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[1] Text with EEA relevance

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

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

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[1] Text with EEA relevance

II

(Non-legislative acts)

REGULATIONS

COUNCIL IMPLEMENTING REGULATION (EU) No 917/2013

of 23 September 2013

amending Implementing Regulation (EU) No 857/2010 imposing a definitive countervailing duty and collecting definitely the provisional duty imposed on imports of certain polyethylene terephthalate originating in Iran, Pakistan and the United Arab Emirates

THE COUNCIL OF THE EUROPEAN UNION,

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

Having regard to Council Regulation (EC) No 597/2009 of 11 June 2009 on protection against subsidised imports from countries not members of the European Community [1] ('the basic Regulation'), and in particular Article 15(1) thereof,

Having regard to the proposal from the European Commission after consulting the Advisory Committee,

Whereas:

A. **PROCEDURE**

(1) By Council Implementing Regulation (EU) No 857/2010 [2] ('the contested Regulation'), the Council imposed definitive countervailing duties ranging from EUR 42,34 per tonne to EUR 139,70 per tonne on imports of certain polyethylene terephthalate having a viscosity number of 78 ml/g or higher, according to the ISO Standard 1628-5, originating in Iran, Pakistan and the United Arab Emirates.

(2) On 6 December 2010, the cooperating exporting producer in Pakistan, namely Novatex Ltd ('Novatex' or 'the company concerned'), lodged an application at the General Court seeking the annulment of the contested Regulation in so far as it applied to the applicant [3].

(3) On 11 October 2012, the General Court in its judgment in Case T-556/10 ('the General Court judgment') found that the failure by the Commission and the Council to take account of the figure resulting from the revision of line 74 of the 2008 tax return of the company concerned, and the error resulting therefrom, affected the legality of Article 1 of the contested Regulation in so far as the definitive countervailing duty fixed by the Council exceeded the duty applicable in the absence of that error. Therefore, the General Court annulled Article 1 of the contested Regulation in so far as it concerned Novatex and in so far as the definitive countervailing duty exceeded that applicable in the absence of the error.

(4) In Case T-2/95 [4], the General Court held that, in cases where a proceeding consists of several administrative steps, the annulment of one of those steps does not annul the complete proceeding. This anti-subsidy proceeding is an example of such a multi-step proceeding. Consequently, the annulment of a part of the contested Regulation does not imply the annulment of the entire procedure prior to the adoption of that Regulation. Moreover, according to Article 266 of the Treaty on the Functioning of the European Union, the Union institutions are obliged to comply with the General Court judgment. This also implies the possibility to remedy the aspects of the contested Regulation which led to its partial annulment, while leaving unchanged the uncontested parts which are unaffected by the General Court judgment. It should be noted that all other findings made in the contested Regulation remain valid.

[1] OJ L 188, 18.7.2009, p. 93.

[2] Council Implementing Regulation (EU) No 857/2010 of 27 September 2010 imposing a definitive countervailing duty and collecting definitely the provisional duty imposed on imports of certain polyethylene terephthalate originating in Iran, Pakistan and the United Arab Emirates (OJ L 254, 29.9.2010, p. 10).

[3] Case T-556/10 *Novatex Ltd* v *Council of the European Union*.

[4] Case T-2/95 *Industrie des poudres sphériques (IPS)* v *Council* [1998] ECR II-3939.

(5) Following the General Court judgment, on 17 May 2013 the Commission partially reopened the anti-subsidy investigation concerning imports of certain polyethylene terephthalate originating, inter alia, in Pakistan ('the notice') ([1]). The reopening was limited in scope to the implementation of the General Court judgment in so far as Novatex is concerned.

(6) The Commission officially advised the exporting producers, importers, users and raw material suppliers known to be concerned, the representatives of the exporting country and the Union industry of the partial reopening of the investigation. Interested parties were given the opportunity to make their views known in writing and to request a hearing within the time-limit set out in the notice. No interested party requested to be heard.

(7) All parties concerned were informed of the essential facts and considerations on the basis of which it was intended to recommend the imposition of an amended definitive countervailing duty on Novatex. They were granted a period within which to make representations subsequent to disclosure.

B. IMPLEMENTATION OF THE GENERAL COURT JUDGMENT

1. Preliminary remark

(8) It is recalled that the reason for the partial annulment of the contested Regulation was that the Commission and the Council should have taken account of the fact that line 74 of the 2008 tax return of the company concerned had been revised.

2. Comments of interested parties

(9) Within the applicable deadline for submitting comments, the company concerned commented that following the General Court judgment, the definitive countervailing duty for imports into the Union of certain polyethylene terephthalate originating in Pakistan should be reduced by 1,02 %. Novatex further stated that the countervailing duty applicable to Novatex should be set at 4,1 % or EUR 35,39 per tonne as from 1 June 2010 (the alleged date of entry into force of the provisional duty).

(10) No further comments of any substance on the partial re-opening were received.

3. Analysis of comments

(11) Having analysed the above comments, it is confirmed that the annulment of the contested Regulation with regard to Novatex, insofar as the definitive countervailing duty exceeded the duty applicable in the absence of the error identified by the Court, should not imply the annulment of the entire procedure prior to the adoption of that Regulation.

(12) The recalculation of Novatex's subsidy duty rate, taking account of the revised line 74 of the company's tax return, indeed results in a corrected amount of EUR 35,39 per tonne.

(13) The revised duty rate should indeed be applied retroactively, i.e. from the date of entry into force of the contested Regulation.

4. Conclusion

(14) Account has been taken of the comments made, and having analysed them it is concluded that the implementation of the General Court judgment should take the form of a revision of the countervailing duty rate applicable to Novatex, which should be reduced from EUR 44,02 per tonne to EUR 35,39 per tonne. As Novatex was the sole exporting producer of the product concerned in Pakistan during the investigation period, this revised duty rate applies to all imports from Pakistan. The revised duty rate should be applied retroactively, i.e. from the date of entry into force of the contested Regulation. However, as provided for by Article 2 of that Regulation, the amounts secured by way of provisional countervailing duty pursuant to Regulation (EU) No 473/2010 ([2]) on imports from Pakistan can only be definitively collected at the rate of the definitive countervailing duty of EUR 35,39 per tonne, imposed pursuant to the present amendment to Article 1 of the contested Regulation. The amounts secured in excess of the rate of the definitive countervailing duty should be released. In addition, for the sake of transparency, it should be pointed out that Regulation (EU) No 473/2010 entered into force on the day following that of its publication in the *Official Journal of the European Union*, namely on 2 June 2010 (and not on 1 June 2010, as stated by Novatex).

(15) Customs authorities should be instructed to proceed with the reimbursement of the amount of duties paid in excess of the amount of EUR 35,39 per tonne for the imports concerned, in compliance with the applicable customs legislation.

([1]) OJ C 138, 17.5.2013, p. 32–34.

([2]) Commission Regulation (EU) No 473/2010 of 31 May 2010 imposing a provisional countervailing duty on imports of certain polyethylene terephthalate originating in Iran, Pakistan and the United Arab Emirates (OJ L 134, 1.6.2010, p. 25-58).

C. **DISCLOSURE**

(16) Interested parties were informed of the essential facts and considerations on the basis of which it was intended to implement the General Court judgment. All interested parties were given an opportunity to comment within the 10-day period prescribed in Article 30(5) of the basic Regulation.

(17) No comments of substance were received.

D. **AMENDMENT OF THE MEASURES**

(18) In light of the results of the partial reopening, it is considered appropriate to amend the countervailing duty applicable to imports of certain polyethylene terephthalate having a viscosity number of 78 ml/g or higher, according to the ISO Standard 1628-5, originating in Pakistan to EUR 35,39 per tonne.

(19) This procedure does not affect the date on which the measures imposed by the contested Regulation will expire, namely 30 September 2015,

HAS ADOPTED THIS REGULATION:

Article 1

1. The table in Article 1(2) of Implementing Regulation (EU) No 857/2010 is replaced by the following:

'Country	Definitive countervailing duty rate (EUR/tonne)
Iran: all companies	139,70
Pakistan: all companies	35,39
United Arab Emirates: all companies	42,34'

2. The revised duty rate of EUR 35,39 per tonne for Pakistan shall be applicable as from 30 September 2010.

3. The amounts of duties paid or entered into the accounts pursuant to Article 1 of Implementing Regulation (EU) No 857/2010 in its initial version and the amounts of provisional duties definitively collected pursuant to Article 2 of the same Regulation in its initial version, which exceed those as established on the basis of Article 1 of this Regulation, shall be repaid or remitted. Repayment and remission shall be requested from national customs authorities in accordance with the applicable customs legislation. Unless otherwise specified, the provisions in force concerning customs duties shall apply.

