstrate that the verifications have been carried out.

5. The air navigation service provider must ensure that the personnel involved in verification processes are able to perform their checks with impartiality. Their remuneration shall not depend on the number of checks carried out, or on the results of such checks.

COMMISSION IMPLEMENTING REGULATION (EU) No 1080/2012

of 16 November 2012

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, 16 November 2012.

For the Commission,
On behalf of the President,
José Manuel SILVA RODRÍGUEZ
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	40,0
	MA	45,9
	MK	36,9
	TR	69,6
	ZZ	48,1
0707 00 05	AL	57,9
	EG	209,3
	MK	42,0
	TR	87,0
	ZZ	99,1
0709 93 10	MA	129,8
	TR	106,8
	ZZ	118,3
0805 20 10	MA	137,9
	ZA	144,8
	ZZ	141,4
0805 20 30, 0805 20 50, 0805 20 70, 0805 20 90	HR	62,3
	TR	81,8
	ZA	193,6
	ZZ	112,6
0805 50 10	AR	57,4
	TR	85,1
	ZA	61,3
	ZZ	67,9
0806 10 10	BR	287,7
	LB	256,5
	PE	322,4
	TR	114,3
	US	314,0
	ZZ	259,0
0808 10 80	CA	156,2
	CL	151,2
	CN	79,8
	MK	36,9
	NZ	162,5
	US	193,0
	ZA	132,8
	ZZ	130,3
0808 30 90	CN	47,2
	TR	110,0
	ZZ	78,6

(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

COMMISSION DECISION

of 13 July 2011

on the State aid SA.28903 (C 12/10) (ex N 389/09) implemented by Bulgaria in favour of Ruse Industry

(notified under document C(2011) 4903)

(Only the Bulgarian text is authentic)

(Text with EEA relevance)

(2012/706/EU)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union, and in particular the first subparagraph of Article 108(2) thereof,

Having regard to the Agreement on the European Economic Area, and in particular Article 62(1)(a) thereof,

Having called on interested parties to submit their comments pursuant to the provisions cited above [1],

Whereas:

I PROCEDURE

(1) On 30 June 2009 the Bulgarian authorities notified the Commission a restructuring measure in favour of Ruse Industry AD (hereinafter 'Ruse Industry' or 'the company'), in form of deferral and rescheduling of public debt amounting to EUR 9,85 million.

(2) A detailed information request was sent to the Bulgarian authorities on 28 July 2009. Bulgaria replied partially on 24 August 2009 and asked for an extension of delay by the same letter, which was granted by letter of 28 August 2009. Bulgaria submitted further information on 30 September 2009. The Commission asked further clarification on 27 November 2009 to which Bulgaria replied on 15 December 2009. A further extension to complete the missing information was granted on 20 December 2009. Bulgaria submitted further information on 17 February 2010.

(3) By letter dated 14 April 2010 the Commission informed Bulgaria that it had decided to initiate the procedure laid down in Article 108(2) of the Treaty on the Functioning of the European Union [2] ('TFEU') in respect of the aid.

(4) The Commission decision to initiate the procedure was published in the *Official Journal of the European Union* [3].

(5) The Commission received no comments from interested parties.

(6) Bulgaria submitted comments to the Commission's opening decision by letter dated 10 May 2010, sent to the Commission and registered by it on 17 June 2010. On 7 June 2010 the Bulgarian authorities provided further information.

(7) A further request for information was sent by the Commission on 29 October 2010, to which the Bulgarian authorities replied by letter dated 12 November 2010, sent to the Commission and registered on 23 November 2010 and by letter dated 3 December 2010, sent to the Commission and registered on 6 December 2010.

(8) On 11 November 2010 the Bulgarian authorities filed bankruptcy proceedings against the company.

(9) By letter dated 14 June 2010 sent to the Commission on 23 November 2010, the Bulgarian authorities withdrew their notification of 30 June 2009.

II DESCRIPTION

The beneficiary

(10) The beneficiary of the aid measure is Ruse Industry. The company (initially called Ruse Shipyard [4]) was created in 1991 and is located in Ruse, Bulgaria, a region eligible for aid under Article 107(3)(a) TFEU. The company was privatised in April 1999, when 80 % of its shares were sold to the German firm Rousse Beteiligungsgesellschaft mbH.

[1] OJ C 187, 10.7.2010, p. 7.

