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[1] Text with EEA relevance

I

(Legislative acts)

DECISIONS

DECISION No 1082/2013/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 22 October 2013

on serious cross-border threats to health and repealing Decision No 2119/98/EC

(Text with EEA relevance)

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 168(5) 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) Article 168 of the Treaty on the Functioning of the European Union (TFEU) states, inter alia, that a high level of human health protection is to be ensured in the definition and implementation of all Union policies and activities. That Article further provides that Union action is to complement national policies, is to cover monitoring, early warning of, and combating serious cross-border threats to health, and that Member States are, in liaison with the Commission, to coordinate among themselves their policies and programmes in the areas covered by Union action in the field of public health.

(2) Pursuant to Decision No 2119/98/EC of the European Parliament and of the Council [3] a network for the epidemiological surveillance and control of communicable diseases in the Community was set up. Experience gained in the implementation of that Decision confirms that coordinated Union action on monitoring, early warning of and combating those threats adds value to the protection and improvement of human health. However, a number of developments at Union and international level in the past decade have made a review of that legal framework necessary.

(3) Apart from communicable diseases, a number of other sources of danger to health, in particular related to other biological or chemical agents or environmental events, which include hazards related to climate change, could by reason of their scale or severity, endanger the health of citizens in the entire Union, lead to the malfunctioning of critical sectors of society and the economy and jeopardise an individual Member State's capacity to react. The legal framework set up under Decision No 2119/98/EC should, therefore, be extended to cover other threats and provide for a coordinated wider approach to health security at Union level.

(4) An important role in the coordination of recent crises of Union relevance has been played by an informal group composed of high-level representatives from Member States, referred to as the Health Security Committee, and established on the basis of the Presidency Conclusions of 15 November 2001 on bioterrorism. It is necessary to give this group a formalised status and to assign it a well-defined role to avoid duplications with other Union entities responsible for risk management.

[1] OJ C 181, 21.6.2012, p. 160.

[2] Position of the European Parliament of 3 July 2013 (not yet published in the Official Journal) and decision of the Council of 7 October 2013.

[3] OJ L 268, 3.10.1998, p. 1.

(5) Regulation (EC) No 851/2004 of the European Parliament and of the Council of 21 April 2004 establishing a European Centre for Disease Prevention and Control [1] ('ECDC') provides the ECDC with a mandate covering surveillance, detection and risk- assessment of threats to human health from communicable diseases and outbreaks of unknown origin. The ECDC has progressively taken over the epidemiological surveillance of communicable diseases and the operation of the Early Warning and Response System ('EWRS') from the Community network set up under Decision No 2119/98/EC. Those changes are not reflected in Decision No 2119/98/EC, because it was adopted before the establishment of the ECDC.

(6) The International Health Regulations (2005) ('IHR') adopted by the Fifty-eighth World Health Assembly on 23 May 2005 reinforced the coordination among States Parties to the World Health Organisation (WHO), which include all the Member States of the Union, of the preparedness for, and response to, a public health emergency of international concern. Union legislation should take this development into account, including the integrated all-hazards approach of the WHO covering all categories of threat regardless of their origin.

(7) This Decision should apply without prejudice to other binding measures concerning specific activities or setting the standards of quality and safety of certain goods, which provide for special obligations and tools for monitoring, early warning and combating specific threats of a cross-border nature. Those measures include in particular relevant Union legislation in the area of common safety concerns in public health matters, covering goods such as pharmaceutical products, medical devices and foodstuffs, and exposure to ionising radiation.

(8) The protection of human health is a matter which has a cross-cutting dimension and is relevant to numerous Union policies and activities. In order to achieve a high level of human health protection, and to avoid any overlap of activities, duplication or conflicting actions, the Commission, in liaison with the Member States, should ensure coordination and exchange of information between the mechanisms and structures established under this Decision, and other mechanisms and structures established at Union level and under the Treaty establishing the European Atomic Energy Community (the Euratom Treaty), the activities of which are relevant to the preparedness and response planning, monitoring, early warning of, and combating serious cross-border threats to health. In particular the Commission should ensure that relevant information from the various rapid alert and information systems at Union level and under the Euratom Treaty is gathered and communicated to the Member States through the EWRS.

(9) The structures for coordinating responses to serious cross-border health threats established by this Decision, should, in exceptional circumstances, be available to the Member States and the Commission also when the threat is not covered by this Decision and where it is possible that public health measures taken to counter that threat are insufficient to ensure a high level of protection of human health. The Member States should, in liaison with the Commission, coordinate the response within the Health Security Committee ('HSC') as established by this Decision in close cooperation with, where applicable, other structures, established at Union level and under the Euratom Treaty, for the monitoring, early warning or combating of such threats.

(10) Preparedness and response planning is an essential element for effective monitoring, early warning of and combating serious cross-border threats to health. Such planning should include in particular adequate preparedness of critical sectors of society, such as energy, transport, communication or civil protection, which rely, in a crisis situation, on well-prepared public health systems that are also in turn dependent on the functioning of those sectors and on maintenance of essential services at an adequate level. In the event of a serious cross-border threat to health originating from a zoonotic infection, it is important to ensure the interoperability between health and veterinary sectors for preparedness and response planning.

(11) Cross-border threats to health are often related to pathogenic agents that can be transmitted between individuals. While such transmission cannot be completely prevented, general hygiene measures can make an important contribution by reducing the speed and extent of the spread of the agent and thus reducing the general risk. Such measures could include information on good hygiene practices, such as effective hand washing and drying, in collective settings and in the workplace, and should take into account the existing recommendations of the WHO.

(12) The IHR already require Member States to develop, strengthen and maintain their capacity to detect, assess, notify and respond to a public health emergency of international concern. Consultation with a view to coordinating among the Member States is necessary in order to promote interoperability between national

[1] OJ L 142, 30.4.2004, p. 1.

preparedness planning in view of the international standards, while respecting Member States' competence to organise their health systems. Member States should regularly provide the Commission with an update on the status of their preparedness and response planning at national level. Information provided by the Member States should include the elements that Member States are obliged to report to the WHO in the context of the IHR. That information should particularly address the cross-border dimension of preparedness and response planning. The Commission should compile the information received and should ensure its exchange among Member States through the HSC. When a Member State decides to substantially revise its national preparedness planning, it should inform the Commission thereof and submit the information about the main aspects of that revision in a timely manner to the Commission to allow for information exchange and possible consultations within the HSC.

(13) The European Parliament in its resolution of 8 March 2011 and the Council in its Conclusions of 13 September 2010 stressed the need to introduce a common procedure for the joint procurement of medical countermeasures, and in particular of pandemic vaccines, to allow Member States, on a voluntary basis, to benefit from such group purchases, e.g. by obtaining advantageous prices and order flexibility with regard to a given product. With regard to pandemic vaccines, in the context of limited production capacities at global level, such a procedure would be undertaken with the aim of enabling more equitable access to vaccines for the Member States involved, to help them to better meet the vaccination needs of their citizens, in line with vaccination policies in the Member States.

(14) Unlike communicable diseases, the surveillance of which at Union level is carried out on a permanent basis by the ECDC, other serious cross-border threats to health do not currently necessitate a systematic monitoring. A risk-based approach, whereby monitoring is carried out by Member States' monitoring systems and available information is exchanged through the EWRS, is therefore more appropriate to those threats.

(15) The Commission will strengthen cooperation and activities with the ECDC, the Member States, the European Medicines Agency and the WHO to improve the methods and processes through which information related to the coverage of vaccine-preventable diseases is provided.

(16) A system enabling the notification at Union level of alerts related to serious cross-border threats to health should be put in place in order to ensure that competent public health authorities in Member States and the Commission are duly informed in a timely manner. The EWRS should, therefore, be extended to all the serious cross-border threats to health covered by the present Decision. The operation of the EWRS should remain within the remit of the ECDC. The notification of an alert should be required only where the scale and severity of the threat concerned are or could become so significant that they affect or could affect more than one Member State and require or could require a coordinated response at the Union level. To avoid duplication, the Commission should ensure that alert notifications under the EWRS and other rapid alert systems at Union level are linked to each other to the extent possible so that the competent authorities of the Member States can avoid as much as possible notifying the same alert through different systems at Union level.

(17) In order to ensure that the assessment of risks to public health at the Union level from serious cross-border threats to health is consistent as well as comprehensive from a public health perspective, the available scientific expertise should be mobilised in a coordinated manner, through appropriate channels or structures depending on the type of threat concerned. That assessment of risks to public health should be developed by means of a fully transparent process and should be based on principles of excellence, independence, impartiality and transparency. That assessment should be provided by the agencies of the Union in accordance with their missions or by the Commission if the risk assessment required is totally or partially outside the mandates of the agencies of the Union.

(18) Taking account of the applicable rules in each case, scientific experts should make declarations of interest and of commitments. Such declarations should include any activity, position, circumstances or other facts potentially involving direct or indirect interest in order to make it possible to identify interests which could be considered prejudicial to those experts' independence.

(19) Effectively responding to serious cross-border threats to health at national level could require consultation among Member States, in conjunction with the Commission, with a view to coordinating national responses and could necessitate exchange of information. Pursuant to Decision No 2119/98/EC, the Member States already consult each other in liaison with the Commission with a view to coordinating their efforts and their response at Union level with regard to communicable diseases. A similar mechanism should apply to all serious cross-border threats to health regardless of their origin. It should also be recalled that, independently of this Decision, a Member State may, in the case of a major

emergency, request assistance under Council Decision 2007/779/EC, Euratom of 8 November 2007 establishing a Community Civil Protection Mechanism [1].

(20) The obligations of Member States to provide information under this Decision do not affect the application of point (a) of Article 346(1) TFEU pursuant to which no Member State is obliged to supply information the disclosure of which it considers contrary to the essential interests of its security.

(21) The Member States have a responsibility to manage public health crises at national level. However, measures taken by individual Member States could damage the interests of other Member States if they are inconsistent with one another or based on diverging risk assessments. The aim to coordinate the response at Union level should, therefore, seek to ensure, inter alia, that measures taken at national level are proportionate and limited to public health risks related to serious cross-border threats to health, and do not conflict with obligations and rights laid down in the TFEU such as those related to the restriction on travel and trade.