Article 2

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

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

Done at Brussels, 23 September 2013.

For the Council
The President
V. JUKNA

COMMISSION REGULATION (EU) No 918/2013

of 20 September 2013

establishing a prohibition of fishing for haddock in EU and international waters of Vb and VIa by vessels flying the flag of Spain

THE EUROPEAN COMMISSION,

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

Having regard to Council Regulation (EC) No 1224/2009 of 20 November 2009 establishing a Community control system for ensuring compliance with the rules of the common fisheries policy [1], and in particular Article 36(2) thereof,

Whereas:

(1) Council Regulation (EU) No 39/2013 of 21 January 2013 fixing for 2013 the fishing opportunities available to EU vessels for certain fish stocks and groups of fish stocks which are not subject to international negotiations or agreements [2], lays down quotas for 2013.

(2) According to the information received by the Commission, catches of the stock referred to in the Annex to this Regulation by vessels flying the flag of or registered in the Member State referred to therein have exhausted the quota allocated for 2013.

(3) It is therefore necessary to prohibit fishing activities for that stock,

HAS ADOPTED THIS REGULATION:

Article 1

Quota exhaustion

The fishing quota allocated to the Member State referred to in the Annex to this Regulation for the stock referred to therein for 2013 shall be deemed to be exhausted from the date set out in that Annex.

Article 2

Prohibitions

Fishing activities for the stock referred to in the Annex to this Regulation by vessels flying the flag of or registered in the Member State referred to therein shall be prohibited from the date set out in that Annex. In particular it shall be prohibited to retain on board, relocate, tranship or land fish from that stock caught by those vessels after that date.

Article 3

Entry into force

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, 20 September 2013.

For the Commission,
On behalf of the President,
Lowri EVANS
Director-General for Maritime Affairs and Fisheries

[1] OJ L 343, 22.12.2009, p. 1.
[2] OJ L 23, 25.1.2013, p. 1.

ANNEX

No	42/TQ39
Member State	Spain
Stock	HAD/5BC6A.
Species	Haddock (*Melanogrammus aeglefinus*)
Zone	EU and international waters of Vb and VIa
Date	20.8.2013

COMMISSION REGULATION (EU) No 919/2013

of 20 September 2013

establishing a prohibition of fishing for greater forkbeard in EU and international waters of VIII and IX by vessels flying the flag of Spain

THE EUROPEAN COMMISSION,

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

Having regard to Council Regulation (EC) No 1224/2009 of 20 November 2009 establishing a Community control system for ensuring compliance with the rules of the common fisheries policy [1], and in particular Article 36(2) thereof,

Whereas:

(1) Council Regulation (EU) No 1262/2012 of 20 December 2012 fixing for 2013 and 2014 the fishing opportunities for EU vessels for certain deep-sea fish stocks [2], lays down quotas for 2013.

(2) According to the information received by the Commission, catches of the stock referred to in the Annex to this Regulation by vessels flying the flag of or registered in the Member State referred to therein have exhausted the quota allocated for 2013.

(3) It is therefore necessary to prohibit fishing activities for that stock,

HAS ADOPTED THIS REGULATION:

Article 1

Quota exhaustion

The fishing quota allocated to the Member State referred to in the Annex to this Regulation for the stock referred to therein for 2013 shall be deemed to be exhausted from the date set out in that Annex.

Article 2

Prohibitions

Fishing activities for the stock referred to in the Annex to this Regulation by vessels flying the flag of or registered in the Member State referred to therein shall be prohibited from the date set out in that Annex. In particular it shall be prohibited to retain on board, relocate, tranship or land fish from that stock caught by those vessels after that date.

Article 3

Entry into force

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, 20 September 2013.

For the Commission,
On behalf of the President,
Lowri EVANS
Director-General for Maritime Affairs and Fisheries

[1] OJ L 343, 22.12.2009, p. 1.
[2] OJ L 356, 22.12.2012, p. 22.

ANNEX

No	41/DSS
Member State	Spain
Stock	GFB/89-
Species	Greater Forkbeard (*Phycis blennoides*)
Zone	EU and international waters of VIII and IX
Date	20.8.2013

COMMISSION IMPLEMENTING REGULATION (EU) No 920/2013

of 24 September 2013

on the designation and the supervision of notified bodies under Council Directive 90/385/EEC on active implantable medical devices and Council Directive 93/42/EEC on medical devices

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices [1], and in particular Article 11(2) thereof,

Having regard to Council Directive 93/42/EEC of 14 June 1993 concerning medical devices [2], and in particular Article 16(2) thereof,

Whereas:

(1) Technical progress has led to more complex devices and production methods implying new conformity assessment challenges for notified bodies. Those developments have resulted in variations in the level of competence of notified bodies and in different degrees of stringency applied by them. Accordingly, to ensure the smooth functioning of the internal market, it is necessary to determine a common interpretation of the main elements of the criteria for designation of notified bodies set out in Directive 90/385/EEC and Directive 93/42/EEC.

(2) The common interpretation of the criteria for designation provided by this Regulation does not suffice to assure their consistent application. The assessment methods in the Member States differ. They have a tendency to differ ever more due to the mentioned increased complexity of the work of conformity assessment bodies. Furthermore, many ad hoc questions arise in the day-to-day designation practice, in relation with new technologies and products. For these reasons, it is necessary to provide for procedural obligations which ensure a constant dialogue between Member States on their general practices and on ad hoc questions. This will bring to the surface discrepancies in the methods used to assess the conformity assessment bodies and in the interpretation of the criteria for their designation set out in Directive 90/385/EEC and Directive 93/42/EEC. Bringing the discrepancies to the surface will permit to develop a common interpretation of the assessment methods, especially with regard to new technologies and devices.

(3) To ensure a common approach from the designating authorities and neutral conditions for competition those authorities should base their decisions on a common set of documents which lay the ground for the verification of the criteria for designation set out in Directive 90/385/EEC and Directive 93/42/EEC.

(4) To facilitate, in a view of the increasingly complex work of conformity assessment bodies, a common application of the criteria established for their designation, those bodies should be assessed by teams of assessors representing the knowledge and experience of different Member States and of the Commission. To facilitate such assessments, certain essential documents should be accessible to those involved in these activities. Designating authorities from Member States other than the Member State where the conformity assessment body is established should have the possibility to review the documentation related to the assessment and to comment on intended designations if they so wish. The access to those documents is necessary in order to allow the identification of weaknesses of the applicant conformity assessment bodies as well as discrepancies in the Member States' assessment methods and in their interpretation of the criteria for designation set out in Directive 90/385/EEC and Directive 93/42/EEC.

(5) In order to ensure that the common interpretation of the criteria established applies similarly to scope extensions, which often reflect new technologies or product types and renewal of designations of notified bodies, the procedure for the designation of conformity assessment bodies should also be followed in those situations.

(6) The need for control and monitoring of notified bodies by the designating authorities has increased since technical progress has raised the risk that notified bodies do not possess the necessary competence with regard to new technologies or devices emerging within their scope of designation. As technical progress shortens product cycles and as the intervals of surveillance on-site assessments and of the monitoring vary between designating authorities, minimum requirements with regard to the intervals of the surveillance and monitoring of the notified bodies should be established and unannounced or short-notice on-site assessments should be organised.

[1] OJ L 189, 20.7.1990, p. 17.
[2] OJ L 169, 12.7.1993, p. 1.

(7) When, in spite of the measures taken to ensure a coherent application and follow up of the requirements by the Member States, the competence of a notified body is in doubt, the Commission should have the possibility to investigate individual cases. The need for investigation by the Commission is exacerbated since technical progress has increased the risk that notified bodies do not possess the necessary competence with regard to new technologies or products falling under their scope of designation.

(8) In order to increase transparency and mutual trust and to further align and develop their designation, extension and renewal procedures, above all in a view of new emerging interpretative questions regarding new technologies and devices, Member States should cooperate with each other and with the Commission. They should consult each other and the Commission on questions with general relevance for the implementation of this Regulation and inform each other and the Commission on their model assessment checklist, which constitutes the basis for their assessment practice.

