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Legislation

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[1] Text with EEA relevance

EN

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

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

EN

[1] Text with EEA relevance

(Continued on inside back cover)

I

(Legislative acts)

DIRECTIVES

DIRECTIVE 2013/35/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 26 June 2013

on the minimum health and safety requirements regarding the exposure of workers to the risks arising from physical agents (electromagnetic fields) (20th individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC) and repealing Directive 2004/40/EC

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 153(2) thereof,

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national parliaments,

Having regard to the opinion of the European Economic and Social Committee [1],

After consulting the Committee of the Regions,

Acting in accordance with the ordinary legislative procedure [2],

Whereas:

(1) Under the Treaty, the European Parliament and the Council may, by means of directives, adopt minimum requirements for the encouragement of improvements, in particular of the working environment, to guarantee a better level of protection of the health and safety of workers. Such directives are to avoid imposing administrative, financial and legal constraints in a way which would hold back the creation and development of small and medium-sized undertakings.

(2) Article 31(1) of the Charter of Fundamental Rights of the European Union provides that every worker has the right to working conditions which respect his or her health, safety and dignity.

(3) Following the entry into force of Directive 2004/40/EC of the European Parliament and of the Council of 29 April 2004 on the minimum health and safety requirements regarding the exposure of workers to the risks arising from physical agents (electromagnetic fields) (18th individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC) [3], serious concerns were expressed by stakeholders, in particular those from the medical community, as to the potential impact of the implementation of that Directive on the use of medical procedures based on medical imaging. Concerns were also expressed as to the impact of the Directive on certain industrial activities.

(4) The Commission examined attentively the arguments put forward by stakeholders and, after several consultations, decided to thoroughly reconsider some provisions of Directive 2004/40/EC on the basis of new scientific information produced by internationally recognised experts.

(5) Directive 2004/40/EC was amended by Directive 2008/46/EC of the European Parliament and of the Council [4], with the effect of postponing, by four years, the deadline for the transposition of Directive 2004/40/EC, and subsequently by Directive 2012/11/EU of the European Parliament and of the Council [5], with the effect of postponing that deadline for transposition until 31 October 2013. This was to allow the Commission to present a new proposal, and the co-legislators to adopt a new directive, based on fresher and sounder evidence.

(6) Directive 2004/40/EC should be repealed and more appropriate and proportionate measures to protect workers from the risks associated with electromagnetic fields should be introduced. That Directive did not address the long-term effects, including the possible carcinogenic effects, of exposure to time-varying

[1] OJ C 43, 15.2.2012, p. 47.
[2] Position of the European Parliament of 11 June 2013 (not yet published in the Official Journal) and decision of the Council of 20 June 2013.
[3] OJ L 159, 30.4.2004, p. 1.
[4] OJ L 114, 26.4.2008, p. 88.
[5] OJ L 110, 24.4.2012, p. 1.

electric, magnetic and electromagnetic fields, for which there is currently no conclusive scientific evidence establishing a causal relationship. This Directive is intended to address all known direct biophysical effects and indirect effects caused by electromagnetic fields, in order not only to ensure the health and safety of each worker on an individual basis, but also to create a minimum basis of protection for all workers in the Union, while reducing possible distortions of competition.

(7) This Directive does not address suggested long-term effects of exposure to electromagnetic fields, since there is currently no well-established scientific evidence of a causal relationship. However, if such well-established scientific evidence emerges, the Commission should consider the most appropriate means for addressing such effects, and should, through its report on the practical implementation of this Directive, keep the European Parliament and Council informed in this regard. In doing so, the Commission should, in addition to the appropriate information that it receives from Member States, take into account the latest available research and new scientific knowledge arising from the data in this area.

(8) Minimum requirements should be laid down, thereby giving Member States the option of maintaining or adopting more favourable provisions for the protection of workers, in particular by fixing lower values for the action levels (ALs) or the exposure limit values (ELVs) for electromagnetic fields. However, the implementation of this Directive should not serve to justify any regression in relation to the situation already prevailing in each Member State.

(9) The system of protection against electromagnetic fields should be limited to a definition, which should be free of excessive detail, of the objectives to be attained, the principles to be observed and the fundamental values to be applied, in order to enable Member States to apply the minimum requirements in an equivalent manner.

(10) In order to protect workers exposed to electromagnetic fields it is necessary to carry out an effective and efficient risk assessment. However, this obligation should be proportional to the situation encountered at the workplace. Therefore, it is appropriate to design a protection system that groups different risks in a simple, graduated and easily understandable way. Consequently, the reference to a number of indicators and standard situations, to be provided by practical guides, can usefully assist employers in fulfilling their obligations.

(11) The undesired effects on the human body depend on the frequency of the electromagnetic field or radiation to which it is exposed. Therefore, exposure limitation systems need to be exposure-pattern and frequency dependent in order to adequately protect workers exposed to electromagnetic fields.

(12) The level of exposure to electromagnetic fields can be more effectively reduced by incorporating preventive measures into the design of workstations and by giving priority, when selecting work equipment, procedures and methods, to reducing risks at source. Provisions relating to work equipment and methods thereby contribute to the protection of the workers involved. There is, however, a need to avoid duplication of assessments where work equipment meets the requirements of relevant Union law on products that establishes stricter safety levels than those provided for by this Directive. This allows for simplified assessment in a large number of cases.

(13) Employers should make adjustments in the light of technical progress and scientific knowledge regarding the risks related to exposure to electromagnetic fields, with a view to improving the safety and health protection of workers.

(14) Since this Directive is an individual Directive within the meaning of Article 16(1) of Council Directive 89/391/EEC of 12 June 1989 on the introduction of measures to encourage improvements in the safety and health of workers at work [1], it follows that Directive 89/391/EEC applies to the exposure of workers to electromagnetic fields, without prejudice to more stringent and/or specific provisions contained in this Directive.

(15) The physical quantities, ELVs and ALs, laid down in this Directive are based on the recommendations of the International Commission on Non-Ionizing Radiation Protection (ICNIRP) and should be considered in accordance with ICNIRP concepts, save where this Directive specifies otherwise.

(16) In order to ensure that this Directive remains up-to-date, the power to adopt acts in accordance with Article 290 of the Treaty on the Functioning of the European Union should be delegated to the Commission in respect of purely technical amendments of the Annexes, to reflect the adoption of regulations and directives in the field of technical harmonisation and standardisation, technical progress, changes in the most relevant standards or specifications and new scientific findings concerning hazards presented by electromagnetic fields, as well as to adjust ALs. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level. The Commission, when preparing and drawing-up delegated acts, should ensure a simultaneous, timely and appropriate transmission of relevant documents to the European Parliament and to the Council.

[1] OJ L 183, 29.6.1989, p. 1.

(17) If amendments of a purely technical nature to the Annexes become necessary, the Commission should work in close cooperation with the Advisory Committee for Safety and Health at Work set up by Council Decision of 22 July 2003 ([1]).

(18) In exceptional cases, where imperative grounds of urgency so require, such as possible imminent risks to workers' health and safety arising from their exposure to electromagnetic fields, the possibility should be given to apply the urgency procedure to delegated acts adopted by the Commission.

(19) In accordance with the Joint Political Declaration of 28 September 2011 of Member States and the Commission on explanatory documents ([2]), Member States have undertaken to accompany, in justified cases, the notification of their transposition measures with one or more documents explaining the relationship between the components of a directive and the corresponding parts of national transposition instruments. With regard to this Directive, the legislator considers the transmission of such documents to be justified.

(20) A system including ELVs and ALs, where applicable, should be seen as a means to facilitate the provision of a high level of protection against the adverse health effects and safety risks that may result from exposure to electromagnetic fields. However, such a system may conflict with specific conditions in certain activities, such as the use of the magnetic resonance technique in the medical sector. It is therefore necessary to take those particular conditions into account.

(21) Given the specificities of the armed forces and in order to allow them to operate and interoperate effectively, including in joint international military exercises, Member States should be able to implement equivalent or more specific protection systems, such as internationally agreed standards, for example NATO standards, provided that adverse health effects and safety risks are prevented.

(22) Employers should be required to ensure that risks arising from electromagnetic fields at work are eliminated or reduced to a minimum. It is nevertheless possible that in specific cases and in duly justified circumstances, the ELVs set out in this Directive are only temporarily exceeded. In such a case, employers should be required to take the necessary actions in order to return to compliance with the ELVs as soon as possible.

(23) A system ensuring a high level of protection as regards the adverse health effects and safety risks that may result from exposure to electromagnetic fields should take due account of specific groups of workers at particular risk and avoid interference problems with, or effects on the functioning of, medical devices such as metallic prostheses, cardiac pacemakers and defibrillators, cochlear implants and other implants or medical devices worn on the body. Interference problems, especially with pacemakers, may occur at levels below the ALs and should therefore be the object of appropriate precautions and protective measures,

HAVE ADOPTED THIS DIRECTIVE:

CHAPTER I

GENERAL PROVISIONS

Article 1

Subject-matter and scope

1. This Directive, which is the 20th individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC, lays down minimum requirements for the protection of workers from risks to their health and safety arising, or likely to arise, from exposure to electromagnetic fields during their work.

2. This Directive covers all known direct biophysical effects and indirect effects caused by electromagnetic fields.

3. The exposure limit values (ELVs) laid down in this Directive cover only scientifically well-established links between short-term direct biophysical effects and exposure to electromagnetic fields.

4. This Directive does not cover suggested long-term effects.

The Commission shall keep under review the latest scientific developments. If well-established scientific evidence on suggested long-term effects becomes available, the Commission shall consider a suitable policy response, including, if appropriate, the submission of a legislative proposal to address such effects. The Commission shall, through its report referred to in Article 15, keep the European Parliament and the Council informed in this regard.

5. This Directive does not cover the risks resulting from contact with live conductors.

6. Without prejudice to the more stringent or more specific provisions in this Directive, Directive 89/391/EEC shall continue to apply in full to the whole area referred to in paragraph 1.

Article 2

Definitions

For the purposes of this Directive, the following definitions shall apply:

(a) 'electromagnetic fields' means static electric, static magnetic and time-varying electric, magnetic and electromagnetic fields with frequencies up to 300 GHz;

([1]) OJ C 218, 13.9.2003, p. 1.
([2]) OJ C 369, 17.12.2011, p. 14.

(b) 'direct biophysical effects' means effects in the human body directly caused by its presence in an electromagnetic field, including:

(i) thermal effects, such as tissue heating through energy absorption from electromagnetic fields in the tissue;

(ii) non-thermal effects, such as the stimulation of muscles, nerves or sensory organs. These effects might have a detrimental effect on the mental and physical health of exposed workers. Moreover, the stimulation of sensory organs may lead to transient symptoms, such as vertigo or phosphenes. These effects might create temporary annoyance or affect cognition or other brain or muscle functions, and may thereby affect the ability of a worker to work safely (i.e. safety risks); and

(iii) limb currents;

(c) 'indirect effects' means effects, caused by the presence of an object in an electromagnetic field, which may become the cause of a safety or health hazard, such as:

(i) interference with medical electronic equipment and devices, including cardiac pacemakers and other implants or medical devices worn on the body;

(ii) the projectile risk from ferromagnetic objects in static magnetic fields;

(iii) the initiation of electro-explosive devices (detonators);

(iv) fires and explosions resulting from the ignition of flammable materials by sparks caused by induced fields, contact currents or spark discharges; and

(v) contact currents;

(d) 'exposure limit values (ELVs)' means values established on the basis of biophysical and biological considerations, in particular on the basis of scientifically well-established short-term and acute direct effects, i.e. thermal effects and electrical stimulation of tissues;

(e) 'health effects ELVs' means those ELVs above which workers might be subject to adverse health effects, such as thermal heating or stimulation of nerve and muscle tissue;

(f) 'sensory effects ELVs' means those ELVs above which workers might be subject to transient disturbed sensory perceptions and minor changes in brain functions;

(g) 'action levels (ALs)' means operational levels established for the purpose of simplifying the process of demonstrating the compliance with relevant ELVs or, where appropriate, to take relevant protection or prevention measures specified in this Directive.

The AL terminology used in Annex II is as follows:

(i) for electric fields, 'low ALs' and 'high ALs' means levels which relate to the specific protection or prevention measures specified in this Directive; and

(ii) for magnetic fields, 'low ALs' means levels which relate to the sensory effects ELVs and 'high ALs' to the health effects ELVs.

Article 3

Exposure limit values and action levels

1. Physical quantities regarding exposure to electromagnetic fields are indicated in Annex I. Health effects ELVs, sensory effects ELVs and ALs are set out in Annexes II and III.

2. Member States shall require that employers ensure that the exposure of workers to electromagnetic fields is limited to the health effects ELVs and sensory effects ELVs set out in Annex II, for non-thermal effects, and in Annex III, for thermal effects. Compliance with health effects ELVs and sensory effects ELVs must be established by the use of relevant exposure assessment procedures referred to in Article 4. Where the exposure of workers to electromagnetic fields exceeds the ELVs, the employer shall take immediate action in accordance with Article 5(8).

3. For the purpose of this Directive, where it is demonstrated that the relevant ALs set out in Annex II and III are not exceeded, the employer shall be deemed to be in compliance with the health effects ELVs and sensory effects ELVs. Where the exposure exceeds the ALs, the employer shall act in accordance with Article 5(2), unless the assessment carried out in accordance with Article 4(1), (2) and (3) demonstrates that the relevant ELVs are not exceeded and that safety risks can be excluded.

Notwithstanding the first subparagraph, exposure may exceed:

(a) low ALs for electric fields (Annex II, Table B1), where justified by the practice or process, provided that either the sensory effects ELVs (Annex II, Table A3) are not exceeded; or

(i) the health effects ELVs (Annex II, Table A2) are not exceeded;

(ii) the excessive spark discharges and contact currents (Annex II, Table B3) are prevented by specific protection measures as set out in Article 5(6); and

(iii) information on the situations referred to in point (f) of Article 6 has been given to workers;

(b) low ALs for magnetic fields (Annex II, Table B2) where justified by the practice or process, including in the head and torso, during the shift, provided that either the sensory effects ELVs (Annex II, Table A3) are not exceeded; or

(i) the sensory effects ELVs are exceeded only temporarily;

(ii) the health effects ELVs (Annex II, Table A2) are not exceeded;

(iii) action is taken, in accordance with Article 5(9), where there are transient symptoms under point (a) of that paragraph; and

(iv) information on the situations referred to in point (f) of Article 6 has been given to workers.

4. Notwithstanding paragraphs 2 and 3, exposure may exceed:

(a) the sensory effects ELVs (Annex II, Table A1) during the shift, where justified by the practice or process, provided that:

(i) they are exceeded only temporarily;

(ii) the health effects ELVs (Annex II, Table A1) are not exceeded;

(iii) specific protection measures have been taken in accordance with Article 5(7);

(iv) action is taken in accordance with Article 5(9), where there are transient symptoms under point (b) of that paragraph; and

(v) information on the situations referred to in point (f) of Article 6 has been given to workers;

(b) the sensory effects ELVs (Annex II, Table A3 and Annex III, Table A2) during the shift, where justified by the practice or process, provided that:

(i) they are exceeded only temporarily;

(ii) the health effects ELVs (Annex II, Table A2 and Annex III, Table A1 and Table A3) are not exceeded;

(iii) action is taken in accordance with Article 5(9), where there are transient symptoms under point (a) of that paragraph; and

(iv) information on the situations referred to in point (f) of Article 6 has been given to workers.

CHAPTER II

OBLIGATIONS OF EMPLOYERS

Article 4

Assessment of risks and determination of exposure

1. In carrying out the obligations laid down in Articles 6(3) and 9(1) of Directive 89/391/EEC, the employer shall assess all risks for workers arising from electromagnetic fields at the workplace and, if necessary, measure or calculate the levels of electromagnetic fields to which workers are exposed.

Without prejudice to Article 10 of Directive 89/391/EEC and Article 6 of this Directive, that assessment can be made public on request in accordance with relevant Union and national laws. In particular, in the case of processing the personal data of employees in the course of such an assessment, any publication shall comply with Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data [1] and the national laws of the Member States implementing that Directive. Unless there is an overriding public interest in disclosure, public authorities that are in possession of a copy of the assessment may refuse a request for access to it or a request to make it public, where disclosure would undermine the protection of commercial interests of the employer, including those relating to intellectual property. Employers may refuse to disclose or make public the assessment under the same conditions in accordance with the relevant Union and national laws.

2. For the purpose of the assessment provided for in paragraph 1 of this Article the employer shall identify and assess electromagnetic fields at the workplace, taking into account the relevant practical guides referred to in Article 14 and other relevant standards or guidelines provided by the Member State concerned, including exposure databases. Notwithstanding the employer's obligations under this Article, the employer shall also be entitled, where relevant, to take into account the emission levels and other appropriate safety-related data provided, by the manufacturer or distributor, for the equipment, in accordance with relevant Union law, including an assessment of risks, if applicable to the exposure conditions at the workplace or place of installation.

3. If compliance with the ELVs cannot be reliably determined on the basis of readily accessible information, the assessment of the exposure shall be carried out on the basis of measurements or calculations. In such a case, the assessment shall take into account uncertainties concerning the measurements or calculations, such as numerical errors, source modelling, phantom geometry and the electrical properties of tissues and materials, determined in accordance with relevant good practice.

[1] OJ L 281, 23.11.1995, p. 31.

4. The assessment, measurement and calculations referred to in paragraphs 1, 2 and 3 of this Article shall be planned and carried out by competent services or persons at suitable intervals, taking into account the guidance given under this Directive and taking particular account of Articles 7 and 11 of Directive 89/391/EEC concerning the necessary competent services or persons and the consultation and participation of workers. The data obtained from the assessment, measurement or calculation of the level of exposure shall be preserved in a suitable traceable form so as to permit consultation at a later stage, in accordance with national law and practice.

5. When carrying out the risk assessment pursuant to Article 6(3) of Directive 89/391/EEC, the employer shall give particular attention to the following:

(a) the health effects ELVs, the sensory effects ELVs and the ALs referred to in Article 3 and Annexes II and III to this Directive;

(b) the frequency, the level, duration and type of exposure, including the distribution over the worker's body and over the volume of the workplace;

(c) any direct biophysical effects;

(d) any effects on the health and safety of workers at particular risk, in particular workers who wear active or passive implanted medical devices, such as cardiac pacemakers, workers with medical devices worn on the body, such as insulin pumps, and pregnant workers;

(e) any indirect effects;

(f) the existence of replacement equipment designed to reduce the level of exposure to electromagnetic fields;

(g) appropriate information obtained from the health surveillance referred to in Article 8;

(h) information provided by the manufacturer of equipment;

(i) other relevant health and safety related information;

(j) multiple sources of exposure;

(k) simultaneous exposure to multiple frequency fields.

6. In workplaces open to the public it is not necessary for the exposure assessment to be carried out if an evaluation has already been undertaken in accordance with the provisions on the limitation of exposure of the general public to electromagnetic fields, if the restrictions specified in those provisions are respected for workers and if the health and safety risks are excluded. Where equipment intended for the public use is used as intended and complies with Union law on products that establishes stricter safety levels than those provided for by this Directive, and no other equipment is used, these conditions are deemed to be met.

7. The employer shall be in possession of an assessment of the risks in accordance with Article 9(1)(a) of Directive 89/391/EEC and shall identify which measures must be taken in accordance with Article 5 of this Directive. The risk assessment may include the reasons why the employer considers that the nature and the extent of the risks related to electromagnetic fields make a further detailed risk assessment unnecessary. The risk assessment shall be updated on a regular basis, particularly if there have been significant changes which could render it out of date, or if the results of the health surveillance referred to in Article 8 show this to be necessary.

Article 5

Provisions aimed at avoiding or reducing risks

1. Taking account of technical progress and the availability of measures to control the production of electromagnetic fields at the source, the employer shall take the necessary actions to ensure that risks arising from electromagnetic fields at the workplace are eliminated or reduced to a minimum.

The reduction of risks arising from exposure to electromagnetic fields shall be based on the general principles of prevention set out in Article 6(2) of Directive 89/391/EEC.

2. On the basis of the risk assessment referred to in Article 4, once the relevant ALs, referred to in Article 3 and in Annexes II and III, are exceeded and unless the assessment carried out in accordance with Article 4(1), (2) and (3) demonstrates that the relevant ELVs are not exceeded and that safety risks can be excluded, the employer shall devise and implement an action plan that shall include technical and/or organisational measures to prevent exposure exceeding the health effects ELVs and sensory effects ELVs, taking into account, in particular:

(a) other working methods that entail less exposure to electromagnetic fields;

(b) the choice of equipment emitting less intense electromagnetic fields, taking account of the work to be done;

(c) technical measures to reduce the emission of electromagnetic fields, including, where necessary, the use of interlocks, shielding or similar health protection mechanisms;

(d) appropriate delimitation and access measures, such as signals, labels, floor markings, barriers, in order to limit or control access;

(e) in the case of exposure to electric fields, measures and procedures to manage spark discharges and contact currents through technical means and through the training of workers;

(f) appropriate maintenance programmes for work equipment, workplaces and workstation systems;

(g) the design and layout of workplaces and workstations;

(h) limitations of the duration and intensity of the exposure; and

(i) the availability of adequate personal protection equipment.

3. On the basis of the risk assessment referred to in Article 4, the employer shall devise and implement an action plan that shall include technical and/or organisational measures to prevent any risks to workers at particular risk, and any risks due to indirect effects, referred to in Article 4.

4. In addition to providing the information set out in Article 6 of this Directive, the employer shall, pursuant to Article 15 of Directive 89/391/EEC, adapt the measures referred to in this Article to the requirements of workers at particular risk and, where applicable, to individual risks assessments, in particular in respect of workers who have declared the use of active or passive implanted medical devices, such as cardiac pacemakers, or the use of medical devices worn on the body, such as insulin pumps, or in respect of pregnant workers who have informed their employer of their condition.

5. On the basis of the risk assessment referred to in Article 4, workplaces where workers are likely to be exposed to electromagnetic fields that exceed the ALs shall be indicated by appropriate signs in accordance with Annexes II and III and with Council Directive 92/58/EEC of 24 June 1992 on the minimum requirements for the provision of safety and/or health signs at work (ninth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC) ([1]). The areas in question shall be identified and access to them limited, as appropriate. Where access to these areas is suitably restricted for other reasons and workers are informed of the risks arising from electromagnetic fields, signs and access restrictions specific to electromagnetic fields shall not be required.

6. Where Article 3(3)(a) applies, specific protection measures shall be taken, such as the training of workers in accordance with Article 6 and the use of technical means and personal protection, for example the grounding of work objects, the bonding of workers with work objects (equipotential bonding) and, where appropriate and in accordance with Article 4(1)(a) of Council Directive 89/656/EEC of 30 November 1989 on the minimum health and safety requirements for the use by workers of personal protective equipment at the workplace (third individual directive within the meaning of Article 16(1) of Directive 89/391/EEC) ([2]), the use of insulating shoes, gloves and protective clothing.

7. Where Article 3(4)(a) applies, specific protection measures, such as controlling movements, shall be taken.

8. Workers shall not be exposed above the health effects ELVs and sensory effects ELVs, unless the conditions under either Article 10(1)(a) or (c) or Articles 3(3) or (4) are fulfilled. If, despite the measures taken by the employer, the health effects ELVs and sensory effects ELVs are exceeded, the employer shall take immediate action to reduce exposure below these ELVs. The employer shall identify and record the reasons why the health effects ELVs and sensory effects ELVs have been exceeded, and shall amend the protection and prevention measures accordingly in order to prevent them being exceeded again. The amended protection and prevention measures shall be preserved in a suitable traceable form so as to permit consultation at a later stage, in accordance with national law and practice.

9. Where paragraphs 3 and 4 of Article 3 apply and where the worker reports transient symptoms, the employer shall, if necessary, update the risk assessment and the prevention measures. Transient symptoms may include:

(a) sensory perceptions and effects in the functioning of the central nervous system in the head evoked by time varying magnetic fields; and

(b) static magnetic field effects, such as vertigo and nausea.

Article 6

Worker information and training

Without prejudice to Articles 10 and 12 of Directive 89/391/EEC, the employer shall ensure that workers who are likely to be exposed to risks from electromagnetic fields at work and/or their representatives receive any necessary information and training relating to the outcome of the risk assessment provided for in Article 4 of this Directive, concerning in particular:

(a) measures taken in application of this Directive;

(b) the values and concepts of the ELVs and ALs, the associated possible risks and the preventive measures taken;

(c) the possible indirect effects of exposure;

(d) the results of the assessment, measurement or calculations of the levels of exposure to electromagnetic fields, carried out in accordance with Article 4 of this Directive;

(e) how to detect adverse health effects of exposure and how to report them;

(f) the possibility of transient symptoms and sensations related to effects in the central or peripheral nervous system;

([1]) OJ L 245, 26.8.1992, p. 23.
([2]) OJ L 393, 30.12.1989, p. 18.

(g) the circumstances in which workers are entitled to health surveillance;

(h) safe working practices to minimise risks resulting from exposure;

(i) workers at particular risk, as referred to in Article 4(5)(d) and Article 5(3) and (4) of this Directive.

Article 7

Consultation and participation of workers

Consultation and participation of workers and/or their representatives shall take place in accordance with Article 11 of Directive 89/391/EEC.

CHAPTER III

MISCELLANEOUS PROVISIONS

Article 8

Health surveillance

1. With the objective of the prevention and the early diagnosis of any adverse health effects due to exposure to electromagnetic fields, appropriate health surveillance shall be carried out in accordance with Article 14 of Directive 89/391/EEC. Health records and their availability shall be provided for in accordance with national law and/or practice.

2. In accordance with national law and practice, the results of health surveillance shall be preserved in a suitable form that allows them to be consulted at a later date, subject to compliance with confidentiality requirements. Individual workers shall, at their request, have access to their own personal health records.

If any undesired or unexpected health effect is reported by a worker, or in any event where exposure above the ELVs is detected, the employer shall ensure that appropriate medical examinations or individual health surveillance is provided to the worker(s) concerned, in accordance with national law and practice.

Such examinations or surveillance shall be made available during hours chosen by the worker, and any costs arising shall not be borne by the worker.

Article 9

Penalties

Member States shall provide for adequate penalties applicable in the event of infringements of national legislation adopted pursuant to this Directive. These penalties must be effective, proportionate and dissuasive.

Article 10

Derogations

1. By way of derogation from Article 3 but without prejudice to Article 5(1), the following shall apply:

(a) exposure may exceed the ELVs if the exposure is related to the installation, testing, use, development, maintenance of or research related to magnetic resonance imaging (MRI) equipment for patients in the health sector, provided that all the following conditions are met:

(i) the risk assessment carried out in accordance with Article 4 has demonstrated that the ELVs are exceeded;

(ii) given the state of the art, all technical and/or organisational measures have been applied;

(iii) the circumstances duly justify exceeding the ELVs;

(iv) the characteristics of the workplace, work equipment, or work practices have been taken into account; and

(v) the employer demonstrates that workers are still protected against adverse health effects and against safety risks, including by ensuring that the instructions for safe use provided by the manufacturer in accordance with Council Directive 93/42/EEC of 14 June 1993 concerning medical devices [1] are followed;

(b) Member States may allow for an equivalent or more specific protection system to be implemented for personnel working in operational military installations or involved in military activities, including in joint international military exercises, provided that adverse health effects and safety risks are prevented;

(c) Member States may allow, in duly justified circumstances and only for as long as they remain duly justified, for the ELVs to be temporarily exceeded in specific sectors or for specific activities outside the scope of points (a) and (b). For the purposes of this point, 'duly justified circumstances' shall mean circumstances in which the following conditions are met:

(i) the risk assessment carried out in accordance with Article 4 has shown that the ELVs are exceeded;

(ii) given the state of the art, all technical and/or organisational measures have been applied;

(iii) the specific characteristics of the workplace, work equipment, or work practices have been taken into account; and

(iv) the employer demonstrates that workers are still protected against adverse health effects and safety risks, including using comparable, more specific and internationally recognised standards and guidelines.

[1] OJ L 169, 12.7.1993, p. 1.

2. Member States shall inform the Commission of any derogation under points (b) and (c) of paragraph 1 and shall state the reasons that justify them in the report referred to in Article 15.

Article 11

Technical amendments of the Annexes

1. The Commission shall be empowered to adopt delegated acts in accordance with Article 12 amending, in a purely technical way, the Annexes, so as to:

(a) take into account the adoption of regulations and directives in the field of technical harmonisation and standardisation with regard to the design, building, manufacture or construction of work equipment or workplaces;

(b) take into account technical progress, changes in the most relevant standards or specifications, and new scientific findings concerning electromagnetic fields;

(c) make adjustments to the ALs where there is new scientific evidence, provided that employers continue to be bound by the existing ELVs set out in Annexes II and III.

2. The Commission shall adopt a delegated act, in accordance with Article 12, to insert into Annex II the ICNIRP guidelines for limiting exposure to electric fields induced by movement of the human body in a static magnetic field and by time-varying magnetic fields below 1 Hz as soon as they are available.

3. Where, in the case of the amendments referred to in paragraphs 1 and 2, imperative grounds of urgency so require, the procedure provided for in Article 13 shall apply to delegated acts adopted pursuant to this Article.

Article 12

Exercise of the delegation

1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.

2. The power to adopt delegated acts referred to in Article 11 shall be conferred on the Commission for a period of five years from 29 June 2013. The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five-year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.

3. The delegation of powers referred to in Article 11 may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the *Official Journal of the European Union* or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.

4. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.

5. A delegated act adopted pursuant to Article 11 shall enter into force only if no objection has been expressed either by the European Parliament or the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or of the Council.

Article 13

Urgency procedure

1. Delegated acts adopted under this Article shall enter into force without delay and shall apply as long as no objection is expressed in accordance with paragraph 2. The notification of a delegated act to the European Parliament and to the Council shall state the reasons for the use of the urgency procedure which shall relate to the health and protection of workers.

2. Either the European Parliament or the Council may object to a delegated act in accordance with the procedure referred to in Article 12(5). In such a case, the Commission shall repeal the act without delay following the notification of the decision to object by the European Parliament or by the Council.

CHAPTER IV

FINAL PROVISIONS

Article 14

Practical guides

In order to facilitate the implementation of this Directive the Commission shall make available non-binding practical guides at the latest six months before 1 July 2016. Those practical guides shall, in particular relate to the following issues:

(a) the determination of exposure, taking into account appropriate European or international standards, including:

— calculation methods for the assessment of the ELVs,

— spatial averaging of external electric and magnetic fields,

— guidance for dealing with measurements and calculations uncertainties;

(b) guidance on demonstrating compliance in special types of non-uniform exposure in specific situations, based on well-established dosimetry;

(c) the description of the 'weighted peak method' for the low frequency fields and of the 'multifrequency fields summation' for high frequency fields;

(d) the conduct of the risk assessment and, wherever possible, the provision of simplified techniques, taking into account in particular the needs of SMEs;

(e) measures aimed at avoiding or reducing risks, including specific prevention measures depending on the level of exposure and the workplace characteristics;

(f) the establishment of documented working procedures, as well as specific information and training measures for workers exposed to electromagnetic fields during MRI-related activities falling under Article 10(1)(a);

(g) the evaluation of exposures in the frequency range from 100 kHz to 10 MHz, where both thermal and non-thermal effects are to be considered;

(h) the guidance on medical examinations and health surveillance to be provided by the employer in accordance with Article 8(2).

The Commission shall work in close cooperation with the Advisory Committee for Safety and Health at Work. The European Parliament shall be kept informed.

Article 15

Review and reporting

Taking into account Article 1(4), the report on the practical implementation of this Directive shall be established in accordance with Article 17a of Directive 89/391/EEC.

Article 16

Transposition

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 1 July 2016.

When Member States adopt those provisions, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such a reference is to be made.

2. Member States shall communicate to the Commission the text of the main provisions of national law which they adopt in the field covered by this Directive.

Article 17

Repeal

1. Directive 2004/40/EC is repealed from 29 June 2013.

2. References to the repealed Directive shall be construed as references to this Directive and shall be read in accordance with the correlation table set out in Annex IV.

Article 18

Entry into force

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

Article 19

Addressees

This Directive is addressed to the Member States.

Done at Brussels, 26 June 2013.

For the European Parliament	*For the Council*
The President	*The President*
M. SCHULZ	A. SHATTER

ANNEX I

PHYSICAL QUANTITIES REGARDING THE EXPOSURE TO ELECTROMAGNETIC FIELDS

The following physical quantities are used to describe the exposure to electromagnetic fields:

Electric field strength (E) is a vector quantity that corresponds to the force exerted on a charged particle regardless of its motion in space. It is expressed in volt per metre (Vm^{-1}). A distinction has to be made between the environmental electric field and the electric field present in the body (in situ) as a result of exposure to the environmental electric field.