[2] With effect from 1 December 2009, Articles 87 and 88 of the EC Treaty have become Articles 107 and 108, respectively, of the TFEU; the two sets of provisions are, in substance, identical. For the purposes of this Decision, references to Articles 107 and 108 of the TFEU should be understood as references to Articles 87 and 88, respectively, of the EC Treaty where appropriate.

[3] Cf. footnote 2.

[4] On 4 April 2009 the trade register of Bulgaria recorded the change of the name of Ruse Shipyard into Ruse Industry

(11) Ruse Industry is engaged in the production and repair of metal structures as well as the manufacturing of cranes, ships and marine equipment ([5]). The company had 196 employees in 2009.

(12) Financially, the company showed a constant trend of declining turnover and growing losses over several years prior to the notification, as indicated in the table below. In 2008 the company featured a negative operating profit and negative cash flow.

Table 1

Ruse Industry's annual turnover and profit

in million BGN ([1])	2005	2006	2007	2008
Annual turnover	76 239	65 086	17 963	7 035
Profit before tax	(2 091)	1 977	(827)	(3 924)

([1]) The exchange rate EUR/BGN is fixed at 1,9558 as of 5 July 1999 due to the currency board regime operating in Bulgaria.

The debt of Ruse Industry to the State

(13) Ruse Industry owed EUR 9,85 million to the Bulgarian State at the time of the notification.

(14) The debt originates from loan agreements ([6]) dating back to 1996 and 1997 between the State Reconstruction and Development Fund and Ruse Shipyard concerning a principal at the time of USD 8,45 million.

(15) In April 1999 an agreement ('the 1999 rescheduling') was concluded between the Ministry of Finance (hereinafter 'MoF') which has taken over the claims of the State Reconstruction and Development Fund, under which USD 8 million out of the debt described above plus interest accrued were renominated ([7]) in EUR and Rousse Beteiligungsgesellschaft mbH undertook to repay this sum between 1 December 2000 and 30 June 2006 under a rescheduled reimbursement plan.

(16) On 21 May 2001 the MoF and Ruse Industry concluded a further agreement, according to which the full reimbursement of the company's public debt ([8]), plus the interest accrued, was deferred until 30 September 2015, with a grace period (with payment of only interest, not principal) until 31 March 2006 ('the 2001 rescheduling').

(17) According to the 2001 rescheduling the entire debt was as follows: the principal was set at EUR 7,97 million and the interest (accrued until 1 April 1999) set at EUR 2 million. According to this agreement, the principal was subject to an interest of 1 % p.a., whereas penalty interest of 3 % p.a. was applicable on overdue amounts (i.e. in case the company is late with the reimbursement).

(18) In September 2005, just before the end of the grace period, the beneficiary requested a new rescheduling of its public debt (in addition to the 2001 agreement). In December 2006 the Bulgarian Competition Commission found this request inadmissible under Bulgaria's State aid rules. Ruse Industry lodged an appeal against the Competition Commission's decision before the Supreme Administrative Court, which was rejected in July 2007. A further appeal against this decision was ruled out as well. Nevertheless, the State did not attempt to effectively enforce the debt overdue in accordance with the 2001 rescheduling.

(19) In July 2008 the beneficiary offered voluntarily to pay EUR 1 million of the amount overdue in two equal instalments. According to this offer the first instalment was to be paid by October 2008 and the second one by February 2009. When Ruse Industry did not pay any of these, the State – upon the company's request — extended twice the deadline of the first instalment, until December 2008 and until January 2009, respectively.

(20) Given that no reimbursement of the amounts promised by Ruse Industry took place, the Bulgarian authorities sent a reminder for payment in February 2009. Additional reminders for reimbursement of the amounts overdue were filed in April and twice in June 2010. Nevertheless, the State failed to effectively enforce the debt which was not paid in respect to the 2001 rescheduling.

(21) By letter dated 4 June 2009 Ruse Industry asked further the Bulgarian authorities to reschedule the public debt until 2019 with a grace period until 2012. Upon this request and in accordance with Article 108(3) of TFEU Bulgaria notified the envisaged debt rescheduling as restructuring aid.

(22) By letter dated 28 June 2010 Ruse Industry offered again to the State to repay its outstanding liabilities according

([5]) This was the information received in the notification. It shall be noted, that at a later stage Bulgaria claimed that the company does not manufacture vessels, only metal parts.

([6]) Agreement of 15.11.1996 on a foreign currency loan of USD 1 402 341,08; agreement of 22.11.1996 on an amount of USD 450 131,17; and agreement of 27.1.1997 on the repayment of the company's earlier debt of USD 6 597 658,92 (principal) and USD 365 575,86 (interest payable as of 1.11.1996). All these debts were transferred to DFRR from *Stopanksa Banka* (State bank which went bankrupt).