(9) The increased complexity of the tasks regarding the designation of the conformity assessment bodies, reflecting the increasing complexity of the work of those bodies, requires significant resources. Therefore, requirements should be imposed on the Member States with regard to the minimum level of available competent personnel, able and entrusted to operate in an independent way.

(10) Designating authorities who are not in charge of market surveillance and vigilance for medical devices are not necessarily aware of deficiencies in the work of notified bodies which were spotted by the competent authorities when doing product checks. Furthermore, the designating authorities do not necessarily have all the product related knowledge which is sometimes needed to assess whether the notified bodies worked properly. Therefore, the designating authorities should consult the competent authorities.

(11) Where designation is based on accreditation in the meaning of Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93 [1], in order to ensure a transparent and coherent application of the criteria set out in Annex 8 to Directive 90/385/EEC and Annex XI to Directive 93/42/EEC, accreditation bodies on the one hand, and designating and competent authorities on the other hand should exchange information relevant for the assessment of notified bodies. The need for this exchange of information has proven to be particularly strong in respect to the conformity assessment bodies' practices with regard to new technologies and devices and their ability to cover those technologies and devices and thus to fulfil the criteria for designation set out in Directive 90/385/EEC and Directive 93/42/EEC.

(12) It is appropriate to provide for a phase-in period, so as to give designating authorities time to build up the necessary additional resources and adapt their procedures.

(13) The complex technical and production developments have led some notified bodies to outsource parts of their assessments. It is therefore necessary to set the limits and to determine under which conditions this can be done. Notified bodies should be in control of their subcontractors and of their subsidiaries. They need to be endowed with the appropriate resources, including fully qualified staff to make their own assessments or to review the assessments made by external experts.

(14) To ensure that decisions by notified bodies are not influenced by non-legitimate circumstances the organisation and operation of the bodies should ensure full impartiality. To be able to carry out their tasks in a coherent and systematic manner the bodies should possess a satisfactory management system including provisions on professional secrecy. In order to allow notified bodies to perform their work properly, the level of knowledge and competence of the personnel should be guaranteed at all times.

(15) The measures provided for in this Regulation are in accordance with the opinion of the Committee set up by Article 6(2) of Directive 90/385/EEC,

HAS ADOPTED THIS REGULATION:

Article 1

Definitions

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

(a) 'device' means active implantable medical devices as defined in Article 1(2)(c) of Directive 90/385/EEC or medical devices and their accessories as defined in Article 1(2) of Directive 93/42/EEC;

(b) 'conformity assessment body' means a body which performs calibration, testing, certification and inspection activities under Article R1(13) in Annex I to Decision No 768/2008/EC of the European Parliament and of the Council [2];

(c) 'notified body' means a conformity assessment body which has been notified by a Member State in accordance with Article 11 of Directive 90/385/EEC or Article 16 of Directive 93/42/EEC;

(d) 'accreditation body' means the sole body in a Member State that performs accreditation with authority derived from the State as laid down by Article 2(10) of Regulation (EC) No 765/2008;

[1] OJ L 218, 13.8.2008, p. 30.

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

(e) 'designating authority' means the authority(ies) entrusted by a Member State to assess, designate, notify and monitor notified bodies under Directive 90/385/EEC or Directive 93/42/EEC;

(f) 'competent authority' means the authority(ies) in charge of market surveillance and/or of vigilance for devices;

(g) 'on-site assessment' means a verification in the premises of the body or of one of its subcontractors or subsidiaries by the designating authority;

(h) 'surveillance on-site assessment' means a periodic routine on-site assessment which is neither the on-site assessment undertaken for the initial designation, nor the on-site assessment undertaken for the renewal of the designation;

(i) 'observed audit' means a designating authority's assessment of the performance of a notified body's audit team in the premises of the body's client;

(j) 'functions' means the tasks to be fulfilled by the body's staff and its external experts, namely: auditing of the quality systems, product related technical documentation review, review of clinical evaluations and investigations, device testing and, for each of the previously mentioned items, the final review and decision making thereon;

(k) 'subcontracting' means the transfer of tasks to one of the following:

(i) a legal person;

(ii) a natural person who further delegates these tasks or parts thereof;

(iii) several natural or legal persons who jointly perform these tasks.

Article 2

Interpretation of designation criteria

The criteria set out in Annex 8 to Directive 90/385/EEC or in Annex XI to Directive 93/42/EEC shall be applied as laid down in Annex I.

Article 3

Procedure for the designation of notified bodies

1. When applying for designation as a notified body, a conformity assessment body shall use the application form set out in Annex II. If the conformity assessment body submits the application and documents annexed to the application on paper, it shall also submit an electronic copy of the application and its annexes.

The application shall specify the conformity assessment activities, the conformity assessment procedures and the fields of competence for which the conformity assessment body wishes to be notified, the latter by indicating the codes used in the 'New Approach Notified and Designated Organisations' Information System ([1]) and subdivisions of those fields.

([1]) 'NANDO'; see http://ec.europa.eu/enterprise/newapproach/nando

2. The designating authority of the Member State where the conformity assessment body is established shall assess that body in accordance with an assessment check-list that covers at least the items listed in Annex II. The assessment shall include an on-site assessment.

Representatives of designating authorities of two other Member States shall, in coordination with the designating authority of the Member State in which the conformity assessment body is established and together with a representative of the Commission, participate to the assessment of the conformity assessment body, including the on-site assessment. The designating authority of the Member State where the conformity assessment body is established shall give those representatives timely access to the documents necessary to assess the conformity assessment body. They shall produce within 45 days after the on-site assessment a report, which shall contain at least a summary of identified non-compliances with the criteria set out in Annex I and recommendation with regard to the designation of the notified body.

3. The Member States shall make available a pool of assessors for the Commission to call upon for each assessment.

4. The designating authority of the Member State where the conformity assessment body is established shall upload into a data storage system managed by the Commission, the assessment report drafted by the representatives referred to in paragraph 2, its own assessment report and, if not contained therein, an on-site assessment report.

5. The designating authorities of all the other Member States shall be informed of the application and may request to get access to certain or all the documents referred to in paragraph 4. Those authorities and the Commission may review all the documents referred to in paragraph 4, may raise questions or concerns and may request further documentation within one month after the last upload of one of those documents. Within the same period of time, they may request an exchange of views on the application, organised by the Commission.

6. The designating authority of the Member State where the conformity assessment body is established shall respond to the questions, concerns and requests for further documentation within four weeks following their receipt.

The designating authorities of the other Member States or the Commission may individually or jointly address recommendations to the designating authority of the Member State where the conformity assessment body is established within four weeks following the receipt of the response. That designating authority shall take account of the recommendations when it takes the decision on the designation of the conformity assessment body. If it does not follow the recommendations, it shall give the reasons therefor within two weeks after its decision.

7. The Member State shall notify to the Commission its decision on the designation of a conformity assessment body by means of the 'New Approach Notified and Designated Organisations' Information System.

The validity of the designation shall be limited up to a maximum of five years.

Article 4

Extension and renewal of designation

1. An extension of the scope of the notified body's designation may be granted in accordance with Article 3.

2. A designation as notified body may be renewed in accordance with Article 3 before the end of the validity period of the previous designation.

3. For the purposes of paragraph 2, the procedure set out in Article 3(2) shall include, where appropriate, an observed audit.

4. Extension and renewal procedures may be combined.

5. Notified bodies already designated before the entry into force of this Regulation and for which the designation does not have a stated validity period or has a validity period exceeding five years, shall be subject to renewal at least within three years of entry into force of this Regulation.

Article 5

Surveillance and monitoring

1. For the purpose of surveillance, the designating authority of the Member State where the notified body is established shall assess an appropriate number of notified body's reviews of the manufacturer's clinical evaluations and shall carry out an appropriate number of file reviews, surveillance on-site assessments and observed audits at the following intervals:

(a) at least every 12 months for notified bodies with more than 100 clients;

(b) at least every 18 months for all other notified bodies.

That designating authority shall, in particular, examine changes which have occurred since the last assessment and the work the notified body has performed since that assessment.

2. Surveillance and monitoring conducted by the designating authorities shall appropriately address subsidiaries.

3. The designating authority of the Member State where the notified body is established shall continuously monitor that body to ensure ongoing compliance with the applicable requirements. That authority shall provide for a systematic follow-up of complaints, vigilance reports and other information, including from other Member States, which might indicate the non-fulfilment of the obligations by a notified body or its deviation from common or best practice.