Limb current (I_L) is the current in the limbs of a person exposed to electromagnetic fields in the frequency range from 10 MHz to 110 MHz as a result of contact with an object in an electromagnetic field or the flow of capacitive currents induced in the exposed body. It is expressed in ampere (A).

Contact current (I_C) is a current that appears when a person comes into contact with an object in an electromagnetic field. It is expressed in ampere (A). A steady state contact current occurs when a person is in continuous contact with an object in an electromagnetic field. In the process of making such contact, a spark discharge may occur with associated transient currents.

Electric charge (Q) is an appropriate quantity used for spark discharge and is expressed in coulomb (C).

Magnetic field strength (H) is a vector quantity that, together with the magnetic flux density, specifies a magnetic field at any point in space. It is expressed in ampere per metre (Am^{-1}).

Magnetic flux density (B) is a vector quantity resulting in a force that acts on moving charges, expressed in tesla (T). In free space and in biological materials, magnetic flux density and magnetic field strength can be interchanged using the magnetic field strength of $H = 1\ Am^{-1}$ equivalence to magnetic flux density of $B = 4\pi\ 10^{-7}$ T (approximately 1,25 microtesla).

Power density (S) is an appropriate quantity used for very high frequencies, where the depth of penetration in the body is low. It is the radiant power incident perpendicular to a surface, divided by the area of the surface. It is expressed in watt per square metre (Wm^{-2}).

Specific energy absorption (SA) is an energy absorbed per unit mass of biological tissue, expressed in joule per kilogram (Jkg^{-1}). In this Directive, it is used for establishing limits for effects from pulsed microwave radiation.

Specific energy absorption rate (SAR), averaged over the whole body or over parts of the body, is the rate at which energy is absorbed per unit mass of body tissue and is expressed in watt per kilogram (Wkg^{-1}). Whole-body SAR is a widely accepted quantity for relating adverse thermal effects to radio frequency (RF) exposure. Besides the whole-body average SAR, local SAR values are necessary to evaluate and limit excessive energy deposition in small parts of the body resulting from special exposure conditions. Examples of such conditions include: an individual exposed to RF in the low MHz range (e.g. from dielectric heaters) and individuals exposed in the near field of an antenna.

Of these quantities, magnetic flux density (B), contact current (I_C), limb current (I_L), electric field strength (E), magnetic field strength (H), and power density (S) can be measured directly.

ANNEX II

NON-THERMAL EFFECTS

EXPOSURE LIMIT VALUES AND ACTION LEVELS IN THE FREQUENCY RANGE FROM 0 Hz TO 10 MHz

A. EXPOSURE LIMIT VALUES (ELVs)

ELVs below 1 Hz (Table A1) are limits for static magnetic field which is not affected by the tissue of the body.

ELVs for frequencies from 1 Hz to 10 MHz (Table A2) are limits for electric fields induced in the body from exposure to time-varying electric and magnetic fields.

ELVs for external magnetic flux density from 0 to 1 Hz

The sensory effects ELV is the ELV for normal working conditions (Table A1) and is related to vertigo and other physiological effects related to disturbance of the human balance organ resulting mainly from moving in a static magnetic field

The health effects ELV for controlled working conditions (Table A1) is applicable on a temporary basis during the shift when justified by the practice or process, provided that preventive measures, such as controlling movements and providing information to workers, have been adopted.

Table A1

ELVs for external magnetic flux density (B_0) from 0 to 1 Hz

	Sensory effects ELVs
Normal working conditions	2 T
Localised limbs exposure	8 T
	Health effects ELVs
Controlled working conditions	8 T

Health effects ELVs for internal electric field strength from 1 Hz to 10 MHz

Health effects ELVs (Table A2) are related to electric stimulation of all peripheral and central nervous system tissues in the body, including the head.

Table A2

Health effects ELVs for internal electric field strength from 1 Hz to 10 MHz

Frequency range	Health effects ELVs
1 Hz ≤ f < 3 kHz	1,1 Vm^{-1} (peak)
3 kHz ≤ f ≤ 10 MHz	$3{,}8 \times 10^{-4}$ f Vm^{-1} (peak)

Note A2-1: f is the frequency expressed in hertz (Hz).

Note A2-2: The health effects ELVs for internal electric field are spatial peak values in the entire body of the exposed subject.

Note A2-3: The ELVs are peak values in time which are equal to the Root-Mean-Square (RMS) values multiplied by √2 for sinusoidal fields. In the case of non-sinusoidal fields, exposure evaluation carried out in accordance with Article 4 shall be based on the weighted peak method (filtering in time domain), explained in the practical guides referred to in Article 14 but other scientifically proven and validated exposure evaluation procedures can be applied, provided that they lead to approximately equivalent and comparable results.

Sensory effects ELVs for internal electric field strength from 1 Hz to 400 Hz

The sensory effects ELVs (Table A3) are related to electric field effects on the central nervous system in the head, i.e. retinal phosphenes and minor transient changes in some brain functions.

Table A3

Sensory effects ELVs for internal electric field strength from 1 to 400 Hz

Frequency range	Sensory effects ELVs
$1 \leq f < 10$ Hz	$0{,}7/f$ Vm^{-1} (peak)
$10 \leq f < 25$ Hz	$0{,}07$ Vm^{-1} (peak)
$25 \leq f \leq 400$ Hz	$0{,}0028\ f$ Vm^{-1} (peak)

Note A3-1: f is the frequency expressed in hertz (Hz).

Note A3-2: The sensory effects ELVs for internal electric field are spatial peak values in the head of the exposed subject.

Note A3-3: The ELVs are peak values in time which are equal to the Root-Mean-Square (RMS) values multiplied by $\sqrt{2}$ for sinusoidal fields. In the case of non-sinusoidal fields, the exposure evaluation carried out in accordance with Article 4 shall be based on the weighted peak method (filtering in time domain), explained in the practical guides referred to in Article 14, but other scientifically proven and validated exposure evaluation procedures can be applied, provided that they lead to approximately equivalent and comparable results.

B. ACTION LEVELS (ALs)

The following physical quantities and values are used to specify the action levels (ALs), the magnitude of which are established to ensure by simplified assessment the compliance with relevant ELVs or at which relevant protection or prevention measures specified in Article 5 must be taken:

— Low ALs(E) and high ALs(E) for electric field strength E of time varying electric fields as specified in Table B1;

— Low ALs(B) and high ALs(B) for magnetic flux density B of time varying magnetic fields as specified in Table B2;

— ALs(I_C) for contact current as specified in Table B3;

— ALs(B_0) for magnetic flux density of static magnetic fields as specified in Table B4.

ALs correspond to calculated or measured electric and magnetic field values at the workplace in the absence of the worker.

Action levels (ALs) for exposure to electric fields

Low ALs (Table B1) for external electric field are based on limiting the internal electric field below the ELVs (Tables A2 and A3) and limiting spark discharges in the working environment.

Below high ALs, the internal electric field does not exceed the ELVs (Tables A2 and A3) and annoying spark discharges are prevented, provided that the protection measures referred to in Article 5(6) are taken.

Table B1

ALs for exposure to electric fields from 1 Hz to 10 MHz

Frequency range	Electric field strength Low ALs (E)[Vm^{-1}] (RMS)	Electric field strength High ALs (E) [Vm^{-1}] (RMS)
$1 \leq f < 25$ Hz	$2{,}0 \times 10^4$	$2{,}0 \times 10^4$
$25 \leq f < 50$ Hz	$5{,}0 \times 10^5/f$	$2{,}0 \times 10^4$
50 Hz $\leq f <$ 1,64 kHz	$5{,}0 \times 10^5/f$	$1{,}0 \times 10^6/f$

Frequency range	Electric field strength Low ALs (E)[Vm^{-1}] (RMS)	Electric field strength High ALs (E) [Vm^{-1}] (RMS)
1,64 ≤ f < 3 kHz	$5{,}0 \times 10^5/f$	$6{,}1 \times 10^2$
3 kHz ≤ f ≤ 10 MHz	$1{,}7 \times 10^2$	$6{,}1 \times 10^2$

Note B1-1: f is the frequency expressed in hertz (Hz).

Note B1-2: The low ALs (E) and high ALs (E) are the Root-Mean-Square (RMS) values of the electric field strength which are equal to the peak values divided by √2 for sinusoidal fields. In the case of non-sinusoidal fields, the exposure evaluation carried out in accordance with Article 4 shall be based on the weighted peak method (filtering in time domain), explained in the practical guides referred to in Article 14, but other scientifically proven and validated exposure evaluation procedures can be applied, provided that they lead to approximately equivalent and comparable results.

Note B1-3: ALs represent maximum calculated or measured values at the workers' body position. This results in a conservative exposure assessment and automatic compliance with ELVs in all non-uniform exposure conditions. In order to simplify the assessment of compliance with ELVs, carried out in accordance with Article 4, in specific non-uniform conditions, criteria for the spatial averaging of measured fields based on established dosimetry will be laid down in the practical guides referred to in Article 14. In the case of a very localised source within a distance of a few centimetres from the body, the induced electric field shall be determined dosimetrically, case by case.

Action levels (ALs) for exposure to magnetic fields

Low ALs (Table B2) are, for frequencies below 400 Hz, derived from the sensory effects ELVs (Table A3) and, for frequencies above 400 Hz, from the health effects ELVs for internal electric field (Table A2).

High ALs (Table B2) are derived from the health effects ELVs for internal electric field related to electric stimulation of peripheral and autonomous nerve tissues in head and trunk (Table A2). Compliance with the high ALs ensures that health effects ELVs are not exceeded, but the effects related to retinal phosphenes and minor transient changes in brain activity are possible, if the exposure of the head exceeds the low ALs for exposures up to 400 Hz. In such a case, Article 5(6) applies.

ALs for exposure of limbs are derived from the health effects ELVs for internal electric field related to electric stimulation of the tissues in limbs by taking into account that the magnetic field is coupled more weakly to the limbs than to the whole body.

Table B2

ALs for exposure to magnetic fields from 1 Hz to 10 MHz

Frequency range	Magnetic flux density Low ALs(B)[μT] (RMS)	Magnetic flux density High ALs(B) [μT] (RMS)	Magnetic flux density ALs for exposure of limbs to a localised magnetic field [μT] (RMS)
1 ≤ f < 8 Hz	$2{,}0 \times 10^5/f^2$	$3{,}0 \times 10^5/f$	$9{,}0 \times 10^5/f$
8 ≤ f < 25 Hz	$2{,}5 \times 10^4/f$	$3{,}0 \times 10^5/f$	$9{,}0 \times 10^5/f$
25 ≤ f < 300 Hz	$1{,}0 \times 10^3$	$3{,}0 \times 10^5/f$	$9{,}0 \times 10^5/f$
300 Hz ≤ f < 3 kHz	$3{,}0 \times 10^5/f$	$3{,}0 \times 10^5/f$	$9{,}0 \times 10^5/f$
3 kHz ≤ f ≤ 10 MHz	$1{,}0 \times 10^2$	$1{,}0 \times 10^2$	$3{,}0 \times 10^2$

Note B2-1: f is the frequency expressed in hertz (Hz).

Note B2-2: The low ALs and the high ALs are the Root-Mean-Square (RMS) values which are equal to the peak values divided by √2 for sinusoidal fields. In the case of non-sinusoidal fields the exposure evaluation carried out in accordance with Article 4 shall be based on the weighted peak method (filtering in time domain), explained in practical guides referred to in Article 14, but other scientifically proven and validated exposure evaluation procedures can be applied, provided that they lead to approximately equivalent and comparable results.

Note B2-3: ALs for exposure to magnetic fields represent maximum values at the workers' body position. This results in a conservative exposure assessment and automatic compliance with ELVs in all non-uniform exposure conditions. In order to simplify the assessment of compliance with ELVs, carried out in accordance with Article 4, in specific non-uniform conditions, criteria for the spatial averaging of measured fields based on established dosimetry will be laid down in the practical guides referred to in Article 14. In the case of a very localised source within a distance of a few centimetres from the body, the induced electric field shall be determined dosimetrically, case by case.

Table B3

ALs for contact current I_C

Frequency	ALs (I_C) steady state contact current [mA] (RMS)
up to 2,5 kHz	1,0
2,5 ≤ f < 100 kHz	0,4 f
100 ≤ f ≤ 10 000 kHz	40

Note B3-1: f is the frequency expressed in kilohertz (kHz).

Action levels (ALs) for magnetic flux density of static magnetic fields

Table B4

ALs for magnetic flux density of static magnetic fields

Hazards	ALs(B_0)
Interference with active implanted devices, e.g. cardiac pacemakers	0,5 mT
Attraction and projectile risk in the fringe field of high field strength sources (> 100 mT)	3 mT

ANNEX III

THERMAL EFFECTS

EXPOSURE LIMIT VALUES AND ACTION LEVELS IN THE FREQUENCY RANGE FROM 100 kHz TO 300 GHz

A. EXPOSURE LIMIT VALUES (ELVs)

Health effects ELVs for frequencies from 100 kHz to 6 GHz (Table A1) are limits for energy and power absorbed per unit mass of body tissue generated from exposure to electric and magnetic fields.

Sensory effects ELVs for frequencies from 0,3 to 6 GHz (Table A2) are limits on absorbed energy in a small mass of tissue in the head from exposure to electromagnetic fields.

Health effects ELVs for frequencies above 6 GHz (Table A3) are limits for power density of an electromagnetic wave incident on the body surface.

Table A1

Health effects ELVs for exposure to electromagnetic fields from 100 kHz to 6 GHz

Health effects ELVs	SAR values averaged over any six-minute period
ELVs related to whole body heat stress expressed as averaged SAR in the body	0,4 Wkg^{-1}
ELVs related to localised heat stress in head and trunk expressed as localised SAR in the body	10 Wkg^{-1}
ELVs related to localised heat stress in the limbs expressed as localised SAR in the limbs	20 Wkg^{-1}

Note A1-1: Localised SAR averaging mass is any 10 g of contiguous tissue; the maximum SAR so obtained should be the value used for estimating exposure. This 10 g of tissue is intended to be a mass of contiguous tissue with roughly homogeneous electrical properties. In specifying a contiguous mass of tissue, it is recognised that this concept may be used in computational dosimetry but may present difficulties for direct physical measurements. A simple geometry, such as cubic or spheric tissue mass, can be used.

Sensory effects ELVs from 0,3 GHz to 6 GHz

This sensory effects ELVs (Table A2) is related to avoiding auditory effects caused by exposures of the head to pulsed microwave radiation.

Table A2

Sensory effects ELVs for exposure to electromagnetic fields from 0,3 to 6 GHz

Frequency range	Localised specific energy absorption (SA)
$0,3 \leq f \leq 6$ GHz	10 $mJkg^{-1}$

Note A2-1: Localised SA averaging mass is 10 g of tissue.

Table A3

Health effects ELVs for exposure to electromagnetic fields from 6 to 300 GHz

Frequency range	Health effects ELVs related to power density
$6 \leq f \leq 300$ GHz	50 Wm^{-2}

Note A3-1: The power density shall be averaged over any 20 cm^2 of exposed area. Spatial maximum power densities averaged over 1 cm^2 should not exceed 20 times the value of 50 Wm^{-2}. Power densities from 6 to 10 GHz are to be averaged over any six-minute period. Above 10 GHz, the power density shall be averaged over any $68/f^{1,05}$-minute period (where f is the frequency in GHz) to compensate for progressively shorter penetration depth, as the frequency increases.

B. ACTION LEVELS (ALs)

The following physical quantities and values are used to specify the action levels (ALs), the magnitude of which are established to ensure by simplified assessment the compliance with the relevant ELVs or at which relevant protection or prevention measures specified in Article 5 must be taken:

— ALs(E) for electric field strength E of time varying electric field, as specified in Table B1;

— ALs(B) for magnetic flux density B of time varying magnetic field, as specified in Table B1;

— ALs(S) for power density of electromagnetic waves, as specified in Table B1;

— ALs(I_C) for contact current, as specified in Table B2;

— ALs(I_L) for limb current, as specified in Table B2;

ALs correspond to calculated or measured field values at the workplace in the absence of the worker, as maximum value at the position of the body or specified part of the body.

Action levels (ALs) for exposure to electric and magnetic fields

ALs(E) and ALs(B) are derived from the SAR or power density ELVs (Tables A1 and A3) based on the thresholds related to internal thermal effects caused by exposure to (external) electric and magnetic fields.

Table B1

ALs for exposure to electric and magnetic fields from 100 kHz to 300 GHz

Frequency range	Electric field strength ALs(E) [Vm^{-1}] (RMS)	Magnetic flux density ALs(B) [μT] (RMS)	Power density ALs(S) [Wm^{-2}]
100 kHz ≤ f < 1 MHz	$6{,}1 \times 10^2$	$2{,}0 \times 10^6/f$	—
1≤ f < 10 MHz	$6{,}1 \times 10^8/f$	$2{,}0 \times 10^6/f$	—
10 ≤ f < 400 MHz	61	0,2	—
400 MHz ≤ f < 2 GHz	$3 \times 10^{-3}\ f^{½}$	$1{,}0 \times 10^{-5}\ f^{½}$	—
2 ≤ f < 6 GHz	$1{,}4 \times 10^2$	$4{,}5 \times 10^{-1}$	—
6 ≤ f ≤ 300 GHz	$1{,}4 \times 10^2$	$4{,}5 \times 10^{-1}$	50

Note B1-1: f is the frequency expressed in hertz (Hz).

Note B1-2: $[ALs(E)]^2$ and $[ALs(B)]^2$ are to be averaged over a six-minute period. For RF pulses, the peak power density averaged over the pulse width shall not exceed 1 000 times the respective ALs(S) value. For multi-frequency fields, the analysis shall be based on summation, as explained in the practical guides referred to in Article 14.

Note B1-3: ALs(E) and ALs(B) represent maximum calculated or measured values at the workers' body position. This results in a conservative exposure assessment and automatic compliance with ELVs in all non-uniform exposure conditions. In order to simplify the assessment of compliance with ELVs, carried out in accordance with Article 4, in specific non-uniform conditions, criteria for the spatial averaging of measured fields based on established dosimetry will be laid down in the practical guides referred to in Article 14. In the case of a very localised source within a distance of a few centimetres from the body, compliance with ELVs shall be determined dosimetrically, case by case.

Note B1-4: The power density shall be averaged over any 20 cm^2 of exposed area. Spatial maximum power densities averaged over 1 cm^2 should not exceed 20 times the value of 50 Wm^{-2}. Power densities from 6 to 10 GHz are to be averaged over any six-minute period. Above 10 GHz, the power density shall be averaged over any $68/f^{1,05}$-minute period (where f is the frequency in GHz) to compensate for progressively shorter penetration depth as the frequency increases.

Table B2

ALs for steady state contact currents and induced limb currents

Frequency range	Steady state contact current, $ALs(I_C)$ [mA] (RMS)	Induced limb current in any limb, $ALs(I_L)$ [mA] (RMS)
100 kHz ≤ f < 10 MHz	40	—
10 ≤ f ≤ 110 MHz	40	100

Note B2-1: $[ALs(I_L)]^2$ is to be averaged over a six-minute period.

ANNEX IV

Correlation table

Directive 2004/40/EC	This Directive
Article 1(1)	Article 1(1)
Article 1(2)	Article 1(2) and (3)
Article 1(3)	Article 1(4)
Article 1(4)	Article 1(5)
Article 1(5)	Article 1(6)
Article 2(a)	Article 2(a)
—	Article 2(b)
—	Article 2(c)
Article 2(b)	Article 2(d), (e) and (f)
Article 2(c)	Article 2(g)
Article 3(1)	Article 3(1)
Article 3(2)	Article 3(1)
—	Article 3(2)
Article 3(3)	Article 3(2) and (3)
—	Article 3(4)
Article 4(1)	Article 4(1)
Article 4(2)	Article 4(2) and (3)
Article 4(3)	Article 4(3)
Article 4(4)	Article 4(4)
Article 4(5)(a)	Article 4(5)(b)
Article 4(5)(b)	Article 4(5)(a)
—	Article 4(5)(c)
Article 4(5)(c)	Article 4(5)(d)
Article 4(5)(d)	Article 4(5)(e)
Article 4(5)(d)(i)	—
Article 4(5)(d)(ii)	—
Article 4(5)(d)(iii)	—

Directive 2004/40/EC	This Directive
Article 4(5)(d)(iv)	—
Article 4(5)(e)	Article 4(5)(f)
Article 4(5)(f)	Article 4(5)(g)
—	Article 4(5)(h)
—	Article 4(5)(i)
Article 4(5)(g)	Article 4(5)(j)
Article 4(5)(h)	Article 4(5)(k)
—	Article 4(6)
Article 4(6)	Article 4(7)
Article 5(1)	Article 5(1)
Article 5(2), introductory wording	Article 5(2), introductory wording
Article 5(2)(a) to (c)	Article 5(2)(a) to (c)
—	Article 5(2)(d)
—	Article 5(2)(e)
Article 5(2)(d) to (g)	Article 5(2)(f) to (i)
—	Article 5(4)
Article 5(3)	Article 5(5)
—	Article 5(6)
—	Article 5(7)
Article 5(4)	Article 5(8)
—	Article 5(9)
Article 5(5)	Article 5(3)
Article 6, introductory wording	Article 6, introductory wording
Article 6(a)	Article 6(a)
Article 6(b)	Article 6(b)
—	Article 6(c)
Article 6(c)	Article 6(d)
Article 6(d)	Article 6(e)
—	Article 6(f)

Directive 2004/40/EC	This Directive
Article 6(e)	Article 6(g)
Article 6(f)	Article 6(h)
—	Article 6(i)
Article 7	Article 7
Article 8(1)	Article 8(1)
Article 8(2)	—
Article 8(3)	Article 8(2)
Article 9	Article 9
—	Article 10
Article 10(1)	Article 11(1)(c)
Article 10(2)(a)	Article 11(1)(a)
Article 10(2)(b)	Article 11(1)(b)
Article 11	—
—	Article 12
—	Article 13
—	Article 14
—	Article 15
Article 13(1)	Article 16(1)
Article 13(2)	Article 16(2)
—	Article 17
Article 14	Article 18
Article 15	Article 19
Annex	Annex I, Annex II and Annex III
—	Annex IV

II

(Non-legislative acts)

REGULATIONS

COUNCIL REGULATION (EU) No 626/2013

of 27 June 2013

amending Regulation (EU) No 1344/2011 suspending the autonomous Common Customs Tariff duties on certain agricultural, fishery and industrial products

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 31 thereof,

Having regard to the proposal from the European Commission,

Whereas:

(1) It is in the interest of the Union to suspend totally the autonomous Common Customs Tariff duties on 80 new products which are currently not listed in the Annex to Council Regulation (EU) No 1344/2011 [1]. Those products should therefore be inserted in that Annex.

(2) It is no longer in the interest of the Union to maintain the suspension of autonomous Common Customs Tariff duties for 15 of the products which are currently listed in the Annex to Regulation (EU) No 1344/2011. Accordingly, those products should be deleted from that Annex.

(3) It is necessary to modify the product description of 22 suspensions in the Annex to Regulation (EU) No 1344/2011 in order to take account of technical product developments and economic trends on the market as well as linguistic adaptations. Moreover, TARIC codes for eight products should be changed. In addition, for three products multiple classification is considered necessary whereas for 12 products double classification is no longer necessary.

(4) Those suspensions for which technical modifications are necessary should be deleted from the list of suspensions in the Annex to Regulation (EU) No 1344/2011 and should be reinserted in that list with new product descriptions, or new CN or TARIC codes.

(5) For three products it is in the interest of the Union to amend the date for their mandatory review in accordance with Article 2(2) and (3) of Regulation (EU) No 1344/2011. The reviewed suspensions should therefore be deleted from the list of suspensions in the Annex to Regulation (EU) No 1344/2011 and reinserted in that list with new time limits for a mandatory review.

(6) In the interest of clarity, the modified entries should be marked with an asterisk in the lists of inserted and deleted suspensions set out in Annex I and Annex II to this Regulation.

(7) In view of their temporary nature, the suspensions listed in Annex I should be reviewed systematically, at the latest five years after their application or renewal. Moreover, closure of certain suspensions should be warranted at any time, as a result of a proposal of the Commission on the basis of a review carried out on the initiative of the Commission or at the request of one or more Member States, if it is no longer in the Union's interest to maintain the suspensions, or due to technical product developments, changed circumstances or economic trends on the market.

(8) Since it is necessary that the suspensions laid down in this Regulation take effect from 1 July 2013, this Regulation should apply from that date and should enter into force immediately upon its publication in the *Official Journal of the European Union*.

(9) Regulation (EU) No 1344/2011 should therefore be amended accordingly,

HAS ADOPTED THIS REGULATION:

Article 1

The Annex to Regulation (EU) No 1344/2011 is hereby amended as follows:

(1) the rows for the products listed in Annex I to this Regulation are inserted;

(2) the rows for the products for which the CN and TARIC codes are set out in Annex II to this Regulation are deleted.

[1] OJ L 349, 31.12.2011, p. 1.

Article 2

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

It shall apply from 1 July 2013.

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

Done at Brussels, 27 June 2013.

For the Council
The President
E. GILMORE

ANNEX I

Products referred to in point (1) of Article 1

CN code	TARIC	Description	Rate of autonomous duty	Date foreseen for mandatory review
(*) ex 2007 99 50	81	Acerola puree concentrate: — of the genus *Malpighia* spp., — with a sugar content by weight of 13 % or more but not more than 30 % for use in the manufacture of products of food and drink industry (1)	9 % (2)	31.12.2017
(*) ex 2007 99 50	91			
ex 2007 99 50	82	Acidified banana puree concentrate, obtained by cooking: — of the genus *Musa* cavendish, — with a sugar content by weight of 13 % or more but not more than 30 % for use in the manufacture of products of food and drink industry (1)	11,5 % (2)	31.12.2017
ex 2007 99 50	92			
(*) ex 2007 99 50	83	Mango puree concentrate, obtained by cooking: — of the genus *Mangifera* spp., — with a sugar content by weight of not more than 30 % for use in the manufacture of products of food and drink industry (1)	6 % (2)	31.12.2017
(*) ex 2007 99 50	93			
(*) ex 2007 99 93	10			
(*) ex 2007 99 50	84	Papaya puree concentrate, obtained by cooking: — of the genus *Carica* spp., — with a sugar content by weight of 13 % or more but not more than 30 % for use in the manufacture of products of food and drink industry (1)	7,8 % (2)	31.12.2017
(*) ex 2007 99 50	94			
ex 2007 99 50	85	Guava puree concentrate, obtained by cooking: — of the genus *Psidium* spp., — with a sugar content by weight of 13 % or more but not more than 30 % for use in the manufacture of products of food and drink industry (1)	6 % (2)	31.12.2017
ex 2007 99 50	95			
(*) ex 2805 30 90	40	Rare earth metals, scandium and yttrium of a purity by weight of 95 % or more	0 %	31.12.2015
(*) ex 2805 30 90	50			
(*) ex 2805 30 90	60			
(*) ex 2805 30 90	70			
(*) ex 2805 30 90	75			
(*) ex 2805 30 90	79			

CN code	TARIC	Description	Rate of autonomous duty	Date foreseen for mandatory review
ex 2811 19 80	30	Phosphorous acid (CAS RN 10294-56-1)/phosphonic acid (CAS RN 13598-36-2) used as an ingredient for production of additives used in poly(vinyl chloride) industry (1)	0 %	31.12.2017
(*) ex 2818 10 91	10	Sintered corundum with micro crystalline structure, containing by weight: — 94 % or more, but not more than 98,5 % of α-Al2O3, — 2 % (± 1,5 %) of magnesium spinel, — 1 % (± 0,6 %) of yttrium oxide and — 2 % (± 1,2 %) of lanthanum oxide and neodymium oxide with less than 50 % of the total weight having a particle size of more than 10 mm	0 %	31.12.2015
ex 2903 39 90	25	2,3,3,3-Tetrafluoroprop-1-ene (CAS RN 754-12-1)	0 %	31.12.2017
ex 2903 89 90	50	Chlorocyclopentane (CAS RN 930-28-9)	0 %	31.12.2017
ex 2905 39 95	40	Decane-1,10-diol (CAS RN 112-47-0)	0 %	31.12.2017
ex 2906 29 00	30	2-Phenylethanol (CAS RN 60-12-8)	0 %	31.12.2017
ex 2907 23 00	10	4,4'-Isopropylidenediphenol (CAS RN 80-05-7)	0 %	31.12.2017
ex 2907 29 00	55	Biphenyl-2,2'-diol (CAS RN 1806-29-7)	0 %	31.12.2017
ex 2912 29 00	50	4-Isobutylbenzaldehyde (CAS RN 40150-98-9)	0 %	31.12.2017
ex 2914 50 00	45	3,4-Dihydroxybenzophenone (CAS RN 10425-11-3)	0 %	31.12.2017
ex 2914 70 00	20	2,4-Difluorobenzophenone (CAS RN 342-25-6)	0 %	31.12.2017
ex 2915 39 00	20	Isopentyl acetate (CAS RN 123-92-2)	0 %	31.12.2017
ex 2915 60 19	10	Ethyl butyrate (CAS RN 105-54-4)	0 %	31.12.2017
ex 2915 90 70	30	3,3-Dimethylbutyryl chloride (CAS RN 7065-46-5)	0 %	31.12.2017
ex 2916 12 00	70	2-(2-Vinyloxyethoxy)ethyl acrylate (CAS RN 86273-46-3)	0 %	31.12.2017
(*) ex 2917 13 90	10	Dimethyl sebacate (CAS RN 106-79-6)	0 %	31.12.2017
ex 2918 29 00	35	Propyl 3,4,5-trihydroxybenzoate (CAS RN 121-79-9)	0 %	31.12.2017
ex 2918 30 00	50	Ethyl acetoacetate (CAS RN 141-97-9)	0 %	31.12.2017
ex 2918 99 90	15	Ethyl 2,3-epoxy-3-phenylbutyrate (CAS RN 77-83-8)	0 %	31.12.2017
(*) ex 2918 99 90	40	trans-4-Hydroxy-3-methoxycinnamic acid (CAS RN 537-98-4)	0 %	31.12.2013
ex 2920 90 10	60	2,4-Di-tert-butyl-5-nitrophenyl methyl carbonate (CAS RN 873055-55-1)	0 %	31.12.2017
ex 2921 30 99	40	Cyclopropylamin (CAS RN 765-30-0)	0 %	31.12.2017
ex 2922 19 85	20	2-(2-Methoxyphenoxy)ethylamine hydrochloride (CAS RN 64464-07-9)	0 %	31.12.2017

CN code	TARIC	Description	Rate of autonomous duty	Date foreseen for mandatory review
ex 2922 19 85	25	Titanium bis(triethanolamine)diisopropoxide (CAS RN 36673-16-2)	0 %	31.12.2017
ex 2929 10 00	20	Butyl isocyanate (CAS RN 111-36-4)	0 %	31.12.2017
ex 2931 90 90	35	(Z)-Prop-1-en-1-ylphosphonic acid (CAS RN 25383-06-6)	0 %	31.12.2017
ex 2932 99 00	25	1-(2,2-Difluorobenzo[d][1,3]dioxol-5-yl)cyclopropanecarboxylic acid (CAS RN 862574-88-7)	0 %	31.12.2017
ex 2933 19 90	85	Allyl 5-amino-4-(2-methylphenyl)-3-oxo-2,3-dihydro-1H-1-pyrazolcarbothioat (CAS RN 473799-16-5)	0 %	31.12.2017
ex 2933 29 90	80	Imazalil (ISO) (CAS RN 35554-44-0)	0 %	31.12.2017
ex 2933 39 99	57	Tert-butyl 3-(6-amino-3-methylpyridin-2-yl)benzoate (CAS RN 1083057-14-0)	0 %	31.12.2017
ex 2933 49 10	30	Ethyl 4-oxo-1,4-dihydroquinoline-3-carboxylate (CAS RN 52980-28-6)	0 %	31.12.2017
ex 2933 99 80	43	2,3-Dihydro-1H-pyrrole[3,2,1-ij]quinoline (CAS RN 5840-01-7)	0 %	31.12.2017
ex 2933 99 80	47	Paclobutrazol (ISO) (CAS RN 76738-62-0)	0 %	31.12.2017
ex 2934 99 90	37	4-Propan-2-ylmorpholine (CAS RN 1004-14-4)	0 %	31.12.2017
(*) ex 3204 11 00	20	Dye C.I. Disperse Yellow 241 (CAS RN 83249-52-9), with a purity of 97 % or more as determined by high pressure liquid chromatography	0 %	31.12.2015
ex 3204 11 00	80	Dye preparation, non-ionogenic, containing: — N-[5-(acetylamino)-4-[(2-chloro-4,6-dinitrophenyl)azo]-2-methoxyphenyl]- 2-oxo-2-(phenylmethoxy)ethyl-β-alanine (CAS RN 159010-67-0) — N-[4-[(2-cyano-4-nitrophenyl)azo]phenyl]-N-methyl-2-(1,3-dihydro-1,3-dioxo-2H-isoindol-2-yl)ethyl-β-alanine (CAS RN 170222-39-6) and — N-[2-chloro-4-[(4-nitrophenyl)azo]phenyl]-2-[2-(1,3-dihydro-1,3-dioxo-2H-isoindol-2-yl)ethoxy]-2-oxoethyl-β-alanine (CAS RN 371921-34-5)	0 %	31.12.2017
ex 3204 12 00	20	Dye preparation, anionic, containing by weight 75 % or more of disodium-7-((4-chloro-6-(dodecylamino)-1,3,5-triazin-2-yl)amino)-4-hydroxy-3-((4-((4-sulfophenyl)azo)phenyl)azo)-2-naphthalenesulfonate (CAS RN 145703-76-0)	0 %	31.12.2017
ex 3204 12 00	30	Acid dye preparation, anionic, containing: — lithium-amino-4-(4-tert-butylanilino)anthraquinone-2-sulfonate (CAS RN 125328-86-1), — C.I. Acid Green 25 (CAS RN 4403-90-1) and — C.I. Acid Blue 80 (CAS RN 4474-24-2)	0 %	31.12.2017
ex 3204 13 00	30	Dye C.I. Basic Blue 7 (CAS RN 2390-60-5)	0 %	31.12.2017
ex 3204 13 00	40	Dye C.I. Basic Violet 1 (CAS RN 603-47-4)/(CAS RN 8004-87-3)	0 %	31.12.2017
(*) ex 3204 17 00	25	Dye C.I. Pigment Yellow 14 (CAS RN 5468-75-7)	0 %	31.12.2016