([7]) The Bulgarian authorities did not indicate the exchange rate of this transaction.

([8]) I.e. the entire debt which originally amounted to USD 8 450 131,17 and out of which they have already redenominated/rescheduled USD 8 million on 8.4.1999.

to the repayment arrangements of the 2001 rescheduling. In July 2010 the company undertook to cover all amounts overdue and unpaid in two equal instalments: the first one due by the end of July 2010 and the second by the end of August 2010. However, the company failed to fulfil this arrangement.

(23) According to the information submitted by the Bulgarian authorities, by the end of 2010 the beneficiary has reimbursed EUR 1 million out of the total amounts due under the 2001 rescheduling. At the end of 2010, the unpaid and overdue debt in respect of the total sum owed amounted to EUR 3.7 million.

Non-enforcement of the public debt

(24) It results from the correspondence between Ruse Industry and the Bulgarian authorities that the latter have been sending several reminders for the payment of the amounts due but unpaid. Although the beneficiary expressed willingness, or voluntarily offered repayment, in practice it never covered in full the outstanding amounts under rescheduling 2001. Apart from reminders, there is no evidence that the Bulgarian authorities took any steps to seek to enforce effectively their claims.

(25) With regard to the principal, Ruse Industry did not pay the stipulated amounts ([9]) and thus did not comply with the half-yearly repayment schedule. Besides, the ordinary interest was paid only until July 2008.

(26) As regards the penalty interest, the Bulgarian authorities indicated that the contractually stipulated 3 % (see paragraph (17) above) was charged on the due instalments as from 2006, when the company was supposed to start repaying the instalments. These penalty interests were paid by Ruse only between August 2006 and July 2008. Since July 2008 the company did not pay the charged penalty interest.

(27) On 3 November 2010 the Bulgarian authorities made an official request for repayment. At the time of this request the overdue debt amounted to EUR 3,7 million (of which EUR 3,4 million principal, EUR 151 000 interest and EUR 140 000 penalty interest).

(28) At the time of this request the beneficiary had reimbursed in total EUR 1 million due under the 2001 rescheduling (of which EUR 245 000 principal, EUR 705 000 interest and EUR 50 000 penalty interest). The latest actual reimbursement that Ruse Industry made was on 11 July 2008.

(29) Following the request and the company's failure to comply with its obligations the national authorities filed for insolvency proceedings against the beneficiary on 11 November 2010 (i.e. nine years after the 2001 rescheduling, more than four years after the end of the grace period and over two years since the last payment of any kind by Ruse Industry).

([9]) Ruse Industry only paid, in 2008, a part of the first instalment due in 2006 (EUR 245 000). The other instalments were never paid.

(30) On 11 November 2010 the Bulgarian authorities filed for bankruptcy proceedings against the beneficiary.

III THE OPENING DECISION

(31) As mentioned above (see paragraph (21)) in June 2009, the beneficiary submitted further request for rescheduling the debt outstanding under the 2001 agreement. This planned rescheduling was the measure that was notified to the Commission as restructuring aid on 30 June 2009.

(32) According to the notification, the plan would have provided for the repayment of the debt of EUR 9,85 million over a period of 10 years (i.e. until 2019), with a grace period until 30 June 2012.

(33) Bulgaria was of the view that the planned measure is compatible with the Internal Market on the basis of the *Communication from the Commission Community Guidelines on State aid for rescuing and restructuring firms in difficulty* ([10]) as restructuring aid.

(34) The Commission had doubts with regard to the compatibility of the notified aid. Accordingly, on 14 April 2010 the Commission initiated the procedure laid down in Article 108(2) of TFEU.

(35) In addition, the opening decision raised doubts as to whether the past non-enforcement of the company's liabilities overdue under the 2001 rescheduling agreement might constitute further State aid.

(36) The Bulgarian authorities withdrew this notification on 23 November 2010, therefore the formal investigation with regard to the notified measure became without object.

IV BULGARIA'S COMMENTS TO THE OPENING DECISION

(37) Concerning the non-enforcement of the debt, Bulgaria merely asserts that the State behaved in a private market economy investor manner, which maximises the chances to recover its debt by allowing for voluntary repayment. No detailed arguments were submitted by Bulgaria in this regard.