(22) Inconsistent or confusing communication with the public and stakeholders such as healthcare professionals can have a negative impact on the effectiveness of the response from a public health perspective as well as on economic operators. The coordination of the response within the HSC, assisted by relevant subgroups, should, therefore, encompass rapid information exchange concerning communication messages and strategies and addressing communication challenges with a view to coordinating risk and crisis communication, based on robust and independent evaluation of public health risks, to be adapted to national needs and circumstances. Such exchanges of information are intended to facilitate monitoring of the clarity and coherence of messages to the public and to healthcare professionals.

(23) The applicability of certain specific provisions of Commission Regulation (EC) No 507/2006 of 29 March 2006 on the conditional marketing authorisation for medicinal products for human use falling within the scope of Regulation (EC) No 726/2004 of the European Parliament and of the Council [2] and of Commission Regulation (EC) No 1234/2008 of 24 November 2008 concerning the examination of variations to the terms of marketing authorisations for medicinal products for human use and veterinary medicinal products [3] depends on the recognition at Union level, in the framework of Decision No 2119/98/EC, of an emergency situation or of a pandemic situation with respect to human influenza. Those provisions allow for the accelerated marketing of certain medicinal products in the case of urgent need, by means, respectively, of a conditional marketing authorisation and of the temporary option of granting a variation to the terms of a marketing authorisation for a human influenza vaccine even where certain non-clinical or clinical data are missing. However, in spite of the utility of such provisions in the event of a crisis, to date no specific procedure exists for issuing such recognitions at Union level. It is therefore appropriate to provide for such a procedure as part of laying down the standards of quality and safety for medicinal products.

(24) Before recognising a situation of public health emergency at Union level, the Commission should liaise with the WHO in order to share the Commission's analysis of the situation of the outbreak and to inform the WHO of its intention to issue such a decision. Where such a decision is adopted, the Commission should also inform the WHO thereof.

(25) The occurrence of an event that is linked to serious cross-border threats to health and is likely to have Europe-wide consequences could require the Member States concerned to take particular control or contact-tracing measures in a coordinated manner to identify those persons already contaminated and those persons exposed to risk. Such cooperation could require the exchange of personal data through the system, including sensitive information related to health and information about confirmed or suspected human cases of disease, between those Member States directly involved in the contact-tracing measures.

(26) Cooperation with third countries and international organisations in the field of public health should be fostered and it is particularly important to ensure the exchange of information with the WHO on the measures taken pursuant to this Decision. In particular, it could be in the interests of the Union to conclude international cooperation agreements with third countries or international organisations, including the WHO, to foster the exchange of relevant information from monitoring and alerting systems on serious cross-border threats to health. Within the limits of the Union's competences, such agreements could include, where appropriate, the participation of such third countries or international organisations in the relevant epidemiological surveillance monitoring network and the EWRS, exchange of good practice in the areas of preparedness and response planning, public health risk-assessment and collaboration on response coordination.

[1] OJ L 314, 1.12.2007, p. 9.
[2] OJ L 92, 30.3.2006, p. 6.
[3] OJ L 334, 12.12.2008, p. 7.

(27) The processing of personal data for the purpose of implementing this Decision should 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 Regulation (EC) No 45/2001 of the European Parliament and of the Council of 18 December 2000 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data [2]. In particular, the operation of the EWRS should provide for specific safeguards for the safe and lawful exchange of personal data for the purpose of contact tracing measures implemented by Member States at national level.

(28) Since the objectives of this Decision, cannot be sufficiently achieved by the Member States alone due to the cross-border dimension of serious threats to health and can, therefore, be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality, as set out in that Article, this Decision does not go beyond what is necessary in order to achieve those objectives.

(29) As responsibility for public health is not an exclusively national matter in certain Member States, but is substantially decentralised, national authorities should, where appropriate, involve the relevant competent authorities in the implementation of this Decision.

(30) In order to ensure uniform conditions for the implementation of this Decision, implementing powers should be conferred on the Commission to adopt implementing acts in relation to: templates to be used when providing the information on preparedness and response planning; the establishment and update of a list of communicable diseases and related special health issues subject to the network of epidemiological surveillance and the procedures for the operation of such a network; the adoption of case definitions for those communicable diseases and special health issues covered by the epidemiological surveillance network and, where necessary, for other serious cross-border threats to health subject to ad hoc monitoring; the procedures for the operation of the EWRS; the procedures for the information exchange on and the coordination of the responses of the Member States; the recognition of situations of public health emergency at Union level and the termination of such a recognition. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers [3]. As the implementing acts provided for by this Decision concern the protection of human health, the Commission may not adopt a draft implementing act where the Committee on serious cross-border threats to health delivers no opinion, in accordance with point (a) of the second subparagraph of Article 5(4) of Regulation (EU) No 182/2011.

(31) The Commission should adopt immediately applicable implementing acts where, in duly justified cases relating to the severity or novelty of a serious cross-border threat to health or to the rapidity of its spread between the Member States imperative grounds of urgency so require.

(32) The European Data Protection Supervisor has been consulted in accordance with Article 28(2) of Regulation (EC) No 45/2001 and has adopted an opinion [4].

(33) Accordingly, Decision No 2119/98/EC should be repealed and replaced by this Decision,

HAVE ADOPTED THIS DECISION:

CHAPTER I

GENERAL PROVISIONS

Article 1

Subject matter

1. This Decision lays down rules on epidemiological surveillance, monitoring, early warning of, and combating serious cross-border threats to health, including preparedness and response planning related to those activities, in order to coordinate and complement national policies.

2. This Decision aims to support cooperation and coordination between the Member States in order to improve the prevention and control of the spread of severe human diseases across the borders of the Member States, and to combat other serious cross-border threats to health in order to contribute to a high level of public health protection in the Union.

3. This Decision also clarifies the methods of cooperation and coordination between the various actors at Union level.

[1] OJ L 281, 23.11.1995, p. 31.
[2] OJ L 8, 12.1.2001, p. 1.
[3] OJ L 55, 28.2.2011, p. 13.
[4] OJ C 197, 5.7.2012, p. 21.

Article 2

Scope

1. This Decision shall apply to public health measures in relation to the following categories of serious cross-border threats to health:

(a) threats of biological origin, consisting of:

(i) communicable diseases;

(ii) antimicrobial resistance and healthcare-associated infections related to communicable diseases (hereinafter 'related special health issues');

(iii) biotoxins or other harmful biological agents not related to communicable diseases;

(b) threats of chemical origin;

(c) threats of environmental origin;

(d) threats of unknown origin;

(e) events which may constitute public health emergencies of international concern under the IHR, provided that they fall under one of the categories of threats set out in points (a) to (d).

2. This Decision shall also apply to the epidemiological surveillance of communicable diseases and of related special health issues.

3. The provisions of this Decision are without prejudice to provisions of other Union acts governing specific aspects of monitoring, early warning of, the coordination of preparedness and response planning for, and the coordination of, combating serious cross- border threats to health, including measures setting quality and safety standards for specific goods and measures concerning specific economic activities.

4. In exceptional emergency situations, a Member State or the Commission may request response coordination within the HSC, as referred to in Article 11, for serious cross-border threats to health other than those covered in Article 2(1), if it is considered that public health measures taken previously have proven insufficient to ensure a high level of protection of human health.

5. The Commission shall, in liaison with the Member States, ensure coordination and information exchange between the mechanisms and structures established under this Decision and similar mechanisms and structures established at Union level or under the Euratom Treaty whose activities are relevant for preparedness and response planning, monitoring, early warning of, and combating serious cross-border threats to health.

6. Member States shall retain the right to maintain or introduce additional arrangements, procedures and measures for their national systems in the fields covered by this Decision, including arrangements provided for in existing or future bilateral or multilateral agreements or conventions, on condition that such additional arrangements, procedures and measures do not impair the application of this Decision.

Article 3

Definitions

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

(a) 'case definition' means a set of commonly agreed diagnostic criteria that have to be fulfilled in order to accurately identify cases of a targeted serious cross-border threat to health in a given population, while excluding the detection of unrelated threats;

(b) 'communicable disease' means an infectious disease caused by a contagious agent which is transmitted from person to person by direct contact with an infected individual or by indirect means such as exposure to a vector, animal, fomite, product or environment, or exchange of fluid, which is contaminated with the contagious agent;

(c) 'contact tracing' means measures implemented in order to trace persons who have been exposed to a source of a serious cross-border threat to health, and who are in danger of developing or have developed a disease;

(d) 'epidemiological surveillance' means the systematic collection, recording, analysis, interpretation and dissemination of data and analysis on communicable diseases and related special health issues;

(e) 'monitoring' means the continuous observation, detection or review of changes in a condition, in a situation, or in activities, including a continuous function that uses systematic collection of data and analysis on specified indicators relating to serious cross-border threats to health;

(f) 'public health measure' means a decision or an action which is aimed at preventing, monitoring or controlling the spread of diseases or contamination, combating severe risks to public health or mitigating their impact on public health;

(g) 'serious cross-border threat to health' means a life-threatening or otherwise serious hazard to health of biological, chemical, environmental or unknown origin which spreads or entails a significant risk of spreading across the national borders of Member States, and which may necessitate coordination at Union level in order to ensure a high level of human health protection.

CHAPTER II

PLANNING

Article 4

Preparedness and response planning

1. Member States and the Commission shall consult each other within the HSC referred to in Article 17 with a view to coordinating their efforts to develop, strengthen and maintain their capacities for the monitoring, early warning and assessment of, and response to, serious cross-border threats to health. That consultation shall be aimed at:

(a) sharing best practice and experience in preparedness and response planning;

(b) promoting the interoperability of national preparedness planning;

(c) addressing the intersectoral dimension of preparedness and response planning at Union level; and

(d) supporting the implementation of core capacity requirements for surveillance and response as referred to in Articles 5 and 13 of the IHR.

2. For the purpose of paragraph 1, Member States shall by 7 November 2014 and every three years thereafter provide the Commission with an update on the latest situation with regard to their preparedness and response planning at national level.

That information shall cover the following:

(a) identification of, and update on the status of the implementation of, the core capacity standards for preparedness and response planning as determined at national level for the health sector, as provided to the WHO in accordance with IHR;

(b) description of the measures or arrangements aimed at ensuring interoperability between the health sector and other sectors including the veterinary sector, that are identified as being critical in the case of an emergency, in particular:

(i) coordination structures in place for cross-sectoral incidents;

(ii) emergency operational centres (crisis centres);

(c) description of the business continuity plans, measures or arrangements aimed at ensuring the continuous delivery of critical services and products.