CN code	TARIC	Description	Rate of autonomous duty	Date foreseen for mandatory review
(*) ex 3204 17 00	60	Dye C.I. Pigment Red 53:1 (CAS RN 5160-02-1)	0 %	31.12.2016
(*) ex 3204 17 00	70	Dye C.I. Pigment Yellow 13 (CAS RN 5102-83-0)	0 %	31.12.2016
ex 3204 17 00	75	Dye C.I. Pigment Orange 5 (CAS RN 3468-63-1)	0 %	31.12.2017
(*) ex 3204 19 00	73	Dye C.I. Solvent Blue 104 (CAS RN 116-75-6) with a purity of 97 % or more determined by high pressure liquid chromatography	0 %	31.12.2015
ex 3207 40 85	40	Glass flakes (CAS RN 65997-17-3): — of a thickness of 0,3 μm or more but not more than 10 μm, and — coated with titanium dioxide (CAS RN 13463-67-7) or iron oxide (CAS RN 18282-10-5)	0 %	31.12.2017
ex 3215 19 00	20	Ink: — consisting of a polyester polymer and a dispersion of silver (CAS RN 7440-22-4) and silver chloride (CAS RN 7783-90-6) in methyl propyl ketone (CAS RN 107-87-9), — with a total solid content by weight of 55 % or more, but not more than 57 %, and — with a specific gravity of 1,40 g/cm^3 or more, but not more than 1,60 g/cm^3, used to imprint electrodes (1)	0 %	31.12.2017
ex 3707 90 20	50	Dry ink powder or toner blend, consisting of: — styrene acrylate/butadiene copolymer — either carbon black or an organic pigment — whether or not containing polyolefin or amorphous silica for use as a developer in the manufacturing of ink/toner filled bottles or cartridges for facsimile machines, computer printers and copiers (1)	0 %	31.12.2017
(*) ex 3802 90 00	11	Soda flux calcinated diatomaceous earth, acid washed, for use as a filter aid in the manufacture of pharmaceutical and/or biochemical products (1)	0 %	31.12.2017
ex 3812 30 80	75	N,N'-Bis(1,2,2,6,6-pentamethyl-4-piperidinyl)-1,6-hexanediamine, polymer with 2,4-dichloro-6-(4-morpholinyl)-1,3,5-triazine (CAS RN 193098-40-7)	0 %	31.12.2017

CN code	TARIC	Description	Rate of autonomous duty	Date foreseen for mandatory review
ex 3812 30 80	80	UV-stabiliser, consisting of: — a hindered amine: N,N'-bis(1,2,2,6,6-pentamethyl-4-piperidinyl)-1,6-hexanediamine, polymer with 2,4-dichloro-6-(4-morpholinyl)-1,3,5-triazine (CAS RN 193098-40-7) and — either an o-hydroxyphenyl triazine UV light absorber or — a chemically modified phenolic compound	0 %	31.12.2017
(*) ex 3812 30 80	85	Mixture containing by weight: — 70 % or more but not more than 80 % of bis(1,2,2,6,6-pentamethyl-4-piperidyl)sebacate (CAS RN 41556-26-7) and — 20 % or more but not more than 30 % of methyl-1,2,2,6,6-pentamethyl-4-piperidyl sebacate (CAS RN 82919-37-7)	0 %	31.12.2016
(*) ex 3824 90 97	08	Mixture of divinylbenzene-isomers and ethylvinylbenzene-isomers, containing by weight 56 % or more but not more than 85 % of divinylbenzene (CAS RN 1321-74-0)	0 %	31.12.2014
(*) ex 3824 90 97	18	Poly(tetramethylene glycol) bis[(9-oxo-9H-thioxanthen-1-yloxy)acetate] with an average polymer chain length of less than 5 monomer units (CAS RN 515136-48-8)	0 %	31.12.2013
ex 3824 90 97	47	Platinum oxide (CAS RN 12035-82-4) fixed on a porous support of aluminium oxide (CAS RN 1344-28-1), containing by weight: — 0,1 % or more but not more than 1 % of platinum, and — 0,5 % or more but not more than 5 % of ethylaluminium dichloride (CAS RN 563-43-9)	0 %	31.12.2017
ex 3824 90 97	49	Preparation containing: — C,C'-azodi(formamide) (CAS RN 123-77-3), — magnesium oxide (CAS RN 1309-48-4) and — zinc bis(p-toluene sulphinate) (CAS RN 24345-02-6) in which the gas formation from C,C'-azodi(formamide) occurs at 135 °C	0 %	31.12.2017
ex 3824 90 97	51	Diethylene glycol propylene glycol triethanolamine titanate complexes (CAS RN 68784-48-5) dissolved in diethylene glycol (CAS RN 111-46-6)	0 %	31.12.2017
(*) ex 3824 90 97	87	Paste containing by weight: — 75 % or more, but not more than 85 % of copper, — inorganic oxides, — ethyl cellulose, and — a solvent	0 %	31.12.2017
(*) ex 3824 90 97	93	Solution containing by weight 80 % or more of 2,4,6-trimethyl-benzaldehyde (CAS RN 487-68-3) in acetone	0 %	31.12.2013
(*) ex 3824 90 97	94	Particles of silicon dioxide on which are covalently bonded organic compounds, for use in the manufacture of high performance liquid chromatography columns (HPLC) and sample preparation cartridges [1]	0 %	31.12.2013

CN code	TARIC	Description	Rate of autonomous duty	Date foreseen for mandatory review
ex 3905 30 00	10	Viscous preparation, essentially consisting of poly(vinyl alcohol) (CAS RN 9002-89-5), an organic solvent and water for use as protective coating of wafers during the manufacturing of semi-conductors [1]	0 %	31.12.2017
ex 3905 91 00	20	Water soluble copolymer of ethylene and vinyl alcohol (CAS RN 26221-27-2), containing by weight not more than 13 % of the monomer unit ethylene	0 %	31.12.2017
ex 3906 90 90	27	Copolymer of stearyl methacrylate, isooctyl acrylate and acrylic acid, dissolved in isopropyl palmitate	0 %	31.12.2017
ex 3907 20 20	20	Polytetramethylene ether glycol with a weight average molecular weight (Mw) of 2 700 or more but not more than 3 100 (CAS RN 25190-06-1)	0 %	31.12.2017
(*) ex 3907 20 20	30	Mixture, containing by weight 70 % or more but not more than 80 % of a polymer of glycerol and 1,2-epoxypropane and 20 % or more but not more than 30 % of a copolymer of dibutyl maleate and N-vinyl-2-pyrrolidone	0 %	31.12.2013
(*) ex 3907 20 20	40	Copolymer of tetrahydrofuran and tetrahydro-3-methylfuran with a number average molecular weight (Mn) of 3 500 (± 100)	0 %	31.12.2013
(*) ex 3907 40 00	10	Polycarbonate pellets: — containing 7 % or more but not more than 15 % by weight of non-halogen flame retardant, and — with a specific gravity of 1,20 (± 0,01)	0 %	31.12.2016
(*) ex 3907 99 90	30	Poly(hydroxyalkanoate), predominantly consisting of poly(3-hydroxybutyrate)	0 %	31.12.2015
(*) ex 3913 90 00	20			
(*) ex 3909 50 90	10	UV curable water soluble liquid photopolymer consisting of a mixture by weight of — 60 % or more of two-functional acrylated polyurethane oligomers and — 30 % (± 8 %) of mono-functional and tri-functional (metha) acrylates, and — 10 % (± 3 %) of hydroxyl functionalised mono-functional (metha) acrylates	0 %	31.12.2014
ex 3919 10 80 ex 3919 90 00	47 32	Polyester, polyurethane or polycarbonate foil: — with pressure sensitive silicone polymer adhesive, — of a total thickness of not more than 0,7 mm, — of a total width of 1 cm or more, but not more than 1 m, — whether or not in rolls of a kind used for the protection of the surface of products of headings 8521 and 8528	0 %	31.12.2017

CN code	TARIC	Description	Rate of autonomous duty	Date foreseen for mandatory review
ex 3919 10 80 ex 3919 90 00 ex 3920 10 28 ex 3920 10 89	53 34 93 50	Polyethylene foil: — with pressure sensitive, non-rubber adhesive adhering solely to clean and smooth surfaces, — of a total thickness of 0,025 mm or more, but not more than 0,7 mm, and — of a total width of 6 cm or more, but not more than 1 m, — whether or not in rolls, of a kind used for the protection of the surface of products of headings 8521 and 8528	0 %	31.12.2017
ex 3919 90 00 ex 3920 49 10	36 95	Printed laminated sheet with a central layer of poly(vinyl chloride), coated on both sides with a layer of poly(vinyl fluoride) — whether or not with a pressure or heat sensitive adhesive layer — whether or not with a release film — with a toxicity (as determined by test method ABD 0031) of not more than 70 ppm hydrogen fluoride, not more than 120 ppm hydrogen chloride, not more than 10 ppm hydrogen cyanide, not more than 10 ppm nitrogen oxides, not more than 300 ppm carbon monoxide and not more than 10 ppm dihydrogen sulphide and sulphur dioxide taken together — with a flammability within 60 seconds of not more than 130 mm (as determined by test method FAR 25 App.F Pt. I Amdt.83) — with a weight (without release film) of 240 g/m^2 (± 30 g/m^2) without adhesive layer, of 340 g/m^2 (± 40 g/m^2) with heat sensitive adhesive layer or of 330 g/m^2 (± 40 g/m^2) with pressure sensitive layer	0 %	31.12.2017
ex 3919 90 00	38	Self-adhesive film composed of: — a top layer predominantly of polyurethane mixed with acrylic polymer emulsions and titanium dioxide, — whether or not containing a second layer of a mixture of vinyl acetate-ethylene copolymer and cross-linkable vinyl acetate polymer emulsions, — not more than 6 % by weight of other additives, — a pressure sensitive adhesive; and — covered on one side with a release liner, — whether or not with a separate self-adhesive over laminate protective film, — of a total thickness of not more than 400 µm	0 %	31.12.2017
ex 3919 90 00	40	Film, with a total thickness of 40 µm or more, consisting of one or more layers of transparent polyester film: — containing at least one infrared reflective layer with a total normal reflectance according to EN 12898 of 80 % or more — having on one side a layer with a normal emissivity according to EN 12898 of not more than 0,2 — coated on the other side with a pressure sensitive adhesive and a release liner	0 %	31.12.2017

CN code	TARIC	Description	Rate of autonomous duty	Date foreseen for mandatory review
ex 3919 90 00	42	Self-adhesive film composed of: — a first layer containing a mixture of thermoplastic polyurethane and anti-blocking agent, — a second layer containing a maleic anhydride copolymer, — a third layer containing a mixture of low density polyethylene, titanium dioxide and additives, — a fourth layer containing a mixture of low density polyethylene, titanium dioxide, additives and colour pigment, — a pressure sensitive adhesive; and — covered on one side with a release liner — whether or not with a separate self-adhesive over laminate protective film — of a total thickness of not more than 400 μm	0 %	31.12.2017
ex 3919 90 00 ex 3921 90 60	44 95	Printed laminated sheet — with a core layer of glass fabric, coated on each side with a layer of poly(vinyl chloride), — on one side covered with a layer of poly(vinyl fluoride), — whether or not with a pressure sensitive adhesive layer and a release film on the other side, — with a toxicity (as determined by test method ABD 0031) of not more than 50 ppm hydrogen fluoride, not more than 85 ppm hydrogen chloride, not more than 10 ppm hydrogen cyanide, not more than 10 ppm nitrogen oxides, not more than 300 ppm carbon monoxide and not more than 10 ppm dihydrogen sulphide and sulphur dioxide taken together, — with a flammability within 60 seconds of not more than 110 mm (as determined by test method FAR 25 App.F Pt. I Amdt.83), and — with a weight (without release film) of 490 g/m^2 (± 45 g/m^2) without adhesive layer or of 580 g/m^2 (± 50 g/m^2) with pressure sensitive layer	0 %	31.12.2017
ex 3920 20 80	95	Polypropylene sheet, put up in rolls, with: — flame retardant level of UL 94 V-0 for material thicknesses of 0,25 mm or more and level UL 94 VTM-0 for material thicknesses of 0,05 mm or more but not more than 0,25 mm (as determined by Flammability Standard UL-94) — dielectric breakdown of 13,1 kV or more but not more than 60,0 kV(as determined by ASTM D149) — tensile yield in a machine direction of 30 MPa or more but not more than 33 MPa (as determined by ASTM D882) — tensile yield in a transverse direction of 22 MPa or more but not more than 25 MPa (as determined by ASTM D882) — density range of 0,988 gm/cm^3 or more but not more than 1,035 gm/cm^3 (as determined by ASTM D792) — moisture absorption of 0,01 % or more but not more than 0,06 % (as determined by ASTM D570) for use in the manufacture of insulators used in the electronics and electrical industries [1]	0 %	31.12.2017

CN code	TARIC	Description	Rate of autonomous duty	Date foreseen for mandatory review
(*) ex 3920 62 19	02	Co-extruded opaque sheet of poly(ethylene terephthalate), of a thickness of 50 µm or more but not more than 350 µm, consisting especially of a layer containing carbon black	0 %	31.12.2013
(*) ex 3920 62 19	08	Poly(ethylene terephthalate) film, not coated with an adhesive, of a thickness of not more than 25 µm, either: — only dyed in the mass, or — dyed in the mass and metallised on one side	0 %	31.12.2013
(*) ex 3920 62 19	12	Film of poly(ethylene terephthalate) only, of a total thickness of not more than 120 µm, consisting of one or two layers each containing a colouring and/or UV-absorbing material throughout the mass, uncoated with an adhesive or any other material	0 %	31.12.2013
(*) ex 3920 62 19	18	Laminated film of poly(ethylene terephthalate) only, of a total thickness of not more than 120 µm, consisting of one layer which is metallised only and one or two layers each containing a colouring and/or UV-absorbing material throughout the mass, uncoated with an adhesive or any other material	0 %	31.12.2013
(*) ex 3920 62 19	22	Film of poly(ethylene terephthalate), coated or covered on one side or on both sides with a layer of modified polyester, of a total thickness of 7 µm or more but not more than 11 µm, for the manufacture of video tapes with a magnetic layer of metallic pigments and a width of 8 mm or of 12,7 mm [1]	0 %	31.12.2013
(*) ex 3920 62 19	25	Film of poly(ethylene terephthalate) of a thickness of 186 µm or more but not more than 191 µm coated on one side with an acrylic layer in a matrix pattern	0 %	31.12.2014
(*) ex 3920 62 19	38	Poly(ethylene terephthalate) film, of a thickness of not more than 12 µm, coated on one side with a layer of aluminium oxide of a thickness of not more than 35 nm	0 %	31.12.2013
(*) ex 3920 62 19	48	Sheets or rolls of poly(ethylene terephthalate): — coated on both sides with a layer of epoxy acrylic resin, — of a total thickness of 37 µm (± 3 µm)	0 %	31.12.2015
(*) ex 3920 62 19	52	Film of poly(ethylene terephthalate), poly(ethylene naphthalate) or similar polyester, coated on one side with metal and/or metal oxides, containing by weight less than 0,1 % of aluminium, of a thickness of not more than 300 µm and having a surface resistivity of not more than 10 000 ohms (per square) (as determined by the ASTM D 257-99 method)	0 %	31.12.2013
(*) ex 3920 62 19	55	Matt film of poly(ethylene terephthalate), of a specular gloss of 15 measured at an angle of 45° and 18 measured at an angle of 60° using a gloss meter (as determined by the ISO 2813:2000 method) and a width of 1 600 mm or more	0 %	31.12.2013
(*) ex 3920 62 19	58	Film of white poly(ethylene terephthalate), dyed in the mass, of a thickness of 185 µm or more but not more than 253 µm, coated on both sides with an antistatic layer	0 %	31.12.2013

CN code	TARIC	Description	Rate of autonomous duty	Date foreseen for mandatory review
(*) ex 3920 62 19	76	Transparent poly(ethylene terephthalate) film: — coated on both sides with layers of organic substances on the basis of acryl of a thickness of 7 nm or more but not more than 80 nm, — with a surface tension of 36 Dyne/cm or more but not more than 39 Dyne/cm, — with a light transmission of more than 93 %, — with a haze value of not more than 1,3 %, — with a total thickness of 10 µm or more but not more than 350 µm, — with a width of 800 mm or more but not more than 1 600 mm	0 %	31.12.2013
(*) ex 3920 62 19	81	Poly(ethylene terephthalate) film: — of a thickness of not more than 20 µm, — coated on at least one side with a gas barrier layer consisting of a polymeric matrix in which silica has been dispersed and of a thickness of not more than 2 µm	0 %	31.12.2017
(*) ex 3920 92 00	30	Polyamide film: — of a thickness of not more than 20 µm, — coated on at least one side with a gas barrier layer which consists of a polymeric matrix in which silica has been dispersed and of a thickness of not more than 2 µm	0 %	31.12.2013
ex 3920 99 28	55	Thermoplastic polyurethane film extruded, with: — not self-adhesive, — an index of yellow lower of more than 1,0 but not more than 2,5 for 10 mm stacked films (as determined by test method ASTM E 313-10), — a light transmission higher to 87 % for 10 mm stacked films (as determined by test method ASTM D 1003-11), — a total thickness of 0,38 mm or more, but not more than 7,6 mm, — a width of 99 cm or more, but not more than 305 cm, of a kind used in the production of laminated safety glass	0 %	31.12.2017
ex 3921 13 10	20	Rolls of open-cell polyurethane foam: — with a thickness of 2,29 mm (± 0,25 mm), — surface-treated with a foraminous adhesion promoter, and — laminated to a polyester film and a layer of textile material	0 %	31.12.2017
(*) ex 3921 90 55	20	Pre-impregnated reinforced fibreglass containing cyanate ester resin or bismaleimide (B) triazine (T) resin mixed with epoxide resin, measuring: — 469,9 mm (± 2 mm) × 622,3 mm (± 2 mm), or — 469,9 mm (± 2 mm) × 414,2 mm (± 2 mm), or — 546,1 mm (± 2 mm) × 622,3 mm (± 2 mm for use in the manufacture of printed circuit boards [1]	0 %	31.12.2013

CN code	TARIC	Description	Rate of autonomous duty	Date foreseen for mandatory review
(*) ex 3926 90 97	21	Television pedestal stands with or without bracket for fixation to and stabilisation of television cabinet case/body	0 %	31.12.2016
(*) ex 7020 00 10	10			
(*) ex 7326 90 98	40			
(*) ex 7616 99 90	77			
ex 4104 41 19	10	Buffalo leather, split, chrome tanned synthetic retanned (“crust”), dry	0 %	31.12.2017
ex 7009 10 00	10	Mirror-glass for rear-view mirrors: — equipped with plastic backing plate, — having the ability to reflect variable intensities of ambient light, — whether or not equipped with a heating element, and — whether or not equipped with Blind Spot Module (BSM) display	0 %	31.12.2017
(*) ex 7019 12 00	05	Rovings ranging from 1 980 to 2 033 tex, composed of continuous glass filaments of 9 µm (± 0,5 µm)	0 %	31.12.2017
(*) ex 7019 12 00	25			
(*) ex 7607 11 90	30	Laminated aluminium foil with: — 99 % or more of aluminium, — a silica and water glass free hydrophilic coating, — a total thickness of not more than 0,120 mm, — a tensile strength of 100 N/mm^2 or more (as determined by test method ASTM E8), and — an elongation at break of 1 % or more	0 %	31.12.2013
(*) ex 7607 20 90	20	Lubricating entry sheet of a total thickness of not more than 350 µm, comprising of: — a layer of aluminium foil of a thickness of 70 µm or more but not more than 150 µm, — a water soluble lubricant of a thickness of 20 µm or more but not more than 200 µm and solid at room temperature	0 %	31.12.2015
ex 7616 99 90	75	Parts in the shape of a rectangular frame: — of painted aluminium, — with a length of 1 011 mm or more but not more than 1 500 mm, — with a width of 622 mm or more but not more than 900 mm, — with a thickness of 0,6 mm (± 0,1 mm), of a kind used in the manufacture of TV sets	0 %	31.12.2017

CN code	TARIC	Description	Rate of autonomous duty	Date foreseen for mandatory review
ex 8105 90 00	10	Bars or wires made of cobalt alloy containing, by weight: — 35 % (± 2 %) cobalt, — 25 % (± 1 %) nickel, — 19 % (± 1 %) chromium and — 7 % (± 2 %) iron conforming to the material specifications AMS 5842, of a kind used in the aerospace industry	0 %	31.12.2017
(*) ex 8301 60 00	10	Keypads, wholly of either silicone or polycarbonate, including printed keys with electrical contacting elements	0 %	31.12.2015
(*) ex 8413 91 00	20			
(*) ex 8419 90 85	20			
(*) ex 8438 90 00	10			
(*) ex 8468 90 00	10			
(*) ex 8476 90 00	10			
(*) ex 8479 90 80	87			
(*) ex 8481 90 00	20			
(*) ex 8503 00 99	45			
(*) ex 8515 90 00	20			
(*) ex 8531 90 85	20			
(*) ex 8536 90 85	96			
(*) ex 8543 90 00	50			
(*) ex 8708 91 99	10			
(*) ex 8708 99 97	30			
(*) ex 9031 90 85	30			
(*) ex 8305 20 00	10	Staples: — of a length of 28 mm, — unbent, packed in a plastic cartridge for use in copiers and printers resulting in a staple of a width of 12 mm (± 1 mm) and a depth of 8 mm (± 1 mm) [1]	0 %	31.12.2013
ex 8431 20 00	30	Drive axle assembly containing differential, reduction gears, crown wheel, drive shafts, wheel hubs, brakes and mast mounting arms for use in the manufacture of vehicles in heading 8427 [1]	0 %	31.12.2017

CN code	TARIC	Description	Rate of autonomous duty	Date foreseen for mandatory review
ex 8501 10 99	60	DC motor — with a rotor speed of 3 500 rpm or more but not more than 5 000 rpm loaded and not more than 6 500 rpm when not loaded — with a power supply voltage of 100 V or more but not more than 240 V for use in the manufacture of electric fryers [1]	0 %	31.12.2017
ex 8503 00 99	40	Fuel cell membrane, in rolls or sheets, with a width of not more than 150 cm, of a kind used for manufacture of fuel cells in heading 8501	0 %	31.12.2017
(*) ex 8504 40 82	40	Printed circuit board equipped with a bridge rectifier circuit and other active and passive components — with two output connectors — with two input connectors which are available and useable in parallel — able to switch between bright and dimmed operation mode — with an input voltage of 40 V (+ 25 % -15 %) or 42 V (+ 25 % -15 %) in bright operation mode, with an input voltage of 30 V (± 4 V) in dimmed operation mode, or — with an input voltage of 230 V (+ 20 % -15 %) in bright operation mode, with an input voltage of 160 V (± 15 %) in dimmed operation mode, or — with an input voltage of 120 V (15 % -35 %) in bright operation mode, with an input voltage of 60 V (± 20 %) in dimmed operation mode — with an input current reaching 80 % of its nominal value within 20 ms — with an input frequency of 45 Hz or more, but not more than 65 Hz for 42 V and 230 V, and 45-70 Hz for 120 V versions — with an maximum inrush current overshoot of not more than 250 % of the input current — with a period of the inrush current overshoot of not more than 100 ms — with an input current undershoot of not less than 50 % of the input current — with a period of the inrush current undershoot of not more than 20 ms — with a presettable output current — with an output current reaching 90 % of its nominal pre-set value within 50 ms — with an output current reaching zero within 30 ms after removal of the input voltage — with an defined failure status in case of no-load or too-high load (end-of-life function)	0 %	31.12.2017

CN code	TARIC	Description	Rate of autonomous duty	Date foreseen for mandatory review
(*) ex 8504 40 82	50	Rectifier in a housing with — a rated power of not more than 250 W — an input voltage of 90 V or more, but not more than 305 V — a certified input frequency of 47 Hz or more, but not more than 440 Hz — a constant current output of 350 mA or more, but not more than 15 A — an inrush current of not more than 10 A — an operating temperature range of – 40 °C or more, but not more than + 85 °C, — suitable for driving of LED-illuminants	0 %	31.12.2017
ex 8505 11 00	35	Permanent magnets of an alloy of either neodymium, iron and boron, or samarium and cobalt coated having undergone inorganic passivation (inorganic coating) using zinc phosphate for the industrial manufacture of products in motor or sensory applications [1]	0 %	31.12.2017
ex 8507 60 00	25	Rectangular modules for incorporation in lithium-ion rechargeable batteries, with: — a width of 352,5 mm (± 1 mm) or 367,1 mm (± 1 mm) — a depth of 300 mm (± 2 mm) or 272,6 mm (± 1 mm) — a height of 268,9 mm (± 1,4 mm) or 229,5 mm (± 1 mm) — a weight of 45,9 kg or 46,3 kg — a rating of 75 Ah and — a nominal voltage of 60 V	0 %	31.12.2017
ex 8507 60 00	35	Lithium-ion rechargeable batteries, with: — a length of 1 475 mm or more, but not more than 1 515 mm, — a width of 1 365 or more, but not more than 1 375 mm, — a height of 260 mm or more, but not more than 270 mm, — a weight of 320 kg or more, but not more than 330 kg, — a nominal capacity of 18,4 Ah or more, but not more than 130 Ah, — put up in packs of 12 or 16 modules	0 %	31.12.2017
(*) ex 8507 60 00	50	Modules for the assembly of batteries of ion lithium electric accumulators with: — a length of 298 mm or more, but not more than 408 mm, — a width of 33,5 mm or more, but not more than 209 mm, — a height of 138 mm or more, but not more than 228 mm, — a weight of 3,6 kg or more, but not more than 17 kg, and — a power of 458 kWh or more, but not more than 2 158 kWh	0 %	31.12.2017

CN code	TARIC	Description	Rate of autonomous duty	Date foreseen for mandatory review
ex 8516 90 00	70	Inner pot — containing side and central openings, — of annealed aluminium, — with a ceramic coating, heat resistant to more than 200 °C for use in the manufacture of an electric fryer (1)	0 %	31.12.2017
ex 8522 90 80	15	Heat sinks and cooling fins of aluminium, for maintaining the operating temperature of transistors and/or integrated circuits in products of heading 8521	0 %	31.12.2017
ex 8525 80 19	45	Camera module with a resolution of 1 280 * 720 P HD, with two microphones, for use in the manufacture of products of heading 8528 (1)	0 %	31.12.2017
(*) ex 8526 91 20 (*) ex 8527 29 00	80 10	Integrated audio module (IAM) with a digital video output for connection to an LCD touch screen monitor, interfaced over the Media Oriented Systems Transport (MOST) network and transported over the MOST High protocol, with: — a printed circuit board (PCB) containing a Global Positioning System (GPS) receiver, a gyroscope, and a Traffic Message Channel (TMC) tuner, — a hard disk drive supporting multiple maps, — a HD radio, — a voice recognition system, — a CD and DVD drive, — Bluetooth, MP3 and USB input connectivity, — a voltage of 10 V or more but not more than 16 V, for the use in the manufacture of vehicles in Chapter 87 (1)	0 %	31.12.2015
ex 8529 90 92	70	Rectangular fastening and covering frame: — of an aluminium alloy containing silicon and magnesium, — with a length of 900 mm or more but not more than 1 500 mm, — with a width of 600 mm or more but not more than 950 mm, of a kind used for the production of TV sets	0 %	31.12.2017
ex 8529 90 92 ex 9405 40 39	80 40	Printed circuit board for backlight: — with LED diodes equipped with prisms, — whether or not with connector(s) fitted at one or both ends, to be incorporated in goods of heading 8528 (1)	0 %	31.12.2013
ex 8536 69 90	51	SCART type connectors, built into a plastic or metal housing, with 21 pins in 2 rows, for use in the manufacture of products falling within headings 8521 and 8528 (1)	0 %	31.12.2017
(*) ex 8540 20 80	91	Photomultiplier	0 %	31.12.2016

CN code	TARIC	Description	Rate of autonomous duty	Date foreseen for mandatory review
ex 8544 42 90	30	PET insulated electric conductor with: — 10 or 80 individual wires, — a length of 50 mm or more, but not more than 800 mm, — connector(s) and/or plug(s) fitted at one or both ends, for use in the manufacture of products falling within headings 8521 and 8528 (1)	0 %	31.12.2017
ex 9001 90 00	25	Unmounted optical elements made from moulded infrared transmitting chalcogenide glass, or a combination of infrared transmitting chalcogenide glass and another lens material	0 %	31.12.2017
ex 9002 90 00	40	Mounted lenses made from infrared transmitting chalcogenide glass, or a combination of infrared transmitting chalcogenide glass and another lens material	0 %	31.12.2017

(1) Suspension of duties is subject to Articles 291 to 300 of Commission Regulation (EEC) No 2454/93 (OJ L 253 11.10.1993, p. 1).
(2) The specific duty rate is applicable.
(*) Suspension relating to a product in the Annex to Regulation (EU) No 1344/2011 for which the CN or TARIC code or the product description is modified by this Regulation.

ANNEX II

Products referred to in point (2) of Article 1

CN code	TARIC
(*) ex 2007 99 50	40
(*) ex 2007 99 50	50
(*) ex 2007 99 50	60
ex 2008 60 19	30
ex 2008 60 39	30
(*) ex 2008 99 48	20
(*) ex 2008 99 48	93
(*) ex 2008 99 49	50
(*) ex 2805 30 90	40
(*) ex 2805 30 90	50
(*) ex 2805 30 90	60
(*) ex 2818 10 91	10
ex 2916 19 95	30
ex 2917 39 95	10
(*) ex 2918 99 90	40
ex 2934 99 90	12
ex 3204 11 00	10
(*) ex 3204 11 00	20
(*) ex 3204 17 00	25
ex 3204 17 00	45
ex 3204 17 00	55
(*) ex 3204 17 00	60
(*) ex 3204 17 00	70
ex 3204 19 00	72
(*) ex 3204 19 00	73
(*) ex 3802 90 00	11
(*) ex 3824 90 97	08
(*) ex 3824 90 97	31
(*) ex 3824 90 97	70
(*) ex 3824 90 97	72

CN code	TARIC
(*) ex 3824 90 97	73
(*) ex 3824 90 97	75
(*) ex 3907 20 20	11
(*) ex 3907 20 20	12
(*) ex 3907 40 00	10
(*) ex 3907 99 90	30
(*) ex 3909 50 90	10
ex 3911 90 99	75
(*) ex 3920 62 19	01
(*) ex 3920 62 19	03
(*) ex 3920 62 19	07
(*) ex 3920 62 19	09
(*) ex 3920 62 19	11
(*) ex 3920 62 19	13
(*) ex 3920 62 19	17
(*) ex 3920 62 19	19
(*) ex 3920 62 19	21
(*) ex 3920 62 19	23
(*) ex 3920 62 19	24
(*) ex 3920 62 19	26
(*) ex 3920 62 19	37
(*) ex 3920 62 19	39
(*) ex 3920 62 19	47
(*) ex 3920 62 19	49
(*) ex 3920 62 19	51
(*) ex 3920 62 19	53
(*) ex 3920 62 19	54
(*) ex 3920 62 19	56
(*) ex 3920 62 19	57
(*) ex 3920 62 19	59
(*) ex 3920 62 19	75
(*) ex 3920 62 19	77
(*) ex 3920 62 19	81

CN code	TARIC
(*) ex 3920 92 00	30
(*) ex 3921 90 55	20
(*) ex 7019 12 00	05
(*) ex 7019 12 00	25
(*) ex 7326 90 98	40
(*) ex 7607 11 90	30
(*) ex 7607 20 90	20
ex 8108 20 00	20
ex 8108 90 50	40
ex 8108 90 50	80
(*) ex 8305 20 00	10
(*) ex 8504 40 82	40
(*) ex 8504 40 82	50
(*) ex 8507 60 00	50
(*) ex 8526 91 20	80
(*) ex 8528 59 80	10
(*) ex 8536 90 85	96
(*) ex 8538 90 99	94
(*) ex 8540 20 80	91
(*) ex 8543 90 00	50
ex 8708 80 99	10
ex 9405 40 39	30

(*) Suspension relating to a product in the Annex to Regulation (EU) No 1344/2011 for which the CN or TARIC code or the product description is modified by this Regulation.