V ASSESSMENT

The notified restructuring aid

(38) Bulgaria withdrew the notification of the rescheduling of the public debt of Ruse Industry in November 2010. As a result, the formal investigation with regard to the notified restructuring aid measure has become without object pursuant to Article 8(2) of *Council Regulation (EC) No 659/1999 of 22 March 1999 laying down detailed rules for the application of Article 93 of the EC Treaty* ([11]).

([10]) OJ C 244 1.10.2004, p. 2.
([11]) OJ L 83, 27.3.1999, p. 1.

Non-enforcement of past debt

Existence of State aid

(39) The measure under assessment is the non-enforcement of the debt in compliance with the 2001 Rescheduling.

(40) With regard to Bulgaria's accession to the EU and thus whether this non-enforcement of the debt as of 1 January 2007 potentially constitutes new aid in the sense of Article 1(e) of the Procedural Regulation, the Commission notes that the failure of the beneficiary to repay the amounts due under the 2001 rescheduling and the lack of State action led to changes in the total exposure of the State under the 2001 rescheduling. This increase in the liability of the State (i.e. the non-enforcement) produces effects after the date of accession and therefore the measure is to be regarded as applicable after accession and thus to involve new State aid.

(41) It must be also noted that this non-notified measure was not covered by Appendix to Annex V of Bulgaria's Act of accession ([12]). In particular, it was a) neither put into effect before 31 December 1994, b) nor listed in the Appendix to Annex V, and c) nor covered by the interim mechanism that applied in connection with the accession.

(42) Against this background, the Commission will assess in the following whether the non-enforcement of the debt as from 1 January 2007 constitutes new aid in the meaning of Article 107(1) TFEU.

(43) According to Article 107(1) TFEU, any aid granted by a Member State or through state resources in any form whatsoever which distorts or threatens to distort competition by favouring certain undertakings or the production of certain goods, and affects trade between Member States is incompatible with the Internal Market.

(44) The measure is financed by State resources – as it results in forgone revenues to the State – and the decisions of the MoF are directly imputable to the State.

(45) The non-enforcement of the debt also concerns Ruse Industry individually and as such is selective.

(46) In addition, Ruse Industry is an undertaking producing goods which are freely traded within the Union. The Commission thus considers that the condition of the affectation of competition and trade within the Union is fulfilled.

(47) The Commission should further assess whether the measure in the form of non-enforcement of debt confers an advantage to the company which it would not have been able to obtain otherwise in the market.

(48) As explained above, the debt dates back to 1996-97 and has been rescheduled already twice (in 1999 and 2001). With regard to the non-enforcement of the debt under the 2001 rescheduling and the company's previous failures to meet its obligations, no private creditor would have behaved like the Bulgarian State. Indeed, from the information available it results that no concrete steps were taken to enforce the debt as from 30 March 2006, when the grace period ended and the first instalments of the principal became due but were not paid. Moreover, the company's financial situation was weak (see Table 1 above) as it showed diminishing turnover and increasing losses, and there was no prospect of the company returning to profitability. Furthermore, it has to be also noted that even if part of the debt (BGN 1,13 million ([13])) was secured with collaterals ([14]), the Bulgarian authorities did not take any steps to enforce that part of the debt either.

(49) In fact, the Bulgarian authorities did not provide any justifications as to why the repayment schedule was not enforced and did not justify their claim that waiting for voluntary repayment (in the light of the debt default history of the company) would have maximised their chance for the recovery of the debt.

(50) In similar circumstances, a private creditor would have pursued the enforcement of the agreement. Therefore, the non-compliance with the 2001 rescheduling and Bulgaria's failure to enforce its debt confers an advantage to Ruse Industry.

Conclusion on the existence of State aid

(51) On the basis of the above, the Commission considers the non-enforcement of public debt in favour of Ruse industry constitutes new aid as from 1 January 2007 in the meaning of Article 107(1) TFEU.

Compatibility

(52) Concerning possible compatibility of the measure, it should be noted that Bulgaria did not bring forward any arguments in this respect.

(53) Even if Ruse Industry were to formally qualify as a company in difficulty in the sense of the *Communication from the Commission Community Guidelines on State aid for rescuing and restructuring firms in difficulty*, the criteria for compatible rescue or restructuring aid are not met. In particular as regards rescue aid, it has not been demonstrated that the measure would be restricted to the minimum necessary, would be warranted on the grounds of serious social difficulties and has no unduly adverse spill-over effects on other Member States. Moreover, it goes beyond 6 months. From the restructuring aid point of view in the absence of restructuring plan, the restoration of long-term viability is not proven. In addition it has not been demonstrated that the aid is kept to a minimum, and that undue distortions of competition are avoided.