The obligation to provide the information referred to in points (b) and (c) shall only apply if such measures or arrangements are in place or are provided for as part of national preparedness and response planning.

3. For the purpose of paragraph 1, when substantially revising national preparedness planning, Member States shall inform the Commission in a timely manner of the main aspects of the revision of their preparedness planning at national level that are relevant to the objectives referred to in paragraph 1 and to the specific issues referred to in paragraph 2.

4. When receiving classified information transmitted pursuant to paragraphs 2 and 3 of this Article, the Commission and the HSC shall apply the rules set out in the Annex to Commission Decision 2001/844/EC, ECSC, Euratom of 29 November 2001 amending its internal Rules of Procedure [1].

Each Member State shall ensure that its national security regulations apply to all natural persons resident on its territory and all legal persons established on its territory that handle the information referred to in paragraphs 2 and 3 of this Article. Those national security regulations shall offer a degree of protection of classified information at least equivalent to that provided by the rules on security as set out in the Annex to Commission Decision 2001/844/EC, ECSC, Euratom and by Council Decision 2011/292/EU of 31 March 2011 on the security rules for protecting EU classified information [2].

[1] OJ L 317, 3.12.2001, p. 1.
[2] OJ L 141, 27.5.2011, p. 17.

5. The Commission shall make the information received in accordance with paragraphs 2 and 3 available to the members of the HSC.

On the basis of that information, and for the purpose of paragraph 1, the Commission shall, in a timely manner, initiate discussion in the HSC, including, where appropriate, on the basis of synthesis or thematic progress reports.

6. The Commission shall, by means of implementing acts, adopt templates to be used by the Member States when providing the information referred to in paragraphs 2 and 3 in order to ensure its relevance to the objectives identified in paragraph 1 and its comparability.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 18(2).

Article 5

Joint procurement of medical countermeasures

1. The institutions of the Union and any Member States which so desire may engage in a joint procurement procedure conducted pursuant to the third subparagraph of Article 104(1) of Regulation (EU, Euratom) No 966/2012 of the European Parliament and of the Council of 25 October 2012 on the financial rules applicable to the general budget of the Union [1] and pursuant to Article 133 of Commission Delegated Regulation (EU) No 1268/2012 of 29 October 2012 on the rules of application of Regulation (EU, Euratom) No 966/2012 of the European Parliament and of the Council on the financial rules applicable to the general budget of the Union [2], with a view to the advance purchase of medical countermeasures for serious cross-border threats to health.

2. The joint procurement procedure referred to in paragraph 1 shall comply with the following conditions:

(a) participation in the joint procurement procedure is open to all Member States until the launch of the procedure;

(b) the rights and obligations of Member States not participating in the joint procurement are respected, in particular those relating to the protection and improvement of human health;

(c) the joint procurement does not affect the internal market, does not constitute discrimination or a restriction of trade or does not cause distortion of competition;

(d) the joint procurement does not have any direct financial impact on the budget of Member States not participating in the joint procurement.

3. The joint procurement procedure referred to in paragraph 1 shall be preceded by a Joint Procurement Agreement between the Parties determining the practical arrangements governing that procedure, and the decision-making process with regard to the choice of the procedure, the assessment of the tenders and the award of the contract.

CHAPTER III

EPIDEMIOLOGICAL SURVEILLANCE AND AD HOC MONITORING

Article 6

Epidemiological surveillance

1. A network for the epidemiological surveillance of the communicable diseases and of the related special health issues referred to in points (i) and (ii) of point (a) of Article 2(1), is hereby established. The network shall be operated and coordinated by the ECDC.

2. The epidemiological surveillance network shall bring into permanent communication the Commission, the ECDC, and the competent authorities responsible at national level for epidemiological surveillance.

3. The national competent authorities referred to in paragraph 2 shall communicate the following information to the participating authorities of the epidemiological surveillance network:

(a) comparable and compatible data and information in relation to the epidemiological surveillance of communicable diseases and related special health issues referred to in points (i) and (ii) of point (a) of Article 2(1);

(b) relevant information concerning the progression of epidemic situations;

(c) relevant information concerning unusual epidemic phenomena or new communicable diseases of unknown origin, including those in third countries.

4. When reporting information on epidemiological surveillance, the national competent authorities shall, where available, use the case definitions adopted in accordance with paragraph 5 for each communicable disease and related special health issue referred to in paragraph 1.

5. The Commission shall, by means of implementing acts, establish and update:

[1] OJ L 298, 26.10.2012, p. 1.
[2] OJ L 362, 31.12.2012, p. 1.

(a) the list of communicable diseases and related special health issues established according to the criteria set out in the Annex and referred to in points (i) and (ii) of point (a) of Article 2(1), in order to ensure coverage of communicable diseases and related special health issues by the epidemiological surveillance network;

(b) case definitions concerning each communicable disease and related special health issue subject to epidemiological surveillance, in order to ensure the comparability and compatibility at Union level of the collected data;

(c) procedures for the operation of the epidemiological surveillance network as developed in application of Articles 5, 10 and 11 of Regulation (EC) No 851/2004.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 18(2).

On duly justified imperative grounds of urgency related to the severity or novelty of a serious cross-border threat to health or to the rapidity of its spread between the Member States, the Commission may adopt the measures referred to in points (a) and (b) through immediately applicable implementing acts in accordance with the procedure referred to in Article 18(3).

Article 7

Ad hoc monitoring

1. Following an alert notified pursuant to Article 9 concerning a threat to health as referred to in point (iii) of point (a) of Article 2(1) and in points (b), (c) or (d) of Article 2(1), the Member States shall, in liaison with the Commission and on the basis of the available information from their monitoring systems, inform each other through the EWRS and, if the urgency of the situation so requires, through the HSC about developments with regard to the threat concerned at national level.

2. The information transmitted pursuant to paragraph 1, shall include in particular any change in geographical distribution, spread and severity of the threat concerned and of the means of detection, if available.

3. The Commission shall, by means of implementing acts, adopt, where necessary, the case definitions to be used for ad hoc monitoring, in order to ensure the comparability and compatibility at Union level of the collected data.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 18(2).

On duly justified imperative grounds of urgency related to the severity of a serious cross-border threat to health or to the rapidity of its spread between the Member States, the Commission may adopt or update the case definitions referred to in the first subparagraph through immediately applicable implementing acts in accordance with the procedure referred to in Article 18(3).

CHAPTER IV

EARLY WARNING AND RESPONSE

Article 8

Establishment of an early warning and response system

1. A rapid alert system for notifying at Union level alerts in relation to serious cross-border threats to health, an 'Early Warning and Response System' (EWRS), is hereby established. The EWRS shall enable the Commission and the competent authorities responsible at national level to be in permanent communication for the purposes of alerting, assessing public health risks and determining the measures that may be required to protect public health.

2. The Commission shall, by means of implementing acts, adopt procedures concerning the information exchange in order to ensure the proper functioning of the EWRS and the uniform implementation of Articles 8 and 9 and to avoid overlap of activities or conflicting actions with existing structures and mechanisms for monitoring, early warning and combating serious cross-border threats to health.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 18(2).

Article 9

Alert notification

1. National competent authorities or the Commission shall notify an alert in the EWRS where the emergence or development of a serious cross-border threat to health fulfils the following criteria:

(a) it is unusual or unexpected for the given place and time, or it causes or may cause significant morbidity or mortality in humans, or it grows rapidly or may grow rapidly in scale, or it exceeds or may exceed national response capacity; and

(b) it affects or may affect more than one Member State; and

(c) it requires or may require a coordinated response at Union level.

2. Where the national competent authorities notify the WHO of events that may constitute public health emergencies of international concern in accordance with Article 6 of the IHR, they shall at the latest simultaneously notify an alert in the EWRS, provided that the threat concerned falls within those referred to in Article 2(1) of this Decision.

3. When notifying an alert, the national competent authorities and the Commission shall promptly communicate through the EWRS any available relevant information in their possession that may be useful for coordinating the response such as:

(a) the type and origin of the agent;

(b) the date and place of the incident or outbreak;

(c) means of transmission or dissemination;

(d) toxicological data;

(e) detection and confirmation methods;

(f) public health risks;

(g) public health measures implemented or intended to be taken at national level;

(h) measures other than public health measures;

(i) personal data necessary for the purpose of contact tracing in accordance with Article 16;

(j) any other information relevant to the serious cross-border threat to health in question.

4. The Commission shall make available to the national competent authorities through the EWRS any information that may be useful for coordinating the response referred to in Article 11, including information related to serious cross-border threats to health and public health measures related to serious cross-border threats to health transmitted through rapid alert and information systems established under other provisions of Union law or the Euratom Treaty.

Article 10

Public health risk assessment

1. Where an alert is notified pursuant to Article 9, the Commission shall, where necessary for the coordination of the response at Union level and upon request of the HSC referred to in Article 17 or on its own initiative, make promptly available to the national competent authorities and to the HSC, through the EWRS, a risk assessment of the potential severity of the threat to public health, including possible public health measures. That risk assessment shall be carried out by:

(a) the ECDC in accordance with Article 7(1) of Regulation (EC) No 851/2004 in the case of a threat referred to in points (i) and (ii) of point (a) of Article 2(1) or point (d) of Article 2(1); and/or

(b) the European Food Safety Authority (EFSA) in accordance with Article 23 of Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety [1] in the case of a threat referred to in Article 2 of this Decision where the threat falls under the mandate of the EFSA; and/or

(c) other relevant Union agencies.

2. Where the risk assessment needed is totally or partially outside the mandates of the agencies referred to in paragraph 1, and it is considered necessary for the coordination of the response at Union level, the Commission shall, upon request of the HSC or its own initiative, provide an ad hoc risk assessment.

The Commission shall make the risk assessment available to the national competent authorities promptly through the EWRS. Where the risk assessment is to be made public, the national competent authorities shall receive it prior to its publication.

The risk assessment shall take into account, if available, relevant information provided by other entities, in particular by the WHO in the case of a public health emergency of international concern.

3. The Commission shall ensure that information that may be relevant for the risk assessment is made available to the national competent authorities through the EWRS and to the HSC.

Article 11

Coordination of response

1. Following an alert pursuant to Article 9, on a request from the Commission or a Member State and on the basis of the available information, including the information referred to in Article 9 and the risk assessments referred to in Article 10, Member States shall consult each other within the HSC and in liaison with the Commission with a view to coordinating:

[1] OJ L 31, 1.2.2002, p. 1.