COUNCIL REGULATION (EU) No 627/2013

of 27 June 2013

amending Regulation (EU) No 7/2010 opening and providing for the management of autonomous tariff quotas of the Union for certain agricultural and industrial products

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 31 thereof,

Having regard to the proposal from the European Commission,

Whereas:

(1) In order to ensure sufficient and uninterrupted supplies of certain goods that are insufficiently produced in the Union and to avoid any disturbances on the market for certain agricultural and industrial products, autonomous tariff quotas have been opened by Council Regulation (EU) No 7/2010 ([1]). Products within those tariff quotas can be imported at reduced or zero duty rates. For the same reasons relating to supplies and disturbances it is necessary to open, with effect from 1 July 2013, new tariff quotas at reduced or zero duty rates for an appropriate volume for the ten products with order numbers 09.2644 and 09.2663 to 09.2671.

(2) Moreover, for the autonomous tariff quotas of the Union with order numbers 09.2620 and 09.2633 the product description should be adapted, and for order number 09.2629 another TARIC code should be added.

(3) For the autonomous tariff quotas of the Union with the order numbers 09.2917 and 09.2632, an end date of 31 December 2013 should be inserted, as it is not in the interest of the Union to continue granting such quotas beyond that date.

(4) Since the new tariff quotas should take effect from 1 July 2013, this Regulation should apply from that date and enter into force immediately upon its publication in the *Official Journal of the European Union*.

(5) Regulation (EU) No 7/2010 should therefore be amended accordingly,

HAS ADOPTED THIS REGULATION:

Article 1

The Annex to Regulation (EU) No 7/2010 is hereby amended as follows:

(1) the rows with order numbers 09.2644 and 09.2663 to 09.2671 set out in Annex I to this Regulation are inserted;

(2) the rows for the tariff quotas with order numbers 09.2620, 09.2629, 09.2632, 09.2633 and 09.2917 are replaced by the rows set out in Annex II 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*.

It shall apply from 1 July 2013.

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

Done at Brussels, 27 June 2013.

For the Council
The President
E. GILMORE

([1]) OJ L 3, 7.1.2010, p. 1.

ANNEX I

Tariff quotas referred to in point (1) of Article 1

Order number	CN code	TARIC	Description	Quota period	Quota volume	Quota duty (%)
09.2663	ex 1104 29 17	10	Milled sorghum grains that have been at least hulled and de-germed for use in the manufacture of loose fill packaging products (1)	1.7-31.12	750 tonnes	0 %
09.2664	ex 2008 60 19 ex 2008 60 39	30 30	Sweet cherries containing added spirit, whether or not with a sugar content of 9 % by weight, of a diameter of not more than 19,9 mm, with stone, for use in chocolate products (1)	1.7-31.12	500 tonnes	10 % (2)
09.2665	ex 2916 19 95	30	Potassium (E,E)-hexa-2,4-dienoate (CAS RN 24634-61-5)	1.7-31.12	4 000 tonnes	0 %
09.2666	ex 3204 17 00	55	Dye C.I. Pigment Red 169 (CAS RN 12237-63-7)	1.7-31.12	20 tonnes	0 %
09.2644	ex 3824 90 97	96	Preparation containing by weight: — 55 % or more but not more than 78 % of dimethyl glutarate — 10 % or more but not more than 28 % of dimethyl adipate and — not more than 25 % of dimethyl succinate	1.7-31.12	3 000 tonnes	0 %
09.2671	ex 3905 99 90	81	Poly(butyral of vinyl) (CAS RN 63148-65-2): — containing hydroxyl groups of 17,5 - 20 mol %, and — with a median particle size (D50) greater than 0,6 mm	1.7-31.12	5 500 tonnes	0 %
09.2667	ex 8537 10 99	51	Electromechanical switch board: — with a 5-way switch, — with an electric conductor, — with an integrated circuit, — with or without an infra-red receiver for use in the manufacture of products falling within headings 8521 and 8528 (1)	1.7-31.12	3 000 000 units	0 %
09.2668	ex 8714 91 10 ex 8714 91 10	21 31	Bicycle frame, constructed from carbon fibres and artificial resin, painted, lacquered and/or polished, for use in the manufacture of bicycles (1)	1.7-31.12	38 000 units	0 %
09.2669	ex 8714 91 30 ex 8714 91 30	21 31	Bicycle front fork, constructed from carbon fibres and artificial resin, painted, lacquered and/or polished, for use in the manufacture of bicycles (1)	1.7-31.12	26 000 units	0 %

Order number	CN code	TARIC	Description	Quota period	Quota volume	Quota duty (%)
09.2670	ex 9405 40 39	30	Electric light assembly containing: — printed circuit boards and — Light Emitting Diodes (LED) for the manufacture of backlight units for flat TV sets [1]	1.7-31.12	8 500 000 pieces	0 %

[1] Suspension of duties is subject to Articles 291 to 300 of Commission Regulation (EEC) No 2454/93 (OJ L 253 11.10.1993, p. 1).
[2] The specific duty shall apply.

ANNEX II

Tariff quotas referred to in point (2) of Article 1

Order number	CN code	TARIC	Description	Quota period	Quota volume	Quota duty (%)
09.2632	ex 2921 22 00	10	Hexamethylenediamine (CAS RN 124-09-4)	1.1-31.12.2013	40 000 tonnes	0 %
09.2917	ex 2930 90 13	90	Cystine (CAS RN 56-89-3)	1.1-31.12.2013	600 tonnes	0 %
09.2629	ex 7616 99 90 ex 8302 49 00	85 91	Aluminium telescopic handle for use in the manufacture of luggage [1]	1.1-31.12	800 000 units	0 %
09.2633	ex 8504 40 82	20	Electric rectifier, with a capacity of not more than 1 kVA, for use in the manufacture of appliances falling within headings 8509 80 and 8510 [1]	1.1-31.12	4 500 000 units	0 %
09.2620	ex 8526 91 20	20	Assembly for GPS system having a position determination function, without display, and a weight of not more than 2 500 g	1.1-31.12	3 000 000 units	0 %

[1] Suspension of duties is subject to Articles 291 to 300 of Commission Regulation (EEC) No 2454/93 (OJ L 253 11.10.1993, p. 1).

COMMISSION IMPLEMENTING REGULATION (EU) No 628/2013

of 28 June 2013

on working methods of the European Aviation Safety Agency for conducting standardisation inspections and for monitoring the application of the rules of Regulation (EC) No 216/2008 of the European Parliament and of the Council and repealing Commission Regulation (EC) No 736/2006

(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 216/2008 of the European Parliament and of the Council of 20 February 2008 on common rules in the field of civil aviation and establishing a European Aviation Safety Agency, and repealing Council Directive 91/670/EEC, Regulation (EC) No 1592/2002 and Directive 2004/36/EC [1], and in particular Article 24(5) thereof,

Whereas:

(1) Article 24(1) and Article 54 of Regulation (EC) No 216/2008 require the European Aviation Safety Agency (hereinafter 'the Agency'), to assist the Commission in monitoring the application of its provisions, as well as its implementing rules, by Member States' competent authorities, by conducting standardisation inspections.

(2) Article 54(4) of Regulation (EC) No 216/2008 stipulates that where an inspection of a Member State competent authority entails an inspection of an undertaking or an association of undertakings, the Agency should follow the provisions of Article 55.

(3) Commission Regulation (EC) No 736/2006 [2] lays down the working methods of the Agency for conducting standardisation inspections (hereinafter 'the current working methods').

(4) Six years have passed since the adoption of the current working methods. Considerable changes to the common rules have been adopted; a number of international agreements have also been adopted; the Agency and the Member States have also accumulated valuable experience that needs to be accounted for.

(5) When Regulation (EC) No 736/2006 was adopted, the common rules in the field of civil aviation were limited to initial and continuing airworthiness. Commission Regulation (EC) No 1702/2003 [3] laid down implementing rules for the airworthiness and environmental certification of aircraft and related products, parts and appliances, as well as for the certification of design and production organisations; Commission Regulation (EC) No 2042/2003 [4] laid down implementing rules for the continuing airworthiness of aircraft and aeronautical products, parts and appliances, and on the approval of organisations and personnel involved in these tasks.

(6) Since that time, Regulation (EC) No 216/2008 has replaced Regulation (EC) No 1592/2002 of the European Parliament and of the Council of 15 July 2002 on common rules in the field of civil aviation and establishing a European Aviation Safety Agency [5] and the common rules have been extended twice: first to include air crew, air operations and ramp inspections; secondly to include air traffic management and air navigations services (ATM/ANS) as well as airport safety, as a consequence of which the Commission has adopted several implementing rules corresponding to those new fields of competence such as Commission Regulation (EU) No 805/2011 of 10 August 2011 laying down detailed rules for air traffic controllers' licences and certain certificates [6], Commission Implementing Regulation (EU) No 1034/2011 [7] laying down administrative procedures for the safety oversight of air traffic management and air navigation services, Commission Implementing Regulation (EU) No 1035/2011 of 17 October 2011 laying down common requirements for the provision of air navigation services [8], Commission Regulation (EU) No 691/2010 of 29 July 2010 laying down a performance scheme for air navigation services and network functions and amending Regulation (EC) No 2096/2005 laying down common requirements for the provision of air navigation services [9], Council Regulation (EEC) No 3922/91 of 16 December 1991 on the harmonization of technical requirements and administrative procedures in the field of civil aviation [10], amended by Commission Regulation (EC) No 859/2008 [11], Directive 2004/36/EC of the European Parliament and of the Council of 21 April 2004 on the safety of third-country aircraft using Community airports [12], amended by Commission Directive 2008/49/EC of 16 April 2008 amending Annex II to Directive 2004/36/EC of the European

[1] OJ L 79, 19.3.2008, p. 1.
[2] OJ L 129, 17.5.2006, p. 10.
[3] OJ L 243, 27.9.2003, p. 6.
[4] OJ L 315, 28.11.2003, p. 1.
[5] OJ L 240, 7.9.2002, p. 1.
[6] OJ L 206, 11.8.2011, p. 21.
[7] OJ L 271, 18.10.2011, p. 15.
[8] OJ L 271, 18.10.2011, p. 23.
[9] OJ L 201, 3.8.2010, p. 1.
[10] OJ L 373, 31.12.1991, p. 4.
[11] OJ L 254, 20.9.2008, p. 1.
[12] OJ L 143, 30.4.2004, p. 76.

Parliament and of the Council regarding the criteria for the conduct of ramp inspections on aircraft using Community airports [1] Commission Regulation (EU) No 965/2012 of 5 October 2012 laying down technical requirements and administrative procedures related to air operations [2], and Commission Regulation (EU) No 1178/2011 of 3 November 2011 laying down technical requirements and administrative procedures related to civil aviation aircrew [3].

(7) Regulation (EC) No 216/2008 has also introduced a number of new provisions that need to be reflected in the Agency's working methods for carrying out standardisation inspections. In particular, Article 11 establishes the conditions for the mutual recognition of certificates issued by competent authorities of Member States, as well as conditions for suspending this recognition, where standardisation inspections constitute an important instrument for such decision-making. Article 15 establishes an information network that provides useful information to be taken into account for standardisation inspections, whilst certain results of such standardisation inspections may need to be made available without delay to this information network. Article 27(3) establishes that the Agency has to support the Member States in discharging their obligations towards ICAO.

(8) Notwithstanding further changes of the common rules as established by Regulation (EC) No 216/2008 and its implementing rules, the Agency should support the Commission in monitoring the implementation of other aviation safety requirements stemming, for instance, from the Single European Sky legislation or the legislation on accident investigation or occurrence reporting.

(9) Since 2006, the European external aviation policy has also experienced significant developments, both regarding International Civil Aviation Organisation (ICAO), States in the neighbourhood of the European Union and certain key partners at global level.

(10) A Memorandum of Cooperation with the International Civil Aviation Organisation (ICAO) was signed in 2010 [4] which creates the framework for a structured cooperation between parties, in particular regarding the exchange of information related to safety, with a view to avoid duplication of tasks where possible, as a consequence of which the Agency's standardisation inspection programme and the ICAO Universal Safety Oversight Audit Programme (USOAP) should become more inter-related. The inspection working methods should also take into account ICAO Doc 9735 — the USOAP continuous Monitoring Manual.

(11) With regard to the States part of the EU neighbourhood and enlargement policy, including notably States Party to the European Common Aviation Area agreement, standardisation inspections should be organised in accordance with the same working methods and in accordance with the same standards as for the Member States, subject to appropriate Agreements or Working Arrangements.

(12) With regard to the States having signed Bilateral Air Safety Agreements providing for the mutual acceptance of certain certification findings and approvals, standardisation inspections should support the monitoring of the implementation of the agreement and report the results to the appropriate bilateral oversight board in view of possible adjustments. The inspections of those Member States whose certification findings and approvals are accepted in the framework of the bilaterals should include additional verifications to ensure competent authorities discharge correctly their responsibilities stemming from the bilateral agreements.

(13) In order to monitor the application of Regulation (EC) No 216/2008 and its implementing rules, as well as other aviation safety rules stemming from existing Regulations and agreements efficiently, it is necessary to review the current working methods, notably to ensure they become more system oriented, follow a more continuous monitoring approach more focused on safety performance, provide for more efficient use of resources in order not to generate an undue burden on the competent authorities and include a feedback loop to the Agency's rulemaking activities. Inspection teams should be set up with adequately trained and qualified personnel and the Agency shall endeavour to balance the participation of authorised personnel from different Member States.

(14) The working methods should reflect the definitions and principles of auditing as defined in ISO 19011.

(15) Beyond the inspection-level, the working methods should elaborate on the monitoring at system-level and at finding-level.

(16) The working methods should provide more flexibility to the Agency in taking action where this corresponds to its technical competence whilst maintaining legal certainty on the working methods.

(17) Regulation (EC) No 736/2006 should therefore be repealed accordingly.

(18) The measures provided for in this Regulation are in accordance with the opinion of the Committee established by Article 65 of Regulation (EC) No 216/2008,

[1] OJ L 109, 19.4.2008, p. 17.
[2] OJ L 296, 25.10.2012, p. 1.
[3] OJ L 311, 25.11.2011, p. 1.
[4] Council Decision 2011/531/EU, OJ L 232, 9.9.2011, p. 8.

HAS ADOPTED THIS REGULATION:

Article 1

Subject matter and scope

1. This Regulation lays down the working methods for:

(a) monitoring the application by competent authorities of the Member States of Regulation (EC) No 216/2008 and its implementing rules in the fields covered by Article 1(1) of that Regulation;

(b) conducting standardisation inspections of the competent authorities of Member States;

(c) verifying that the competent authorities of Member States are issuing and overseeing certificates in accordance with Regulation (EC) No 216/2008 and its implementing rules;

(d) contributing to the assessment of the impact of the implementation by the competent authorities of Member States of Regulation (EC) No 216/2008 and its implementing rules.

2. The working methods established in this Regulation shall also apply, as far as practicable, when the Agency is charged with the task to monitor the application of aviation safety requirements established by other EU legislation, agreements concluded by the Union or working arrangements concluded by the Agency.

Article 2

Definitions

For the purposes of this Regulation the following definitions apply:

(1) 'inspection' means the standardisation inspection referred to in Article 24(1) and Article 54 of Regulation (EC) No 216/2008, including the inspection of undertakings or associations of undertakings referred to in Article 54(4) and Article 55 of that Regulation, carried out by the Agency;

(2) 'competent authority' means the entity designated by the Member State as competent for the implementation of Regulation (EC) No 216/2008 and its implementing rules;

(3) 'authorised personnel' means the persons authorised by the Agency to carry out inspections, including seconded personnel;

(4) 'seconded personnel' means the officials made available by the competent authorities of Member States, the International Civil Aviation Organisation (ICAO), other international aviation organisations or the competent authorities of Third Countries having agreements with the Union or working arrangements with the Agency, who are nominated by these authorities to assist the Agency in carrying out inspections;

(5) 'evidence' means records, statements of fact, or other information which are relevant and verifiable;

(6) 'finding' means the result of the comparison between the available evidence and the applicable requirements;

(7) 'correction' means an action to eliminate a finding of non-conformity with the applicable requirements;

(8) 'corrective action' means an action to eliminate the cause of a finding of non-conformity with the applicable requirements in order to prevent recurrence;

(9) 'immediate safety concern' means a situation where there is evidence that a product, service, system, constituent, equipment or facility is either in such a condition, or is being operated, supplied or maintained in such a manner that harm to persons is likely to occur unless the situation is corrected immediately.

Article 3

Principles applicable to monitoring

1. The Agency shall monitor the application by competent authorities of the requirements referred in Article 1 as well as their uniform implementation according to the methodology laid down in this Regulation and shall report thereon.

2. The monitoring shall be continuous and risk-based, on the basis of the information available to the Agency. It shall entail assessing the competent authorities' ability to discharge their safety oversight responsibilities, conducting inspections as necessary, as well as the follow-up of findings stemming from inspections, in order to ensure that appropriate corrections and corrective actions are timely implemented.

3. The monitoring shall follow a system approach. It shall address all domains and critical elements of the safety oversight system as defined by ICAO. Particular attention shall be given to interfaces between domains.

4. The monitoring shall be conducted in a transparent, efficient, effective, harmonised and consistent manner.

5. The Agency shall analyse the outcome of its monitoring activities in order to identify the need for regulatory improvements.

Article 4

Principles applicable to inspections and findings

1. Inspections of competent authorities shall take into account the results of previous inspections and address in particular changes to the regulatory requirements, to the safety oversight capability of the competent authority and be proportionate to the level and complexity of the industry under their oversight, ensuring as a priority a high and uniform level of safety for commercial air transport.

2. Inspections may include inspections of undertakings or associations of undertakings under the oversight of the competent authority inspected.

3. Inspections may include, when so agreed by the parties concerned, inspections of military facilities open to public use or of services provided by military personnel to the public, for the purpose of verifying that the requirements of Article 1(3) of Regulation (EC) No 216/2008 are complied with.

4. Inspections shall be carried out by a team composed of personnel authorised by the Agency, which shall be qualified and trained in their respective domain(s). Authorised personnel shall apply the principles of independence, integrity, ethical conduct, due diligence, fair presentation and confidentiality.

5. Where the Agency finds that one or more certificates do not comply with Regulation (EC) No 216/2008 and its Implementing Rules, that finding of non-conformity shall be reported to the competent authority concerned. Where the finding of non-conformity is not corrected in a timely manner the Agency shall make recommendations pursuant to Article 11(2) of Regulation (EC) No 216/2008 in order to allow a decision on the mutual recognition of the said certificate(s).

6. The Agency shall classify and follow-up the findings of non-conformity identified during inspections referred to in paragraphs 1, 2 and 3 depending on their impact on safety and safety related findings shall be prioritised. The Agency shall also inform without delay the competent authorities of Member States when the correction of an immediate safety concern has not been satisfactorily addressed.

7. This Regulation is without prejudice to Articles 15 and 58 of Regulation (EC) No 216/2008, to Commission Decision 2001/844/EC, ECSC, Euratom [1], to Regulation (EC) No 2111/2005 of the European Parliament and of the Council [2] and Commission Regulation (EC) No 473/2006 [3].

Article 5

Exchange of information

1. Competent authorities of Member States shall provide the Agency with all necessary information relevant to their safety oversight, addressing all the critical elements of their safety oversight system, including the undertakings or associations of undertakings under their oversight. The information shall be provided in a form and a manner specified by the Agency, taking into account the information that has been made available to ICAO.

2. The Agency may also request ad-hoc information from the competent authorities of Member States. When submitting such a request for information the Agency shall state its legal basis and purpose, specify what information is required and set the time-limit within which the information is to be provided.

3. The Agency shall provide competent authorities of Member States with relevant information to support the uniform implementation of the applicable requirements.

[1] OJ L 317, 3.12.2001, p. 1.
[2] OJ L 344, 27.12.2005, p. 15.
[3] OJ L 84, 23.3.2006, p. 8.

Article 6

National Standardisation Coordinator

1. Member States shall designate a national standardisation coordinator, acting as their primary point of contact for all standardisation activities and in particular to coordinate the exchange of information provided for in Article 5(1). The national standardisation coordinator shall be responsible for:

(a) maintaining and updating the information provided to the Agency on an on-going basis, including information requested in accordance with Articles 3, 4 and 5, corrections and corrective action plans and evidence of implementation of the agreed corrective actions;

(b) assisting the Agency at all stages of an inspection and ensuring that the inspection team is accompanied throughout the on-site inspections.

2. Competent authorities shall ensure that there are clear lines of communication between the national standardisation coordinator designated and their internal organisation, in order for him/her to properly discharge his/her responsibilities.

Article 7

Continuous monitoring

1. The continuous monitoring referred to in Article 3 shall comprise the following:

(a) the collection and analysis of data and information provided by the competent authorities of Member States, the International Civil Aviation Organisation (ICAO), the Commission or other relevant sources;

(b) the assessment of the competent authority's ability to discharge its safety oversight responsibilities;

(c) depending on the assessment referred to in point (b), the prioritisation, planning and determination of the scope of inspections;

(d) the conduct of such inspections, including the related reporting;

(e) the follow-up and closure of findings of non-conformity stemming from the inspections.

2. For the assessment referred to in point (b) of paragraph 1, the Agency shall establish, develop and maintain a single model taking into account at least the following elements:

(a) the size and complexity of the aviation industry;

(b) serious incidents, accidents, fatal accidents and related fatalities;

(c) the results of ramp inspections;

(d) the results of previous inspections;

(e) the ability of the competent authorities to implement effectively corrections and corrective actions;

(f) the result of audits carried out under international conventions or State safety assessment programmes;

(g) the existence of measures pursuant to Article 11(2) of Regulation (EC) No 216/2008 or to Article 258 of the Treaty.

3. The outcome of the model as established in paragraph 2 and the input data and results of the assessment shall be made available to the national standardisation coordinator of the Member State concerned.

4. The Agency shall adapt the inspection programme in the light of its continuous monitoring, reflecting both improvements and deteriorations in safety performance. The Agency shall take appropriate action when there is evidence that the safety performance deteriorates.

Article 8

Inspection programme

1. The Agency shall establish, in coordination with the Commission, a multi-annual programme, indicating the inspections referred to in Article 10(1)(a), as well as an annual programme indicating the inspections referred to in Article 10(1)(a) and (b).

2. The inspection programmes shall specify the Member State(s) concerned, the type of inspection, the domains to be inspected and the foreseen timeframe for the on-site phase, taking into account the model referred to in Article 7.

3. The inspection programmes may be adjusted by the Agency to take into account emerging risks stemming from the continuous monitoring referred to in Article 7.

4. The annual programme shall be communicated to the Commission, to the members of the Management Board of the Agency as part of the Agency's work programme pursuant to Article 33(2)(c) of Regulation (EC) No 216/2008, and to the national standardisation coordinator of the Member State concerned.

Article 9

Inspection domains

1. The Agency shall carry out inspections addressing each domain defined in Chapter II of Regulation (EC) No 216/2008. These domains shall include:

(a) airworthiness, as defined in Article 5 and environmental protection, as defined in Article 6 of the said Regulation

(b) Air crew, as defined in Articles 7 and 8 of the said Regulation;

(c) Air operations, as defined in Articles 8 and 9 of the said Regulation;

(d) Ramp inspections, as defined in Article 10 of the said Regulation;

(e) Aerodromes, as defined in Article 8a of the said Regulation;

(f) ATM/ANS and air traffic controllers, as defined in Articles 8b and 8c of the said Regulation;

Further domains may be defined depending on the evolutions of Regulation (EC) No 216/2008 or upon the request of the Commission.

2. The Agency shall ensure that its resources are appropriately allocated to monitoring and inspecting the different domains depending on the results of the continuous monitoring referred to in Article 7.

Article 10

Types of inspections

1. The Agency shall conduct:

(a) comprehensive inspections, for the purpose of inspecting one or more domains; these inspections shall be performed at intervals determined based on the results of the continuous monitoring;

(b) focused inspections, for the purpose of inspecting specific areas within one or more domains, and/or for the purpose of assessing the implementation status of agreed corrections and corrective actions;

(c) ad hoc inspections, for the purpose of investigating specific concerns arising from the Agency's continuous monitoring or upon request from the Commission.

2. Notwithstanding the inspections referred to in paragraph 1, the Agency may raise off-site findings when it has collected sufficient evidence of non-conformity.

Article 11

Training, qualification and authorisation criteria for inspection teams

1. The Agency shall establish qualification criteria for the personnel who participate in inspection teams.

2. The qualification criteria shall include:

(a) knowledge of the institutional and regulatory framework, in particular of this Regulation as well as on the relevant international agreements;

(b) knowledge and experience of auditing techniques;

(c) technical competence and practical experience in the relevant domain(s) referred to in Article 9.

3. Team leaders shall be personnel employed by the Agency. Their qualification criteria shall include in addition to those referred to in paragraph 2, team management and communication capabilities in an international environment and in sensitive situations.

4. Team members shall be personnel employed by the Agency or seconded personnel.

5. Both team leaders and team members shall be trained on the applicable requirements and the Agency's procedures. The Agency shall ensure the continued competence of team leaders and team members in order to participate in inspections as authorised personnel. The Agency shall establish appropriate continuous training programmes for that purpose.

6. Personnel who meet the qualification criteria and have received appropriate training may be authorised by the Agency to participate in inspection teams.

Article 12

Setting up teams for inspections

1. Inspections shall be carried out by teams set up by the Agency composed by authorised personnel pursuant to Article 11.

2. The Agency shall determine the team composition in order to establish the minimum team size necessary to cover the required technical competencies and workload, taking into account the type of inspection, the scope, the number of domains considered and the expected programme. Each team shall have a team leader and one team member as a minimum. In all cases, the Agency shall ensure the size of the teams remains commensurate to the scope.

3. The Agency shall ensure that, in setting up the teams, there shall be no conflict of interests either with the competent authorities inspected or with the undertakings or associations of undertakings inspected.

4. The Agency shall request in due time before an inspection information from seconding authorities or organisations as to the availability of team members for participating in the on-site phase.

5. Expenses arising from the participation of national standardisation coordinators as provided for in Article 14(2), Article 19(2) and of seconded personnel to inspections carried out by the Agency shall be borne by the Agency, in compliance with Union rules and without prejudice to the annual budgetary procedure of the Union.

Article 13

Conduct of inspections

1. Inspections referred to in Article 10(1)(a) and (b) shall include the following phases:

(a) a preparatory phase, lasting a minimum of 10 weeks prior to the inspection;

(b) an on-site phase;

(c) a reporting phase, lasting a maximum of 10 weeks following the end of the on-site phase.

2. Ad hoc inspections referred to in Article 10(1)(c) shall be announced to the competent authority concerned with a notice of two weeks but need not to comply with the deadlines and the procedures provided for in Articles 14, 15 and 16, except for the need of a final report.

3. Findings of non-conformity identified during inspections referred to in Article 10 shall be reported in accordance with Article 16, followed-up and closed in accordance with Article 17 and classified in accordance with Article 18.

Article 14

Preparatory phase

1. During the preparatory phase of an inspection, the Agency shall:

(a) give notice of the inspection to the competent authority at least 10 weeks before the on-site phase, including the intended type, domain(s) and areas for inspection;

(b) collect the necessary information for the preparation of the inspection, taking duly into account the information available from continuous monitoring;

(c) define the scope, the extent and the programme of the inspection, including the inspection of undertakings or association of undertakings, taking into account the information from continuous monitoring;

(d) determine the size and the composition of the inspection team.

2. Upon notice of the inspection, the competent authority shall cooperate with the Agency in order to prepare the on-site phase swiftly. If deemed necessary, a preliminary meeting may be organised between the inspection team and the national standardisation coordinator.

3. The Agency shall provide the inspection programme and the composition of the team to the competent authority at least 2 weeks before the on-site phase.

Article 15

On-site phase

1. During the on-site phase of an inspection, the Agency shall:

(a) organise an opening meeting with the national standardisation coordinator and the competent authority inspected;

(b) follow up findings of non-conformity identified in previous inspections and that remain open, and review the corresponding corrections and corrective actions;

(c) notify the competent authority of any immediate safety concern, where such concern is identified during the inspection;

(d) at a closing session, present to the competent authority inspected a list of preliminary findings of non-conformity identified or followed up in the course of the inspection.

2. In addition, the Agency may:

(a) inspect the main offices and to the extent deemed necessary, any regional offices of the competent authority and of the qualified entities to which the competent authority may have allocated tasks;

(b) inspect undertakings or associations of undertakings under the oversight of the competent authority as part of the inspection of this competent authority; in that case, the competent authority may accompany the inspection team;

(c) carry out interviews with the staff of the competent authority inspected and qualified entities, if any, and of undertakings or association of undertakings visited, if any;

(d) examine legislation, procedures, certificates, records, data and any other relevant material.

Article 16

Reporting phase

1. During the reporting phase of an inspection, the Agency shall, within 6 weeks after the closing session of the on-site phase, review the preliminary findings, classify them and establish on this basis a draft report addressed to the competent authority inspected.

2. The draft report shall contain at least:

(a) an executive summary presenting the conclusions;

(b) details on the conduct of the inspection, including the type of the inspection, domains covered, scope and composition of the team;

(c) an analysis by critical element focusing on the main findings;

(d) a list of findings of non-conformity identified or followed up during the inspection together with their classification;

(e) recommendations, including where necessary on the mutual recognition of certificates.

3. Findings of non-conformity shall be notified by means of the draft report referred to in paragraph 2, except if already notified in writing by the Agency by other means.

4. The competent authority may submit written comments to the Agency within two weeks from the notification.

5. The Agency shall, within 10 weeks after the closing session, issue a final report on the basis of the draft report mentioned in paragraph 2, reflecting the comments of the competent authority inspected, if any. The Agency may adapt the description of the finding of non-conformity, its legal basis, its classification or its status as appropriate to take into account the comments as well as the corrections or corrective actions submitted during the reporting phase.

6. The Agency shall establish and maintain a continuous monitoring status for each Member State which shall be provided on request to the Member State concerned and to the Commission.

7. The final report shall be addressed to the competent authority inspected and to the Commission, who may subsequently transmit this report to the Member State concerned and other competent authorities as appropriate.

Article 17

Findings follow-up and closure

1. For all findings of non-conformity classified under Article 18(1)(b) and (c), the competent authority shall propose a correction and a corrective action no later than four weeks after receipt of the notification from the Agency.

2. For all findings of non-conformity classified under Article 18(1)(a), the competent authority shall propose a corrective action no later than 10 weeks after receipt of the notification from the Agency;

3. The competent authority shall report to the Agency in due time on the completion of corrective actions and provide evidence thereof.

4. The Agency shall:

(a) evaluate the corrections and the corrective actions submitted by the competent authority or request further clarification in a timely manner;

(b) agree with or reject the corrections and/or corrective actions submitted within 16 weeks after the notification;

(c) monitor the satisfactory implementation of corrective actions;

(d) identify any need for supplementary actions in accordance with Article 22;

(e) report on a regular basis to the competent authority and to the Commission the status of findings of non-conformity and the related corrections/corrective actions by means of status reports;

(f) close the findings of non-conformity once satisfied with the completion of the corrective actions and the evidence provided, record the closure of the findings of non-conformity and inform the competent authority accordingly.

5. For the purposes of point (c), the Agency may request evidence or clarifications to the competent authority. The Agency may also decide to verify the implementation on site by means of an inspection.