([12]) OJ L 157, 21.6.2005, p. 93.

([13]) Ca. EUR 565 thousand

([14]) In 2001 the pledged assets had a value of BGN 1,18 million (ca EUR 590 thousand).

(54) The company is located in an assisted area pursuant to Article 107(3)(a) TFEU and as such eligible for regional aid under the *Guidelines on national regional aid for 2007-2013* ([15]) (hereinafter: 'RAG'). The measure, however, does not comply with the RAG. In particular, as regards possible operating aid, this aid does not facilitate the development of any activities or economic areas and it is not limited in time, degressive or proportionate to what is necessary to remedy specific economic handicaps.

(55) No other grounds for compatibility seem to apply. Therefore, the aid is unlawful and incompatible with the TFEU.

Recovery

(56) According to the TFEU and the Court of Justice's established case law, the Commission is competent to decide that the State concerned must abolish or alter aid ([16]) when it has found that it is incompatible with the internal market. The Court has also consistently held that the obligation on a State to abolish aid regarded by the Commission as being incompatible with the internal market is designed to re-establish the previously existing situation ([17]). In this context, the Court has established that that objective is attained once the recipient has repaid the amounts granted by way of unlawful aid, thus forfeiting the advantage which it had enjoyed over its competitors on the market, and the situation prior to the payment of the aid is restored ([18]).

(57) Following that case-law, Article 14 of Regulation (EC) No 659/1999 laid down that 'where negative decisions are taken in respect of unlawful aid, the Commission shall decide that the Member State concerned shall take all necessary measures to recover the aid from the beneficiary.'

(58) Thus, given that the measure at hand is to be considered as unlawful and incompatible aid, the amounts of aid must be recovered in order to re-establish the situation that existed on the market prior to the granting of the aid. Recovery shall be hence affected from the time when the advantage occurred to the beneficiary, i.e. when the aid was put at the disposal of the beneficiary and shall bear recovery interest until effective recovery.

(59) The incompatible *aid element* of the measures is calculated as the amount due and unpaid according to 2001 rescheduling starting from 1 January 2007 until 11 November 2010, when Bulgaria registered its claim in the liquidation procedure. At that time, the overdue amount was estimated to be EUR 3,7 million. The exact recovery amount and the recovery interest to be applied on these amounts have to be calculated by Bulgaria. Payments made other than the amounts paid under the agreement may be deducted from the sum to be recovered as unlawful and incompatible aid.

([15]) OJ C 54, 4.3.2006, p. 13.
([16]) Case C-70/72 *Commission v Germany* [1973] ECR 813, point 13.
([17]) Joined Cases C-278/92, C-279/92 and C-280/92 *Spain v Commission* [1994] ECR I-4103, point 75.
([18]) Case C-75/97 *Belgium v Commission* [1999] ECR I-3671, points 64-65.

VI **CONCLUSION**

(60) First, the Commission notes that Bulgaria withdrew the notification concerning the notified debt rescheduling of EUR 9,85 million, the formal investigation procedure with regard to this measure has thus become without object.

(61) Second, the Commission concludes that non-enforcement of public debt as from 1 January 2007 constitutes new State aid in favour of Ruse industry in the meaning of Article 107(1) TFEU.

(62) As this State aid is illegal and incompatible, it has to be recovered from the beneficiary.

HAS ADOPTED THIS DECISION:

Article 1

The Commission has decided to close the formal investigation procedure under Article 108(2) of the Treaty on the Functioning of the European Union in respect of the notified debt rescheduling of EUR 9,85 recording that Bulgaria has withdrawn its notification.

Article 2

The State aid unlawfully granted by Bulgaria in breach of Article 108(3) of the Treaty on the Functioning of the European Union, in favour of Ruse Industry, by way of non-effective enforcement of public debt as from 1 January 2007, is incompatible with the internal market.

Article 3

1. Bulgaria shall recover the aid referred to in Article 2 from the beneficiary.

2. The sums to be recovered shall bear interest from 1 January 2007 until their actual recovery.

3. The interest shall be calculated on a compound basis in accordance with Chapter V of Commission Regulation (EC) No 794/2004 ([19]).

Article 4

1. Recovery of the aid referred to in Article 2 shall be immediate and effective.

2. Bulgaria shall ensure that this decision is implemented within four months following the date of notification of this Decision.