(a) national responses to the serious cross-border threat to health, including where a public health emergency of international concern is declared in accordance with the IHR and falls within Article 2 of this Decision;

(b) risk and crisis communication, to be adapted to Member State needs and circumstances, aimed at providing consistent and coordinated information in the Union to the public and to healthcare professionals.

2. Where a Member State intends to adopt public health measures to combat a serious cross-border threat to health, it shall, before adopting those measures, inform and consult the other Member States and the Commission on the nature, purpose and scope of the measures, unless the need to protect public health is so urgent that the immediate adoption of the measures is necessary.

3. Where a Member State has to adopt, as a matter of urgency, public health measures in response to the appearance or resurgence of a serious cross-border threat to health, it shall, immediately upon adoption, inform the other Member States and the Commission on the nature, purpose and scope of those measures.

4. In the event of a serious cross-border threat to health overwhelming the national response capacities, an affected Member State may also request assistance from other Member States through the Community Civil Protection Mechanism established by Decision 2007/779/EC, Euratom.

5. The Commission shall, by means of implementing acts, adopt the procedures necessary for the uniform implementation of the information exchange, consultation and coordination provided for in paragraphs 1 to 3.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 18(2).

CHAPTER V

EMERGENCY SITUATIONS

Article 12

Recognition of emergency situations

1. The Commission may recognise a situation of public health emergency in relation to:

(a) epidemics of human influenza considered to have pandemic potential, where the Director-General of the WHO has been informed and has not yet adopted a decision declaring a situation of pandemic influenza in accordance with the applicable rules of the WHO; or

(b) cases other than that referred to in point (a) where the Director-General of the WHO has been informed and has not yet adopted a decision declaring a public health emergency of international concern in accordance with the IHR, and where:

(i) the serious cross-border threat to health in question endangers public health at the Union level;

(ii) medical needs are unmet in relation to that threat, which means that no satisfactory method of diagnosis, prevention or treatment is authorised in the Union or, despite the existence of such a method, the authorisation of a medicinal product would nonetheless be of major therapeutic advantage to those affected.

2. The Commission shall adopt the measure referred to in paragraph 1 by means of implementing acts.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 18(2).

On duly justified imperative grounds of urgency related to the severity of a serious cross-border threat to health or to the rapidity of its spread among Member States, the Commission may recognise situations of public health emergency pursuant to paragraph 1 through immediately applicable implementing acts in accordance with the procedure referred to in Article 18(3).

3. The Commission shall inform the Director-General of the WHO of the adoption of the measures referred to in paragraph 1.

Article 13

Legal effects of recognition

The recognition of an emergency situation pursuant to Article 12(1) shall have the sole legal effect of enabling point 2 of Article 2 of Regulation (EC) No 507/2006 to apply or, where the recognition specifically concerns epidemics of human influenza considered as having a pandemic potential, of enabling Article 21 of Regulation (EC) No 1234/2008 to apply.

Article 14

Termination of the recognition

The Commission shall, by means of implementing acts, terminate the recognition referred to in Article 12(1) as soon as one of the applicable conditions laid down therein is no longer met.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 18(2).

Termination of the recognition, as referred to in the first paragraph, shall not affect the validity of marketing authorisations granted on the basis of Regulation (EC) No 507/2006 to medicinal products referred to in point 2 of Article 2 thereof or granted in accordance with the procedure referred to in Article 21 of Regulation (EC) No 1234/2008.

CHAPTER VI

PROCEDURAL PROVISIONS

Article 15

Designation of national authorities and representatives

1. Each Member State shall designate, by 7 March 2014:

(a) the competent authorities responsible within the Member State for epidemiological surveillance as referred to in Article 6;

(b) the competent authority or authorities responsible at national level for notifying alerts and determining the measures required to protect public health, for the purposes of Articles 8, 9 and 10;

(c) one representative and an alternate in the HSC referred to in Article 17.

2. Member States shall notify the Commission and other Member States of the designations referred to in paragraph 1 and of any change thereof. In the event of such change, the Commission shall distribute immediately to the HSC an updated list of such designations.

3. The Commission shall make publicly available the updated list of the authorities designated in accordance with points (a) and (c) of paragraph 1, as well as the updated list of the authorities to which the representatives in the HSC belong.

Article 16

Protection of personal data

1. In the application of this Decision, personal data shall be processed in accordance with Directive 95/46/EC and Regulation (EC) No 45/2001. In particular, appropriate technical and organisational measures shall be taken to protect such personal data against accidental or illegal destruction, accidental loss, or unauthorised access and against any form of illegal processing.

2. The EWRS shall include a selective messaging functionality allowing personal data to be communicated only to national competent authorities involved in contact tracing measures. That selective messaging functionality shall be designed and operated so as to ensure safe and lawful exchange of personal data.

3. Where competent authorities implementing contact tracing measures communicate personal data necessary for contact tracing purposes through the EWRS pursuant to Article 9(3), they shall use the selective messaging functionality referred to in paragraph 2 of this Article and communicate the data only to the other Member States involved in the contact tracing measures.

4. When circulating the information referred to in paragraph 3, the competent authorities shall refer to the alert communicated previously through the EWRS.

5. Messages containing personal data shall automatically be erased from the selective message functionality 12 months after the date of their posting.

6. Where a competent authority establishes that notification of personal data made by it pursuant to Article 9(3) has subsequently proved to be in breach of Directive 95/46/EC because that notification was unnecessary for the implementation of the contact tracing measures at issue, it shall inform immediately the Member States to which that notification was transmitted.

7. In relation to their responsibilities to notify and rectify personal data through the EWRS, the national competent authorities shall be regarded as controllers within the meaning of point (d) of Article 2 of Directive 95/46/EC.

8. In relation to its responsibilities concerning storage of personal data, the Commission shall be regarded as a controller within the meaning of point (d) of Article 2 of Regulation (EC) No 45/2001.

9. The Commission shall adopt:

(a) guidelines aimed at ensuring that the day-by-day operation of the EWRS complies with Directive 95/46/EC and Regulation (EC) No 45/2001;

(b) a recommendation providing an indicative list of the personal data that may be exchanged for the purpose of the coordination of contact tracing measures.

Article 17

Health Security Committee

1. A Health Security Committee, composed of representatives of the Member States designated under point (c) of Article 15(1), is hereby established.

2. The HSC shall have the following tasks:

(a) supporting the exchange of information between the Member States and the Commission on the experience acquired with regard to the implementation of this Decision;

(b) coordination in liaison with the Commission of the preparedness and response planning of the Member States in accordance with Article 4;

(c) coordination in liaison with the Commission of the risk and crisis communication and responses of the Member States to serious cross-border threats to health, in accordance with Article 11.

3. The HSC shall be chaired by a representative of the Commission. The HSC shall meet at regular intervals and whenever the situation requires, on a request from the Commission or a Member State.

4. The secretariat shall be provided by the Commission.

5. The HSC shall adopt, by a majority of two thirds of its members, its rules of procedure. Those rules of procedure shall establish working arrangements, in particular with regard to:

(a) the procedures for plenary meetings at high level and working groups;

(b) the participation of experts in plenary meetings, the status of observers, including from third countries;

(c) the arrangements for the HSC to examine the relevance to its mandate of a matter submitted to it and the possibility of recommending referral of that matter to a body competent under a provision of another act of the Union or under the Euratom Treaty; those arrangements shall not affect the obligations of the Member States under Articles 4 and 11 of this Decision.

Article 18

Committee procedure

1. The Commission shall be assisted by a committee on serious cross-border threats to health. That Committee shall be a committee within the meaning of Article 3(2) of Regulation (EU) No 182/2011.

2. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.

Where the Committee delivers no opinion, the Commission shall not adopt the draft implementing act and the third subparagraph of Article 5(4) of Regulation (EU) No 182/2011 shall apply.

3. Where reference is made to this paragraph, Article 8 of Regulation (EU) No 182/2011, in conjunction with Article 5 thereof, shall apply.

Article 19

Reports concerning this Decision

The Commission shall submit to the European Parliament and the Council by 7 November 2015, and every three years thereafter a report on the implementation of this Decision. The report shall include, in particular, an assessment of the operation of the EWRS and of the epidemiological surveillance network, as well as information on how the mechanisms and structures established under this Decision complement other alert systems at Union level and under the Euratom Treaty to protect public health effectively, while avoiding structural duplications. The Commission may accompany the report with proposals to modify the relevant Union provisions.

CHAPTER VII

FINAL PROVISIONS

Article 20

Repeal of Decision No 2119/98/EC

1. Decision No 2119/98/EC is hereby repealed.

2. References to the repealed Decision shall be construed as references to this Decision.

Article 21

Entry into force

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

Article 22

Addressees

This Decision is addressed to the Member States.

Done at Strasbourg, 22 October 2013.

For the European Parliament	*For the Council*
The President	*The President*
M. SCHULZ	V. LEŠKEVIČIUS

ANNEX

Criteria for selection of communicable diseases and related special health issues to be covered by epidemiological surveillance within the network

1. Communicable diseases and related special health issues that cause, or have the potential to cause, significant morbidity or mortality, or both, across the Union, especially where the prevention of those diseases requires an approach to coordination at Union level.

2. Communicable diseases and related special health issues where the exchange of information may provide early warning of threats to public health.

3. Rare and serious communicable related diseases and special health issues which would not be recognised at national level and where the pooling of data would allow hypothesis generation from a wider knowledge base.

4. Communicable diseases and related special health issues for which effective preventive measures are available with a protective health gain.

5. Communicable diseases and related special health issues for which a comparison by Member States would contribute to the evaluation of national and Union programmes.