6. When findings of non-conformity are subject to an infringement action pursuant to Article 11(2) of Regulation (EC) No 216/2008 or to the Treaties, the Agency shall ensure appropriate follow-up in consultation with the Commission and shall not close any such finding without prior coordination with the Commission.

Article 18

Classification of findings

1. All findings of non-conformity identified by the Agency in the framework of the inspections referred to in Article 10 shall be classified and reported by the Agency, whether they pertain to administrative requirements or to technical requirements, in one of the following classes:

(a) Class C: non-conformity with the applicable requirements, raising mainly standardisation concerns;

(b) Class D: non-conformity with the applicable requirements, raising standardisation concerns and safety concerns if not timely corrected;

(c) Class G: immediate safety concern.

2. The reporting, follow-up and closure shall be prioritised depending on their classification.

Article 19

Immediate safety concern

1. When an immediate safety concern has been notified by the Agency:

(a) the Agency shall request the competent authority to take adequate corrective actions, including immediate corrections;

(b) the competent authority shall apply effective corrections to remove the finding and shall provide the Agency with evidence thereof.

2. The Agency may request within two weeks from the notification of the immediate safety concern the competent authority to attend a meeting to assess the implementation of the immediate corrections.

3. When the corrections do not satisfy the Agency, the Agency shall make recommendations to the Commission, including where necessary a request with regard to the mutual recognition of the certificate(s) issued by the competent authority. The Agency shall also inform the competent authorities of the Member States immediately.

Article 20

Records

1. The Agency shall establish a system of record-keeping providing for adequate storage, accessibility and reliable traceability of changes for:

(a) training, qualification and authorisation of team leaders and team members;

(b) inspection programmes;

(c) reports;

(d) findings and related evidence;

(e) agreed corrections and corrective actions;

(f) closure of findings of non-conformity and related evidence;

(g) recommendations regarding the mutual recognition of certificates;

(h) assessments referred to in Article 7(1)(b).

2. All records shall be kept for a minimum period of 15 years, subject to applicable data protection law.

Article 21

Access to information contained in inspection reports

1. Where information contained in an inspection report concerns an undertaking or association of undertakings under the safety oversight of a third country and falls within the scope of application of a Union agreement concluded pursuant to Article 12 of Regulation (EC) No 216/2008, that information shall be made available to the third country as a party to such an agreement in accordance with its relevant provisions.

2. Where information contained in an inspection report falls within the scope of application of the Memorandum of Cooperation between the Union and ICAO, that information shall be made available to ICAO in accordance with the provisions of this Memorandum of Cooperation and the corresponding safety annex.

3. Where information contained in an inspection report relates to ongoing safety investigations conducted in accordance with Regulation (EU) No 996/2010 of the European Parliament and of the Council [1], that information shall be made available without delay to the authority in charge of the safety investigation.

4. For the purpose of Regulation (EC) No 1049/2001 of the European Parliament and of the Council [2], the decision-making process related to an inspection report shall not be deemed to be concluded before the related findings of non-conformity are closed.

Article 22

Supplementary actions

1. The Agency shall identify any failure to follow up a finding of non-conformity such as:

(a) corrective action not submitted within the period referred to in Article 17(1);

(b) corrective action not agreed by the Agency within the period referred to in Article 17(4)(b);

(c) corrective action not duly implemented.

2. In the cases referred to in paragraph 1, the Agency shall request the competent authority to provide clarifications on the failure and to submit supplementary actions, setting a time-limit for the response.

3. The Agency shall assess the consequence of the failure together with the response provided by the competent authority within the set time-limit. Based on the outcome of such assessment, the Agency may:

(a) agree with the supplementary actions submitted; or

(b) issue a supplementary report to the competent authority concerned and to the Commission. That report shall include the Agency's assessment and recommendations to the Commission, including when deemed necessary recommendations on the mutual recognition of certificate(s) issued by the competent authority.

[1] OJ L 295, 12.11.2010, p. 35.
[2] OJ L 145, 31.5.2001, p. 43.

4. Without prejudice to Regulation (EC) No 2111/2005, following receipt of the supplementary report referred to in paragraph 3(b), the Commission may take any of the following steps:

(a) address comments to the Member State concerned or request further explanation to clarify all or part of the findings of non-conformity;

(b) require the Agency to carry out an ad-hoc inspection to check the satisfactory implementation of corrections and corrective actions;

(c) initiate the procedure referred to in Article 11(2) of Regulation (EC) No 216/2008 to decide whether certificates issued by the competent authority comply with the applicable requirements;

(d) initiate a procedure under Article 258 of the Treaty.

Article 23

Annual report

The Agency shall submit to the Commission, no later than 31 March of each year, an annual report on the continuous monitoring activities and the inspections carried out in the previous year. The report shall include an analysis of the results of the activities and inspections, reflecting the competent authorities' ability to discharge their safety oversight responsibilities, as well as recommendations for possible improvements. The recommendations shall in particular identify those technical rules that would need to be established or amended pursuant to Article 17(2)(b) of Regulation (EC) No 216/2008 as well as those Agency measures that would need to be established or amended pursuant to Article 18(c) of Regulation (EC) No 216/2008.

Article 24

Working procedures

The Agency shall revise its working procedures in order to implement the tasks conferred upon it under Articles 3 to 23 within six months following the entry into force of this Regulation at the latest.

Article 25

Transitional arrangements

1. Findings of non-conformity identified by the Agency pursuant to Regulation (EC) No 736/2006 and for which evidence of closure has not been submitted to the Agency at the time of entry into force of this Regulation shall be deemed to have been made in accordance with this Regulation and shall be treated accordingly.

2. Corrective action plans agreed by the Agency pursuant to Regulation (EC) No 736/2006 shall be deemed to have been agreed in accordance with this Regulation.

3. Team members and team leaders authorised by the Agency pursuant to Regulation (EC) No 736/2006 shall be deemed authorised personnel according to this Regulation.

Article 26

Repeal

Regulation (EC) No 736/2006 is repealed.

Article 27

Entry into force and application

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

It shall apply from 1 January 2014.

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

Done at Brussels, 28 June 2013.

For the Commission
The President
José Manuel BARROSO

COMMISSION IMPLEMENTING REGULATION (EU) No 629/2013

of 28 June 2013

laying down further exceptional measures as regards the release of out-of-quota sugar and isoglucose on the Union market at reduced surplus levy during the 2012/13 marketing year

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], and in particular Article 64(2) and Article 186, in conjunction with Article 4 thereof,

Whereas:

(1) During the 2011/12 sugar marketing year, the Union average bulk white sugar ex-factory price reached a level of 175 % of the reference price of EUR 404/tonne and was approximately EUR 275/tonne higher than the world market price. The Union price is now stable at a level of around EUR 700/tonne, which is the highest level reached since the reform of the sugar market organisation and disturbs the optimal fluidity of the sugar supply on the Union market. The expected increase of this already high price level at the beginning of the 2012/13 marketing year substantiated the risk of serious market disturbances which had to be prevented by the necessary measures. On 18 January, 15 February and 22 March 2013 the Commission adopted Implementing Regulations (EU) No 36/2013 [2], (EU) No 131/2013 [3] and (EU) No 281/2013 [4] providing exceptional measures intended to address the market disturbance. Notwithstanding the measures taken, the current prices registered on the market show that it is necessary to adopt further measures to address the persisting market disturbance.

(2) Based on the estimated supply and demand for 2012/13, the ending stocks for the sugar market are expected to be lower by at least 500 000 tonnes than in 2011/12. This figure already takes into account the imports from third countries benefiting from certain preferential agreements.

(3) On the other hand, the expectations of a good harvest lead to estimate the production of nearly 4 600 000 tonnes in excess of the sugar quota set out in Article 56 of Regulation (EC) No 1234/2007. Taking account of the foreseeable contractual commitments of sugar producers in respect of certain industrial uses provided for in Article 62 of that Regulation and of the 2012/13 export commitments for out-of-quota sugar, substantial quantities of out-of-quota sugar of at least 1 200 000 tonnes would still be available. Part of this sugar could be made available to alleviate the tight supply of the Union sugar food market and to avoid excessive price increases.

(4) In order to ensure the fluidity of the market, it is necessary to release out-of-quota sugar. It should be possible to take such a measure each time it is necessary during the marketing year 2012/13.

(5) Pursuant to Articles 186 and 188 of Regulation (EC) No 1234/2007 measures may be taken, when necessary, to remedy market disturbances or the risk of disturbances, where, in particular, these result from a significant rise of prices in the Union, provided that this objective cannot be reached by means of other measures available under that Regulation. Given the current market circumstances, Regulation (EC) No 1234/2007 does not provide for any specific measures aimed at limiting the high sugar price trend and allowing sugar supply at reasonable prices on the Union market, other than those based on Article 186 of that Regulation.

(6) Article 64(2) of Regulation (EC) No 1234/2007 empowers the Commission to fix the surplus levy on sugar and isoglucose produced in excess of the quota at a sufficiently high level in order to avoid the accumulation of surplus quantities. Article 3(1) of Commission Regulation (EC) No 967/2006 of 29 June 2006 laying down detailed rules for the application of Council Regulation (EC) No 318/2006 as regards sugar production in excess of the quota [5] has fixed that levy at EUR 500 per tonne.

(7) For a limited quantity of sugar produced in excess of the quota, a reduced surplus levy should be fixed at a level per tonne allowing for a fair treatment of Union sugar producers, ensuring the good functioning of the Union sugar market and helping to reduce the difference between Union and world market sugar prices without creating risks of accumulation of surpluses in the Union market.

(8) As Regulation (EC) No 1234/2007 fixes quotas for both sugar and isoglucose, a similar measure should apply for an appropriate quantity of isoglucose produced in excess of the quota because the latter product is, to some extent, a commercial substitute for sugar.

[1] OJ L 299, 16.11.2007, p. 1.
[2] OJ L 16, 19.1.2013, p. 7.
[3] OJ L 45, 16.2.2013, p. 1.
[4] OJ L 84, 23.3.2013, p. 19.
[5] OJ L 176, 30.6.2006, p. 22.

(9) With a view to increasing the supply, sugar and isoglucose producers should apply to the competent authorities of the Member States for certificates allowing them to sell certain quantities, produced above the quota limit, on the Union market with a reduced surplus levy.

(10) The reduced surplus levy should be paid after the application is admitted and before the certificate is issued.

(11) The validity of the certificates should be limited in time to encourage a fast improvement of the supply situation.

(12) Fixing upper limits of the quantities for which each producer can apply in one application period and restricting the certificates to products of the applicant's own production should prevent speculative actions within the system created by this Regulation.

(13) With their application, sugar producers should commit themselves to pay the minimum price for sugar beet used to produce the quantity of sugar for which they apply. The minimum eligibility requirements for applications should be specified.

(14) The competent authorities of the Member States should notify the Commission of the applications received. In order to simplify and standardise those notifications, models should be made available.

(15) The Commission should ensure that certificates are granted only within the quantitative limits fixed in this Regulation. Therefore, if necessary, the Commission should be able to fix an allocation coefficient applicable to the applications received.

(16) Member States should immediately inform the applicants whether the quantity applied for was fully or partially granted.

(17) The competent authorities should notify the Commission of the quantities for which certificates with a reduction of the surplus levy have been issued. For this purpose, models should be made available by the Commission.

(18) Sugar quantities released on the Union market of quantities in excess of the certificates issued under this Regulation should be subject the surplus levy set out in Article 64(2) of Regulation (EC) No 1234/2007. It is therefore appropriate to provide that any applicant not fulfilling his commitment to release on the Union market the quantity covered by a certificate delivered to him, should also pay an amount of EUR 500 per tonne. This consistent approach is aimed at preventing abuse of the mechanism introduced by this Regulation.

(19) For the purpose of establishing average prices for quota and out-of-quota sugar on the Union market in accordance with Article 13(1) of Commission Regulation (EC) No 952/2006 of 29 June 2006 laying down detailed rules for the application of Council Regulation (EC) No 318/2006 as regards the management of the Community market in sugar and the quota system [1], sugar covered by a certificate issued pursuant to this Regulation should be considered as quota sugar.

(20) In accordance with Article 2(1)(a) of Council Decision 2007/436/EC, Euratom of 7 June 2007 on the system of the European Communities' own resources [2] contributions and other duties provided for within the framework of the common organisation of the markets in the sugar sector are to constitute own resources. It is therefore necessary to set the date of establishment of the amounts in question within the meaning of Article 2(2) and Article 6(3)(a) of Council Regulation (EC, Euratom) No 1150/2000 of 22 May 2000 implementing Decision 2007/436/EC, Euratom on the system of the Communities' own resources [3].

(21) The measures provided for in this Regulation are in accordance with the opinion of the Management Committee for the Common Organisation of Agricultural Markets,

HAS ADOPTED THIS REGULATION:

Article 1

Temporary reduction of the surplus levy

1. By way of derogation from Article 3(1) of Regulation (EC) No 967/2006, the amount of the surplus levy for a maximum quantity of 150 000 tonnes of sugar in white sugar equivalent and 8 000 tonnes of isoglucose in dry matter, produced in excess of the quota fixed in Annex VI to Regulation (EC) No 1234/2007 and released on the Union market in the 2012/13 marketing year, shall be fixed at EUR 148 per tonne.

2. The reduced surplus levy provided for in paragraph 1 shall be paid after the application referred to in Article 2 is admitted and before the certificate referred to in Article 6 is issued.

Article 2

Application for certificates

1. In order to benefit from the conditions specified in Article 1, sugar and isoglucose producers shall apply for a certificate.

2. Applicants may be only undertakings producing beet and cane sugar or isoglucose, which are approved in accordance with Article 57 of Regulation (EC) No 1234/2007 and have been allocated a production quota for the 2012/13 marketing year, in accordance with Article 56 of that Regulation.

3. Each applicant may submit not more than one application for sugar and one for isoglucose per application period.

[1] OJ L 178, 1.7.2006, p. 39.
[2] OJ L 163, 23.6.2007, p. 17.
[3] OJ L 130, 31.5.2000, p. 1.

4. Applications for certificates shall be submitted by fax or electronic mail to the competent authority in the Member State in which the undertaking was approved. The competent authorities of the Member States may require that electronic applications be accompanied by an advance electronic signature within the meaning of Directive 1999/93/EC of the European Parliament and of the Council [1].

5. To be admissible, the applications shall fulfil the following conditions:

(a) the applications shall indicate:

(i) the name, address and VAT number of the applicant; and

(ii) the quantities applied for, expressed in tonnes of white sugar equivalent and tonnes of isoglucose in dry matter, rounded to no decimal places;

(b) the quantities applied for in this application period, expressed in tonnes of white sugar equivalent and tonnes of isoglucose in dry matter, shall not exceed 50 000 tonnes in the case of sugar and 2 500 tonnes in the case of isoglucose;

(c) if the application concerns sugar, the applicant shall commit himself to pay the minimum beet price, set out in Article 49 of Regulation (EC) No 1234/2007, for the quantity of sugar covered by certificates issued in accordance with Article 6 of this Regulation;

(d) the application shall be written in the official language or one of the official languages of the Member State in which the application is lodged;

(e) the application shall indicate a reference to this Regulation and the expiry date for the submission of the applications;

(f) the applicant shall not introduce any additional conditions to those laid down in this Regulation.

6. An application which is not submitted in accordance with paragraphs 1 to 5 shall not be admissible.

7. An application may not be withdrawn or amended after its submission, even if the quantity applied for is granted only partially.

Article 3

Submission of applications

The period during which applications may be submitted shall end on 10 July 2013 at 12 noon, Brussels time.

Article 4

Transmission of applications by the Member States

1. The competent authorities of the Member States shall decide on the admissibility of applications on the basis of the conditions set out in Article 2. Where the competent authorities decide that an application is inadmissible, they shall inform the applicant without delay.

2. The competent authority shall notify the Commission on Friday at the latest, by fax or electronic mail, of the admissible applications submitted during the preceding application period. That notification shall not contain the data referred to in Article 2(5)(a)(i). Member States that received no applications but have sugar or isoglucose quota allocated to them in the 2012/13 marketing year, shall also send their nil returns notifications to the Commission within the same time limit.

3. The form and content of the notifications shall be defined on the basis of models made available by the Commission to the Member States.

Article 5

Exceeded limits

When the information notified by the competent authorities of the Member States pursuant to Article 4(2) indicates that the quantities applied for exceed the limits set out in Article 1, the Commission shall:

(a) fix an allocation coefficient, which the Member States shall apply to the quantities covered by each notified certificate application;

(b) reject applications not yet notified.

Article 6

Issue of certificates

1. Without prejudice to Article 5, on the 10th working day following a week where the application period ended, the competent authority shall issue certificates for the applications notified to the Commission, in accordance with Article 4(2).

2. Each Monday Member States shall notify the Commission of the quantities of sugar and/or isoglucose for which they issued certificates in the preceding week.

3. A template of the certificate is set out in the Annex.

Article 7

Validity of certificates

Certificates shall be valid until the end of the second month following the month of issue.

Article 8

Transferability of certificates

Neither the rights nor the obligations deriving from the certificates shall be transferable.

Article 9

Price reporting

For the purpose of Article 13(1) of Regulation (EC) No 952/2006, the quantity of sugar sold which is covered by a certificate issued pursuant to this Regulation shall be considered as quota sugar.

Article 10

Monitoring

1. Applicants shall add to their monthly notifications provided for in Article 21(1) of Regulation (EC) No 952/2006 the quantities for which they received certificates in accordance with Article 6 of this Regulation.

[1] OJ L 13, 19.1.2000, p. 12.

2. Before 31 October 2013, each holder of a certificate under this Regulation shall submit to the competent authorities of the Member States proof that all quantities covered by his certificates were released on the Union market. Each tonne covered by a certificate but not released on the Union market for reasons other than *force majeure*, shall be subject to payment of an amount of EUR 352/tonne.

3. Member States shall notify the Commission of the quantities not released on the Union market.

4. Member States shall calculate and notify the Commission of the difference between the total quantity of sugar and isoglucose produced by each producer in excess of the quota and the quantities which have been disposed by the producers in accordance with the second subparagraph of Article 4(1) of Regulation (EC) No 967/2006. If the remaining quantities of out-of-quota sugar or isoglucose of a producer are less than the quantities issued for that producer for under this Regulation, the producer shall pay an amount of EUR 500/tonne on that difference.

5. The notifications provided for in paragraphs 3 and 4 shall be made not later than 30 June 2014.

Article 11

Date of establishment

For the purposes of Article 2(2) and Article 6(3)(a) of Regulation (EC, Euratom) No 1150/2000, the date of establishment of the Union's entitlement shall be the date on which the surplus levy is paid by the applicants in accordance with Article 1(2) of this Regulation.

Article 12

Entry into force

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

It shall expire on 30 June 2014.

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

Done at Brussels, 28 June 2013.

For the Commission
The President
José Manuel BARROSO

ANNEX

Model for the certificate referred to in Article 6(3)

CERTIFICATE

for the reduction, for the 2012/13 marketing year, of the levy provided for in Article 3 of Regulation (EC) No 967/2006

<table>
<tr><td colspan="3">Member State:</td></tr>
<tr><td colspan="3">Quota holder:</td></tr>
<tr><td colspan="3"></td></tr>
<tr><td colspan="2">Product:</td><td></td></tr>
<tr><td colspan="2">Quantities applied:</td><td></td></tr>
<tr><td colspan="2">Quantities issued:</td><td></td></tr>
<tr><td colspan="2">Levy paid (EUR/t):</td><td>EUR 148/tonne</td></tr>
<tr><td colspan="3">For the 2012/13 marketing year, the levy referred to in Article 3 of Regulation (EC) No 967/2006 shall not apply to the quantities issued of this certificate, subject to the respect of the rules laid down in Commission Implementing Regulation (EU) No 629/2013, in particular in Article 2(5)(c).</td></tr>
<tr><td colspan="2">Signature of the competent authority of the Member State:</td><td>Date of issue:</td></tr>
<tr><td colspan="3">This certificate shall be valid until the end of the second month following the date of issue.</td></tr>
</table>

COMMISSION REGULATION (EU) No 630/2013

of 28 June 2013

amending the Annexes to Regulation (EC) No 999/2001 of the European Parliament and of the Council laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies

(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 999/2001 of the European Parliament and of the Council of 22 May 2001 laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies ([1]), and in particular the first paragraph of Article 23 thereof,

Whereas:

(1) Regulation (EC) No 999/2001 lays down rules for the prevention, control and eradication of transmissible spongiform encephalopathies (TSEs) in bovine, ovine and caprine animals. It applies to the production and placing on the market of live animals and products of animal origin and in certain specific cases to exports thereof.

(2) On 19 January 2011, the European Food Safety Authority (EFSA) published a joint opinion prepared with the European Centre for Disease Prevention and Control (ECDC) on any possible epidemiological or molecular association between TSEs in animals and humans ('the joint EFSA and ECDC Opinion') ([2]). In the joint EFSA and ECDC opinion, the EFSA and ECDC confirmed the identification of atypical forms of bovine spongiform encephalopathy (BSE) in cattle and made the distinction between classical BSE, L-type atypical BSE and H-type atypical BSE. It is therefore appropriate to insert definitions for classical BSE cases and atypical BSE cases in Annex I to Regulation (EC) No 999/2001.

(3) Part I of Chapter A of Annex III to Regulation (EC) No 999/2001 lays down rules for monitoring BSE in bovine animals slaughtered for human consumption. It refers to animals slaughtered in accordance with 'special emergency slaughter' as defined in Article 2(n) of Council Directive 64/433/EEC of 26 June 1964 on health conditions for the production and marketing of fresh meat ([3]). That Directive has since been repealed by Directive 2004/41/EC of the European Parliament and of the Council ([4]). This has led to legal uncertainty and caused reduced testing in animals that should have been tested. It is therefore necessary to clearly define emergency slaughter in the framework of the rules for monitoring BSE in bovine animals slaughtered for human consumption in Annex III to Regulation (EC) No 999/2001.

(4) Part II of Chapter A of Annex III to Regulation (EC) No 999/2001 lays down rules for monitoring in ovine and caprine animals. The annual reports carried out by the Member States on the monitoring and testing of ruminants for the presence of Transmissible Spongiform Encephalopathy (TSE) in the Union have shown in recent years that the testing of ovine and caprine animals not slaughtered for human consumption is usually more efficient to identify cases of TSE than the testing of animals slaughtered for human consumption. More flexibility should therefore be given to the Member States to focus a larger part of the limited number of tests required by that Annex in the subpopulations where there is a greater chance to identify such cases.

(5) Annex VII to Regulation (EC) No 999/2001 lays down the eradication measures to be carried out following the confirmation of the presence of TSE in bovine, ovine and caprine animals and the minimum requirements for breeding programmes for resistance to TSEs in sheep. That Annex has been amended several times, including by Commission Regulations (EC) No 727/2007 ([5]) and (EC) No 746/2008 ([6]).

(6) On 17 July 2007, in Case T-257/07, France brought an action against the Commission before the General Court, applying for the suspension of the operation of point (3) of the Annex to Regulation (EC) No 727/2007 insofar as it introduces point 2.3(b)(iii), point 2.3(d) and point 4 into Chapter A of Annex VII to Regulation (EC) No 999/2001, or alternatively the entire annulment of that Regulation. According to France, those points would authorise less restrictive measures of surveillance and eradication than those earlier prescribed for sheep and goats. In its Order of 28 September 2007 ([7]), the Court suspended the application of those provisions until judgment would be given in the main action.

(7) The Commission subsequently asked the EFSA to assist it in clarifying the main premises on which Regulation (EC) No 727/2007 was based. In view of the EFSA

([1]) OJ L 147, 31.5.2001, p. 1.
([2]) *EFSA Journal 2011*;9(1):1945
([3]) OJ 121, 29.7.1964, p. 2012.
([4]) OJ L 157, 30.4.2004, p. 33.
([5]) OJ L 165, 27.6.2007, p. 8.
([6]) OJ L 202, 31.7.2008, p. 11.
([7]) OJ C 283, 24.11.2007, p. 28.

clarifications, Regulation (EC) No 999/2001 was amended by Regulation (EC) No 746/2008, which reinstated provisions the application of which had been suspended by the General Court. In its Order of 30 October 2008 [1], the General Court suspended the application of point 2.3(b)(iii), point 2.3(d) and point 4 of Chapter A of Annex VII to Regulation (EC) No 999/2001, as amended by Regulation (EC) No 746/2008, until judgment would be given in the main action in Case T-257/07.

(8) In its judgment of 9 September 2011 in Case T-257/07 [2], the General Court dismissed the application by France for the annulment of Regulation (EC) No 746/2008, and lifted the suspension of the application of those provisions of Chapter A of Annex VII to Regulation (EC) No 999/2001.

(9) On 28 November 2011, in Case C-601/11 P [3], an appeal was brought by France against the judgment of the General court in Case T-257/07, requesting the Court to set aside the judgment of the General Court in Case T-257/07 and to give final judgment in the dispute by annulling Regulation (EC) No 746/2008 or to refer the case back to the General Court.

(10) It is appropriate to clarify the very complex construct of management options and derogations for the control and eradication of classical scrapie in ovine and caprine animals set out in Annex VII to Regulation (EC) No 999/2001. Annex VII should only provide for three options in infected flocks or herds of ovine and caprine animals, namely: option 1 for the elimination of all animals; option 2 for the elimination of the susceptible animals only; and option 3 for no mandatory elimination of animals.

(11) The measures to be applied in each of those three options should be re-drafted in order to facilitate comparison between the options and improve awareness of the consequences for the individual holding. As option 1 and option 2 include stringent eradication measures which improve disease control, the post-eradication measures enforced under option 1 and option 2 should be more flexible than under option 3.

(12) It is necessary to clarify the conditions under which the elimination measures set out in option 2 may be delayed. It is appropriate to allow for a short term delay not exceeding three months linked to lambing season considerations. However, a long term delay can only be justified by the need of additional time to increase the level of genetic resistance to classical scrapie in a holding. Since genetic resistance to classical scrapie has so far been proven only in ovine animals, the long term delay should not be permitted for herds comprising only caprine animals. When permitted, it should be limited to a period of three years under certain conditions.

(13) Where classical scrapie is confirmed in holdings keeping a local ovine breed in danger of being lost to farming, the post-eradication measures laid down in Annex VII to Regulation (EC) No 999/2001 should take into consideration the difficulty of introducing and using only resistant ovine animals or ovine germinal products of the same endangered breed. In this particular case, Member States should be permitted to apply more flexible rules regarding the genotype of breeders and germinal products introduced and used in the holdings.

(14) The joint EFSA and ECDC Opinion suggests that atypical scrapie could be little or not contagious at all. That finding mainly relies on the lack of statistical difference of the observed Atypical/Nor98 frequencies between the general population and the flocks where a positive case had been identified. Therefore, restriction measures on the movement of ovine and caprine animals where a case of atypical scrapie has been confirmed are no longer justified. Increased surveillance in those flocks or herds should, however, be maintained in order to gather more scientific data on atypical scrapie. This amendment to Annex VII to Regulation (EC) No 999/2001 is in line with the future policy options envisaged by paragraph 2.4.3 of the Communication from the Commission to the European Parliament and the Council — The TSE Road map 2 — A Strategy paper on Transmissible Spongiform Encephalopathies for 2010-2015 [4].

(15) The participation in breeding programmes has been so far limited to ovine flocks of high genetic merit. Where they have been applied, the breeding programmes have been effective in increasing the resistance to classical scrapie in the high genetic merit sheep population. But the diffusion in the ordinary production population of the hereditary factor (allele) carrying the resistance appears to have been limited so far. Chapter C of Annex VII to Regulation (EC) No 999/2001 should allow the genotyping of the breeding rams of flocks not participating in the breeding programme in order to facilitate a broader diffusion of the resistance factor to classical scrapie in the production population.

(16) Chapter A of Annex VIII to Regulation (EC) No 999/2001 lays down rules governing intra-Union trade in live animals, semen and embryos. As referred to in recital 14, the joint EFSA and ECDC Opinion suggests that atypical scrapie could be little or not contagious at all. The lifting of all restriction measures on the movement of ovine and caprine animals where a case of atypical scrapie has been confirmed should therefore apply to intra-Union trade. This position is also supported by the fact that the Terrestrial Animal Health Code, as voted in 2010 at the 78th General Session of the World Organisation for Animal Health (OIE), does not recommend any trade restriction with regards to atypical scrapie.

[1] OJ C 327, 20.12.2008, p. 26.
[2] OJ C 311, 22.10.2011, p. 33.
[3] OJ C 80, 17.3.2012, p. 5.
[4] COM(2010)384 final.

(17) The rules set out in Annex VIII to Regulation (EC) No 999/2001 relating to intra-Union trade in ovine and caprine animals and their semen and embryos should be made as consistent as possible with the OIE standards, so that they do not preclude Member States with an approved national control programme for classical scrapie from claiming the country freedom status for classical scrapie according to the conditions laid out in the OIE code. The amended intra-Union trade provisions should however not adversely impact existing intra-Union trade flows among Member States where no national control programme for classical scrapie has been approved.

(18) For that purpose, and as proposed in paragraph 2.4.3 of the TSE Roadmap 2, a framework enabling the Member States to establish an official scheme for the recognition of classical scrapie status in holdings should be set out in Annex VIII to Regulation (EC) No 999/2001. The possibility for a holding to engage in intra-Union trade of ovine and caprine animals, with regards to classical scrapie, should be determined by its classical scrapie status.

(19) A two tiered system for classical scrapie status in holdings should be established in Annex VIII to Regulation (EC) No 999/2001. A negligible risk status, equivalent in technical terms to the scrapie free status in a holding, as laid down in Article 14.9.5. of the OIE Terrestrial Animal Health code and based on compliance with the full list of the OIE requirements for at least seven years (in line with the rule laid down in article 6a and Annex VII to Regulation (EC) No 999/2001 favouring the development of the resistant genotypes in ovines, the proposal however recognises the ARR/ARR genotype as a valid option), should be required for transporting animals for breeding and rearing to the Member States with an approved national control programme for classical scrapie. Animals for breeding intended to other Member States should only be required to come from holdings with a controlled risk of classical scrapie based on compliance with a shorter list of requirements for at least three years, as is presently the case.

(20) Considering the difficulty to demonstrate freedom in the territory of part of the territory of a Member State for a disease as complex as classical scrapie, which is characterised by a long incubation delay, the absence of any in-vivo diagnostic method and a variable individual susceptibility of the animals depending on their genetic profile, the concept of 'classical scrapie free Member State' should be replaced in Annex VIII to Regulation (EC) No 999/2001 by that of 'Member State or zone of a Member State with a negligible risk of classical scrapie'. The conditions for the recognition of a Member State or zone of a Member State with a negligible risk of classical scrapie should also be updated and largely brought in line with the recommendations laid down in Article 14.9.3 of the OIE Terrestrial Animal Health code.

(21) As Annex VIII to Regulation (EC) No 999/2001 should cover all trade aspects related to classical scrapie, and considering that the proposed creation of an official scheme for the recognition of classical scrapie status in holdings constitutes an appropriate basis for establishing differentiated guarantees for animals to be traded with Member States with an approved national control plan for classical scrapie and with other Member States, that Annex should also include the list of Member States with an approved national control plan for classical scrapie.

(22) Chapter C of Annex IX to Regulation (EC) No 999/2001 lays down rules relating to imports into the Union of products of animal origin from bovine, ovine and caprine animals, in particular gelatine intended for human consumption. Section A of Chapter D of Annex IX to Regulation (EC) No 999/2001 lays down rules related to imports into the Union of animal by-products and derived products from bovine, ovine and caprine origin, in particular gelatine intended to be used as feed ingredient. Since collagen intended to be used for food or feed is produced from the same raw materials as gelatine, import conditions for collagen to be used for food or feed should be aligned with those laid down for gelatine intended for the same usage.

(23) Section B of Chapter D of Annex IX to Regulation (EC) No 999/2001 provides specific attestations which are to accompany imports into the Union of certain animal by-products and derived products of bovine, ovine and caprine origin. Those attestations should be amended in order to also apply to products processed in a third country classified as posing a controlled or undetermined BSE risk and made from mixed material originating from this third country as well as from a third country with a negligible BSE risk. The specific attestation regarding the importation of products containing milk of ovine and caprine origin and intended for feeding farmed animals should also be amended to better reflect the restrictions applicable to intra-Union trade in these products.

(24) Chapters E and H of Annex IX to Regulation (EC) No 999/2001 lay down rules for the importation in the Union of ovine and caprine animals, and ovine and caprine semen and embryos. Those import rules should be updated to reflect the conditions for intra-Union trade laid down in Annex VIII to Regulation (EC) No 999/2001, including the general pre-requisites in terms of monitoring and eradication of classical scrapie laid down in Annexes III and VII to Regulation (EC) No 999/2001, as well as feed ban provisions laid down in Annex IV to Regulation (EC) No 999/2001.