Article 5

1. Within two months following notification of this Decision, Bulgaria shall submit the following information to the Commission:

(a) the total amount (principal and recovery interests) to be recovered from the beneficiary;

(b) a detailed description of the measures already taken and planned to comply with this Decision;

(c) documents demonstrating that the beneficiary has been ordered to repay the aid.

([19]) OJ L 140, 30.4.2004, p. 1.

2. Bulgaria shall keep the Commission informed of the progress of the national measures taken to implement this Decision until recovery of the aid referred to in Article 2 has been completed. It shall immediately submit, on simple request by the Commission, information on the measures already taken and planned to comply with this Decision. It shall also provide detailed information concerning the amounts of aid and recovery interest already recovered from the beneficiary

Article 6

This Decision is addressed to Bulgaria.

Done at Brussels, 13 July 2011.

For the Commission
Joaquín ALMUNIA
Vice-President

COMMISSION IMPLEMENTING DECISION

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

(notified under document C(2012) 8064)

(Text with EEA relevance)

(2012/707/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) Directive 2010/63/EU provides for the harmonisation of national provisions required to improve the welfare of animals used for scientific purposes and aims at the replacement, reduction and refinement of the use of animals for such purposes.

(2) Article 54(1) of Directive 2010/63/EU requires Member States to send information on the implementation of that Directive to the Commission by 10 November 2018, and every 5 years thereafter.

(3) Article 54(2) of Directive 2010/63/EU requires Member States to collect and make publicly available, on an annual basis, statistical information on the use of animals in procedures. Member States are to submit that statistical information to the Commission by 10 November 2015 and every year thereafter.

(4) In accordance with Article 54(3) of Directive 2010/63/EU, Member States are to submit to the Commission annually detailed information on exemptions granted under Article 6(4)(a) of that Directive.

(5) A common format for submitting the information referred to in paragraphs 1, 2, and 3 of Article 54 of Directive 2010/63/EU should be established in order to ensure consistency in the implementation of that Directive.

(6) In order to have comparable information on the implementation of Directive 2010/63/EU and to enable the Commission to assess the effectiveness of the implementation of that Directive at Union level, data submissions from the Member States on implementation, annual statistics on the use of animals in procedures and exemptions granted under Article 6(4)(a) should be accurate and consistent, and therefore the reporting requirements should be harmonised across Member States by establishing a common format for the submission of that information.

(7) On the basis of the statistical information submitted by Member States under Article 54(2) of Directive 2010/63/EU, the Commission is required in accordance with Article 57(2) of that Directive to submit to the European Parliament and the Council a summary report on that information. In order for the data to be meaningful, accurate and comparable, it is essential to have a common format to ensure uniform reporting by all Member States.

(8) To allow the list of methods for killing animals contained in Annex IV to Directive 2010/63/EU to be kept up to date with the latest scientific development, it is necessary to receive detailed information on methods granted exceptionally under Article 6(4)(a) of that Directive.

(9) The measures provided for in this Decision are in accordance with the opinion of the Committee established under Article 56(3) of Directive 2010/63/EU,

HAS ADOPTED THIS DECISION:

Article 1

Member States shall use the common reporting format set out in Annex I to this Decision for the submission of the information referred to in Article 54(1) of Directive 2010/63/EU.

Article 2

Member States shall use the common reporting format and the detailed instructions set out in Annex II to this Decision for the submission of the statistical information referred to in Article 54(2) of Directive 2010/63/EU.

Article 3

Member States shall use the common reporting format set out in Annex III to this Decision for the submission of the information on the exemptions granted under Article 6(4)(a) of Directive 2010/63/EU referred to in Article 54(3) of that Directive.

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

Article 4

This Decision is addressed to the Member States.

Done at Brussels, 14 November 2012.

For the Commission
Janez POTOČNIK
Member of the Commission

ANNEX I

REPORTING FORMAT FOR THE SUBMISSION OF THE INFORMATION REFERRED TO IN ARTICLE 54(1) OF DIRECTIVE 2010/63/EU

Details on specific events (such as numbers) are either to be collected as a snapshot covering the last year of the five-year cycle or exceptionally for the full five-year period broken down by year.

A. **GENERAL INFORMATION**

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)

   information on the framework for competent authorities, including the numbers and types of authorities.

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

   information on the structure and operation of the national committee.

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

   information on the minimum requirements referred to in Article 23(3) of Directive 2010/63/EU including 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)

   description of the processes of project evaluation and authorisation and how the requirements of Articles 38 and 40 of Directive 2010/63/EU are met.