In addition to surveillance or renewal on-site assessments, the designating authority of the Member State where the notified body is established shall initiate unannounced or short-notice on-site assessments if those on-site assessments are needed to verify compliance.

Article 6

Investigation of the competence of a notified body

1. The Commission may investigate cases regarding the competence of a notified body or the fulfilment of the requirements and responsibilities to which a notified body is subject under Directive 90/385/EEC and Directive 93/42/EEC.

2. Investigations will start with a consultation of the designating authority of the Member State where the notified body is established. Upon request, that designating authority shall, within four weeks, provide the Commission with all relevant information concerning the relevant notified body.

3. The Commission will ensure that all sensitive information obtained in the course of its investigations is treated confidentially.

4. When the notified body no longer meets the requirements for its notification, the Commission will inform the Member State where that body is established and may request the Member State to take the necessary corrective measures.

Article 7

Exchange of experience on designation and supervision of conformity assessment bodies

1. Designating authorities shall consult each other and the Commission on questions with general relevance with regard to the implementation of this Regulation and the interpretation of the provisions of Directive 90/385/EEC and of Directive 93/42/EEC in relation with conformity assessment bodies.

2. Designating authorities shall communicate to each other and the Commission by 31 December 2013 the model assessment check-list used in accordance with Article 3(2) and thereafter the adaptations made to this check-list.

3. When the assessment reports referred to in Article 3(4) indicate discrepancies in the general practice of designating authorities, Member States or the Commission may request an exchange of views, which will be organised by the latter.

Article 8

Operating of designating authorities

1. Designating authorities shall have a sufficient number of competent personnel at their disposal for the proper performance of their tasks. Those authorities shall be established, organised and operated so as to safeguard the objectivity and impartiality of their activities and to avoid any conflicts of interests with conformity assessment bodies. The designating authorities shall be organised so that each decision relating to a notification of a conformity assessment body is not taken by the same member of personnel who carried out the assessment of that body.

2. Where designating authorities are not in charge of market surveillance and vigilance for medical devices, they shall involve the competent authorities of that Member State for all tasks incumbent to them in accordance with this Regulation. They shall in particular consult the competent authorities of that Member State prior to taking decisions and invite them to attend all types of assessments.

Article 9

Cooperation with accreditation bodies

Where designation is based on accreditation in the meaning of Regulation (EC) No 765/2008, Member States shall ensure that the accreditation body that has accredited a particular notified body is kept informed by the competent authorities on incident reports and other information that relate to matters under the control of the notified body when the information may be relevant for the assessment of the performance of the notified body. Member States shall ensure that the accreditation body in charge of the accreditation of a particular conformity assessment body is kept informed by the designating authority of the Member State where the conformity assessment body is established on findings relevant for the accreditation. The accreditation body shall inform the designating authority of the Member State where the conformity assessment body is established on its findings.

Article 10

Entry into force and date of application

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

It shall apply to extension of designations as from 25 December 2013.

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

Done at Brussels, 24 September 2013.

For the Commission
The President
José Manuel BARROSO

ANNEX I

Interpretation of the criteria set out in Annex 8 to Directive 90/385/EEC and in Annex XI to Directive 93/42/EEC

1. Sections 1 and 5 of Annex 8 to Directive 90/385/EEC and of Annex XI to Directive 93/42/EEC shall be interpreted as including the following elements:

1.1. The conformity assessment body shall be a third-party body that is independent of the manufacturer of the product in relation to which it performs conformity assessment activities. The conformity assessment body shall also be independent of any other economic operator having an interest in the product as well as of any competitor of the manufacturer.

1.2. That conformity assessment body shall be organised and operated so as to safeguard the independence, objectivity and impartiality of its activities. The conformity assessment body shall have procedures in place that effectively ensure identification, investigation and resolution of any case in which a conflict of interests may arise, including involvement of its staff in consultancy services in the field of medical devices prior to taking up employment with the body.

1.3. That conformity assessment body, its top management and the personnel responsible for carrying out the conformity assessment tasks shall not:

(a) engage in any activity that may conflict with their independence of judgement or integrity in relation to conformity assessment activities for which they are notified;

(b) offer or provide any service which may jeopardise the confidence in their independence, impartiality or objectivity. In particular, they shall not offer or provide or have offered or provided, during the last three years, consultancy services to the manufacturer, his authorised representative, a supplier or a commercial competitor as regards Union requirements for the design, construction, marketing or maintenance of the products or processes under assessment. This does not preclude conformity assessment activities for manufacturers and economic operators mentioned above or general training activities relating to medical device regulations or related standards that are not client specific.

1.4. The conformity assessment body's top level management and its assessment personnel shall be impartial. The remuneration of the top level management and assessment personnel of a conformity assessment body shall not depend on the number or the results of assessments carried out.

1.5. When a conformity assessment body is owned by a public entity or institution, the Member State shall ensure and document the independence of the conformity assessment body and the absence of any conflict of interests between, on the one hand, the designating authority and/or competent authority and, on the other hand, the conformity assessment body.

1.6. The conformity assessment body shall ensure and document that the activities of its subsidiaries or subcontractors, or of any associated body, do not affect its independence, impartiality or objectivity in its conformity assessment activities.

1.7. The requirements of points 1.1 to 1.6 do not preclude exchanges of technical information and regulatory guidance between a body and a manufacturer seeking their conformity assessment.

2. The second paragraph of Section 2 of Annex XI to Directive 93/42/EEC shall be interpreted as including the following elements:

2.1. Subcontracting shall be limited to specific tasks. The subcontracting of the auditing of quality management systems or of products related reviews in its entirety is not allowed. The conformity assessment body shall in particular keep internal the review of the qualification and the monitoring of the performance of the external experts, the experts' assignment to specific conformity assessment activities, and the final review and decision-making functions.

2.2. Where a conformity assessment body subcontracts specific tasks or consults external experts related to the conformity assessment, it shall have a policy describing the conditions under which subcontracting or the consultation of external experts may take place. Any subcontracting or consultation of external experts shall be properly documented and be subject to a written agreement covering, among others, confidentiality and conflict of interests.

2.3. The conformity assessment body shall establish procedures for assessing and monitoring the competence of all subcontractors and external experts used.

3. Sections 3 and 4 of Annex 8 to Directive 90/385/EEC and of Annex XI to Directive 93/42/EEC shall be interpreted as including the following elements:

3.1. At all times and for each conformity assessment procedure and each kind or category of products in relation to which it has been or wishes to be notified, a conformity assessment body shall have within its organisation the following elements:

(a) the necessary administrative, technical, clinical and scientific personnel with technical and scientific knowledge and sufficient and appropriate experience relating to medical devices and the corresponding technologies to perform the conformity assessment tasks, including the assessment of clinical data;

(b) a documented process for the conduct of the conformity assessment procedures for which it is designated [1] taking into account their respective specificities, including legally required consultations, in respect of the different categories of devices covered by the scope of notification, ensuring transparency and the ability of reproduction of those procedures.

3.2. The conformity assessment body shall have the necessary personnel and shall possess or have access to all equipment and facilities needed to perform properly the technical and administrative tasks entailed in the conformity assessment activities in relation to which it has been notified.

3.3. The conformity assessment body shall have at its disposal the financial resources required to conduct its conformity assessment activities and related business operations. It shall document and provide evidence of its financial capacity and its sustainable economic viability, taking into account specific circumstances during an initial start-up phase.

3.4. The conformity assessment body shall have a quality management system in place and operating.

3.5. The experience and knowledge of the personnel responsible for carrying out conformity assessment activities shall be interpreted as including the following:

(a) sound scientific, technical and vocational training, in particular in the relevant fields of medicine, pharmacy, engineering or other relevant sciences, covering all the conformity assessment activities in relation to which the body has been notified or wishes to be notified;

(b) substantial relevant experience covering all the conformity assessment activities in relation to which the body has been notified or wishes to be notified;

(c) satisfactory knowledge of the requirements of the assessments they carry out and adequate authority to carry out those assessments;

(d) appropriate knowledge and understanding of the relevant provisions of the medical devices legislation and of the applicable harmonised standards;

(e) the ability to draw up certificates, records and reports demonstrating that assessments have been carried out.

[1] See Annex II Item 41.

3.6. The conformity assessment body shall establish and document qualification criteria and procedures for selection and authorisation of persons involved in conformity assessment activities (knowledge, experience and other competence required) and the required training (initial and ongoing training). The qualification criteria shall address the various functions within the conformity assessment process (e.g. auditing, product evaluation/testing, design dossier/file review, decision-making) as well as the devices, technologies and areas (e.g. biocompatibility, sterilisation, tissues and cells of animal origin, clinical evaluation) covered by the scope of designation.