(25) Annex X to Regulation (EC) No 999/2001 lays down the methods of analysis applicable to TSE testing in bovine, ovine and caprine animals. The joint EFSA and ECDC Opinion indicated that the L-type Atypical BSE agent has a significant zoonotic potential (transmission from animals to humans), which appears similar or even higher than that of the Classical BSE agent. L-type and H-type cases of atypical BSE have been identified in several countries throughout the world and EFSA indicated that the unusually old age of all H-BSE and L-BSE identified cases and their apparent low prevalence in the population could suggest that these Atypical BSE forms are arising spontaneously. In order to gain more knowledge on atypical BSE, more relevant data need to be gathered.

(26) For that purpose, it is necessary to require that material from all future cases of BSE confirmed in the Union is submitted to discriminatory tests that allow the precise identification of the agent, namely classical BSE, L-type atypical BSE and H-type atypical BSE. As certain Member States and third countries have already published details of the phenotype of their recent BSE cases, discriminatory testing of future BSE cases confirmed in the Union should be made mandatory in Chapter C of Annex X to Regulation (EC) No 999/2001.

(27) Point 4 of Chapter C of Annex X to Regulation (EC) No 999/2001 sets out a list of rapid tests approved for the monitoring of TSEs in bovine, ovine and caprine animals.

(28) Considering that the two following rapid test kits for the monitoring of BSE in bovine animals are not manufactured any more, as confirmed in the letters sent by Enfer Scientific on 21 August 2012 and Roche Diagnostics GmbH on 31 August 2012, they should be deleted from the list of rapid tests set out in Point 4 of Chapter C of Annex X: Enfer test & Enfer TSE Kit version 2.0, automated sample preparation; Roche Applied Science PrionScreen.

(29) As Member States need sufficient time to adapt their national instructions to the new requirements introduced by this Regulation, this Regulation should apply on 1 July 2013.

(30) Regulation (EC) No 999/2001 should therefore be amended accordingly.

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

HAS ADOPTED THIS REGULATION:

Article 1

The Annexes to Regulation (EC) No 999/2001 are amended in accordance with the Annex to this Regulation.

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*.

It shall apply from 1 July 2013.

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

Done at Brussels, 28 June 2013.

For the Commission
The President
José Manuel BARROSO

ANNEX

The Annexes to Regulation (EC) No 999/2001 are amended as follows:

(1) In Annex I, point 2 is replaced by the following:

'2. For the purpose of this Regulation, the following definitions shall also apply:

(a) 'BSE indigenous case' means a case of bovine spongiform encephalopathy which has not been clearly demonstrated to be due to infection prior to importation as a live animal;

(b) 'cohort' means a group of bovine animals which includes both:

(i) animals born in the same herd as the affected bovine animal, and within 12 months preceding or following the date of birth of the affected bovine animal; and

(ii) animals which at any time during the first year of their lives were reared together with the affected bovine animal during the first year of its life;

(c) 'index case' means the first animal on a holding, or in an epidemiologically defined group, in which a TSE infection is confirmed;

(d) 'TSE in small ruminants' means a transmissible spongiform encephalopathy case detected in an ovine or caprine animal following a confirmatory test for abnormal PrP protein;

(e) 'scrapie case' means a transmissible spongiform encephalopathy confirmed case in an ovine or caprine animal where a diagnosis of BSE has been excluded in accordance with the criteria laid down in the European Union reference laboratory's technical handbook on TSE strain characterisation in small ruminants (*);

(f) 'classical scrapie case' means a scrapie confirmed case classified as classical in accordance with the criteria laid down in the European Union reference laboratory's technical handbook on TSE strain characterisation in small ruminants;

(g) 'atypical scrapie case' means a scrapie confirmed case which is distinguishable from classical scrapie in accordance with the criteria laid down in the European Union reference laboratory's technical handbook on TSE strain characterisation in small ruminants;

(h) 'Prion protein genotype' in ovine animals means a combination of two alleles as described in point 1 of Annex I to Commission Decision 2002/1003/EC (**);

(i) 'BSE case' means a case of BSE confirmed in a national reference laboratory according to the methods and protocols in point 3.1.(a) and (b) of Chapter C of Annex X;

(j) 'classical BSE case' means a BSE case classified as such in accordance with the criteria laid down in the European Union reference laboratory's method for the classification of bovine TSE isolates (***);

(k) 'atypical BSE case' means a BSE case which cannot be classified as a classical BSE case in accordance with the criteria laid down in the European Union reference laboratory's method for the classification of bovine TSE isolates;

(l) 'ovine and caprine animals over 18 months of age' means ovine and caprine animals:

(i) whose age is confirmed by the registers or movement documents referred to in point 1(b), (c) and (d) of Article 3 of Council Regulation (EC) No 21/2004 (****), or

(ii) which have more than two permanent incisors erupted through the gum.

(*) http://vla.defra.gov.uk/science/docs/sci_tse_rl_handbookv4jan10.pdf
(**) OJ L 349, 24.12.2002, p. 105.
(***) http://vla.defra.gov.uk/science/docs/sci_tse_rl_2blot.pdf
(****) OJ L 5, 9.1.2004, p. 8.'

(2) In Annex III, Chapter A is amended as follows:

(a) In Part I, point 2 is replaced by the following:

'2. **Monitoring in animals slaughtered for human consumption**

2.1. All bovine animals over 24 months of age shall be tested for BSE where they have undergone:

— emergency slaughter in accordance with point 1 of Chapter VI of Section I of Annex III to Regulation (EC) No 853/2004 (*), or

— an ante mortem inspection with observations concerning accidents, or serious physiological and functional problems, or signs in accordance with point 2 of Part B of Chapter II of Section I of Annex I to Regulation (EC) No 854/2004 (**).

2.2. All healthy bovine animals over 30 months of age slaughtered normally for human consumption shall be tested for BSE.

(*) OJ L 139, 30.4.2004, p. 55.
(**) OJ L 139, 30.4.2004, p. 206.'

(b) Part II is amended as follows:

(i) Point 2 is replaced by the following:

'2. **Monitoring in ovine and caprine animals slaughtered for human consumption**

(a) Member States in which the population of ewes and ewe lambs put to the ram exceeds 750 000 animals shall test, in accordance with the sampling rules set out in point 4, a minimum annual sample of 10 000 ovine animals slaughtered for human consumption;

(b) Member States in which the population of goats which have already kidded and goats mated exceeds 750 000 animals shall test, in accordance with the sampling rules set out in point 4, a minimum annual sample of 10 000 caprine animals slaughtered for human consumption;

(c) A Member State may choose to replace a maximum of:

— 50 % of its minimum sample size of ovine and caprine animals slaughtered for human consumption set out in points (a) and (b) by testing dead ovine or caprine animals over the age of 18 months at the ratio of one to one and in addition to the minimum sample size set out in point 3;

— 10 % of its minimum sample size set out in points (a) and (b) by testing ovine or caprine animals killed in the framework of a disease eradication campaign over the age of 18 months at the ratio of one to one.'

(ii) Point 5 is replaced by the following:

'5. **Monitoring in holdings under TSE control and eradication measures**

Animals over 18 months of age which are killed for destruction in accordance with Annex VII, Chapter B, Part 2, point 2.2.1. and point 2.2.2.(b) or (c), shall be tested for the presence of TSE in accordance with the laboratory methods and protocols set out in Annex X, Chapter C, Part 3, point 3.2.(b), based on the selection of a simple random sample, in accordance with the sample size set out in the following table.

Number of animals over 18 months of age killed for destruction in the herd or flock	Minimum sample size
70 or less	All eligible animals
80	68
90	73
100	78
120	86
140	92
160	97
180	101
200	105
250	112
300	117

Number of animals over 18 months of age killed for destruction in the herd or flock	Minimum sample size
350	121
400	124
450	127
500 or more	150'

(3) Annex VII is replaced by the following:

'*ANNEX VII*

CONTROL AND ERADICATION OF TRANSMISSIBLE SPONGIFORM ENCEPHALOPATHIES

CHAPTER A

Measures following the suspicion of the presence of a TSE in ovine and caprine animals

If a TSE is suspected in an ovine or caprine animal on a holding in a Member State and until the results of the confirmatory examinations are available, all other ovine and caprine animals on that holding shall be placed under an official movement restriction.

If there is evidence that the holding where the animal was present when the TSE was suspected is unlikely to be the holding where the animal could have been exposed to the TSE, the Member State may decide that other holdings or only the holding of exposure shall be placed under official control, depending on the epidemiological information available.

The milk and the milk products derived from the ovine and caprine animals of a holding placed under official control, which are present on that holding from the date when the presence of the TSE is suspected until the results of the confirmatory examinations are available, shall only be used within that holding.

CHAPTER B

Measures following confirmation of the presence of a TSE in bovine, ovine and caprine animals

1. The inquiry referred to in Article 13(1)(b) must identify:

(a) in the case of bovine animals:

— all other ruminants on the holding of the animal in which the disease was confirmed,

— where the disease was confirmed in a female animal, its progeny born within a period of two years prior to, or after, the clinical onset of the disease,

— all animals of the cohort of the animal in which the disease was confirmed,

— the possible origin of the disease,

— other animals on the holding of the animal in which the disease was confirmed or on other holdings which may have become infected by the TSE agent or been exposed to the same feed or contamination source,

— the movement of potentially contaminated feedingstuffs, of other material or any other means of transmission, which may have transmitted the TSE agent to or from the holding in question;

(b) in the case of ovine and caprine animals:

— all ruminants other than ovine and caprine animals on the holding of the animal in which the disease was confirmed,

— insofar as they are identifiable, the parents, and in the case of females all embryos, ova and the last progeny of the female animal in which the disease was confirmed,

— all other ovine and caprine animals on the holding of the animal in which the disease was confirmed in addition to those referred to in the second indent,

— the possible origin of the disease and the identification of other holdings on which there are animals, embryos or ova which may have become infected by the TSE agent or been exposed to the same feed or contamination source,

— the movement of potentially contaminated feedingstuffs, other material or any other means of transmission, which may have transmitted the TSE agent to or from the holding in question.

2. The measures laid down in Article 13(1)(c) shall comprise at least the following:

2.1. In the case of confirmation of BSE in a bovine animal, the killing and complete destruction of bovine animals identified by the inquiry referred to in the second and third indents of point 1(a); however, the Member State may decide:

— not to kill and destroy animals of the cohort referred to in the third indent of point 1(a) if evidence has been provided that such animals did not have access to the same feed as the affected animal,

— to defer the killing and destruction of animals of the cohort referred to in the third indent of point 1(a) until the end of their productive life, provided that they are bulls continuously kept at a semen collection centre and it can be ensured that they are completely destroyed following death.

2.2. In the case of confirmation of TSE in an ovine or caprine animal:

2.2.1. In cases where BSE cannot be excluded

If BSE cannot be excluded after the results of a ring trial carried out in accordance with the methods and protocols set out in Annex X, Chapter C, Part 3, point 3.2(c), the killing and complete destruction, without delay, of all animals, embryos and ova identified by the inquiry referred to in the second to fifth indents of point 1(b).

The animals over 18 months of age killed for destruction shall be tested for the presence of TSE in accordance with the laboratory methods and protocols set out in Annex X, Chapter C, Part 3, point 3.2, as laid down in Annex III, Chapter A, Part II, point 5.

The prion protein genotype of all ovine animals, up to a maximum of 50, shall be determined.

The milk and the milk products derived from the animals to be destroyed, which were present on the holding between the date of confirmation that BSE cannot be excluded and the date of complete destruction of the animals, shall be disposed of in accordance with Article 12 of Regulation (EC) No 1069/2009 of the European Parliament and of the Council (*).

Following the killing and complete destruction of all animals, the conditions set out in point 3 shall apply to the holding.

2.2.2. In cases where BSE and atypical scrapie can be excluded

If BSE and atypical scrapie are excluded in accordance with the laboratory methods and protocols set out in Annex X, Chapter C, Part 3, point 3.2(c), the holding shall be subject to the conditions set out in point (a) and, pursuant to the decision of the Member State responsible for the holding, to the conditions of either option 1 set out at point (b), or option 2 set out at point (c), or option 3 set out at point (d):

(a) The milk and milk products derived from the animals to be destroyed or slaughtered and which were present on the holding between the date of confirmation of the case of TSE and the date of the completion of the measures to be applied in the holding as laid down in point (b) and (c), or derived from the infected flock/herd until all the restrictions laid down in point (d) and point 4 are lifted, shall not be used for the feeding of ruminants, except for the feeding of ruminants within that holding.

The placing on the market of such milk and milk products as feed for non-ruminants shall be limited to the territory of the Member State responsible for the holding.

The commercial document accompanying consignments of such milk and milk products and any packaging containing such consignments shall be clearly marked with the words: 'shall not be fed to ruminants'.

The use and the storage of feedingstuffs containing such milk and milk products shall be prohibited on holdings where ruminants are kept.

Bulk feedingstuffs containing such milk and milk products shall be transported by means of vehicles which do not transport feedingstuffs for ruminants at the same time.

If those vehicles are subsequently used for the transport of feedingstuffs intended for ruminants, they shall be thoroughly cleaned in order to avoid cross- contamination, in accordance with a procedure approved by the Member State responsible for the holding.

(b) Option 1 — killing and complete destruction of all animals

The killing and complete destruction, without delay, of all animals, embryos and ova identified by the inquiry referred to in the second and third indents of point 1(b).

The animals over 18 months of age killed for destruction shall be tested for the presence of TSE in accordance with the laboratory methods and protocols set out in Annex X, Chapter C, Part 3, point 3.2, as laid down in Annex III, Chapter A, Part II, point 5.

The prion protein genotype of all ovine animals, up to a maximum of 50, shall be determined.

By way of derogation from the conditions set out in the first paragraph of option 1, Member States may decide instead to carry out the measures listed in (i) or (ii):

(i) to replace the killing and complete destruction of all animals, without delay, by their slaughtering for human consumption, without delay, provided that:

— the animals are slaughtered for human consumption within the territory of the Member State responsible for the holding;

— all animals which are over 18 months of age slaughtered for human consumption shall be tested for the presence of TSE in accordance with the laboratory methods and protocols set out in Annex X, Chapter C, Part 3, point 3.2.

(ii) to exempt the lambs and kids less than three months old from killing and complete destruction without delay, provided that they are slaughtered for human consumption not later than when they are three months of age.

Pending the killing and complete destruction or slaughtering for human consumption of all animals, the measures set out in point 2.2.2.(a) and point 3.4.(b) third and fourth indents shall apply on the holding where it has been decided to apply option 1.

Following the killing and complete destruction or slaughtering for human consumption of all animals the conditions set out in point 3 shall apply to the holding where it has been decided to apply option 1.

(c) Option 2 — killing and complete destruction of the susceptible animals only

The prion protein genotyping of all ovine animals present on the holding followed by the killing and complete destruction, without delay, of all animals, embryos and ova identified by the inquiry referred to in the second and third indents of point 1(b), with the exception of:

— breeding rams of the ARR/ARR genotype,

— breeding ewes carrying at least one ARR allele and no VRQ allele and, where such breeding ewes are pregnant at the time of the inquiry, the lambs subsequently born, if their genotype meets the requirements of this subparagraph,

— ovine animals carrying at least one ARR allele which are intended solely for slaughter for human consumption,

— if the Member State responsible for the holding so decides, lambs and kids less than three months old provided that they are slaughtered for human consumption not later than when they are three months of age. These lambs and kids shall be exempted from the genotyping.

The animals over 18 months of age killed for destruction shall be tested for the presence of TSE in accordance with the laboratory methods and protocols set out in Annex X, Chapter C, Part 3, point 3.2, as laid down in Annex III, Chapter A, Part II, point 5.

By way of derogation from the conditions set out in the first paragraph of option 2, Member States may decide instead to carry out the measures listed in (i), (ii) and (iii):

(i) to replace the killing and complete destruction of the animals referred to in the first paragraph of option 2 by their slaughtering for human consumption, provided that:

— the animals are slaughtered for human consumption within the territory of the Member State responsible for the holding;

— all animals which are over 18 months of age slaughtered for human consumption shall be tested for the presence of TSE in accordance with the laboratory methods and protocols set out in Annex X, Chapter C, Part 3, point 3.2.

(ii) to delay the genotyping and subsequent killing and complete destruction or slaughtering for human consumption of the animals referred to in the first paragraph of option 2 for a period not exceeding three months in situations where the index case is confirmed close to the commencement of the lambing season, provided that the ewes, goats and their new-born are kept isolated from ovine and caprine animals of other holdings during the whole period;

(iii) to delay the killing and complete destruction or slaughtering for human consumption of the animals referred to in the first paragraph of option 2 for a maximum period of three years from the date of confirmation of the index case, in ovine flocks and holdings where ovine and caprine animals are kept together. The application of the derogation set out in the present paragraph shall be limited to cases where the Member State responsible for the holding considers that the epidemiological situation cannot be handled without killing the relevant animals, but that this cannot be carried out immediately due to the low level of resistance in the ovine population of the holding coupled with other considerations, including economic factors. Breeding rams other than those of the ARR/ARR genotype shall be killed or castrated without delay and all possible measures to quickly build up genetic resistance in the ovine population of the holding, including by reasoned breeding and culling of ewes to increase the frequency of the ARR allele and eliminate the VRQ allele, shall be implemented. The Member State responsible for the holding shall ensure that the number of animals to be killed at the end of the period of delay is not greater than immediately after the index case was confirmed.

Pending the killing and complete destruction or slaughtering for human consumption of the animals referred to in the first paragraph of option 2, the following measures shall apply on the holding where it has been decided to apply option 2: point 2.2.2.(a), point 3.1., point 3.2.(a) and (b), point 3.3. and point 3.4.(a) first and second indents, (b) first, third and fourth indents, and (c). However, where the Member State responsible for the holding decides to delay the killing and complete destruction or slaughtering for human consumption of the animals in accordance with point (iii), the following measures shall instead apply on the holding: point 2.2.2.(a) and points 4.1. to 4.6.

Following the killing and complete destruction, or slaughtering for human consumption of the animals referred to in the first paragraph of option 2 the conditions set out in point 3 shall apply to the holding where it has been decided to apply option 2.

(d) Option 3 — no mandatory killing and complete destruction of animals

A Member State may decide not to kill and completely destroy the animals identified by the inquiry referred to in the second and third indents of point 1(b) where the criteria laid down in at least one of the following four indents are met:

— it is difficult to obtain replacement ovine animals of genotypes allowed under point 3.2.(a) and (b),

— the frequency of the ARR allele within the breed or holding is low,

— it is deemed necessary in order to avoid inbreeding,

— it is deemed necessary by the Member State based on a reasoned consideration of all the epidemiological factors.

The Member States allowing recourse to option 3 in the management of classical scrapie outbreaks shall keep records of the reasons and criteria founding each individual application decision.

When additional classical scrapie cases are detected in a holding where option 3 is being applied, the relevance of the reasons and criteria founding the decision to apply option 3 to this holding shall be reassessed by the Member State. If it is concluded that applying option 3 does not ensure a proper control of the outbreak, the Member State shall switch the management of this holding from option 3 to either option 1 or option 2, as laid down in points (b) and (c).

The prion protein genotype of all ovine animals, up to a maximum of 50, shall be determined within a period of three months from the date of confirmation of the index case of classical scrapie.

The conditions set out in point 2.2.2.(a) and point 4 shall immediately apply to a holding where it has been decided to apply option 3.

2.2.3. In cases where atypical scrapie is confirmed

Where the TSE case confirmed on a holding is an atypical scrapie case, the holding shall be subject to the following intensified TSE monitoring protocol for a period of two years from the date of the detection of the last atypical scrapie case: all ovine and caprine animals which are over the age of 18 months and slaughtered for human consumption and all ovine and caprine animals over the age of 18 months which have died or been killed on the holding shall be tested for the presence of TSE in accordance with the laboratory methods and protocols set out in Annex X, Chapter C, Part 3, point 3.2.

If a case of TSE other than atypical scrapie is confirmed during the intensified TSE monitoring period of two years referred to in the first paragraph, the holding shall be subject to the measures referred to in point 2.2.1 or point 2.2.2.

2.3. If an animal infected with TSE has been introduced from another holding:

(a) a Member State may decide, based on the history of the infected animal, to apply eradication measures in the holding of origin in addition to, or instead of, the holding in which the infection was confirmed;

(b) in the case of land used for common grazing by more than one flock or herd, Member States may decide to limit the application of eradication measures to a single flock or herd, based on a reasoned consideration of all the epidemiological factors;

(c) where more than one flock or herd is kept on a single holding, Member States may decide to limit the application of the eradication measures to the flock or herd in which the TSE has been confirmed, provided it has been verified that the flocks or herds have been kept isolated from each other and that the spread of infection between the flocks or herds through either direct or indirect contact is unlikely.

3. Following the killing and complete destruction or slaughtering for human consumption of all animals identified on a holding, in accordance with point 2.2.1., point 2.2.2.(b) or point 2.2.2.(c):

3.1. The holding shall be subjected to an intensified TSE monitoring protocol including the testing for the presence of TSE, in accordance with the laboratory methods and protocols set out in Annex X, Chapter C, Part 3, point 3.2, of all of the following animals which are over the age of 18 months, except ovine animals of the ARR/ARR genotype:

(a) animals which were kept in the holding at the time when the TSE case was confirmed, in accordance with point 2.2.2.(c), and which have been slaughtered for human consumption;

(b) animals which have died or been killed on the holding but which were not killed in the framework of a disease eradication campaign.

3.2. Only the following animals may be introduced to the holding:

(a) male ovine animals of the ARR/ARR genotype;

(b) female ovine animals carrying at least one ARR allele and no VRQ allele;

(c) caprine animals, provided that a cleaning and disinfection of all animal housing on the premises has been carried out following destocking.

3.3. Only the following breeding rams and ovine germinal products may be used in the holding:

(a) male ovine animals of the ARR/ARR genotype;

(b) semen from rams of the ARR/ARR genotype;

(c) embryos carrying at least one ARR allele and no VRQ allele.

3.4. Movement of animals from the holding shall either be allowed for the purposes of destruction, or shall be subject to the following conditions:

(a) the following animals may be moved from the holding for all purposes, including breeding:

— ARR/ARR ovine animals;

— ewes carrying one ARR allele and no VRQ allele, provided that they are moved to other holdings which are restricted following the application of measures in accordance with point 2.2.2.(c) or 2.2.2.(d);

— caprine animals, provided that they are moved to other holdings which are restricted following the application of measures in accordance with point 2.2.2.(c) or 2.2.2.(d);

(b) the following animals may be moved from the holding to go directly for slaughter for human consumption:

— ovine animals carrying at least one ARR allele;

— caprine animals;

— if the Member State so decides, lambs and kids less than three months old on the date of slaughter;

— all animals when the Member State has decided to apply the derogations laid down in point 2.2.2.(b)(i) and point 2.2.2.(c)(i);

(c) if the Member State so decides, lambs and kids may be moved to one other holding located within its territory solely for the purposes of fattening prior to slaughter subject to compliance with the following conditions:

— the holding of destination does not contain any ovine or caprine animals other than those being fattened prior to slaughter;

— at the end of the fattening period, the lambs and kids originating from the holdings subject to the eradication measures shall be transported directly to a slaughterhouse located within the territory of the same Member State to be slaughtered not later than when they are 12 months of age.

3.5. The restrictions set out in points 3.1 to 3.4 shall continue to apply to the holding:

(a) until the date of attainment of ARR/ARR status by all ovine animals on the holding, provided that no caprine animals are kept on the holding; or

(b) for a period of two years from the date when all the measures referred to in point 2.2.1., point 2.2.2.(b) or point 2.2.2.(c) have been completed, provided that no TSE case other than atypical scrapie is detected during this two-year period. If a case of atypical scrapie is confirmed during this two-year period the holding shall also be subject to the measures referred to in point 2.2.3.

4. Following the decision to implement option 3 laid down in point 2.2.2.(d) or the derogation provided for in point 2.2.2.(c)(iii), the following measures shall immediately apply to the holding:

4.1. The holding shall be subjected to an intensified TSE monitoring protocol including the testing for the presence of TSE in accordance with the laboratory methods and protocols set out in Annex X, Chapter C, Part 3, point 3.2, of all of the following animals which are over the age of 18 months, except ovine animals of the ARR/ARR genotype:

(a) animals which have been slaughtered for human consumption;

(b) animals which have died or been killed on the holding but which were not killed in the framework of a disease eradication campaign.

4.2. Only the following ovine animals may be introduced to the holding:

(a) male ovine animals of the ARR/ARR genotype;

(b) female ovine animals carrying at least one ARR allele and no VRQ allele.

However, by way of derogation from points (a) and (b), a Member State may allow the animals referred to in points (c) and (d) to be introduced to the holding where the breed reared in the holding is listed by the Member State as a local breed in danger of being lost to farming in accordance with Annex IV to Commission Regulation (EC) No 1974/2006 (**), and where the frequency of the ARR allele within the breed is low:

(c) male ovine animals carrying at least one ARR allele and no VRQ allele;

(d) female ovine animals carrying no VRQ allele.

4.3. Only the following breeding rams and ovine germinal products may be used in the holding:

(a) male ovine animals of the ARR/ARR genotype;

(b) semen from rams of the ARR/ARR genotype;

(c) embryos carrying at least one ARR allele and no VRQ allele.

However, by way of derogation from points (a), (b) and (c), a Member State may allow the breeding rams and ovine germinal products referred to in points (d), (e) and (f) to be used in the holding where the breed reared in the holding is listed by the Member State as a local breed in danger of being lost to farming in accordance with Annex IV to Commission Regulation (EC) No 1974/2006, and where the frequency of the ARR allele within the breed is low:

(d) male ovine animals carrying at least one ARR allele and no VRQ allele;

(e) semen from male ovine animals carrying at least one ARR allele and no VRQ allele;

(f) embryos carrying no VRQ allele.

4.4. Movement of animals from the holding shall be allowed for the purposes of destruction, or shall be subject to the following conditions:

(a) rams and ewes of the ARR/ARR genotype may be moved from the holding for all purposes, including breeding, provided that they are moved to other holdings which are subject to the application of measures in accordance with point 2.2.2.(c) or 2.2.2.(d);

(b) the following animals may be moved from the holding to go directly for slaughter for human consumption:

— either ovine animals carrying at least one ARR allele and, if the Member State so decides, lambs and kids less than three months old on the date of slaughter;

— or all animals when the Member State has decided to apply the derogation from option 2 laid down in point 2.2.2.(c)(iii) or option 3 laid down in point 2.2.2.(d).

(c) if the Member State so decides, lambs and kids may be moved to one other holding located within its territory solely for the purposes of fattening prior to slaughter subject to compliance with the following conditions:

— the holding of destination shall not contain any ovine or caprine animals other than those being fattened prior to slaughter;

— at the end of the fattening period, the lambs and kids originating from the holdings subject to the eradication measures shall be transported directly to a slaughterhouse located within the territory of the same Member State to be slaughtered not later than when they are 12 months of age.

4.5. Movement of germinal products from the holding shall be subject to the following conditions: the Member State shall ensure that no semen, embryo and ova are dispatched from the holding.

4.6. Common grazing of all ovine and caprine animals in the holding with ovine and caprine animals of other holdings shall be prohibited during the lambing and kidding period.

Outside of the lambing and kidding period, common grazing shall be subject to restrictions to be determined by the Member State, based on a reasoned consideration of all the epidemiological factors.

4.7. The restrictions set out in point 2.2.2.(a) and in points 4.1 to 4.6 shall continue to apply for a period of two years following the detection of the last TSE case, other than atypical scrapie, on the holdings where option 3 laid down in point 2.2.2.(d) has been implemented. If a case of atypical scrapie is confirmed during this two-year period the holding shall also be subject to the measures referred to in point 2.2.3.

In holdings where the derogation from option 2 provided for in point 2.2.2.(c)(iii) has been implemented, the restrictions set out in point 2.2.2.(a) and in points 4.1 to 4.6 shall apply until the complete destruction or slaughtering for human consumption of the animals identified for killing in accordance with point 2.2.2.(c), after which the restrictions laid out in point 3 shall be applicable.

CHAPTER C

Minimum requirements for a breeding programme for resistance to TSEs in ovine animals in accordance with article 6A

PART 1

General requirements

1. The breeding programme shall concentrate on flocks of high genetic merit, as defined in point 3 of Annex I of Commission Decision 2002/1003/EC.

However, Member States where a breeding programme is in place may decide to allow sampling and genotyping of breeding rams only, in flocks not participating in the breeding programme.

2. A database shall be established containing at least the following information:

   (a) the identity, breed and number of animals in all flocks participating in the breeding programme;

   (b) the identification of the individual animals sampled under the breeding programme, including breeding rams sampled in flocks not participating in the breeding programme;

   (c) the results of any genotyping tests.

3. A system of uniform certification shall be established in which the genotype of each animal sampled under the breeding programme, including breeding rams sampled in flocks not participating in the breeding programme, is certified by reference to its individual identification number.

4. A system for the identification of animals and samples, the processing of samples and the delivery of results shall be established which minimises the possibility of human error. The effectiveness of that system shall be subject to regular random checking.

5. Genotyping of blood or other tissues collected for the purposes of the breeding programme, including from breeding rams sampled in flocks not participating in the breeding programme, shall be carried out in laboratories that have been approved under the breeding programme.

6. The competent authority of the Member State may assist breed societies, to establish genetic banks consisting of semen, ova and embryos representative of prion protein genotypes which are likely to become rare as a result of the breeding programme.

7. Breeding programmes shall be drawn up for each breed, taking account of:

   (a) frequencies of the different alleles within the breed;

   (b) rarity of the breed;

   (c) avoidance of inbreeding or genetic drift.

PART 2

Specific rules for participating flocks

1. The breeding programme shall be aimed at increasing the frequency of the ARR allele within the flock, while reducing the prevalence of those alleles which have been shown to contribute to susceptibility to TSEs.

2. The minimum requirements for participating flocks shall be the following:

   (a) all animals in the flock that are to be genotyped shall be individually identified using secure means;

   (b) all rams intended for breeding within the flock shall be genotyped before being used for breeding;

   (c) any male animal carrying the VRQ allele shall be slaughtered or castrated, within six months following the determination of its genotype; any such animal shall not leave the holding except for slaughter;

   (d) female animals that are known to carry the VRQ allele shall not leave the holding except for slaughter;

   (e) male animals, including semen donors used for artificial insemination, other than those certified under the breeding programme, shall not be used for breeding within the flock.

3. Member States may decide to grant derogations from the requirements set out in point 2(c) and (d) for the purposes of the protection of breeds and production traits.

4. Member States shall inform the Commission of any derogation granted under point 3 and of the criteria used.

PART 3

Specific rules for breeding rams sampled in flocks not participating in the breeding programme

1. Rams to be sampled shall be individually identified using secure means.

2. Any ram found to carry the VRQ allele shall not leave the holding except for slaughter.

PART 4

The framework for the recognition of the TSE-resistant status of flocks of ovine animals

1. The framework for the recognition of the TSE-resistant status of flocks of ovine animals shall recognise the TSE-resistant status of flocks of ovine animals that as a result of participation in the breeding programme as provided for in Article 6a, satisfy the criteria required in that programme.

   That recognition shall be granted on at least the following two levels:

   (a) level I flocks shall be flocks composed entirely of ovine animals of the ARR/ARR genotype;

   (b) level II flocks shall be flocks whose progeny have been sired exclusively by rams of the ARR/ARR genotype.

   Member States may decide to grant recognition on further levels to suit national requirements.

2. Regular random sampling of ovine animals from TSE-resistant flocks shall be carried out:

   (a) on the holding or at the slaughterhouse to verify their genotype;

   (b) in the case of level I flocks, in animals over 18 months of age at the slaughterhouse, for TSE testing in accordance with Annex III.

PART 5

Reports to be provided to the Commission by the Member States

Member States introducing national breeding programmes to select for resistance to TSE in their ovine populations shall:

1. notify to the Commission the requirements for such programmes;

2. submit to the Commission an annual report on their progress.

The report for each calendar year shall be submitted at the latest by 31 March of the following year.

(*) OJ L 300, 14.11.2009, p. 1.
(**) OJ L 368, 23.12.2006, p. 15.'

(4) In Annex VIII, Chapter A is replaced by the following:

'CHAPTER A

Conditions for intra-Union trade in live animals, semen and embryos

SECTION A

Conditions which apply to ovine and caprine animals and semen and embryos thereof

1. Holdings with a negligible risk of classical scrapie and a controlled risk of classical scrapie:

   1.1. Member States may establish or supervise an official scheme for the recognition of holdings with a negligible risk of classical scrapie and holdings with a controlled risk of classical scrapie.