II

(Non-legislative acts)

REGULATIONS

COMMISSION DELEGATED REGULATION (EU) No 1083/2013

of 28 August 2013

establishing rules related to the procedure for temporary withdrawal of tariff preferences and adoption of general safeguard measures under Regulation (EU) No 978/2012 of the European Parliament and the Council applying a scheme of generalised tariff preferences

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 207 thereof,

Having regard to Regulation (EU) No 978/2012 of the European Parliament and of the Council of 25 October 2012 applying a scheme of generalised tariff preferences and repealing Council Regulation (EC) No 732/2008 [1], and in particular Articles 15(12), 19(14), and 22(4) thereof,

Whereas:

To ensure the transparency and predictability of the temporary withdrawal of preferences and of the adoption of general safeguards, the Commission has been empowered by the European Parliament and the Council to adopt a delegated act to establish rules, in particular, with respect to deadlines, rights of parties, confidentiality and review,

HAS ADOPTED THIS REGULATION:

CHAPTER I

RULES RELATED TO THE PROCEDURE FOR TEMPORARY WITHDRAWAL OF TARIFF PREFERENCES

Article 1

Examination of information

1. The Commission shall seek all information it considers necessary, including, inter alia, the conclusions and recommendations of the relevant monitoring bodies. In drawing its conclusions, the Commission shall assess all relevant information

2. The Commission shall provide a reasonable period of time within which third parties may make their views known in writing by sending the relevant information to the Commission. This period shall be specified in the notice announcing the initiation of the procedure for temporary withdrawal. The Commission shall take into account the views submitted by those third parties where they are backed by sufficient evidence.

3. Where the Commission finds that the beneficiary country concerned or any third party which has come forward in accordance with paragraph 2 has supplied it with false or misleading information, it shall disregard that information.

Article 2

Constituted file

1. Where the Commission has initiated the procedure for the temporary withdrawal of the tariff preferences it shall establish a constituted file. A constituted file shall contain the documents which are relevant for drawing conclusions, including, information provided by the concerned GSP beneficiary country, GSP + beneficiary country or EBA beneficiary country (the 'beneficiary country'), information submitted by third parties which have come forward in accordance with Article 1(2) and any relevant information obtained by the Commission.

2. The beneficiary country and the third parties which have submitted information supported by sufficient evidence in accordance with Article 1(2) have the right of access to the constituted file upon written request. They may inspect all information contained in the constituted file except internal documents prepared by the Union institutions or Member States authorities and with due regard to the confidentiality obligations contained in Article 38 of Regulation (EU) No 978/2012 (GSP Regulation).

3. The content of a constituted file shall comply with provisions of confidentiality in accordance with Article 38 of the GSP Regulation

[1] OJ L 303, 31.10.2012, p. 1.

Article 3

Obligation to cooperate for GSP + beneficiary countries

1. Where the Commission has initiated the procedure for the temporary withdrawal of the tariff preferences provided under the special incentive arrangement for sustainable development and good governance (GSP+), the GSP + beneficiary country concerned shall submit all necessary information providing proof of compliance with obligations resulting from its binding undertakings within a period provided in the Commission's notice.

2. Lack of cooperation of the GSP + beneficiary country concerned shall not impede the right of the access to the constituted file.

3. If the GSP + beneficiary country concerned refuses to cooperate, or does not provide the necessary information within the relevant time limit or significantly impedes the procedure, the Commission findings, affirmative or negative, may be made on the basis of the facts available.

Article 4

General hearing

1. The beneficiary country concerned and third parties which have submitted information supported by sufficient evidence in accordance with Article 1(2) have the right to be heard by the Commission.

2. They shall submit a written request specifying the reasons for them to be heard orally. Such a request shall be received by the Commission at the latest one month after the date of initiation of a temporary withdrawal procedure.

Article 5

Involvement of the Hearing Officer

1. The beneficiary country concerned and third parties which have submitted information supported by sufficient evidence in accordance with Article 1(2) may also request the intervention of the Hearing Officer. The Hearing Officer shall review requests for access to the constituted file, disputes on the confidentiality of documents, requests for extension of time limits and requests to be heard.

2. Third parties which have submitted information supported by sufficient evidence in accordance with Article 1(2) may request the intervention of the Hearing Officer to verify whether their observations have been considered by the Commission. The written request shall be submitted no later than 10 days after expiry of the period provided to make their views known.

3. If the beneficiary country concerned or third parties which have submitted information supported by sufficient evidence in accordance with Article 1(2)) have an oral hearing with the Hearing Officer the relevant Commission service shall participate in it.

Article 6

Disclosure for investigations under Article 15 of the GSP Regulation

1. The Commission shall disclose to the GSP + beneficiary country concerned the details underlying the essential facts and considerations on the basis of which the Commission intends to take decisions pursuant to article 15(8) and 15(9) of the GSP Regulation.

2. Disclosure shall be given in writing. It shall contain the Commission's findings and shall reflect its provisional intention whether to terminate the temporary withdrawal procedure or to temporarily withdraw the tariff preferences.

3. Disclosure shall be made, with due regard to the protection of confidential information in accordance with Article 38 of the GSP Regulation, as soon as possible and, normally, not later than 45 days prior to a definitive decision by the Commission of any proposal for final action. Where the Commission is not in a position to disclose certain facts or considerations at that time, these shall be disclosed as soon as possible thereafter.

4. Disclosure shall not prejudice any subsequent decision which may be taken but where such a decision is based on any different facts and considerations, these shall be disclosed as soon as possible.

5. Submissions made after disclosure shall be taken into consideration only if received within a period to be set by the Commission in each case, which shall be at least 14 days after disclosure, due consideration being given to the urgency of the matter.

Article 7

Review

1. Where the tariff preferences have been temporarily withdrawn from a beneficiary country, the beneficiary country concerned may submit a written request for reinstatement of the tariff preferences if it considers that the reasons justifying temporary withdrawal no longer apply.

2. The Commission may review the need for the temporary withdrawal of preferences wherever it considers that the conditions for such withdrawal are no longer met.

3. The provisions of this chapter shall apply *mutatis mutandis* to the review of temporary withdrawal of tariff preferences.

CHAPTER II

RULES RELATED TO THE PROCEDURE FOR ADOPTING THE GENERAL SAFEGUARD MEASURES

Article 8

Initiation of investigation on request

1. A request for the initiation of a safeguard investigation shall be submitted in writing, in confidential and non-confidential form. It shall contain such information as is reasonably available to the requesting party on the following:

(a) the identity of the complaining Union producers and a description of the volume and value of their Union production of the like product or directly competing product. Where a written complaint is made on their behalf, the complaint shall identify the Union producers on behalf of which the complaint is made. The complaint shall also list other known producers (or associations of Union producers of the like product) in the Union which are not complaining, and describe the volume and value of their Union production;

(b) a complete description of the like product, the name of the beneficiary country concerned, the identity of each known exporter or foreign producer and a list of known persons importing the product in question;

(c) information on levels and trends of volumes and prices of the imports of the like product originating in the beneficiary country concerned. This information shall distinguish amongst preferential imports under the GSP Regulation, other preferential imports, and imports not enjoying preferences;

(d) information on the situation of the complaining Union producers, on the basis of the factors listed in Article 23 of the GSP Regulation;

(e) information on the effect the imports as described under (c) have had on the complaining Union producers, due account being taken of other additional factors affecting the situation of Union producers.

2. The request together with the accompanying documents shall be submitted to the Commission's mail reception service:

Central mail service (Courrier central)
Bâtiment DAV1
Avenue du Bourget 1/Bourgetlaan 1
1140 Bruxelles/Brussel
BELGIQUE/BELGIË

The request shall be deemed to have been lodged on the first working day following its delivery to the Commission by registered mail or the issuing of an acknowledgement of receipt by the Commission.

The Commission shall send to the Member States a copy of the request once it has been received.

3. In addition to the formal written submission, the request and the accompanying documents shall also be submitted in electronic format. Any request submitted exclusively in electronic format will not be considered valid for the purposes of this Regulation.

4. The authorities shall avoid, unless a decision has been made to initiate an investigation, any publicising of the request seeking the initiation of an investigation. However, after receipt of a properly documented request and before proceeding to initiate an investigation, the government of the exporting country concerned shall be notified.

5. The request may be withdrawn prior to initiation, in which case it shall be considered not to have been lodged.

Article 9

Ex officio initiation of investigation

Commission can initiate an investigation without request on the basis of sufficient *prima facie* evidence that the conditions for imposing the safeguard measure set out in Article 22(1) of GSP Regulation are met.

Article 10

Information on initiation of investigation

1. The notice of initiation published in the *Official Journal of the European Union* shall:

(a) give a summary of the information received, and require that all relevant information is to be communicated to the Commission;

(b) state the period within which interested parties may make known their views in writing and submit information, in order for such views and information to be taken into account during the investigation;

(c) state the period of investigation, which shall normally, cover a period of no less than 3 years immediately prior to the initiation of the investigation proceeding. Information relating to a period subsequent to the investigation period shall, normally, not be taken into account;

(d) state the period within which interested parties may apply to be heard orally by the Commission;

(e) state the period within which interested parties may request the intervention of the Hearing Officer.

2. The Commission shall advise the exporters, importers and representative associations of importers or exporters known to it to be concerned, as well as representatives of the beneficiary country concerned and the complaining Union producers, of the initiation of the investigation and, with due regard to the protection of confidential information, provide the full text of the written complaint to the known exporters and to the authorities of the exporting country, and make it available upon request to other interested parties involved. Where the number of exporters involved is particularly high, the full text

of the written complaint may instead be provided only to the authorities of the exporting country or to the relevant trade association.

Article 11

Investigation

1. The Commission shall seek all information which it deems necessary to carry out an investigation.

2. Interested parties may make their views known in writing by sending the relevant information to the Commission. Those views shall be taken into consideration where they are backed by sufficient evidence. The Commission may verify the information received with the beneficiary country concerned and any interested party.

3. Parties receiving questionnaires used in the investigation shall be given at least 30 days to reply. An extension to the 30 day period may be granted, due account being taken of the time-limits of the investigation, provided that the party shows due cause for such extension, in terms of its particular circumstances.

4. The Commission may request Member States to supply information, and Member States shall take whatever steps are necessary in order to give effect to such requests.

5. The Commission may request Member States to carry out all necessary checks and inspections, particularly amongst importers, traders and Union producers, and to carry out investigations in third countries, provided that the economic operators concerned give their consent and that the government of the country in question has been officially notified and raises no objection. Member States shall take whatever steps are necessary in order to give effect to such requests from the Commission. Officials of the Commission shall be authorised, if the Commission or a MemberStateso requests, to assist the officials of Member States in carrying out their duties.

6. In cases where the number of interested parties, types of product or transactions is large, the investigation may be limited to a reasonable number of parties, products or transactions by using samples which are statistically valid on the basis of information available at the time of the selection, or to the largest representative volume of production, sales or exports which can reasonably be investigated within the time available. The final selection of parties, types of products or transactions made under these sampling provisions shall rest with the Commission, though preference shall be given to choosing a sample in consultation with, and with the consent of, the parties concerned, provided such parties make themselves known and make sufficient information available to enable a representative sample to be chosen. Where it is decided to sample and there is a degree of non-cooperation by some or all of the parties selected which is likely to materially affect the outcome of the investigation, a new sample may be selected. However, if a material degree of non-cooperation persists or there is insufficient time to select a new sample, the relevant provisions of Article 13 shall apply.