3.7. The conformity assessment body shall have procedures in place to ensure that its subsidiaries operate on the basis of the same operating procedures and with the same stringency as its headquarters.

3.8. Where subcontractors or external experts are used in the context of the conformity assessment, in particular regarding novel, invasive and implantable medical devices or technologies, the conformity assessment body shall have adequate internal competence in each product area for which it is designated to direct the conformity assessment, to verify the appropriateness and validity of expert opinions and make the decision on the certification. The internal competence requested shall cover technological, clinical and auditing aspects.

4. Sections 6 of Annex 8 to Directive 90/385/EEC and of Annex XI to Directive 93/42/EEC shall be interpreted as including the following elements:

4.1. The conformity assessment body shall take out appropriate liability insurance corresponding to the conformity assessment activities for which it is notified, including the possible suspension, restriction or withdrawal of certificates, and the geographic scope of its activities, unless liability is assumed by the State under domestic legislation or the Member State itself carries out the inspections directly.

5. Sections 7 of Annex 8 to Directive 90/385/EEC and of Annex XI to Directive 93/42/EEC shall be interpreted as including the following elements:

5.1. The conformity assessment body shall ensure that confidentiality of the information which comes into its possession during the performance of the conformity assessment activities is observed by its personnel, committees, subsidiaries, subcontractors or any associated body, except when disclosure is required by law. To this end, it shall have documented procedures in place.

5.2. The personnel of a conformity assessment body shall observe professional secrecy with regard to all information obtained in carrying out their tasks, except in relation to the designating authorities and the competent authorities or the Commission. Proprietary rights shall be protected. To this end, the conformity assessment body shall have documented procedures in place.

ANNEX II

Application form to be submitted when applying for designation as notified body

Designating authority: .....

Name of the applying conformity assessment body: .....

Previous name (if applicable): .....

EU Notified Body number (if applicable): .....

Address: .....

.....

.....

.....

Contact person: .....

E-mail: .....

Telephone: .....

Legal form of the conformity assessment body: .....

Company registration number: .....

At company register: .....

.....

.....

The following documents shall be added. In case of extension or renewal, only new or modified documents shall be submitted.

	Item/issue	Corresponding Annex I section	Attachment number + Reference (Section/page)
	ORGANISATIONAL AND GENERAL REQUIREMENTS		
	Legal status and organisational structure		
1	Company statutes		
2	Extract of company registration or enrolment act (Company register)		
3	Documentation on the activities of the organisation to which the conformity assessment body belongs (if any) and its relationship with the conformity assessment body		
4	Documentation on entities the conformity assessment body owns (if any), either within the Member State or outside, and the relationship with those entities		
5	Description of legal ownership and the legal or natural persons exercising control of the conformity assessment body		
6	Description of organisational structure and the operational management of the conformity assessment body		
7	Descriptions of functions, responsibilities and authorities of top-level management		
8	List of all staff who have an influence in the conformity assessment activities		
9	Documentation on other services provided by the conformity assessment body (if any) (e.g. consultancy relevant to devices, training etc.)		
10	Documentation on accreditation(s) relevant to this application		

	Item/issue	Corresponding Annex I section	Attachment number + Reference (Section/page)
Independence and impartiality			
11	Documentation on structures, policies and procedures to safeguard and promote the principles of impartiality throughout the organisation, personnel and assessment activities, including ethical rules or codes of conduct		
12	Description of how the conformity assessment body ensures that the activities of subsidiaries, subcontractors and external experts do not affect its independence, impartiality or objectivity		
13	Documentation on the impartiality of the top-level management and personnel involved in conformity assessment activities, including their remuneration and bonuses		
14	Documentation on conflict of interest and resolution of potential conflict procedure/form		
15	Description of independence of the conformity assessment body from the designating authority and from the competent authority, in particular when this body is a public entity/institution		
Confidentiality			
16	Documentation on professional secrecy procedure including protection of proprietary data		
Liability			
17	Documentation of the liability insurance, proof that the liability insurance covers cases where the notified body may be obliged to withdraw or suspend certificates		
Financial resources			
18	Documentation of the financial resources required to conduct the conformity assessment activities, related operations, including the ongoing commitments for certificates issued to demonstrate the continuing viability of the notified body and consistency with the range of products certified		
Quality system			
19	Quality Manual and a list of related documentation on the implementation, maintenance and operation of a quality management system, including policies for assignment of personnel to activities and their responsibilities		
20	Documentation on the procedure(s) for control of documents		
21	Documentation on the procedure(s) for control of records		
22	Documentation on the procedure(s) for management review		
23	Documentation on the procedure(s) for internal audits		
24	Documentation on the procedure(s) for corrective and preventive actions		
25	Documentation on the procedure(s) for complaints and appeals		

	Item/issue	Corresponding Annex I section	Attachment number + Reference (Section/page)
Resource requirements			
General			
26	Description of own laboratories and testing facilities		
27	Employment contracts and other agreements with internal personnel, in particular in relation to impartiality, independence, conflict of interest (attach a standard contract template)		
28	Contracts and other agreements with subcontractors and external experts, in particular for impartiality, independence, conflict of interest (attach a standard contract template)		
Qualification and authorisation of personnel			
29	List of all permanent and temporary personnel (technical, administrative etc.) including information on professional qualification, past experience and the types of contracts held		
30	List of all external personnel (e.g. external experts, external auditors) including information on professional qualification, past experience and on the types of contracts held		
31	Qualification matrix linking the body's staff and its external experts to the functions to be accomplished by them and to the fields of competence for which the body has been notified or wishes to be notified		
32	Qualification criteria for the different functions (see point 31)		
33	Documentation on the procedure(s) for selection and assignment of internal or external personnel involved in the conformity assessment activities, including conditions for the attribution of tasks to external personnel and the supervision of their expertise		
34	Documentation demonstrating that the management of the conformity assessment body has appropriate knowledge to set up and operate a system for: — the selection of the personnel deployed during the conformity assessment, — the verification of the knowledge and experience of this personnel, — the assignment of the personnel to their tasks, — the verification of the performance of the personnel, — the definition and the verification of their initial and ongoing training		
35	Documentation on the procedure assuring ongoing monitoring of competences and performance monitoring		
36	Documentation on standard training programmes conducted by the conformity assessment body relevant to the conformity assessment activities		
Subcontractors			
37	List of all subcontractors (not individual external experts) used for conformity assessment activities		

	Item/issue	Corresponding Annex I section	Attachment number + Reference (Section/page)
38	Subcontractor policy and procedure		
39	Documentation demonstrating adequate core competence within the conformity assessment body to assess, select, contract, and to verify the appropriateness and validity of subcontractor activities		
40	Examples of standard template contract, prohibiting further subcontracting by legal persons and specifically including provisions to ensure confidentiality and conflict of interest management with subcontractors (attach examples)		
Process			
41	Documentation on procedures relating to conformity assessment activities and other related documents reflecting the scope of conformity assessment activities including, in particular procedures relating to: — Qualification and classification — Quality system assessments — Risk management — Pre-clinical data evaluation — Clinical evaluation — Representative sampling of technical documentation — Post-market clinical follow up — Communications from regulatory authorities including competent authorities and designating authorities — Communication and analysis of the impact of vigilance reports on device certification — Consultation procedures for drug-device combination products, devices utilising animal tissue, devices utilising human blood derivatives — Review and decision making on certificate issuance including approval responsibilities — Review and decision making on certificate suspension, restriction, withdrawal and refusal including approval responsibilities		
42	Checklists, templates, reports and certificates used for the conformity assessment activities		

Name and signature of an authorised representative of the applicant conformity assessment body (unless electronic signature is accepted)

Place and date

COMMISSION IMPLEMENTING REGULATION (EU) No 921/2013

of 24 September 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, 24 September 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	MK	71,2
	XS	41,5
	ZZ	56,4
0707 00 05	MK	46,1
	TR	116,3
	ZZ	81,2
0709 93 10	TR	130,4
	ZZ	130,4
0805 50 10	AR	113,8
	CL	125,3
	IL	142,1
	TR	97,0
	UY	127,6
	ZA	116,8
	ZZ	120,4
0806 10 10	EG	187,8
	TR	146,5
	ZZ	167,2
0808 10 80	AR	100,9
	BA	68,5
	BR	78,8
	CL	122,2
	CN	71,1
	NZ	129,9
	US	144,6
	ZA	118,6
	ZZ	104,3
0808 30 90	CN	80,2
	TR	131,4
	ZA	108,3
	ZZ	106,6
0809 30	TR	118,4
	ZZ	118,4
0809 40 05	BA	41,0
	XS	46,6
	ZZ	43,8

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

DECISIONS

COUNCIL DECISION

of 23 September 2013

on the granting of daily allowances to and the reimbursement of travelling expenses of members of the European Economic and Social Committee and their alternates

(2013/471/EU)

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular the third paragraph of Article 301 thereof,

Whereas:

(1) Council Decision 81/121/EEC [1] laid down rules on the granting of daily allowances to and the reimbursement of travelling expenses of members of the European Economic and Social Committee ('the Committee'), alternates and experts.