   When they do so, they shall maintain a list of holdings of ovine and caprine animals with a negligible risk and holdings with a controlled risk of classical scrapie.

   1.2. A holding of ovine animals having the TSE-resistance level I status, as laid down in Annex VII, Chapter C, Part 4, point 1.(a), and where no case of classical scrapie has been confirmed for at least seven years may be recognised as having a negligible risk of classical scrapie.

   A holding of ovine animals, caprine animals, or ovine and caprine animals may also be recognised as having a negligible risk of classical scrapie provided that it has complied with the following conditions for at least seven years:

(a) ovine and caprine animals are permanently identified and records are maintained, to enable them to be traced back to their holding of birth;

(b) records of movements of ovine and caprine animals in and out of the holding are maintained;

(c) only the following ovine and caprine animals may be introduced:

(i) ovine and caprine animals from holdings with a negligible risk of classical scrapie;

(ii) ovine and caprine animals from holdings which have met the conditions laid down in points (a) to (i) for a minimum of seven years or for at least the same period of time as the holding where they are to be introduced;

(iii) ovine animals of the ARR/ARR prion protein genotype.

(d) the holding is subject to regular checks to verify compliance with the provisions set out in point (a) to (i) by an official veterinarian or a veterinarian authorised for that purpose by the competent authority, to be conducted at least on an annual basis from 1 January 2014;

(e) no case of classical scrapie has been confirmed;

(f) all ovine and caprine animals over 18 months of age slaughtered for human consumption are inspected by an official veterinarian, and all those exhibiting wasting signs, neurological signs or sent for emergency slaughter are tested in a laboratory for classical scrapie in accordance with the laboratory methods and protocols set out in Annex X, Chapter C, Part 3, point 3.2.

Until 31 December 2013, all ovine and caprine animals referred to in Annex III, Chapter A, Part II, point 3 over 18 months of age that have died or have been killed for reasons other than slaughter for human consumption are tested in a laboratory for classical scrapie in accordance with the laboratory methods and protocols set out in Annex X, Chapter C, Part 3, point 3.2.

From 1 January 2014, all ovine and caprine animals over 18 months of age that have died or have been killed for reasons other than slaughter for human consumption shall be tested in a laboratory for classical scrapie in accordance with the laboratory methods and protocols set out in Annex X, Chapter C, Part 3, point 3.2.

By way of derogation from the conditions set out in the second and third paragraphs of point (f), Member States may decide to apply the provisions of the first paragraph of point (f) to the ovine and caprine animals over 18 months of age with no commercial value culled at the end of their productive life instead of being slaughtered for human consumption.

In addition to the conditions set out in points (a) to (f), the following conditions shall be complied with from 1 January 2014:

(g) only the following ovine and caprine embryos/oocytes may be introduced:

(i) embryos/oocytes from donor animals which have been kept since birth in a Member State with a negligible risk of classical scrapie, or in a holding with a negligible or a controlled risk of classical scrapie, or which meet the following requirements:

— they are permanently identified to enable trace back to their holding of birth;

— they have been kept since birth in holdings in which no case of classical scrapie has been confirmed during their residency;

— they showed no clinical sign of classical scrapie at the time of embryo/oocyte collection;

(ii) ovine embryos/oocytes of the ARR/ARR prion protein genotype.

(h) only the following ovine and caprine semen may be introduced:

(i) semen from donor animals which have been kept since birth in a Member State with a negligible risk of classical scrapie, or in a holding with a negligible risk or a controlled risk of classical scrapie, or which meet the following requirements:

— they are permanently identified to enable trace back to their holding of birth;

— they showed no clinical sign of classical scrapie at the time of semen collection;

(ii) ovine semen from a ram of the ARR/ARR prion protein genotype;

(i) ovine and caprine animals on the holding have no direct or indirect contact, including sharing grazing, with ovine and caprine animals from holdings of a lower status.

1.3. A holding of ovine and/or caprine animals may be recognised as having a controlled risk of classical scrapie provided that it has complied with the following conditions for a period of at least three years:

(a) ovine and caprine animals are permanently identified and records are maintained, to enable them to be traced back to their holding of birth;

(b) records of movements of ovine and caprine animals in and out of the holding are maintained;

(c) only the following ovine and caprine animals may be introduced:

(i) ovine and caprine animals from holdings with a negligible or a controlled risk of classical scrapie;

(ii) ovine and caprine animals from holdings which have met the conditions laid down in points (a) to (i) for a minimum of three years or for at least the same period of time as the holding where they are to be introduced;

(iii) ovine animals of the ARR/ARR prion protein genotype.

(d) the holding is subject to regular checks to verify compliance with the provisions set out in point (a) to (i) by an official veterinarian or a veterinarian authorised for that purpose by the competent authority, to be conducted at least on an annual basis from 1 January 2014;

(e) no case of classical scrapie has been confirmed;

(f) all ovine and caprine animals over 18 months of age slaughtered for human consumption are inspected by an official veterinarian, and all those exhibiting wasting signs, neurological signs or sent for emergency slaughter are tested in a laboratory for classical scrapie in accordance with the laboratory methods and protocols set out in Annex X, Chapter C, Part 3, point 3.2.

Until 31 December 2013, all ovine and caprine animals referred to in Annex III, Chapter A, Part II, point 3 over 18 months of age that have died or have been killed for reasons other than slaughter for human consumption are tested in a laboratory for classical scrapie in accordance with the laboratory methods and protocols set out in Annex X, Chapter C, Part 3, point 3.2.

From 1 January 2014, all ovine and caprine animals over 18 months of age that have died or have been killed for reasons other than slaughter for human consumption shall be tested in a laboratory for classical scrapie in accordance with the laboratory methods and protocols set out in Annex X, Chapter C, Part 3, point 3.2.

By way of derogation from the conditions set out in the second and third paragraphs of point (f), Member States may decide to apply the provisions of the first paragraph of point (f) to the ovine and caprine animals over 18 months of age with no commercial value culled at the end of their productive life instead of being slaughtered for human consumption.

In addition to the conditions set out in points (a) to (f), the following conditions shall be complied with from 1 January 2014:

(g) only the following ovine and caprine embryos/oocytes may be introduced:

(i) embryos/oocytes from donor animals which have been kept since birth in a Member State with a negligible risk of classical scrapie, or in a holding with a negligible risk or with a controlled risk of classical scrapie, or which meet the following requirements:

— they are permanently identified to enable trace back to their holding of birth;

— they have been kept since birth in holdings in which no case of classical scrapie has been confirmed during their residency;

— they showed no clinical sign of classical scrapie at the time of embryo/oocyte collection;

(ii) ovine embryos/oocytes of the ARR/ARR prion protein genotype.

(h) only the following ovine and caprine semen may be introduced:

(i) semen from donor animals which have been kept since birth in a Member State with a negligible risk of classical scrapie, or in a holding with a negligible risk or with a controlled risk of classical scrapie, or which meet the following requirements:

— they are permanently identified to enable trace back to their holding of birth;

— they showed no clinical sign of classical scrapie at the time of semen collection;

(ii) ovine semen from a ram of the ARR/ARR prion protein genotype;

(i) ovine and caprine animals of the holding have no direct or indirect contact, including sharing grazing, with ovine and caprine animals from holdings of lower status.

1.4. If a case of classical scrapie is confirmed in a holding with a negligible risk or a controlled risk of classical scrapie, or in a holding found to have an epidemiological link to a holding with a negligible risk or a controlled risk of classical scrapie as a result of an inquiry referred to in Part 1 of Chapter B of Annex VII, the holding with a negligible risk or a controlled risk of classical scrapie shall be immediately deleted from the list referred to in point 1.1.

The Member State shall immediately inform the other Member States which have imported ovine and caprine animals originating from, or semen or embryos collected from ovine and caprine animals kept in that holding during the last seven years in the case of a holding with a negligible risk or during the last three years in the case of a holding with a controlled risk.

2. Member States or zones of a Member State with a negligible risk of classical scrapie

2.1. Where a Member State considers that its territory or part of its territory poses a negligible risk of classical scrapie, it shall submit to the Commission appropriate supporting documentation, setting out in particular that:

(a) a risk assessment has been conducted, and it has demonstrated that appropriate measures are currently in place and have been taken for the relevant period of time to manage any risk identified. This risk assessment shall identify all potential factors for classical scrapie occurrence and their historic perspective, in particular the:

(i) importation or introduction of ovine and caprine animals or their semen and embryos potentially infected with classical scrapie;

(ii) extent of knowledge of the population structure and husbandry practices of ovine and caprine animals;

(iii) feeding practices, including consumption of meat-and-bone meal or greaves derived from ruminants;

(iv) importation of milk and milk products of ovine and caprine animals origin intended for use in feeding of ovine and caprine animals;

(b) for a period of at least seven years, ovine and caprine animals displaying clinical signs compatible with classical scrapie have been tested;

(c) for a period of at least seven years, a sufficient number of ovine and caprine animals over 18 months of age, representative of slaughtered, culled or found dead on farm, have been tested annually, to provide a 95 percent level of confidence of detecting classical scrapie if it is present in that population at a prevalence rate exceeding 0,1 percent and no case of classical scrapie has been reported during that period;

(d) the feeding to ovine and caprine animals of meat-and-bone meal or greaves of ruminant origin has been banned and effectively enforced in the whole Member State for a period of at least seven years;

(e) introductions from other Member States of ovine and caprine animals and semen and embryos thereof are carried out in accordance with point 4.1.(b) or point 4.2.;

(f) introductions from third countries of ovine and caprine animals and semen and embryos thereof are carried out in accordance with Chapter E or Chapter H of Annex IX.

2.2. The negligible risk status for classical scrapie of the Member State or of the zone of the Member State may be approved in accordance with the procedure referred to in Article 24(2).

The Member State is to notify the Commission of any change in the information submitted according to point 2.1. relating to the disease.

The negligible risk status approved in accordance with point 2.2. may, in the light of such notification, be withdrawn in accordance with the procedure referred to in Article 24(2).

3. National control programme for classical scrapie:

3.1. a Member State which has a national control programme for classical scrapie covering all of its territory:

(a) may submit its national control programme to the Commission, outlining in particular:

— the distribution of classical scrapie in the Member State,

— the reasons for national control programme, taking into consideration the importance of the disease and the cost/benefit ratio,

— the status categories defined for holdings and the standards which must be attained in each such category,

— the test procedures to be used,

— the national control programme monitoring procedures,

— the action to be taken if, for any reason, a holding loses its status,

— the measures to be taken if the results of checks carried out in accordance with the national control programme programme are positive,

(b) the programme referred to in point (a) may be approved if it complies with the criteria laid down in that point, in accordance with the procedure referred to in Article 24(2); amendments or additions to the programmes submitted by Member States may be approved in accordance with the procedure referred to in Article 24(2).

3.2. The national scrapie control programmes of following Member States are hereby approved:

— Denmark

— Austria

— Finland

— Sweden.

4. Intra-Union trade in ovine and caprine animals and semen and embryos thereof

The following conditions shall apply:

4.1. ovine and caprine animals:

(a) ovine and caprine animals for breeding intended for Member States other than those with a negligible risk of classical scrapie or with an approved national scrapie control programme shall:

(i) come from a holding or holdings with a negligible risk or a controlled risk of classical scrapie; however ovine and caprine animals for breeding coming from a holding or holdings which have complied with all the requirements laid down in point 1.3. (a) to (f), for a period of at least three years may be subject to intra-Union trade until 31 December 2014; or

(ii) come from a Member State or zone of a Member State with a negligible risk of classical scrapie; or

(iii) in the case of ovine animals, be of the ARR/ARR prion protein genotype, provided they do not come from a holding subject to the restrictions laid down in Annex VII, Chapter B, points 3 and 4.

(b) ovine and caprine animals for all intended use except immediate slaughter intended for the Member States with a negligible risk of classical scrapie or with an approved national scrapie control programme shall:

(i) come from a holding or holdings with a negligible risk of classical scrapie; however ovine and caprine animals coming from a holding or holdings which have complied with all the requirements laid down in point 1.2. (a) to (i), for a period of at least seven years may be subject to intra-Union trade until 31 December 2014; or

(ii) come from a Member State or zone of a Member State with a negligible risk of classical scrapie; or

(iii) in the case of ovine animals, be of the ARR/ARR prion protein genotype, provided they do not come from a holding subject to the restrictions laid down in Annex VII, Chapter B, points 3 and 4.

4.2. semen and embryos of ovine and caprine animals shall:

(a) be collected from animals which have been kept continuously since birth on a holding or holdings with a negligible risk or a controlled risk of classical scrapie; or

(b) be collected from animals which have been kept continuously for the last three years before the collection on a holding or holdings which have complied with all the requirements laid down in Part 1, point 1.3. (a) to (f) for three years; or

(c) be collected from animals which have been kept continuously since birth in a country or zone with a negligible risk of classical scrapie; or

(d) in the case of ovine semen, be collected from male animals of the ARR/ARR prion protein genotype; or

(e) in the case of ovine embryos, be of the ARR/ARR prion protein genotype.

SECTION B

Conditions which apply to bovine animals

The United Kingdom shall ensure that bovine animals born or reared on its territory before 1 August 1996 are not dispatched from its territory to other Member States or third countries.'

(5) Annex IX is amended as follows:

(a) In Chapter C, Section A is replaced by the following:

'*SECTION A*

Products

The following products of bovine, ovine and caprine origin, as defined by points 1.10, 1.13, 1.15, 7.1, 7.5, 7.6, 7.7, 7.8 and 7.9 of Annex I to Regulation (EC) No 853/2004 of the European Parliament and of the Council, shall be subject to the conditions laid down in Sections B, C or D of this Chapter depending on the BSE risk category of the country of origin:

— fresh meat,

— minced meat,

— meat preparations,

— meat products,

— rendered animal fat,

— greaves,

— gelatine and collagen other than derived from hides and skins,

— treated intestines.'

(b) Chapters D and E are replaced by the following:

'CHAPTER D

Imports of animal by-products and derived products from bovine, ovine and caprine origin

SECTION A

Animal by-products

This Chapter shall apply to the following animal by-products and derived products, as defined in points (1) and (2) of Article 3 of Regulation (EC) No 1069/2009 of the European Parliament and of the Council, provided that those products are of bovine, ovine and caprine animal origin:

(a) Rendered fats derived from Category 2 material, which are intended to be used as organic fertilisers or soil improvers, as defined in point 22 of Article 3 of Regulation (EC) No 1069/2009, or their starting materials or intermediate products;

(b) Bones and bone products derived from Category 2 material;

(c) Rendered fats derived from Category 3 material which are intended to be used as organic fertilisers or soil improvers or as feed, as defined in points 22 and 25 of Article 3 of Regulation (EC) No 1069/2009, or their starting materials or intermediate products;

(d) Pet food including dog chews;

(e) Blood products;

(f) Processed animal protein;

(g) Bones and bone products derived from Category 3 material;

(h) Gelatine and collagen derived from materials other than hides and skins;

(i) Category 3 material and derived products other than those referred to in points (c) to (h) excluding:

(i) fresh hides and skins, treated hides and skins;

(ii) gelatine and collagen derived from hides and skins;

(iii) fat derivatives.

SECTION B

Health certificate requirements

Imports of the animal by-products and derived products of bovine, ovine and caprine origin referred to in Section A shall be subject to the presentation of a health certificate which has been completed with the following attestation:

(a) the animal by-product or derived product does not contain and is not derived from specified risk material or mechanically separated meat obtained from bones of bovine, ovine or caprine animals and, except for animals born, continuously reared and slaughtered in a country or region classified as posing a negligible BSE risk by a decision in accordance with Article 5(2), the animals from which this animal by-product or derived product is derived, have not been slaughtered after stunning by means of gas injected into the cranial cavity or killed by the same method or slaughtered by laceration of central nervous tissue by means of an elongated rod-shaped instrument introduced into the cranial cavity; or

(b) the animal by-product or derived product does not contain and is not derived from bovine, ovine and caprine materials other than those derived from animals born, continuously reared and slaughtered in a country or region classified as posing a negligible BSE risk by a decision in accordance with Article 5(2).

In addition to points (a) and (b), imports of the animal by-products and derived products referred to in Section A, containing milk or milk products of ovine or caprine animal origin and intended for feed, shall be subject to the presentation of a health certificate which has been completed with the following attestation:

(c) the ovine and caprine animals from which those products are derived have been kept continuously since birth in a country where the following conditions are fulfilled:

(i) classical scrapie is compulsorily notifiable;

(ii) an awareness, surveillance and monitoring system is in place;

(iii) official restrictions apply to holdings of ovine or caprine animals in case of a suspicion of TSE or a confirmation of classical scrapie;

(iv) ovine and caprine animals affected with classical scrapie are killed and completely destroyed;

(v) the feeding to ovine and caprine animals of meat-and-bone meal or greaves of ruminant origin has been banned and effectively enforced in the whole country for a period at least seven years;

(d) the milk and milk products of ovine or caprine animals derive from holdings where no official restriction is imposed due to a suspicion of TSE;

(e) the milk and milk products of ovine or caprine animals derive from holdings where no case of classical scrapie has been diagnosed for the last seven years or, following the confirmation of a case of classical scrapie:

(i) all ovine and caprine animals on the holding have been killed and destroyed or slaughtered, except for breeding rams of the ARR/ARR genotype, breeding ewes carrying at least one ARR allele and no VRQ allele and other ovine animals carrying at least one ARR allele; or

(ii) all animals in which classical scrapie was confirmed have been killed and destroyed, and the holding has been subjected for two years at least since the confirmation of the last classical scrapie case to intensified TSE monitoring, including testing with negative results for the presence of TSE in accordance with the laboratory methods set out in Annex X, Chapter C, point 3.2, of all of the following animals which are over the age of 18 months, except ovine animals of the ARR/ARR genotype:

— animals which have been slaughtered for human consumption; and

— animals which have died or been killed on the holding but which were not killed in the framework of a disease eradication campaign.

CHAPTER E

Imports of ovine and caprine animals

Ovine and caprine animals imported into the Union are to be subject to the presentation of an animal health certificate attesting that they have been kept continuously since birth in a country where the following conditions are fulfilled:

1. classical scrapie is compulsorily notifiable;

2. an awareness, surveillance and monitoring system is in place;

3. ovine and caprine animals affected with classical scrapie are killed and completely destroyed;

4. the feeding to ovine and caprine animals of meat-and-bone meal or greaves of ruminant origin has been banned and effectively enforced in the whole country for a period of at least seven years;

In addition to the conditions set out in points 1 to 4, the animal health certificate shall attest that:

5. For ovine and caprine animals for breeding imported into the Union and intended for Member States other than those with a negligible risk of classical scrapie or those with an approved national scrapie control programme listed in point 3.2 of Section A of Chapter A of Annex VIII, the following conditions shall be complied with:

— the imported ovine and caprine animals come from a holding or holdings that have complied with the conditions of point 1.3 of Section A of Chapter A of Annex VIII; or

— they are ovine animals of the ARR/ARR prion protein genotype and they come from a holding where no official movement restriction has been imposed due to BSE or classical scrapie during the last two years.

6. For ovine and caprine animals for all uses except immediate slaughter imported into the Union and intended for a Member State with a negligible risk of classical scrapie or with an approved national scrapie control programme listed in point 3.2 of Section A of Chapter A of Annex VIII, the following conditions shall be complied with:

— they come from a holding or holdings that have complied with the conditions of point 1.2 of Section A of Chapter A of Annex VIII; or

— they are ovine animals of the ARR/ARR prion protein genotype and they come from a holding where no official movement restriction has been imposed due to BSE or classical scrapie during the last two years.'

(c) Chapter H is replaced by the following:

'CHAPTER H

Import of ovine and caprine semen and embryos

Ovine and caprine semen and embryos imported into the Union are to be subject to the presentation of an animal health certificate attesting that the donor animals:

1. have been kept continuously since birth in a country where the following conditions are fulfilled:

(i) classical scrapie is compulsorily notifiable;

(ii) an awareness, surveillance and monitoring system is in place;

(iii) ovine and caprine animals affected with classical scrapie are killed and completely destroyed;

(iv) the feeding to ovine and caprine animals of meat-and-bone meal, or greaves of ruminant origin has been banned and effectively enforced in the whole country for a period of at least seven years;

2. have been kept continuously for the last three years before the collection of the exported semen or embryos in a holding or holdings which have been satisfying for the last three years at least all the requirements laid down in point 1.3. (a) to (f) of Section A of Chapter A of Annex VIII, or:

(i) in the case of ovine semen, the semen has been collected from male animals of the ARR/ARR prion protein genotype.

(ii) in the case of ovine embryos, the embryos are of the ARR/ARR prion protein genotype.'

(6) Annex X is amended as follows

(a) In Chapter C, in Part 3, in point 3.1, the following point 3.1(c) is added:

'(c) Further examination of positive BSE cases

Samples from all positive BSE cases shall be forwarded to a laboratory, appointed by the competent authority, which has participated successfully in proficiency testing organised by the European Union reference laboratory for discriminatory testing of confirmed BSE cases, where they shall be further tested in accordance with the methods and protocols laid down in the European Union reference laboratory's method for the classification of bovine TSE isolates (*).

(*) http://vla.defra.gov.uk/science/docs/sci_tse_rl_2blot.pdf'

(b) Part 4 of Chapter C of Annex X is replaced by the following:

'4. Rapid tests

For the purposes of carrying out the rapid tests in accordance with Articles 5(3) and 6(1), only the following methods shall be used as rapid tests for the monitoring of BSE in bovine animals:

— the immuno-blotting test based on a Western blotting procedure for the detection of the Proteinase K-resistant fragment PrPRes (Prionics-Check Western test),

— the microplate-based immunoassay for the detection of PrPSc (Enfer TSE Version 3),

— the sandwich immunoassay for PrPRes detection (short assay protocol) carried out following denaturation and concentration steps (Bio-Rad TeSeE SAP rapid test),

— the microplate-based immunoassay (ELISA) which detects Proteinase K-resistant PrPRes with monoclonal antibodies (Prionics-Check LIA test),

— the immunoassay using a chemical polymer for selective PrP Sc capture and a monoclonal detection antibody directed against conserved regions of the PrP molecule (IDEXX HerdChek BSE Antigen Test Kit, EIA & IDEXX HerdChek BSE-Scrapie Antigen Test Kit, EIA),

— the lateral-flow immunoassay using two different monoclonal antibodies to detect Proteinase K-resistant PrP fractions (Prionics Check PrioSTRIP),

— the two-sided immunoassay using two different monoclonal antibodies directed against two epitopes presented in a highly unfolded state of bovine PrP Sc (Roboscreen Beta Prion BSE EIA Test Kit),

For the purposes of carrying out the rapid tests in accordance with Articles 5(3) and 6(1), only the following methods shall be used as rapid tests for the monitoring of TSE in ovine and caprine animals:

— the sandwich immunoassay for PrPRes detection (short assay protocol) carried out following denaturation and concentration steps (Bio-Rad TeSeE SAP rapid test),

— the sandwich immunoassay for PrPRes detection with the TeSeE Sheep/Goat Detection kit carried out following denaturation and concentration steps with the TeSeE Sheep/Goat Purification kit (Bio-Rad TeSeE Sheep/Goat rapid test),

— the immunoassay using a chemical polymer for selective PrP Sc capture and a monoclonal detection antibody directed against conserved regions of the PrP molecule (IDEXX HerdChek BSE-Scrapie Antigen Test Kit, EIA),

— the lateral-flow immunoassay using two different monoclonal antibodies to detect Proteinase K-resistant PrP fractions (rapid test Prionics — Check PrioSTRIP SR, visual reading protocol).

In all rapid tests, sample tissue on which the test must be applied must comply with the manufacturer's instructions for use.

Producers of rapid tests must have a quality assurance system in place that has been approved by the European Union Reference Laboratory and ensures that the test performance does not change. Producers must provide the European Union Reference Laboratory with the test protocols.

Changes to rapid tests and to test protocols may only be made after prior notification to the European Union Reference Laboratory and provided that the European Union Reference Laboratory finds that the change does not alter the sensitivity, specificity or reliability of the rapid test. That finding shall be communicated to the Commission and to the national reference laboratories.'

COMMISSION IMPLEMENTING REGULATION (EU) No 631/2013

of 28 June 2013

repealing Regulation (EC) No 546/2006 and Implementing Regulation (EU) No 233/2012

(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 999/2001 of the European Parliament and of the Council of 22 May 2001 laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies [1], and in particular point (b)(iii) of Section I of Chapter A of Annex VIII thereto,

Whereas:

(1) Regulation (EC) No 999/2001 lays down rules for the prevention, control and eradication of transmissible spongiform encephalopathies ('TSEs') in animals. Annex VIII thereto provides for the approval and subsequent amendment of the national scrapie control programmes of the Member States if they comply with certain criteria laid down in that Regulation.

(2) Commission Regulation (EC) No 546/2006 of 31 March 2006 implementing Regulation (EC) No 999/2001 of the European Parliament and of the Council as regards national scrapie control programmes and additional guarantees and derogating from certain requirements of Decision 2003/100/EC and repealing Regulation (EC) No 1874/2003 [2] approves the national scrapie control programmes of certain Member States. It also lays down the additional guarantees from which those Member States can benefit regarding the movements of ovine and caprine animals, as well as of their semen and embryos.

(3) Commission Implementing Regulation (EU) No 233/2012 of 16 March 2012 implementing Regulation (EC) No 999/2001 of the European Parliament and of the Council as regards the approval of the amended national scrapie control programme for Denmark [3] approves the amended national scrapie control programme for Denmark.

(4) For reasons of clarity and simplification of Union legislation, Annex VIII to Regulation (EC) No 999/2001, as amended by Commission Regulation (EU) No 630/2013 of 28 June 2013 amending the Annexes to Regulation (EC) No 999/2001 of the European Parliament and of the Council laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies [4], sets out the list of the Member States with an approved national control programme for classical scrapie and the corresponding additional guarantees from which those Member States benefit regarding the movements of ovine and caprine animals, as well as of their semen and embryos.

(5) The amendments to Regulation (EC) No 999/2001 set out in Regulation (EU) No 630/2013 apply from 1 July 2013. The provisions of Regulation (EC) No 546/2006 and Implementing Regulation (EU) No 233/2012 become therefore redundant on that date. In the interest of legal clarity and certainty, those Regulations should therefore be repealed on the same date.

(6) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS REGULATION:

Article 1

Regulation (EC) No 546/2006 and Implementing Regulation (EU) No 233/2012 are repealed with effect from 1 July 2013.

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, 28 June 2013.

For the Commission
The President
José Manuel BARROSO

[1] OJ L 147, 31.5.2001, p. 1.
[2] OJ L 94, 1.4.2006, p. 28.
[3] OJ L 78, 17.3.2012, p. 13.
[4] See page 60 of this Official Journal.

COMMISSION IMPLEMENTING REGULATION (EU) No 632/2013

of 28 June 2013

amending for the 194th time Council Regulation (EC) No 881/2002 imposing certain specific restrictive measures directed against certain persons and entities associated with the Al Qaida network

THE EUROPEAN COMMISSION,

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

Having regard to Council Regulation (EC) No 881/2002 of 27 May 2002 imposing certain specific restrictive measures directed against certain persons and entities associated with the Al-Qaida network, [1] and in particular Article 7(1)(a) and 7a(5) thereof,

Whereas:

(1) Annex I to Regulation (EC) No 881/2002 lists the persons, groups and entities covered by the freezing of funds and economic resources under that Regulation.

(2) On 30 May 2013 the Sanctions Committee of the United Nations Security Council (UNSC) decided to amend one entry on the list of persons, groups and entities to whom the freezing of funds and economic resources should apply.

(3) Annex I to Regulation (EC) No 881/2002 should therefore be updated accordingly,

HAS ADOPTED THIS REGULATION:

Article 1

Annex I to Regulation (EC) No 881/2002 is amended in accordance with the Annex to this Regulation.

Article 2

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

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

Done at Brussels, 28 June 2013.

For the Commission,
On behalf of the President,
Head of the Service for Foreign Policy Instruments

[1] OJ L 139, 29.5.2002, p. 9.

ANNEX

Annex I to Regulation (EC) No 881/2002 is amended as follows:

The entry 'Al-Qaida in Iraq (*alias* (a) AQI, (b) al-Tawhid, (c) the Monotheism and Jihad Group, (d) Qaida of the Jihad in the Land of the Two Rivers, (e) Al-Qaida of Jihad in the Land of the Two Rivers, (f) The Organization of Jihad's Base in the Country of the Two Rivers, (g) The Organization Base of Jihad/Country of the Two Rivers, (h) The Organization Base of Jihad/Mesopotamia, (i) Tanzim Qa'idat Al-Jihad fi Bilad al-Rafidayn, (j) Tanzeem Qa'idat al Jihad/Bilad al Raafidaini, (k) Jama'at Al-Tawhid Wa'al-Jihad, (l) JTJ, (m) Islamic State of Iraq, (n) ISI, (o) al-Zarqawi network). Date of designation referred to in Article 2a (4) (b): 18.10.2004.' under the heading 'Legal persons, groups and entities' shall be replaced by the following:

'Al-Qaida in Iraq (*alias* (a) AQI, (b) al-Tawhid, (c) the Monotheism and Jihad Group, (d) Qaida of the Jihad in the Land of the Two Rivers, (e) Al-Qaida of Jihad in the Land of the Two Rivers, (f) The Organization of Jihad's Base in the Country of the Two Rivers, (g) The Organization Base of Jihad/Country of the Two Rivers, (h) The Organization Base of Jihad/Mesopotamia, (i) Tanzim Qa'idat Al-Jihad fi Bilad al-Rafidayn, (j) Tanzeem Qa'idat al Jihad/Bilad al Raafidaini, (k) Jama'at Al-Tawhid Wa'al-Jihad, (l) JTJ, (m) Islamic State of Iraq, (n) ISI, (o) al-Zarqawi network, (p) Jabhat al Nusrah, (q) Jabhet al-Nusra, (r) Al-Nusrah Front, (s) The Victory Front, (t) Al-Nusrah Front for the People of the Levant, (u) Islamic State in Iraq and the Levant). Date of designation referred to in Article 2a (4) (b): 18.10.2004.'

COMMISSION IMPLEMENTING REGULATION (EU) No 633/2013

of 28 June 2013

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, 28 June 2013.

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

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

ANNEX

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

(EUR/100 kg)

CN code	Third country code (1)	Standard import value
0702 00 00	AL	55,3
	MK	46,1
	ZZ	50,7
0707 00 05	MK	25,2
	TR	113,2
	ZZ	69,2
0709 93 10	TR	130,5
	ZZ	130,5
0805 50 10	AR	85,5
	TR	99,2
	ZA	107,4
	ZZ	97,4
0808 10 80	AR	157,4
	BR	111,9
	CL	114,0
	CN	115,2
	NZ	142,9
	TR	99,8
	ZA	120,5
	ZZ	123,1
0809 10 00	IL	275,4
	TR	211,6
	ZZ	243,5
0809 29 00	TR	347,1
	US	605,0
	ZZ	476,1
0809 30	TR	246,3
	ZZ	246,3
0809 40 05	CL	216,9
	IL	308,9
	ZA	377,9
	ZZ	301,2

(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'.

COMMISSION IMPLEMENTING REGULATION (EU) No 634/2013

of 28 June 2013

fixing the import duties in the cereals sector applicable from 1 July 2013

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 Regulation (EU) No 642/2010 of 20 July 2010 laying down detailed rules for the application of Council Regulation (EC) No 1234/2007 in respect of import duties in the cereals sector [2], and in particular Article 2(1) thereof,

Whereas:

(1) Article 136(1) of Regulation (EC) No 1234/2007 states that the import duty on products covered by CN codes 1001 19 00, 1001 11 00, ex 1001 91 20 (common wheat seed), ex 1001 99 00 (high quality common wheat other than for sowing), 1002 10 00, 1002 90 00, 1005 10 90, 1005 90 00, 1007 10 90 and 1007 90 00 is to be equal to the intervention price valid for such products on importation and increased by 55 %, minus the cif import price applicable to the consignment in question. However, that duty may not exceed the rate of duty in the Common Customs Tariff.

(2) Article 136(2) of Regulation (EC) No 1234/2007 lays down that, in order to calculate the import duty referred to in paragraph 1 of that Article, representative cif import prices are to be established on a regular basis for the products in question.

(3) Under Article 2(2) of Regulation (EU) No 642/2010, the price to be used for the calculation of the import duty on products covered by CN codes 1001 19 00, 1001 11 00, ex 1001 91 20 (common wheat seed), ex 1001 99 00 (high quality common wheat other than for sowing), 1002 10 00, 1002 90 00, 1005 10 90, 1005 90 00, 1007 10 90 and 1007 90 00 is the daily cif representative import price determined as specified in Article 5 of that Regulation.