Article 12

Verification visits

1. The Commission may carry out visits to examine the records of importers, exporters, traders, agents, producers, trade associations and organisations and other interested parties to verify information provided on products that may require safeguard measures.

2. The Commission may carry out investigations in third countries as required, provided that it obtains the agreement of the economic operators concerned, that it notifies the representatives of the government of the country in question and that the latter does not object to the investigation. As soon as the agreement of the economic operators concerned has been obtained the Commission should notify the authorities of the exporting country of the names and addresses of the economic operators to be visited and the dates agreed.

3. The economic operators concerned shall be advised of the nature of the information to be verified during verification visits and of any information which needs to be provided during such visits. Further information may be requested.

4. In investigations carried out pursuant to paragraphs 1, 2 and 3, the Commission shall be assisted by officials of those Member States who so request.

Article 13

Non-cooperation

1. In cases in which any interested party refuses access to, or otherwise does not provide, necessary information within the time-limits provided in this Regulation, or significantly impedes the investigation, findings, affirmative or negative, may be made on the basis of the facts available. Where it is found that any interested party has supplied false or misleading information, the information shall be disregarded and use may be made of facts available. Interested parties shall be informed of the consequences of non-cooperation.

2. Where the information submitted by an interested party is not ideal in all respects it should nevertheless not be disregarded, provided that any deficiencies are not such as to cause undue difficulty in arriving at a reasonably accurate finding and that the information is appropriately submitted in good time and is verifiable, and that the party has acted to the best of its ability.

3. If evidence or information is not accepted, the supplying party shall be informed forthwith of the reasons therefor and shall be granted an opportunity to provide further explanations within the time-limit specified. If the explanations are considered unsatisfactory, the reasons for rejection of such evidence or information shall be disclosed and given in published findings.

4. If determinations are based on the provisions of paragraph 1, including the information supplied in the request, it shall, where practicable and with due regard to the time-limits of the investigation, be checked by reference to information from other independent sources which may be available, such as published price lists, official import statistics and customs returns, or information obtained from other interested parties during the investigation.

Such information may include relevant data pertaining to the world market or other representative markets, where appropriate.

5. If an interested party does not cooperate, or cooperates only partially, so that relevant information is thereby withheld, the result may be less favourable to the party than if it had cooperated.

Article 14

Constituted file

1. Where the Commission, in accordance with Article 24(2) of the GSP Regulation, has initiated an investigation, it shall establish a constituted file. A constituted file shall contain information submitted by the Member States, a beneficiary country, interested parties and the relevant information which has been obtained by the Commission and with due regard the confidentiality obligations contained in Article 38 of the GSP Regulation.

2. A beneficiary country concerned and interested parties which have come forward in accordance with Article 11(2) have a right of access to the constituted file upon written request. They may inspect all information contained in the constituted file except internal documents prepared by the authorities of the EU or its MemberStatesand with due regard to the confidentiality obligations contained in Article 38 of the GSP Regulation. They may respond to such information and their comments shall be taken into consideration, wherever they are sufficiently substantiated.

3. The content of a constituted file shall comply with provisions of confidentiality in accordance with Article 38 of the GSP Regulation.

Article 15

General hearing

1. A beneficiary country concerned and interested parties which have come forward in accordance with Article 11(2) have the right to be heard by the Commission.

2. They shall submit a written request within the period laid down in the notice published in the *Official Journal of the European Union*, showing that they are actually likely to be affected by the outcome of the investigation and that there are special reasons for them to be heard orally.

Article 16

Involvement of the Hearing Officer

1. A beneficiary country and interested parties which have come forward in accordance with Article 11(2) may also request the intervention of the Hearing Officer. The Hearing Officer shall review requests for access to the constituted file, disputes on the confidentiality of documents, requests for extension of time limits and requests to be heard.

2. If there is an oral hearing with the Hearing Officer the relevant Commission service shall participate in it.

Article 17

Disclosure

1. The Commission shall disclose the details underlying the essential facts and considerations on the basis of which the Commission's decisions are taken.

2. Disclosure shall be given in writing. It shall contain the Commission's findings and shall reflect its intention to reintroduce normal Common Customs Tariff duties or not.

3. Disclosure shall be made, with due regard to the protection of confidential information, as soon as possible and, normally, not later than 45 days prior to a definitive decision by the Commission of any proposal for final action and in any case at an appropriate time for the parties to make comments and for those comments to be considered by the Commission. Where the Commission is not in a position to disclose certain facts or considerations at that time, these shall be disclosed as soon as possible thereafter.

4. Disclosure shall not prejudice any subsequent decision which may be taken but where such decision is based on any different facts and considerations, these shall be disclosed as soon as possible.

5. Submissions made after disclosure is given shall be taken into consideration only if received within a period to be set by the Commission in each case, which shall be at least 14 days, due consideration being given to the urgency of the matter.

Article 18

Review

1. Wherever normal Common Custom Tariff duties have been reintroduced, any interested party may submit a written request for reinstatement of the tariff preferences providing *prima facie* evidence that the reasons justifying the reintroduction of normal duties no longer apply. Union producers may submit a written request for the extension of the period of reintroduction of the normal duties providing *prima facie* evidence that the reasons justifying the reintroduction of normal duties continue to apply.

2. The Commission may review the need for reinstatement of normal Common Custom Tariff duties wherever it considers such a review to be justified.

3. The provisions of this chapter shall apply *mutatis mutandis* to the review of the safeguard measures.

Article 19

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 August 2013.

For the Commission
The President
José Manuel BARROSO

COMMISSION IMPLEMENTING REGULATION (EU) No 1084/2013

of 30 October 2013

entering a name in the register of protected designations of origin and protected geographical indications [Plátano de Canarias (PGI)]

THE EUROPEAN COMMISSION,

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

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

Whereas:

(1) Regulation (EU) No 1151/2012 repealed and replaced Council Regulation (EC) No 510/2006 on the protection of geographical indications and designations of origin for agricultural products and foodstuffs [2].

(2) Pursuant to Article 6(2) of Regulation (EC) No 510/2006, Spain's application to register the name 'Plátano de Canarias' was published in the *Official Journal of the European Union* [3].

(3) As no statement of objection under Article 7 of Regulation (EC) No 510/2006 has been received by the Commission, the name 'Plátano de Canarias' should therefore be entered in the register,

HAS ADOPTED THIS REGULATION:

Article 1

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

Article 2

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

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

Done at Brussels, 30 October 2013.

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

[1] OJ L 343, 14.12.2012, p. 1.
[2] OJ L 93, 31.3.2006, p. 12.
[3] OJ C 372, 1.12.2012, p. 9.

ANNEX

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

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

SPAIN

Plátano de Canarias (PGI)

COMMISSION IMPLEMENTING REGULATION (EU) No 1085/2013

of 30 October 2013

entering a name in the register of protected designations of origin and protected geographical indications [Westfälischer Knochenschinken (PGI)]

THE EUROPEAN COMMISSION,

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

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

Whereas:

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

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

HAS ADOPTED THIS REGULATION:

Article 1

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

Article 2

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

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

Done at Brussels, 30 October 2013.

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

[1] OJ L 343, 14.12.2012, p. 1.
[2] OJ C 102, 9.4.2013, p. 8.

ANNEX

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

Class 1.2. Meat-based products

GERMANY

Westfälischer Knochenschinken (PGI)

COMMISSION IMPLEMENTING REGULATION (EU) No 1086/2013

of 30 October 2013

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

THE EUROPEAN COMMISSION,

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

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

Whereas:

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

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

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

HAS ADOPTED THIS REGULATION:

Article 1

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

Article 2

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

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

Done at Brussels, 30 October 2013.

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

([1]) OJ L 343, 14.12.2012, p. 1.
([2]) OJ L 163, 2.7.1996, p. 19.
([3]) OJ C 109, 16.4.2013, p. 12.

ANNEX

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

Class 1.3. Cheeses

ITALY

Raschera (PDO)

COMMISSION REGULATION (EU) No 1087/2013

of 4 November 2013

amending Regulation (EC) No 1005/2009 of the European Parliament and of the Council with regard to reporting on methyl bromide

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EC) No 1005/2009 of the European Parliament and of the Council of 16 September 2009 on substances that deplete the ozone layer [1], and in particular Article 26(3) thereof,

Whereas:

(1) According to Article 26(1)(a), Member States should report each year on the quantities of methyl bromide authorised for quarantine and pre-shipment pursuant to Article 12(2), as well as on the quantities of methyl bromide authorised in case of emergency pursuant to Article 12(3).

(2) The deadline of 18 March 2010 contained in Article 12(1) has elapsed and methyl bromide can no longer be placed on the market and used for quarantine and for pre-shipment applications. There is therefore no need to continue asking Member States to report each year on methyl bromide authorised for quarantine and pre-shipment pursuant to Article 12(2).

(3) The temporary authorisation of methyl bromide in emergency cases pursuant to Article 12(3) requires for each case a specific decision of the Commission. There is therefore no need to continue asking Member States to report each year, as the reporting obligation can be directly included in each specific decision.

(4) Article 26(1)(a) should therefore be deleted.

(5) The measures provided for in this Regulation are in accordance with the opinion of the Committee established by Article 25(1) of Regulation (EC) No 1005/2009,

HAS ADOPTED THIS REGULATION:

Article 1

Article 26(1)(a) of Regulation (EC) No 1005/2009 shall be deleted.

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, 4 November 2013.

For the Commission
The President
José Manuel BARROSO

[1] OJ L 286, 31.10.2009, p. 1.

COMMISSION REGULATION (EU) No 1088/2013

of 4 November 2013

amending Regulation (EC) No 1005/2009 of the European Parliament and of the Council with regard to applications for import and export licences of products and equipment containing or relying on halons for critical uses in aircraft

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EC) No 1005/2009 of the European Parliament and of the Council of 16 September 2009 on substances that deplete the ozone layer [1], and in particular Article 18(9) thereof,

Whereas:

(1) Imports and exports of products and equipment containing or relying on halons for critical uses in aircraft set out in points 4.1 to 4.6 of Annex VI to Regulation (EC) No 1005/2009 are subject to licences.