(2) In its resolution of 10 May 2012 [2], the European Parliament noted that the Bureau of the Committee undertook to reform the system for reimbursing expenses to members of the Committee and their alternates.

(3) On 12 October 2012, the Committee requested the Council to adopt a new Decision on the granting of daily allowances and the reimbursement of travelling expenses of members of the Committee and their alternates, repealing and replacing Decision 81/121/EEC.

(4) The amounts of the daily allowances paid to members of the Committee and their alternates should be adapted. Provision should also be made for a system for the reimbursement of transport expenses on the basis of actual costs, as well as for allowances compensating for the time spent by those members and their alternates in performance of their duties and for related administrative costs.

(5) Where appropriate, detailed rules relating to the granting of allowances, the reimbursement of travelling expenses and the setting of the reimbursement ceilings for travelling expenses should be established at the level of the Committee.

(6) In order to guarantee an appropriate degree of continuity for the members of the Committee and their alternates, transitional rules should be provided for.

(7) Decision 81/121/EEC should therefore be repealed,

HAS ADOPTED THIS DECISION:

Article 1

The members of the European Economic and Social Committee ('the Committee') and their alternates (together referred to as the 'beneficiaries') shall be entitled to a daily allowance for meeting days, to the reimbursement of their travelling expenses and to distance and duration allowances in accordance with this Decision.

Article 2

1. The daily allowance for beneficiaries attending meetings shall be set at EUR 290.

The Committee may decide to increase the daily allowance by a maximum of 50 %:

(a) where a beneficiary duly invited to one or more meetings is obliged to pay for overnight accommodation at the meeting venue both before the first meeting and after the last meeting; or

(b) in the event of a mission outside Brussels, where the rates of the hotels selected as accommodation for the beneficiaries exceed EUR 150 per night.

2. The daily allowance may be paid to beneficiaries for a maximum of two days bridging the gap between two meetings, where that allowance is less than the reimbursement of the travelling expenses which would otherwise be incurred by the beneficiary in making a return journey between those meetings.

[1] Council Decision 81/121/EEC of 3 March 1981 on the granting of daily allowances and the reimbursement of travelling expenses of members of the Economic and Social Committee, alternates and experts (OJ L 67, 12.3.1981, p. 29).

[2] OJ L 286, 17.10.2012, p. 110.

Article 3

The travelling expenses of beneficiaries shall be reimbursed on the basis of the expenses actually incurred. The Committee shall set appropriate reimbursement ceilings, with a view to ensuring that its travel-related expenditure does not exceed the level contained within its voted annual budget.

Article 4

Beneficiaries shall be entitled to distance and duration allowances. In the case of journeys between the beneficiary's place of residence and Brussels, the beneficiary shall be entitled to allowances in relation to one journey to Brussels and one journey back from Brussels in respect of each week of work at the Committee.

Article 5

The Committee shall adopt detailed provisions implementing Articles 2, 3 and 4 by 16 January 2014.

Article 6

The distance allowance referred to in Article 4 shall be calculated as follows:

(a) for the part of the journey between 0 and 50 km: EUR 15;

(b) for the part of the journey between 51 and 500 km: EUR 0,08/km;

(c) for the part of the journey between 501 and 1 000 km: EUR 0,04/km;

(d) for the part of the journey between 1 001 and 3 000 km: EUR 0,02/km;

(e) for the part of the journey exceeding 3 000 km: no allowance.

Article 7

The duration allowance referred to in Article 4 shall be calculated as follows:

(a) for a journey of a total duration of between two and four hours: an amount equivalent to one eighth of the daily allowance provided for in Article 2;

(b) for a journey of a total duration of between four and six hours: an amount equivalent to one quarter of the daily allowance provided for in Article 2;

(c) for a journey of a total duration of more than six hours and not requiring an overnight stay: an amount equivalent to half the daily allowance provided for in Article 2;

(d) for a journey of a total duration of more than six hours and requiring an overnight stay: an amount equivalent to the daily allowance provided for in Article 2, subject to the presentation of supporting documents.

Article 8

1. As a transitional measure, and subject to paragraph 2 of this Article, beneficiaries may request that Decision 81/121/EEC continue to be applied with regard to them until the end of their term of office, which expires on 20 September 2015.

2. In applying paragraph 1 of this Article, the Committee may decide to apply a reduction to the amounts set out in Decision 81/121/EEC.

Article 9

The Committee shall, by 30 April of each year, submit to the European Parliament and to the Council a detailed report on the reimbursement of travelling expenses and allowances paid to beneficiaries in the preceding year. That report shall detail the number of beneficiaries, the number of journeys, the destinations, the travel class and the travel costs incurred and reimbursed, as well as the allowances paid.

Article 10

By 16 October 2015, the Committee shall submit to the Council an evaluation report on the application of this Decision, and particularly on its budgetary impact.

That evaluation report shall include the elements that will enable the Council to determine, as necessary, the allowances of beneficiaries.

Article 11

Without prejudice to Article 8(1), Decision 81/121/EEC is repealed with effect from 15 October 2013.

Article 12

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

Done at Brussels, 23 September 2013.

For the Council

The President

V. JUKNA

COMMISSION IMPLEMENTING DECISION

of 23 September 2013

granting derogations for implementing Regulation (EC) No 452/2008 of the European Parliament and of the Council concerning the production and development of statistics on education and lifelong learning with regard to Belgium, Greece, Spain, France, Italy, Poland and Portugal

(notified under document C(2013) 5897)

(Only the Dutch, French, Greek, Italian, Polish, Portuguese and Spanish texts are authentic)

(2013/472/EU)

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EC) No 452/2008 of the European Parliament and of the Council of 23 April 2008 concerning the production and development of statistics on education and lifelong learning [1], and in particular Article 6(3) thereof,

Whereas:

(1) Regulation (EC) No 452/2008 applies to the production of statistics in three specific domains set out in its Article 3.

(2) Article 6(3) of Regulation (EC) No 452/2008 provides for adoption of limited derogations and transition periods for Member States, if necessary, both to be based on objective grounds.

(3) The international comparability of statistics on education requires the Member States and the Union institutions use classifications of education that are compatible with the revised International Standard Classification of Education ISCED 2011 (hereinafter referred to as 'ISCED 2011'), as adopted by the Unesco Member States at their 36th General Conference in November 2011.

(4) Data collection from administrative and other sources on student mobility for all cycles of study should be improved, in order to monitor progress and identify challenges, as well as to contribute to evidence-based policy making.

(5) It emerges from information provided to the Commission that certain Member States' requests for derogations are due to the need for major adaptations to national statistical systems in order to comply in full with Regulation (EC) No 452/2008.

(6) Such derogations should therefore be granted as requested to Belgium, Greece, Spain, France, Italy, Poland and Portugal.

(7) The measures provided for in this Decision are in accordance with the opinion of the European Statistical System Committee,

HAS ADOPTED THIS DECISION:

Article 1

Derogations are hereby granted to the Member States as set out in the Annex.

Article 2

This Decision is addressed to the Kingdom of Belgium, the Hellenic Republic, the Kingdom of Spain, the French Republic, the Italian Republic, the Republic of Poland and the Portuguese Republic.

Done at Brussels, 23 September 2013.

For the Commission

Algirdas ŠEMETA

Member of the Commission

[1] OJ L 145, 4.6.2008, p. 227.

ANNEX

Derogations from Regulation (EC) No 452/2008 concerning Domain 1: Education and training systems

ISCED levels shall refer to ISCED 2011 levels.