(4) Import duties should be fixed for the period from 1 July 2013 and should apply until new import duties are fixed and enter into force.

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

HAS ADOPTED THIS REGULATION:

Article 1

From 1 July 2013, the import duties in the cereals sector referred to in Article 136(1) of Regulation (EC) No 1234/2007 shall be those fixed in Annex I to this Regulation on the basis of the information contained in Annex II.

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, 28 June 2013.

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

[1] OJ L 299, 16.11.2007, p. 1.
[2] OJ L 187, 21.7.2010, p. 5.

ANNEX I

Import duties on the products referred to in Article 136(1) of Regulation (EC) No 1234/2007 applicable from 1 July 2013

CN code	Description	Import duties [1] (EUR/t)
1001 19 00 1001 11 00	Durum wheat, high quality	0,00
	medium quality	0,00
	low quality	0,00
ex 1001 91 20	Common wheat seed	0,00
ex 1001 99 00	High quality common wheat other than for sowing	0,00
1002 10 00 1002 90 00	Rye	0,00
1005 10 90	Maize seed other than hybrid	0,00
1005 90 00	Maize other than seed [2]	0,00
1007 10 90 1007 90 00	Grain sorghum other than hybrids for sowing	0,00

[1] The importer may benefit, under Article 2(4) of Regulation (EU) No 642/2010, from a reduction in the duty of:

— EUR 3/t, where the port of unloading is located on the Mediterranean Sea (beyond the Strait of Gibraltar) or on the Black Sea, for goods arriving in the Union via the Atlantic Ocean or the Suez Canal,

— EUR 2/t, where the port of unloading is located in Denmark, Estonia, Ireland, Latvia, Lithuania, Poland, Finland, Sweden, the United Kingdom or on the Atlantic coast of the Iberian Peninsula, for goods arriving in the Union via the Atlantic Ocean.

[2] The importer may benefit from a flat-rate reduction of EUR 24/t where the conditions laid down in Article 3 of Regulation (EU) No 642/2010 are met.

ANNEX II

Factors for calculating the duties laid down in Annex I

14.6.2013-27.6.2013

1. Averages over the reference period referred to in Article 2(2) of Regulation (EU) No 642/2010:

(EUR/t)

	Common wheat (1)	Maize	Durum wheat, high quality	Durum wheat, medium quality (2)	Durum wheat, low quality (3)
Exchange	Minnéapolis	Chicago	—	—	—
Quotation	238,02	198,43	—	—	—
Fob price USA	—	—	257,40	247,40	227,40
Gulf of Mexico premium	—	28,95	—	—	—
Great Lakes premium	32,94	—	—	—	—

(1) Premium of EUR 14/t incorporated (Article 5(3) of Regulation (EU) No 642/2010).
(2) Discount of EUR 10/t (Article 5(3) of Regulation (EU) No 642/2010).
(3) Discount of EUR 30/t (Article 5(3) of Regulation (EU) No 642/2010).

2. Averages over the reference period referred to in Article 2(2) of Regulation (EU) No 642/2010:

Freight costs: Gulf of Mexico-Rotterdam:	16,34 EUR/t
Freight costs: Great Lakes-Rotterdam:	49,61 EUR/t

DECISIONS

COUNCIL DECISION

of 25 June 2013

increasing the number of Advocates-General of the Court of Justice of the European Union

(2013/336/EU)

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular the first paragraph of Article 252 thereof,

Having regard to the Treaty establishing the European Atomic Energy Community, and in particular Article 106a(1) thereof,

Having regard to the request of the President of the Court of Justice of 16 January 2013,

Whereas:

(1) The first paragraph of Article 252 of the Treaty on the Functioning of the European Union establishes that the Council, acting unanimously, may increase the number of Advocates-General on the request of the Court of Justice.

(2) On 16 January 2013, the Court of Justice requested that the number of Advocates-General of the Court of Justice be increased by three. That request was motivated by the desire to allow the Court to continue to have an Opinion delivered in every case in which it is required without thereby increasing the overall time taken to deal with the cases concerned.

(3) According to Declaration No 38 on Article 252 of the Treaty on the Functioning of the European Union regarding the number of Advocates-General of the Court of Justice, annexed to the Final Act of the Intergovernmental Conference which adopted the Treaty of Lisbon, if the Court of Justice requests that the number of Advocates-General be increased by three (eleven instead of eight), the Council will, acting unanimously, agree on such an increase.

(4) In order best to satisfy the concerns expressed in the second recital and to ensure the optimal integration of the additional Advocates-General, the Court of Justice proposed that one Advocate-General take up his duties on 1 July 2013, the planned date of Croatia's accession, provided that all of the instruments of ratification have been lodged before this date, and that the two other Advocates-General take up their duties on 7 October 2015, on the occasion of the partial replacement of the Members of the Court,

HAS ADOPTED THIS DECISION:

Article 1

The number of Advocates-General of the Court of Justice of the European Union shall be increased to:

— nine, with effect from 1 July 2013;

— eleven, with effect from 7 October 2015.

Article 2

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

Done at Luxembourg, 25 June 2013.

For the Council
The President
E. GILMORE

DECISION OF THE REPRESENTATIVES OF THE GOVERNMENTS OF THE MEMBER STATES

of 26 June 2013

appointing Judges to the General Court

(2013/337/EU)

THE REPRESENTATIVES OF THE GOVERNMENTS OF THE MEMBER STATES OF THE EUROPEAN UNION,

Having regard to the Treaty on European Union, and in particular Article 19 thereof,

Having regard to the Treaty on the Functioning of the European Union, and in particular Articles 254 and 255 thereof,

Having regard to the Treaty establishing the European Atomic Energy Community, and in particular Article 106a(1) thereof,

Whereas:

(1) The terms of office of 13 Judges of the General Court are due to expire on 31 August 2013. New appointments should therefore be made for the period from 1 September 2013 to 31 August 2019.

(2) It has been proposed that the terms of office of Mr Guido BERARDIS, Mr Eugène BUTTIGIEG and Mr Carl WETTER as Judges of the General Court should be renewed.

(3) Mr Anthony COLLINS, Mr Stéphane GERVASONI and Mr Ignacio ULLOA RUBIO have been proposed as candidates for the vacant posts of Judges of the General Court.

(4) The panel set up by Article 255 of the Treaty on the Functioning of the European Union has given an opinion on the suitability of Mr Guido BERARDIS, Mr Eugène BUTTIGIEG, Mr Anthony COLLINS, Mr Stéphane GERVASONI, Mr Ignacio ULLOA RUBIO and Mr Carl WETTER to perform the duties of Judge of the General Court,

HAVE ADOPTED THIS DECISION:

Article 1

The following are hereby appointed Judges to the General Court for the period from 1 September 2013 to 31 August 2019:

— Mr Guido BERARDIS

— Mr Eugène BUTTIGIEG

— Mr Anthony COLLINS

— Mr Stéphane GERVASONI

— Mr Ignacio ULLOA RUBIO

— Mr Carl WETTER.

Article 2

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

Done at Brussels, 26 June 2013.

The President

R. MONTGOMERY

DECISION OF THE REPRESENTATIVES OF THE GOVERNMENTS OF THE MEMBER STATES

of 26 June 2013

appointing Judges to the Court of Justice

(2013/338/EU)

THE REPRESENTATIVES OF THE GOVERNMENTS OF THE MEMBER STATES OF THE EUROPEAN UNION,

Having regard to the Treaty on European Union, and in particular Article 19 thereof,

Having regard to the Treaty on the Functioning of the European Union, and in particular Articles 253 and 255 thereof,

Having regard to the Treaty establishing the European Atomic Energy Community, and in particular Article 106a(1) thereof,

Whereas:

(1) Under Articles 5 and 7 of the Protocol on the Statute of the Court of Justice of the European Union, and following the resignations of Mr Uno LÕHMUS and Mr Jean-Jacques KASEL as of 6 October 2013, two judges should be appointed to the Court of Justice for the remainder of the terms of office of Mr LÕHMUS and Mr KASEL, which run until 6 October 2015.

(2) Ms Küllike JÜRIMÄE and Mr François BILTGEN have been proposed as candidates for the vacant posts.

(3) The panel set up by Article 255 of the Treaty on the Functioning of the European Union has given an opinion on the suitability of Ms Küllike JÜRIMÄE and Mr François BILTGEN to perform the duties of Judges of the Court of Justice,

HAVE ADOPTED THIS DECISION:

Article 1

The following are hereby appointed Judges to the Court of Justice for the period from 6 October 2013 to 6 October 2015:

— Ms Küllike JÜRIMÄE

— Mr François BILTGEN.

Article 2

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

Done at Brussels, 26 June 2013.

The President

R. MONTGOMERY

DECISION OF THE REPRESENTATIVES OF THE GOVERNMENTS OF THE MEMBER STATES

of 26 June 2013

appointing a Judge to the General Court

(2013/339/EU)

THE REPRESENTATIVES OF THE GOVERNMENTS OF THE MEMBER STATES OF THE EUROPEAN UNION,

Having regard to the Treaty on European Union, and in particular Article 19 thereof,

Having regard to the Treaty on the Functioning of the European Union, and in particular Articles 254 and 255 thereof,

Having regard to the Treaty establishing the European Atomic Energy Community, and in particular Article 106a(1) thereof,

Whereas:

(1) Under Articles 5 and 7 of the Protocol on the Statute of the Court of Justice of the European Union, and following the resignation of Mr Josef AZIZI, with effect from 1 September 2013, a Judge should be appointed to the General Court for the remainder of the term of office of Mr AZIZI, which runs until 31 August 2016.

(2) Mr Viktor KREUSCHITZ has been proposed as a candidate for the vacant post.

(3) The panel set up by Article 255 of the Treaty on the Functioning of the European Union has given an opinion on Mr Viktor KREUSCHITZ's suitability to perform the duties of a Judge of the General Court,

HAVE ADOPTED THIS DECISION:

Article 1

Mr Viktor KREUSCHITZ is hereby appointed Judge to the General Court for the period from 1 September 2013 to 31 August 2016.

Article 2

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

Done at Brussels, 26 June 2013.

The President

R. MONTGOMERY

COMMISSION IMPLEMENTING DECISION

of 27 June 2013

amending Decision 2008/855/EC as regards animal health control measures relating to classical swine fever in Croatia

(notified under document C(2013) 3932)

(Text with EEA relevance)

(2013/340/EU)

THE EUROPEAN COMMISSION,

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

Having regard to Council Directive 89/662/EEC of 11 December 1989 concerning veterinary checks in intra-Community trade with a view to the completion of the internal market ([1]), and in particular Article 9(4) thereof,

Having regard to Council Directive 90/425/EEC of 26 June 1990 concerning veterinary and zootechnical checks applicable in intra-Community trade in certain live animals and products with a view to the completion of the internal market ([2]), and in particular Article 10(4) thereof,

Whereas:

(1) Commission Decision 2008/855/EC of 3 November 2008 concerning animal health control measures relating to classical swine fever in certain Member States ([3]) lays down certain control measures in relation to classical swine fever in the Member States or regions thereof listed in the Annex thereto. Different epidemiological situations regarding classical swine fever are registered in Member States or areas thereof. The Annex to Decision 2008/855/EC therefore consists of three parts, each listing areas of Member States, to which different measures apply according to the epidemiological situation.

(2) Pursuant to Decision 2008/855/EC, Member States are to ensure that live pigs are dispatched from their territories to other Member States only if the pigs come from areas outside those listed in the Annex to that Decision.

(3) Part I of the Annex to Decision 2008/855/EC lists Member States and areas thereof where the epidemiological situation for classical swine fever is most favourable. Consequently, Decision 2008/855/EC provides that the dispatch of live pigs originating from holdings located within an area listed in Part I of that Annex to holdings or slaughterhouses located in an area listed in that Part and belonging to another Member States may be authorised by the Member States of dispatch provided that certain conditions are complied with. In addition, fresh pigmeat from holdings located in those areas, and meat preparations and meat products consisting of, or containing meat of those pigs, may be dispatched to other Member States.

(4) An outbreak of classical swine fever in domestic pigs was detected in Croatia in 2008 for the last time. However, seropositive cases in wild boars have been detected also in the hunting season 2012-13. Croatia applied appropriate measures to control classical swine fever, in line with the measures provided for in Council Directive 2001/89/EC of 23 October 2001 on Community measures for the control of classical swine fever ([4]) and a programme for the eradication of the disease is currently in place.

(5) Croatia is expected to accede the Union on 1 July 2013. Given the epidemiological situation for classical swine fever in that country, it is appropriate to lay down measures for the control of classical swine fever in its territory in order to prevent the spread of the disease to other areas of the Union. On the basis of the information provided by the competent authority of Croatia, it is appropriate to include the territory of the counties of Karlovac, Sisak-Moslavina, Slavonski Brod-Posavina and Vukovar-Srijem in Part I of the Annex to Decision 2008/855/EC.

(6) Decision 2008/855/EC should therefore be amended accordingly.

(7) This Decision should apply from the date of accession of Croatia to the European Union.

(8) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS DECISION:

Article 1

In Part I of the Annex to Decision 2008/855/EC, the following entry is added:

'**Croatia**

The territory of the counties of Karlovac, Sisak-Moslavina, Slavonski Brod-Posavina and Vukovar-Srijem'

([1]) OJ L 395, 30.12.1989, p. 13.
([2]) OJ L 224, 18.8.1990, p. 29.
([3]) OJ L 302, 13.11.2008, p. 19.
([4]) OJ L 316, 1.12.2001, p. 5.

Article 2

This Decision shall apply from the date of the entry into force of the Treaty of Accession of Croatia.

Article 3

This Decision is addressed to the Member States.

Done at Brussels, 27 June 2013.

For the Commission
Tonio BORG
Member of the Commission

COMMISSION IMPLEMENTING DECISION

of 27 June 2013

on the approval of the Valeo Efficient Generation Alternator as an innovative technology for reducing CO_2 emissions from passenger cars pursuant to Regulation (EC) No 443/2009 of the European Parliament and of the Council

(Text with EEA relevance)

(2013/341/EU)

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EC) No 443/2009 of the European Parliament and of the Council of 23 April 2009 setting emission performance standards for new passenger cars as part of the Community's integrated approach to reduce CO_2 emissions from light-duty vehicles [1], and in particular Article 12(4) thereof,

Whereas:

(1) The supplier Valeo Equipments Electriques Moteur (the 'Applicant') submitted an application for the approval of the Valeo Efficient Generation (EG) Alternator as an innovative technology on 18 December 2012. The completeness of the application was assessed in accordance with Article 4 of Commission Implementing Regulation (EU) No 725/2011 of 25 July 2011 establishing a procedure for the approval and certification of innovative technologies for reducing CO_2 emissions from passenger cars pursuant to Regulation (EC) No 443/2009 of the European Parliament and of the Council [2]. The application was found to be complete and the period for the Commission's assessment of the application started on the day following the date of official receipt, i.e. 19 December 2012.

(2) The application has been assessed in accordance with Article 12 of Regulation (EC) No 443/2009, Implementing Regulation (EU) No 725/2011 and the Technical Guidelines for the preparation of applications for the approval of innovative technologies pursuant to Regulation (EC) No 443/2009 (the Technical Guidelines) [3].

(3) The application refers to the Valeo EG Alternator, which is an alternator with an efficiency of at least 77 per cent as determined in accordance with the VDA approach described in point 5.1.2 in Annex I to the Technical Guidelines. The Applicant's alternator is equipped with synchronous rectification using metal-oxide-semiconductor field-effect transistors thereby ensuring a high level of efficiency.

(4) The Commission finds that the information provided in the application demonstrates that the conditions and criteria referred to in Article 12 of Regulation (EC) No 443/2009 and in Articles 2 and 4 of Implementing Regulation (EU) No 725/2011 have been met.

(5) The Applicant has demonstrated that a high efficiency alternator of the kind described in this application will only be available on the EU market as from 2013 and that consequently the market penetration in 2009 of this type of alternators was below the 3 per cent threshold specified in Article 2(2)(a) of Implementing Regulation (EU) No 725/2011. This claim is also supported by the accompanying verification report. On that basis, the Commission finds that the high efficiency alternator provided by the Applicant should be considered meeting the eligibility criterion set out in Article 2(2)(a) of Implementing Regulation (EU) No 725/2011.

(6) In order to determine the CO_2 savings that the innovative technology will deliver when fitted to a vehicle, it is necessary to define the baseline vehicle against which the efficiency of the vehicle equipped with the innovative technology should be compared as provided for in Articles 5 and 8 of Implementing Regulation (EU) No 725/2011. The Commission finds that it is appropriate to consider an alternator with 67 % efficiency as an appropriate baseline technology in the case the innovative technology is fitted on a new vehicle type. Where the Valeo EG Alternator is fitted to an existing vehicle type, the baseline technology should be the alternator of the most recent version of that type placed on the market.

(7) The Applicant has provided a comprehensive methodology for testing the CO_2 reductions. It includes formulae that are consistent with the formulae described in the Technical Guidelines for the simplified approach with regard to efficient alternators. The Commission considers that the testing methodology will provide testing results that are verifiable, repeatable and comparable and that it is capable of demonstrating in a realistic manner the CO_2 emissions benefits of the innovative technology with strong statistical significance in accordance with Article 6 of Implementing Regulation (EU) No 725/2011.

[1] OJ L 140, 5.6.2009, p. 1.
[2] OJ L 194, 26.7.2011, p. 19.
[3] http://ec.europa.eu/clima/policies/transport/vehicles/cars/docs/guidelines_en.pdf

(8) Against that background the Commission finds that the Applicant has demonstrated satisfactorily that the emission reduction achieved by the innovative technology is at least 1 g CO_2/km.

(9) The Commission notes that the savings of the innovative technology may be partially demonstrated on the standard test cycle, and the final total savings to be certified should therefore be determined in accordance with the second subparagraph of Article 8(2) of Implementing Regulation (EU) No 725/2011.

(10) The Commission finds that the verification report has been prepared by UTAC which is an independent and certified body and that the report supports the findings set out in the application.

(11) Against that background, the Commission finds that no objections should be raised as regards the approval of the innovative technology in question.

(12) Any manufacturer wishing to benefit from a reduction of its average specific CO_2 emissions for the purpose of meeting its specific emissions target by means of the CO_2 savings from the use of the innovative technology approved by this Decision, should in accordance with Article 11(1) of Implementing Regulation (EU) No 725/2011, refer to this Decision in its application for an EC type-approval certificate for the vehicles concerned,

HAS ADOPTED THIS DECISION:

Article 1

1. The Valeo Efficient Generation Alternator having an efficiency of at least 77 per cent and intended for use in M1 vehicles is approved as an innovative technology within the meaning of Article 12 of Regulation (EC) No 443/2009.

2. The CO_2 emissions reduction from the use of the alternator referred to in paragraph 1 shall be determined using the methodology set out in the Annex.

3. In accordance with the second subparagraph of Article 11(2) of Implementing Regulation (EU) No 725/2011, the CO_2 emission reduction determined in accordance with paragraph 2 of this Article, may only be certified and entered into the certificate of conformity and relevant type approval documentation specified in Annexes I, VIII and IX to Directive 2007/46/EC of the European Parliament and of the Council [1] where the reductions are on or above the threshold specified in Article 9(1) of Implementing Regulation (EU) No 725/2011.

Article 2

This Decision shall enter into force on the 20th day following that of its publication in the *Official Journal of the European Union*.

Done at Brussels, 27 June 2013.

For the Commission
The President
José Manuel BARROSO

[1] OJ L 263, 9.10.2007, p. 1.

ANNEX

Methodology for determining the reduction in CO_2 emissions due to the use of the Valeo Efficient Generation Alternator in an M1 vehicle

1. **Introduction**

In order to determine the CO_2 reductions that can be attributed to the use of the Valeo EG Alternator in an M1 vehicle, it is necessary to establish the following:

(a) the testing procedure to be followed for determining the efficiency of the alternator;

(b) the setting of the test bench;

(c) the formulae for calculating the standard deviation;

(d) the determination of the CO_2 savings for the certification by type approval authorities.

2. **Testing procedure**

The efficiency of the alternator must be determined by doing measurements at different speeds: 1 800, 3 000, 6 000, 10 000 revolutions per minute. At each speed the alternator is charged at 50 % of the maximum load. For calculating the efficiency, a time distribution is to be 25 %, 40 %, 25 %, 10 % for respectively 1 800, 3 000, 6 000, 10 000 revolutions per minute (see the VDA approach as described in point 5.1.2 in Annex I to the Technical Guidelines).

This leads to the following formula (1):

$$\eta_A = 0{,}25 \cdot (\eta\ @1\,800\ \text{rpm}\ @0{,}5{\cdot}I_N) + 0{,}40 \cdot (\eta\ @3\,000\ \text{rpm}\ @0{,}5{\cdot}I_N) + 0{,}25 \cdot (\eta\ @6\,000\ \text{rpm}\ @0{,}5{\cdot}I_N) + 0{,}10 \cdot (\eta\ @10\,000\ \text{rpm}\ @0{,}5{\cdot}I_N)$$

With:

— η_A is the efficiency of the alternator;

— $(\eta\ @1\,800\ \text{rpm}\ @0{,}5{\cdot}I_N)$ is the efficiency of the alternator at a speed of 1 800 rpm and at a load of 50 %;

— $(\eta\ @3\,000\ \text{rpm}\ @0{,}5{\cdot}I_N)$ is the efficiency of the alternator at a speed of 3 000 rpm and at a load of 50 %;

— $(\eta\ @6\,000\ \text{rpm}\ @0{,}5{\cdot}I_N)$ is the efficiency of the alternator at a speed of 6 000 rpm and at a load of 50 %;

— $(\eta\ @10\,000\ \text{rpm}\ @0{,}5{\cdot}I_N)$ is the efficiency of the alternator at a speed of 10 000 rpm and at a load of 50 %;

— I_N = Current (A)

The set-up of the test bench and the testing procedure is to fulfil the precision requirements specified in ISO 8854:2012 ([1]).

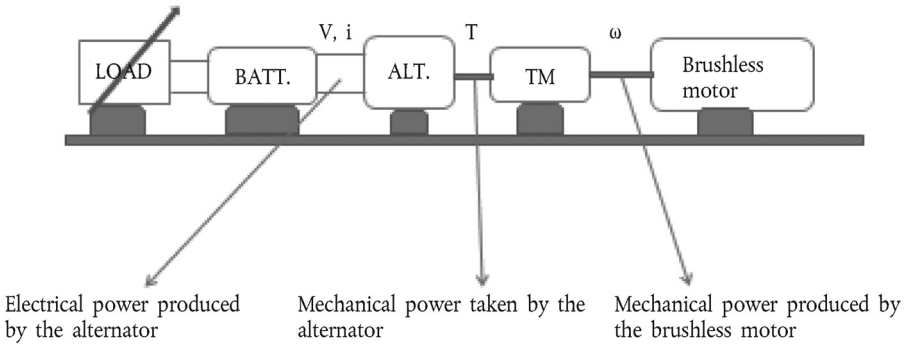
3. **Test bench**

The test bench is to be a 'direct drive' alternator test bench. The alternator is to be directly linked to the torque meter and to the shaft of the drive train. The alternator is to be loaded with a battery and an electronic load. See the test bench configuration in figure 1.

([1]) ISO 8854. Road vehicles — Alternators with regulators — Test methods and general requirements. Reference number ISO 8854:2012(E).

Figure 1

The test bench configuration



TM = Torquemeter
ALT. = Alternator
BATT. = Battery
V,I = Volt, current
T = Torque
ω = Rotational speed

In figure 1 an overview of the test bench configuration is given. The alternator transfers the mechanical power of the brushless motor into electrical power. The brushless motor generates an amount of power which is defined by the torque (Nm) and by the rotational speed (rad.s^{-1}). The torque and the speed are to be measured by the torque meter.

The alternator produces power to overcome the load which is connected to the alternator. This amount of power is equal to the alternator voltage (V) times the alternator current (I).

The efficiency of the alternator is to be defined as the electric power (output of the alternator) divided by the mechanical power (output of the torquemeter).

Formula (2): $\eta_A = (V * i)/(T * \omega)$

Where:

η_A = Efficiency of the alternator;

V = Voltage (V);

I = Current (A);

T = Torque (Nm);

ω = Rotational speed of the alternator (rad. s^{-1})

4. **Measuring the torque and calculating the efficiency of the alternator**

The tests are to be carried out in accordance with the ISO 8854:2012.

The load is to be installed at 50 % of the current which is guaranteed by the alternator at 25 °C and a rotor speed of 6 000 rpm, e.g. if the alternator is a 180 A class alternator (at 25 °C and 6 000 rpm), the load is installed at 90 A.

For each speed the voltage and the output current of the alternator are to be kept constant, the voltage at 14,3 V and the current for a 180 A-alternator at 90 A, i.e. for each speed the torque is to be measured by means of the test bench (see figure 1) and the efficiency is to be calculated by means of formula (2).

This test is to provide the efficiencies of the alternator at 4 different speeds in revolutions per minute (rpm):

— At a speed of 1 800 rpm;

— At a speed of 3 000 rpm;

— At a speed of 6 000 rpm;

— At a speed of 10 000 rpm.

The average efficiency of the alternator is to be calculated by means of formula (1).

5. **Standard deviation of the arithmetic mean value of the efficiency of the alternator**

Statistical errors in the outcomes of the testing methodology caused by the measurements are to be quantified. The format of the error value is to be a standard deviation being equivalent to a two-sided confidence interval of 84 % (see formula (3)).

Formula (3): $s_{\bar{x}} = \sqrt{\frac{\sum_{i=1}^{n}(x_i - \bar{x})^2}{n(n-1)}}$

Where:

$s_{\bar{x}}$: standard deviation of arithmetic mean;

x_i: measurement value;

$\bar{x}$: arithmetic mean;

n: number of measurements

All measurements are to be performed consecutively at least five (5) times. For each speed the standard deviation is calculated.

The standard deviation of the efficiency value of the alternator ($\Delta\eta A$) is calculated by the following formula:

Formula (4): $\Delta\eta_A = \sqrt{(0{,}25 * (S_{1\,800})^2 + 0{,}40 * (S_{3\,000})^2 + 0{,}25 * (S_{6\,000})^2 + 0{,}1 * (S_{10\,000})^2)}$

Where the values 0,25, 0,40, 0,25, and 0,1 are the same weighting values as in formula (2) and $S_{1\,800}$, $S_{3\,000}$, $S_{6\,000}$, and $S_{10\,000}$ are the standard deviations calculated with formula (3).

6. **Error in the CO_2 savings due to the standard deviation (propagation law)**

The standard deviation of the efficiency value of the alternator ($\Delta\eta_A$), leads to an error in the CO_2 savings. This error is to be calculated by means of the following formula ([1]):

Formula (5): $\Delta CO_2 = (P_{m-RW} - P_{m-TA}) \cdot (1/\eta_{A-EI}^2) \cdot \Delta\eta_A \cdot (V_{Pe} \cdot CF_p/v)$

Where:

ΔCO_2 = error in CO_2 savings (g CO_2/km);

P_{RW} = 750 W;

P_{TA} = 350 W;

η_{A-EI} = Efficiency of the high efficient alternator;

$\Delta\eta_A$ = Standard deviation of the efficiency of the alternator (result of equation in Formula (4);

V_{Pe} = Willans' factors (l/kWh);

CF = Conversion factors (g CO_2/l);

v = mean driving speed of the NEDC (km/h)

7. **Calculation of the accountable share of the mechanical power saving**

The high efficient alternator leads to the saved mechanical power which is to be calculated in two steps. In the first step the saved mechanical power is to be calculated under 'real world' conditions. The second step is to calculate the saved mechanical power under type approval conditions. Subtracting these 2 mechanical power savings is to result in the accountable share of the saved mechanical power.

The saved mechanical power under 'real world' conditions is to be calculated with formula (6).

Formula (6): $\Delta P_{m-RW} = (P_{RW}/\eta_A) - (P_{RW}/\eta_{A-EI})$

Where:

ΔP_{m-RW} = Saved mechanical power under real world conditions (W);

P_{RW} = Electric power under real world conditions, which is 750 W;

([1]) This formula (5) can be derived from the error propagation law which is explained in the Technical Guidelines (par. 4.2.1).

η_A = Efficiency of the baseline alternator;

η_{A-EI} = Efficiency of the high efficient alternator

The saved mechanical power under type-approval conditions is to be calculated with formula (7).

Formula (7): $\Delta P_{m-TA} = (P_{TA}/\eta_A) - (P_{TA}/\eta_{A-EI})$

Where:

ΔP_{m-TA} = Saved mechanical power under type approval conditions (W);

P_{TA} = Electric power under type approval conditions, which is 350 W;

η_A = Efficiency of the baseline alternator;

η_{A-EI} = Efficiency of the high efficient alternator

The accountable share of saved mechanical power is calculated with formula (8).

Formula (8): $\Delta P_m = \Delta P_{m-RW} - \Delta P_{m-TA}$

Where:

ΔP_m = Accountable share of saved mechanical power (W);

ΔP_{m-RW} = Saved mechanical power under real world conditions (W);

ΔP_{m-TA} = Saved mechanical power under type approval conditions (W);

8. **Formula to calculate the CO_2 savings**

The CO_2 savings are to be calculated with the following formula:

Formula (9): $C_{CO_2} = \Delta P_m \cdot V_{Pe} \cdot CF/v$

Where:

C_{CO_2} = CO_2 savings (g CO_2/km);

ΔP_m = Accountable share of saved mechanical power as per formula (8) (W);

V_{Pe} = Willans' factors (l/kWh);

CF = Conversion factors (g CO_2/l)

v = mean driving speed of the NEDC (km/h)

For the Willans' factors the data in table 1 is to be used:

Table 1

Willans' factors

Type of engine	Consumption of effective power V_{Pe} [l/kWh]
Petrol (V_{Pe-P})	0,264
Petro Turbo	0,28
Diesel (V_{Pe-D})	0,22

For the conversion factors the data in table 2 is to be used:

Table 2

Conversion factors

Type of fuel	Conversion factor (l/100 km) → (g CO_2/km) [100 g/l]
Petrol	23,3 (= 2 330 g CO_2/l)
Petro Turbo	23,3 (= 2 330 g CO_2/l)
Diesel	26,4 (= 2 640 g CO_2/l)

The mean driving speed of the NEDC is: v = 33,58 km/h

9. **Statistical Significance**

It has to be demonstrated for each type, variant and version of a vehicle fitted with the Valeo EG Alternator that the error in the CO_2 savings calculated with Formula 5 is not greater than the difference between the total CO_2 savings and the minimum savings threshold specified in Article 9(1) of Implementing Regulation (EU) No 725/2011 (see Formula (7)).

Formula (10): $MT < C_{CO_2} - \overline{\Delta C_{CO_2}}$

Where:

MT = minimum threshold (g CO_2/km);

C_{CO_2} = total CO_2 saving, (g CO_2/km);

$\overline{\Delta C_{CO_2}}$ = error in the CO_2 savings (g CO_2/km)

10. **The high efficient alternator to be implemented in vehicles**

For determining the CO_2 savings to be certified due to the use of the Valeo EG Alternator by the type approval authority in accordance with Article 12 of Implementing Regulation (EU) No 725/2011, the manufacturer of the M1 vehicle in which the alternator is fitted has to designate in accordance with Article 5 of that Regulation, an eco-innovation vehicle fitted with the Valeo (EG) Alternator and either of the following baseline vehicles:

(a) if the eco-innovation is fitted to a new vehicle type which will be submitted to a new type approval, the baseline vehicle is to be the same as the new vehicle type in all respects except with regard to the alternator which is to be an alternator with an efficiency of 67 %, or

(b) if the eco-innovation is fitted to an existing vehicle version for which the type approval will be extended following the replacement of the existing alternator by the eco-innovation, the base vehicle is to be the same as the eco-innovation vehicle in all respects except with regard to the alternator which is to be the alternator of the existing vehicle version.

The type approval authority is to certify the CO_2 savings based on measurements of the base vehicle and eco-innovation vehicle in accordance with Article 8(1) and the second subparagraph of Article 8(2) of Implementing Regulation (EU) No 725/2011 using the test methodology set out in this Annex. Where the CO_2 emission savings are below the threshold specified in Article 9(1), the second subparagraph of Article 11(2) of Implementing Regulation (EU) No 725/2011 shall apply.

11. **Eco-innovation code to be entered into type approval documentation**

For the purposes of determining the general eco-innovation code to be used in the relevant type approval documents in accordance with Annexes I, VIII and IX to Directive 2007/46/EC, the individual code to be used for the innovative technology approved through this Decision shall be '2'.

E.g. the code of the eco-innovation in the case of eco-innovation savings certified by the German type approval authority shall be 'e1 2'.

EN

([1]) Text with EEA relevance

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