(2) Article 18(3) of Regulation (EC) No 1005/2009 sets out the list of items that need to be included in an application for a licence. The level of detail of that list requires, in practice, a separate licence for each export and each import.

(3) In the case of products and equipment containing or relying on halons for the critical uses in aircraft set out in points 4.1 to 4.6 of Annex VI to Regulation (EC) No 1005/2009, the obligation to have a separate licence for each export and import has raised concerns due to timing issues specific to the aviation sector, as in some cases, licences are needed within a very short time to avoid grounding of flights. Compared to other sectors of critical uses of halons, the aviation sector is by its nature importing and exporting more frequently and the process is very repetitive.

(4) Imports and exports of products and equipment containing or relying on halons for the critical uses in aircraft set out in points 4.1 to 4.6 of Annex VI to Regulation (EC) No 1005/2009 are not subject to quantitative limits, and therefore do not require separate licences for each export and import to be cross-checked against the quantitative limits.

(5) Fire extinguishing systems on-board of aircraft are regulated by the Convention on International Civil Aviation which establishes common minimum standards for operation of aircraft and airworthiness of aircraft in its Annex 6 and in its Annex 8, and by 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 [2].

(6) Therefore, for the specific case of products and equipment containing or relying on halons for critical uses in aircraft set out in points 4.1 to 4.6 of Annex VI to Regulation (EC) No 1005/2009, the list of items required in an application for a licence should be simplified in order to allow the issue of general licences rather than separate licences for each import and export.

(7) Regulation (EC) No 1005/2009 should therefore be amended accordingly.

(8) The measures provided for in this Regulation are in accordance with the opinion of the Committee established by Article 25(1) of Regulation (EC) No 1005/2009,

HAS ADOPTED THIS REGULATION:

Article 1

In Article 18(3) of Regulation (EC) No 1005/2009, the following point (j) is added:

'(j) by way of derogation from points (a) to (h), in the case of imports and exports of products and equipment containing or relying on halons for critical uses in aircraft set out in points 4.1 to 4.6 of Annex VI:

(1) the purpose and type of the products and equipment to be imported or exported as described in points 4.1 to 4.6 of Annex VI;

[1] OJ L 286, 31.10.2009, p. 1.

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

(2) the types of halons that the products and equipment to be imported or exported contains or relies on;

(3) the Combined Nomenclature code of the products and equipment to be imported or exported.'.

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, 4 November 2013.

For the Commission
The President
José Manuel BARROSO

COMMISSION IMPLEMENTING REGULATION (EU) No 1089/2013

of 4 November 2013

amending Implementing Regulation (EU) No 540/2011 as regards the conditions of approval of the active substance kieselgur (diatomaceous earth)

(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 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC [1], and in particular Article 13(2)(c) and Article 78(2) thereof,

Whereas:

(1) The active substance kieselgur (diatomaceous earth) was included in Annex I to Council Directive 91/414/EEC [2] by Commission Directive 2008/127/EC [3] in accordance with the procedure provided for in Article 24b of Commission Regulation (EC) No 2229/2004 [4]. Since the replacement of Directive 91/414/EEC by Regulation (EC) No 1107/2009, this substance is deemed to have been approved under that Regulation and is listed in Part A of the Annex to Commission Implementing Regulation (EU) No 540/2011 [5].

(2) In accordance with Article 25a of Regulation (EC) No 2229/2004, the European Food Safety Authority, hereinafter 'the Authority', presented to the Commission its view on the draft review report for kieselgur (diatomaceous earth) on 22 June 2012. The Authority communicated its view on kieselgur (diatomaceous earth) to the notifier. The Commission invited it to submit comments on the draft review report for kieselgur (diatomaceous earth). The draft review report and the view of the Authority were reviewed by the Member States and the Commission within the Standing Committee on the Food Chain and Animal Health and the draft review report was finalised on 3 October 2013 in the format of the Commission review report for kieselgur (diatomaceous earth).

(3) It is confirmed that the active substance kieselgur (diatomaceous earth) is to be deemed to have been approved under Regulation (EC) No 1107/2009.

(4) In accordance with Article 13(2) of Regulation (EC) No 1107/2009 in conjunction with Article 6 thereof and in the light of current scientific and technical knowledge, it is necessary to amend the conditions of approval. It is, in particular, appropriate to require further confirmatory information.

(5) The Annex to Implementing Regulation (EU) No 540/2011 should therefore be amended accordingly.

(6) Member States should be provided with time to amend or withdraw authorisations for plant protection products containing kieselgur (diatomaceous earth).

(7) For plant protection products containing kieselgur (diatomaceous earth), where Member States grant any grace period in accordance with Article 46 of Regulation (EC) No 1107/2009, this period should expire at the latest eighteen months after the date of entry into force of the Regulation.

(8) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS REGULATION:

Article 1

Amendment to Implementing Regulation (EU) No 540/2011

Part A of the Annex to Implementing Regulation (EU) No 540/2011 is amended in accordance with the Annex to this Regulation.

Article 2

Transitional measures

Member States shall in accordance with Regulation (EC) No 1107/2009, where necessary, amend or withdraw existing authorisations for plant protection products containing kieselgur (diatomaceous earth) as active substance by 25 May 2014.

[1] OJ L 309, 24.11.2009, p. 1.
[2] Council Directive 91/414/EEC of 15 July 1991 on the placing on the market of plant protection products (OJ L 230, 19.8.1991, p. 1).
[3] Commission Directive 2008/127/EC of 18 December 2008 amending Council Directive 91/414/EEC to include several active substances (OJ L 344, 20.12.2008, p. 89).
[4] Commission Regulation (EC) No 2229/2004 of 3 December 2004 laying down further detailed rules for the implementation of the fourth stage of the programme of work referred to in Article 8(2) of Council Directive 91/414/EEC (OJ L 379, 24.12.2004, p. 13).
[5] Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances (OJ L 153, 11.6.2011, p. 1).

Article 3

Grace period

Any grace period granted by Member States in accordance with Article 46 of Regulation (EC) No 1107/2009 shall be as short as possible and shall expire by 25 May 2015 at the latest.

Article 4

Entry into force

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

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

Done at Brussels, 4 November 2013.

For the Commission
The President
José Manuel BARROSO

ANNEX

In Part A of the Annex to Implementing Regulation (EU) No 540/2011, row 236 on the active substance kieselgur (diatomaceous earth) is replaced by the following:

Number	Common name, Identification numbers	IUPAC name	Purity	Date of approval	Expiration of approval	Specific provisions
'236	Kieselgur (diatomaceous earth) CAS No 61790-53-2 CIPAC No 647	Kieselgur (no IUPAC name) Diatomaceous earth Amorphous silicon dioxide Silica Diatomite	The product consists of 100 % diatomaceous earth. Maximum 0,1 % of particles of crystalline silica with diameter below 50 μm	1 September 2009	31 August 2019	PART A Only indoor uses as insecticide and acaricide by professional users may be authorised. PART B For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on kieselgur (diatomaceous earth) (SANCO/2617/2008) and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 3 October 2013 shall be taken into account. In this overall assessment Member States shall pay particular attention to the safety of operators and workers. Conditions of use shall include the application of adequate personal and respiratory protective equipment. Where necessary, conditions of use shall prohibit the presence of workers after application of the product concerned for a period appropriate in view of the risks caused by that product. The Member States concerned shall ensure that the notifiers submit, by 25 November 2015, to the Commission, the Member States and the Authority information concerning the inhalation toxicity to confirm the occupational limits of kieselgur (diatomaceous earth).'

COMMISSION IMPLEMENTING REGULATION (EU) No 1090/2013

of 4 November 2013

entering a name in the register of protected designations of origin and protected geographical indications [Travia da Beira Baixa (PDO)]

THE EUROPEAN COMMISSION,

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

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

Whereas:

(1) Regulation (EU) No 1151/2012 of the European Parliament and of the Council of 21 November 2012 entered into force on 3 January 2013. It repealed and replaced Council Regulation (EC) No 510/2006 of 20 March 2006 on the protection of geographical indications and designations of origin for agricultural products and foodstuffs [2].

(2) Pursuant to Article 6(2) of Regulation (EC) No 510/2006, Portugal's application to register the name 'Travia da Beira Baixa' was published in the *Official Journal of the European Union* [3].

(3) As no statement of objection under Article 7 of Regulation (EC) No 510/2006 has been received by the Commission, the name 'Travia da Beira Baixa' should therefore be entered in the register,

HAS ADOPTED THIS REGULATION:

Article 1

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

Article 2

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

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

Done at Brussels, 4 November 2013.

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

[1] OJ L 343, 14.12.2012, p. 1.
[2] OJ L 93, 31.3.2006, p. 12.
[3] OJ C 353, 17.11.2012, p. 14.

ANNEX

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

Class 1.4. Other products of animal origin (milk products)

PORTUGAL

Travia da Beira Baixa (PDO)

COMMISSION IMPLEMENTING REGULATION (EU) No 1091/2013

of 4 November 2013

amending for the 206th 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), 7a(1) 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 18 October 2013 the Sanctions Committee of the United Nations Security Council (UNSC) decided to add one natural person and one entity to its list of persons, groups and entities to whom the freezing of funds and economic resources should apply. On 24 October 2013 the Sanctions Committee of the UNSC decided to add another natural person to its list. Furthermore, on 16 October, the Sanctions Committee of the UNSC decided to amend one entry on the list.

(3) Annex I to Regulation (EC) No 881/2002 should therefore be updated accordingly,

(4) In order to ensure that the measures provided for in this Regulation are effective, it should enter into force immediately,

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 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, 4 November 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:

(1) The following entries shall be added under the heading 'Natural persons':

(a) 'Muhammad Jamal Abd-Al Rahim Ahmad **Al-Kashif** (*alias* (a) Muhammad Jamal Abdo Al-Kashif, (b) Muhammad Jamal Abdo Al Kashef, (c) Muhammad Jamal Abd-Al Rahim Ahmad Al-Kashif, (d) Muhammad Jamal Abd-Al Rahim Al-Kashif, (e) Muhammad Jamal Abdu, (f) Muhammad Jamal, (g) Muhammad Jamal Abu Ahmad (nom de guerre), (h) Abu Ahmad (nom de guerre), (i) Abu Jamal (nom de guerre), (j) Muhammad Gamal Abu Ahmed, (k) Mohammad Jamal Abdo Ahmed (nom de guerre), (l) Muhammad Jamal Abduh (nom de guerre), (m) Muhammad Jamal Ahmad Abdu (nom de guerre), (n) Riyadh (nom de guerre)). Address: Egypt. Date of birth: (a) 1.1.1964, (b) 1.2.1964. Place of birth: Cairo, Egypt. Nationality: Egyptian. Passport no.: (a) Egyptian passport number 6487, issued 30 Jan. 1986, under name Muhammad Jamal Abdu, (b) Egyptian passport issued in 1993, under name Muhammad Jamal Abd-Al Rahim Ahmad Al-Kashif, (c) Yemeni passport number 388181, under name Muhammad Jamal Abd-Al Rahim Al-Kashif. Date of designation referred to in Article 2a (4) (b): 21 Oct. 2013.'