C. **OPERATION**

1. Projects

   i. granting of project authorisation (Articles 40 and 41 of Directive 2010/63/EU)

      information on the annual number of projects authorised, and on the number and type authorised as "multiple generic projects";

      information on the circumstances and proportion of total authorisations where the deadline of 40 days has been extended as permitted by Article 41(2) of Directive 2010/63/EU.

   ii. retrospective assessment, non-technical project summaries (Articles 38, 39 and 43 of Directive 2010/63/EU)

      information on the operation of non-technical project summaries; how it is assured that the requirements under Article 43(1) of Directive 2010/63/EU are met and whether the non-technical project summaries will indicate projects chosen for retrospective review (Article 43 (2) of Directive 2010/63/EU);

      information on the proportion and types of projects submitted for retrospective assessment under Article 38(2)(f) of Directive 2010/63/EU beyond those compulsory under Article 39(2) of that Directive.

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

   i. animals bred, killed and not used in procedures including genetically altered animals not covered in the annual statistics, covering the calendar year prior to that in which the 5-year report is submitted; the global figure shall differentiate those animals involved in GA creation and maintenance of established GA-lines (including wild-type offspring);

   ii. the sourcing of non-human primates and how the requirements of Articles 10 and 28 of Directive 2010/63/EU are met.

3. Exemptions

   information on circumstances under which exemptions were granted in accordance with Articles 10(3), 12(1), 33(3) of Directive 2010/63/EU and in particular on the exceptional circumstances referred to in Article 16(2) of that Directive where a reuse of an animal after a procedure in which the actual suffering was assessed as severe was authorised during the reporting period.

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

information on the structure and functioning of animal welfare bodies.

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)

the general measures taken to ensure that the principle of replacement, reduction and refinement is satisfactorily addressed within authorised projects as well as during housing and care also in breeding and supplying establishments.

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

general description of measures taken to ensure that there is no duplication of procedures.

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

representative information on approximate numbers, species, types of methods and their related severities of tissue sampling for the purposes of genetic characterisation carried out with and without project authorisation covering the calendar year prior to that in which the 5-year report is submitted, and on efforts made to refine those methods.

E. **ENFORCEMENT**

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

number of active authorised breeders, suppliers and users; information on suspensions or withdrawals of authorisations of breeders, suppliers and users and the reasons therefore.

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

quantitative and qualitative operational information including criteria applied under Article 34(2) of Directive 2010/63/EU and proportion of unannounced inspections broken down by year.

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

information and reasons for the withdrawals of project authorisation during the reporting period.

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

information on the nature of infringements as well as legal and administrative actions resulting from those infringements during the reporting period.

ANNEX II

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 (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 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*)