Member State	Variables and breakdowns	End of derogation
Belgium	— Number of new entrants by ISCED levels 3 to 7 (ISCED 3 to 5: 2-digit level of detail; ISCED 6 to 7: 1-digit level of detail), sex and age. Till the end of derogation data shall be provided for ISCED 5 at 1-digit level of detail	31 December 2015
	— Number of new entrants by ISCED levels 3 to 5 (ISCED 3 and 4: only vocational; ISCED 5: 2-digit level of detail), sex and field of education (2nd level of detail). Till the end of derogation data shall be provided for ISCED 5 at 1-digit level of detail	31 December 2015
Greece	— Number of mobile students enrolled, by ISCED levels 5 to 8 (1-digit level of detail), fields of education (3rd level of detail) and sex	31 December 2016
	— Number of mobile students enrolled, by ISCED levels 5 to 8 (1-digit level of detail), country of origin and sex	31 December 2016
	— Number of degree mobile graduates, by ISCED levels 5 to 8 (1-digit level of detail), country of origin and sex	31 December 2016
Spain	— Number of new entrants in ISCED level 3 (2nd level of detail), by sex and age.	31 December 2016
	— Number of new entrants in ISCED level 3 vocational, by sex and field of education (2nd level of detail).	31 December 2016
	— Data on degree mobile students and graduates according to the definition of country of origin 'the country where the upper secondary diploma was awarded'	31 December 2016
	— Data on education expenditure for ISCED 3-4 aggregated at 2-digit level of detail. Till end of derogation, data shall be provided for ISCED 3 + 4 aggregated	31 December 2016
France	— Number of new entrants, by ISCED levels 4, 5 and 6 (ISCED 4 and 5: 2-digit level of detail; ISCED 6: 1-digit level of detail), sex and age	31 December 2016
	— Number of new entrants, by ISCED levels 4, 5 and 6 (ISCED 4 only vocational; ISCED 5: 2-digit level of detail; ISCED 6: 1-digit level of detail), sex and field of education (2nd level of detail)	31 December 2016
	— Number of degree mobile graduates, by ISCED levels 5 to 8 (1-digit level of detail), country of origin and sex	31 December 2016
	— Number of graduates, by ISCED levels 4 to 7 (at 3-digit level of detail), sex and age	31 December 2016
Italy	— Number of graduates having had a credit mobility stay of minimum duration of three months throughout the cycle of study, for ISCED level 8 and by type of mobility scheme (EU programmes, other international/ national programmes, other programmes)	31 December 2019

Member State	Variables and breakdowns	End of derogation
	— Number of graduates having had a credit mobility stay of minimum duration of three months throughout the cycle of study, for ISCED level 8 and by country of destination	31 December 2019
Poland	— Number of degree mobile graduates on ISCED level 6 to 8 by country of origin and sex	31 December 2018
	— Number of graduates having had a credit mobility stay of minimum duration of three months throughout the cycle of study by ISCED levels 6 to 8 and type of mobility scheme (EU programmes, other international/ national programmes, other programmes)	31 December 2018
	— Number of graduates having had a credit mobility stay of minimum duration of three months throughout the cycle of study by ISCED levels 6 to 8 and country of destination	31 December 2018
Portugal	— Number of new entrants, in ISCED 3: 2-digit level of detail, by sex and age	31 December 2016
	— Number of new entrants, in ISCED 3: vocational, by sex and by field of education (2nd level of detail)	31 December 2016

RECOMMENDATIONS

COMMISSION RECOMMENDATION

of 24 September 2013

on the audits and assessments performed by notified bodies in the field of medical devices

(Text with EEA relevance)

(2013/473/EU)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 292 thereof,

Whereas:

(1) The proper functioning of notified bodies is crucial for ensuring a high level of health and safety protection, the free movement of medical devices in the internal market, and citizens' confidence in the regulatory system.

(2) Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices [1], Council Directive 93/42/EEC of 14 June 1993 concerning medical devices [2], and Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on *in vitro* diagnostic medical devices [3], contain certain provisions with regard to the audits, assessments and unannounced audits performed by notified bodies in the field of medical devices.

(3) The interpretation of those provisions and the behaviour of notified bodies designated in the field of medical devices differ. Therefore this Recommendation should set benchmarks for assessments and unannounced audits by notified bodies and respond to the most frequent shortcomings of the current practices.

(4) The Recommendation aims at ensuring that the notified body carries out a proper verification of the fulfilment of the legal requirements by the manufacturer.

(5) Subject to the respective conformity assessment procedure, notified bodies perform product assessments or quality system assessments. Accordingly, it is important to differentiate between these two types of assessments. To verify the continuous compliance with legal obligations, notified bodies should perform unannounced audits in addition to product assessments and quality system assessments.

(6) In order to satisfy the legal requirements laid down in Directive 90/385/EEC, in Directive 93/42/EEC and in Directive 98/79/EC, notified bodies should verify, where relevant, the fulfilment of the essential safety and health requirements contained in Directive 2006/42/EC of the European Parliament and of the Council of 17 May 2006 on machinery, and amending Directive 95/16/EC [4], of the requirements contained in Commission Regulation (EU) No 722/2012 of 8 August 2012 concerning particular requirements as regards the requirements laid down in Council Directives 90/385/EEC and 93/42/EEC with respect to active implantable medical devices and medical devices manufactured utilising tissues of animal origin [5] and of the common technical specifications for *in vitro* diagnostic medical devices laid down in Commission Decision 2002/364/EC of 7 May 2002 on common technical specifications for *in vitro* diagnostic medical devices [6].

(7) In order to avoid omissions and mistakes in the verification by the notified bodies of the important aspects of clinical evaluation or, in the case of *in vitro* diagnostic medical devices, of performance evaluation, and with regard to the post-market clinical follow-up, or, in the case of *in vitro* diagnostic medical devices, to post-market follow up, it is important to provide specific advice with regard to the control of those requirements.

(8) To facilitate the verification by the notified bodies of the technical documentation, the manufacturer's device identification system and the declaration of conformity, it is important to provide specific advice with regard to the control of those requirements. Directive 90/385/EEC, Directive 93/42/EEC and Directive 98/79/EC do not provide any exceptions for outsourced production compared to in-house production. Accordingly, it is necessary to include in duly substantiated cases the most important subcontractors and suppliers in the conformity assessment procedures.

[1] OJ L 189, 20.7.1990, p. 17.
[2] OJ L 169, 12.7.1993, p. 1.
[3] OJ L 331, 7.12.1998, p. 1.
[4] OJ L 157, 9.6.2006, p. 24.
[5] OJ L 212, 9.8.2012, p. 3.
[6] OJ L 131, 16.5.2002, p. 17.

(9) Subcontractors or suppliers cannot fulfil in the manufacturers' place crucial obligations of manufacturers, such as keeping available the full technical documentation, as this would void the concept of the manufacturer as responsible in accordance with Directive 90/385/EEC, Directive 93/42/EEC and Directive 98/79/EC. Therefore, the notified bodies should be advised on what they need to verify in case of outsourcing.

(10) Though regarded as two independent exercises, it is necessary to strengthen the link between the quality system review and the review of the technical documentation on a sampling basis.

(11) In the absence of established practice for unannounced audits it is important to determine the practicalities for such audits, as well as to provide advice on the arrangements needed for facilitating these audits,

HAS ADOPTED THIS RECOMMENDATION:

1. PURPOSE

To facilitate the consistent application of the conformity assessment provisions contained in Directive 90/385/EEC, Directive 93/42/EEC and Directive 98/79/EC, the notified bodies should apply the provisions of this Recommendation when they perform product assessments, quality system assessments and unannounced audits.

By providing general guidelines for such assessments and unannounced audits, this Recommendation should facilitate the work of the notified bodies as well as the Member States' evaluation thereof. This Recommendation does not create any new rights and obligations. The legal requirements applicable to all types of devices and conformity assessments are set out in the Union legislation on medical devices.

2. GENERAL GUIDELINES FOR AUDITS AND ASSESSMENTS

The notified bodies should apply the following:

(a) Where the manufacturer has applied for a design dossier examination or for a type examination (hereinafter jointly referred to as 'product assessment'), notified bodies should verify the conformity of the device under all product related aspects referred to in Directive 90/385/EEC, Directive 93/42/EEC and Directive 98/79/EC for detecting any non-compliance of the device and should apply Annex I.