(b) 'Mohamed **Lahbous** (*alias* (a) Mohamed Ennouini, (b) Hassan, (c) Hocine). Date of birth: 1978. Place of birth: Mali. Nationality: Malian. Address: Mali. Date of designation referred to in Article 2a (4) (b): 24 Oct. 2013.'

(2) The following entry shall be added under the heading 'Legal persons, groups and entities':

'**Muhammad Jamal Network** (*alias* (a) MJN, (b) Muhammad Jamal Group, (c) Jamal Network, (d) Abu Ahmed Group, (e) Al-Qaida in Egypt, (f) AQE. Other information: Operates in Egypt, Libya, and Mali. Date of designation referred to in Article 2a (4) (b): 21 Oct. 2013.'

(3) The entry 'Mati ur-Rehman Ali Muhammad (*alias* (a) Mati-ur Rehman, (b) Mati ur Rehman, (c) Matiur Rahman, (d) Matiur Rehman, (e) Matti al-Rehman, (f) Abdul Samad, (g) Samad Sial, (h) Abdul Samad Sial, (i) Ustad Talha, (j) Qari Mushtaq, (k) Tariq, (l) Hussain). Date of birth: Approximately 1977. Place of birth: Chak number 36/DNB, Rajkan, Madina Colony, Bahawalpur District, Punjab Province, Pakistan. Nationality: Pakistani. Date of designation referred to in Article 2a(4)(b): 22.8.2011.' under the heading 'Natural persons' shall be replaced by the following:

'Mati ur-Rehman **Ali Muhammad** (*alias* (a) Mati-ur Rehman, (b) Mati ur Rehman, (c) Matiur Rahman, (d) Matiur Rehman, (e) Matti al-Rehman, (f) Abdul Samad, (g) Samad Sial, (h) Abdul Samad Sial, (i) Ustad Talha, (j) Qari Mushtaq, (k) Tariq, (l) Hussain). Date of birth: Approximately 1977. Place of birth: Chak number 36/DNB, Rajkan, Madina Colony, Bahawalpur District, Punjab Province, Pakistan. Nationality: Pakistani. Other information: Physical description: 5 feet 2 inches; 157,4 cm. Name of father: Ali Muhammad. Date of designation referred to in Article 2a(4)(b): 22.8.2011.'

COMMISSION IMPLEMENTING REGULATION (EU) No 1092/2013

of 4 November 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, 4 November 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	50,8
	MA	41,9
	MK	59,5
	TR	75,3
	ZZ	56,9
0707 00 05	AL	54,1
	EG	180,4
	MK	66,2
	TR	147,3
	ZZ	112,0
0709 93 10	AL	50,7
	TR	120,6
	ZZ	85,7
0805 50 10	CL	81,7
	TR	80,7
	ZA	54,2
	ZZ	72,2
0806 10 10	BR	225,0
	TR	173,7
	ZZ	199,4
0808 10 80	CL	210,3
	NZ	175,8
	US	146,6
	ZA	122,1
	ZZ	163,7
0808 30 90	CN	85,6
	TR	119,7
	ZZ	102,7

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

DECISIONS

COMMISSION IMPLEMENTING DECISION

of 31 October 2013

amending Decisions 2005/734/EC, 2006/415/EC and 2007/25/EC as regards their period of application

(notified under document C(2013) 7148)

(Text with EEA relevance)

(2013/635/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,

Having regard to Regulation (EC) No 998/2003 of the European Parliament and of the Council of 26 May 2003 on the animal health requirements applicable to the non-commercial movement of pet animals and amending Council Directive 92/65/EEC ([3]), and in particular Article 18 thereof,

Having regard to Council Directive 2005/94/EC of 20 December 2005 on Community measures for the control of avian influenza and repealing Directive 92/40/EEC ([4]), and in particular Article 63(3) thereof,

([1]) OJ L 395, 30.12.1989, p. 13.
([2]) OJ L 224, 18.8.1990, p. 29.
([3]) OJ L 146, 13.6.2003, p. 1.
([4]) OJ L 10, 14.1.2006, p. 16.

Whereas:

(1) Commission Decisions 2005/734/EC ([5]), 2006/415/EC ([6]) and 2007/25/EC ([7]) were adopted in relation to outbreaks of highly pathogenic avian influenza of the subtype H5N1 with a view to protecting animal and human health in the Union.

(2) Decision 2005/734/EC lays down biosecurity measures to reduce the risk of transmission of highly pathogenic avian influenza of the subtype H5N1 from birds living in the wild to poultry and other captive birds and provides for an early detection system in areas at particular risk. Decision 2006/415/EC lays down certain protection measures to be applied in case of an outbreak of highly pathogenic avian influenza of the subtype H5N1 in poultry in a Member State, including the establishment of areas A and B following a suspected or confirmed outbreak of that disease. In addition, Decision 2007/25/EC concerns certain protection measures in relation to highly pathogenic avian influenza and movements of pet birds accompanying their owners into the Union.

(3) The measures laid down in those Decisions apply until 31 December 2013. However, outbreaks of highly pathogenic avian influenza of the subtype H5N1 in wild birds and in poultry continue to occur in third countries thereby also posing a risk to animal and human health in the Union.

([5]) Commission Decision 2005/734/EC of 19 October 2005 laying down biosecurity measures to reduce the risk of transmission of highly pathogenic avian influenza caused by Influenza virus A subtype H5N1 from birds living in the wild to poultry and other captive birds and providing for an early detection system in areas at particular risk (OJ L 274, 20.10.2005, p. 105).
([6]) Commission Decision 2006/415/EC of 14 June 2006 concerning certain protection measures in relation to highly pathogenic avian influenza of the subtype H5N1 in poultry in the Community and repealing Decision 2006/135/EC (OJ L 164, 16.6.2006, p. 51).
([7]) Commission Decision 2007/25/EC of 22 December 2006 as regards certain protection measures in relation to highly pathogenic avian influenza and movements of pet birds accompanying their owners into the Community (OJ L 8, 13.1.2007, p. 29).

(4) Given the epidemiological situation regarding highly pathogenic avian influenza of the H5N1 subtype, it is appropriate to continue mitigating the risks posed by that infection by maintaining biosecurity measures, early detection systems and certain protection measures in relation to outbreaks in poultry and the movement of pet birds from third countries to the Union.

(5) In addition, an external evaluation [1] of the Union's emergency response network during 2012 has demonstrated that protection measures in relation to outbreaks of avian influenza including those laid down in Decision 2006/415/EC adopted at Union level are considered relevant and effective by Member States.

(6) The period of application of Decisions 2005/734/EC, 2006/415/EC and 2007/25/EC should therefore be extended until 31 December 2015.

(7) Decisions 2005/734/EC, 2006/415/EC and 2007/25/EC should therefore be amended accordingly.

(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 Article 4 of Decision 2005/734/EC, the date '31 December 2013' is replaced by '31 December 2015'.

Article 2

In Article 12 of Decision 2006/415/EC, the date '31 December 2013' is replaced by '31 December 2015'.

Article 3

In Article 6 of Decision 2007/25/EC, the date '31 December 2013' is replaced by '31 December 2015'.

Article 4

This Decision is addressed to the Member States.

Done at Brussels, 31 October 2013.

For the Commission

Tonio BORG

Member of the Commission

[1] http://ec.europa.eu/food/animal/diseases/strategy/pillars/docs/23_final_report_eu_rapid_response.pdf

COMMISSION IMPLEMENTING DECISION

of 31 October 2013

amending Decision 2008/866/EC, on emergency measures suspending imports from Peru of certain bivalve molluscs intended for human consumption, as regards its period of application

(notified under document C(2013) 7162)

(Text with EEA relevance)

(2013/636/EU)

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety [1], and in particular Article 53(1)(b)(i) thereof,

Whereas:

(1) Regulation (EC) No 178/2002 lays down the general principles governing food and feed in general, and food and feed safety in particular, at Union and national level. It provides for emergency measures where it is evident that food or feed imported from a third country is likely to constitute a serious risk to human health, animal health or the environment, and that such risk cannot be contained satisfactorily by means of measures taken by the Member State(s) concerned.

(2) Commission Decision 2008/866/EC of 12 November 2008 on emergency measures suspending imports from Peru of certain bivalve molluscs intended for human consumption [2] was adopted following an outbreak of hepatitis A in humans related to the consumption of bivalve molluscs imported from Peru contaminated with hepatitis A virus (HAV). That Decision initially applied until 31 March 2009 but this period of application was extended until 30 November 2013 by Commission Implementing Decision 2012/729/EU of 23 November 2012 amending Decision 2008/866/EC, on emergency measures suspending imports from Peru of certain bivalve molluscs intended for human consumption, as regards its period of application [3].

(3) The Peruvian Competent Authority presented additional information regarding the corrective measures that have been implemented to address the deficiencies detected in the control system of certain bivalve molluscs. However, a number of outstanding issues remain. In particular, the monitoring programme results for the last year do not include the control of Donax clams (*Donax* spp.) which was found to be the origin of the outbreak. Therefore, it cannot be concluded that the guarantees provided by the Peruvian Competent Authority to date are sufficient to lift the emergency measure.

(4) The limit of application of Decision 2008/866/EC should therefore be amended accordingly.

(5) 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 Article 5 of Decision 2008/866/EC, the date '30 November 2013' is replaced by the date '30 November 2014'.

Article 2

This Decision is addressed to the Member States.

Done at Brussels, 31 October 2013.

For the Commission

Tonio BORG

Member of the Commission

[1] OJ L 31, 1.2.2002, p. 1.
[2] OJ L 307, 18.11.2008, p. 9.
[3] OJ L 327, 27.11.2012, p. 56.

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