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

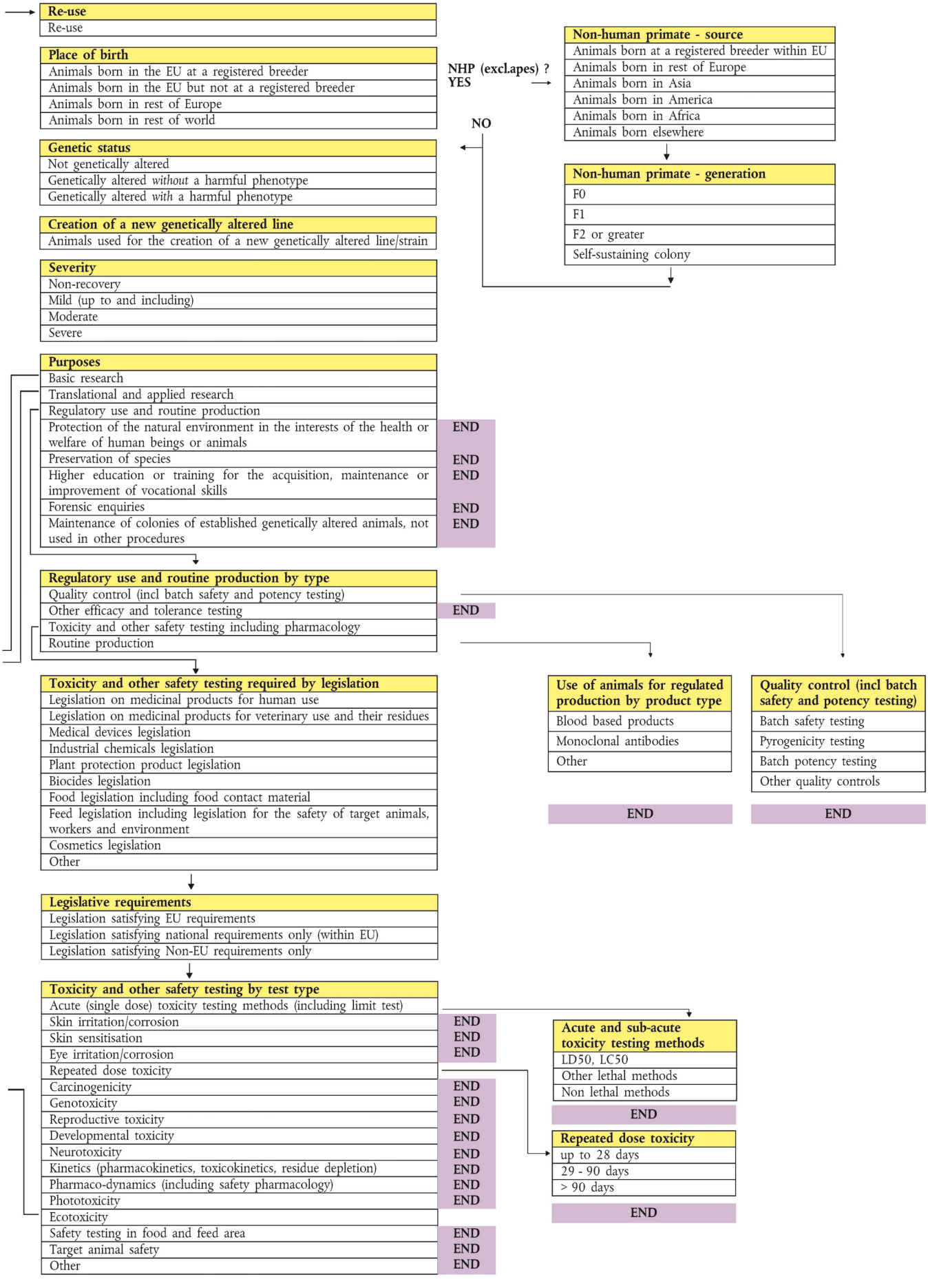
END

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 eco-toxicology

END

Ecotoxicity
Acute toxicity
Chronic toxicity
Reproductive toxicity
Endocrine activity
Bioaccumulation
Other

END


Re-use
Re-use
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
NHP (excl.apes) ?
YES
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
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
Regulatory use and routine production by type
Quality control (incl batch safety and potency testing)
Other efficacy and tolerance testing
END
Toxicity and other safety testing including pharmacology
Routine production
Use of animals for regulated production by product type
Blood based products
Monoclonal antibodies
Other
END
Quality control (incl batch safety and potency testing)
Batch safety testing
Pyrogenicity testing
Batch potency testing
Other quality controls
END
Toxicity and other safety testing required 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
Legislative requirements
Legislation satisfying EU requirements
Legislation satisfying national requirements only (within EU)
Legislation satisfying Non-EU requirements only
Toxicity and other safety testing by test type
Acute (single dose) toxicity testing methods (including limit test)
Skin irritation/corrosion
END
Skin sensitisation
END
Eye irritation/corrosion
END
Repeated dose toxicity
Carcinogenicity
END
Genotoxicity
END
Reproductive toxicity
END
Developmental toxicity
END
Neurotoxicity
END
Kinetics (pharmacokinetics, toxicokinetics, residue depletion)
END
Pharmaco-dynamics (including safety pharmacology)
END
Phototoxicity
END
Ecotoxicity
Safety testing in food and feed area
END
Target animal safety
END
Other
END
Acute and sub-acute toxicity testing methods
LD50, LC50
Other lethal methods
Non lethal methods
END
Repeated dose toxicity
up to 28 days
29 - 90 days
> 90 days
END

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 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, 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 seven 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 + 28C) 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), 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. N.B. 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. 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.

v. 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.

14. **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.

15. **Toxicity and other safety testing required 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

16. **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.

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 sub-acute toxicity testing methods**

LD50, LC50
Other lethal methods
Non lethal methods

19. **Repeated dose toxicity**

Up to 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.

ANNEX III

REPORTING FORMAT FOR THE SUBMISSION OF THE INFORMATION ON THE EXEMPTIONS GRANTED UNDER ARTICLE 6(4)(a) OF DIRECTIVE 2010/63/EU REFERRED TO IN ARTICLE 54(3) OF THAT DIRECTIVE

Type of method	Species	Justification

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