(b) Where the manufacturer has applied for an assessment of its quality system, notified bodies should verify the conformity of the quality system with the quality-system related requirements contained in Directive 90/385/EEC, Directive 93/42/EEC and Directive 98/79/EC for detecting non-compliances of the quality system and should apply Annex II.

(c) To verify the day-to-day compliance with legal obligations, notified bodies should, in addition to the initial, surveillance or renewal audits, visit the manufacturer or, if this is likely to ensure more efficient control, one of its subcontractors in charge of processes which are essential for ensuring compliance with legal requirements ('critical subcontractor') or a supplier of crucial components or of the entire devices (both: 'crucial supplier') without prior notice ('unannounced audits') in accordance with Annex III.

3. FOLLOW-UP

Member States should draw this Recommendation to the attention of the notified bodies in the field of medical devices and should supervise the practice of notified bodies with respect to this Recommendation. They should evaluate the notified bodies' readiness to apply this Recommendation and in particular to perform unannounced audits when deciding on designations of bodies and on renewal or withdrawal of designations.

4. ADDRESSEES

This Recommendation is addressed to the Member States.

Done at Brussels, 24 September 2013.

For the Commission

Neven MIMICA

Member of the Commission

ANNEX I

Product assessment

1. Notified bodies should verify if the device is correctly qualified as a medical device and, in particular, whether the manufacturer has assigned a medical purpose to the device. They should furthermore verify the classification of the device and whether the manufacturer has fulfilled the applicable conformity assessment obligations. They should satisfy the obligations of consultation for certain devices that incorporate a substance which, in case used separately, may be considered to be a medicinal product, a human blood derivative or an animal tissue ([1]).

2. Notified bodies should verify the compliance of the device with the relevant Essential Requirements set out in Annex 1 to Directive 90/385/EEC, Annex I to Directive 93/42/EEC and Annex I to Directive 98/79/EC and, if applicable, with the essential safety and health requirements (ESHR) set out in Directive 2006/42/EC. In the case of *in vitro* diagnostic medical devices, where applicable, they should also verify the compliance of the device with the common technical specifications laid down in Decision 2002/364/EC or, when duly justified, with other technical solutions of a level at least equivalent. Where doubts arise, in the framework of a design dossier examination, as to the conformity of a device, notified bodies should carry out or ask for relevant tests of the device.

3. Notified bodies should examine the requirements regarding design and construction and the ESHR prior to examining the general requirements set out in Part I of Annex 1 to Directive 90/385/EEC, in Part A of Annex I to Directive 93/42/EEC and in Part A of Annex I to Directive 98/79/EC. They should apply special care to examine all the following aspects of the essential requirements:

   (a) design, manufacture and packaging;

   (b) labelling on the device, on the packaging for each unit or on the sales packaging and instructions for use.

4. The examination of the general requirements should ascertain that among others the following requirements have been met:

   (a) all hazards have been identified;

   (b) all risks associated with these hazards have been evaluated and have become part of the overall risk-benefit evaluation;

   (c) all these risks have been reduced as far as possible;

   (d) all remaining risks have been subject to protection measures;

   (e) safety principles have been applied in a way that is compatible with the state-of-the art.

5. For medical devices other than *in vitro* diagnostic devices, notified bodies should review all relevant preclinical data, the clinical evaluation and the post-market clinical follow-up undertaken or planned by the manufacturer. They should verify that the clinical evaluation is up-to-date. They should assess the need for and the appropriateness of a post-market clinical follow-up plan ([2]). If no clinical investigation has been undertaken, they should verify that the device type in question and all the different types of risks linked to the device design, its materials, and its use are appropriately assessed by means of scientific literature or other existing clinical data so that no clinical investigation is needed; they should furthermore examine the special justification ([3]) needed for implantable devices and devices classified within class III according to Annex IX to Directive 93/42/EEC.

6. In the case of *in vitro* diagnostic medical devices, notified bodies should review the performance evaluation undertaken by the manufacturer and post-market follow up undertaken or planned by the manufacturer.

7. Notified bodies should verify all documentation related to the device's conformity assessment. To that end, they should verify that the technical documentation is correct, consistent, relevant, up-to-date and complete ([4]) and that it covers all variants and trade names of the device. They should furthermore verify that the manufacturer's device identification

([1]) See Section 10 of Annex 1, Section 4.3 of Annex 2 and Section 5 of Annex 3 to Directive 90/385/EEC, Section 7.4 of Annex I, Section 4.3 of Annex II and Section 5 of Annex III to Directive 93/42/EEC and Regulation (EU) No 722/2012.
([2]) See Section 1.4 of Annex 7 to Directive 90/385/EEC and Section 1.1c of Annex X to Directive 93/42/EEC.
([3]) See Annex 7 to Directive 90/385/EEC and Annex X to Directive 93/42/EEC.
([4]) To be regarded as complete, a technical documentation should cover with appropriate depth the items listed in the document of the Global Harmonization Task Force 'Summary Technical Documentation for Demonstrating Conformity to the Essential Principles of Safety and Performance of Medical Devices (STED)' as well as additional items required by the European legislation or, for *in vitro* diagnostic medical devices, 'Summary Technical Documentation (STED) for Demonstrating Conformity to the Essential Principles of Safety and Performance of In Vitro Diagnostic Medical Devices' as well as additional items required by the European legislation, see for these documents http://www.imdrf.org/ghtf/ghtf-archives-sg1.asp

system and its practice of defining which devices belong to the same type ensure that the notified body's certificates, the manufacturer's declarations of conformity and the manufacturer's technical documentations can unequivocally be attributed to the device examined. They should finally verify that the draft declaration of conformity contains all the necessary items.

8. The notified body should clearly document the conclusions of its assessment and it should be clearly evidenced how the conclusions are taken into account as part of the notified body's decision making process.

ANNEX II

Quality system assessment

1. In the case of full quality assurance system, the verification should ascertain that the application of the quality system assures the conformity of the devices ([1]) with the legal requirements set out in Directive 90/385/EEC, Directive 93/42/EEC and Directive 98/79/EC. In the case of production or product quality assurance, the verification should ascertain that the application of the quality system ensures the conformity of the devices with the device type ([2]).

2. The quality system assessment should include audits on the premises of the manufacturer and, if this is also necessary to ensure efficient control, on those of its critical subcontractors or of its crucial suppliers. Notified bodies should establish a risk-based approach to identify such subcontractors and suppliers and should clearly document this decision process.

3. Notified bodies should identify which products the manufacturer regards as covered by its application, whether these products fall under Directive 90/385/EEC, Directive 93/42/EEC and Directive 98/79/EC and whether there have been changes to these products or to the quality system since the last audit or since the application. Furthermore, notified bodies should identify the post-market information available to them or to the manufacturer, which might need to be taken into account when planning and executing the audit.

4. For medical devices of Class IIa or IIb, the notified bodies should review the technical documentation on the basis of representative samples with a frequency and depth following established best practices, taking account of the device's class, risk and novelty. Samples chosen and reviews conducted should be clearly documented and justified. Over the period of certification of the specific quality system (i.e. for a maximum of five years) the sampling plan should be sufficient to ensure that every device category covered by the certificate has been sampled. Where doubts arise as to the conformity of a device, including its documentation, notified bodies should carry out or ask for relevant tests of the device. Where any non-conformity of a device is detected, they should investigate whether elements of the quality system or incorrect application thereof caused the non-conformity. Where a test has been carried out, notified bodies should provide the manufacturer with a test report and with an audit report which highlights in particular the link between quality system deficiencies and detected non-conformities of devices.

5. Notified bodies should verify whether the quality objectives and the quality manual or procedures developed by the manufacturer are appropriate to ensure the conformity of the devices falling under the application of the manufacturer.

6. Notified bodies should verify whether the manufacturer's business organisation is appropriate for ensuring the conformity of the quality system and of the medical devices. In particular, the following aspects should be examined: the organisational structure, the qualification of managerial staff and their organisational authority, the qualification and the training of other staff, the internal auditing, the infrastructure, and the monitoring of the quality system in operation, including with regard to involved third parties such as suppliers or subcontractors.

7. Notified bodies should verify the existence of an unequivocal product identification system. This system should ensure that the notified body's certificates, the manufacturer's declarations of conformity and the manufacturer's technical documentations can, in conjunction with that system, unequivocally be attributed to certain devices and not to others.

8. Notified bodies should verify the manufacturer's procedures with regard to the product documentation. The procedures relating to the product documentation should ensure that all products intended to be placed on the market or put into service are covered by the necessary certificates issued or to be issued by the notified body. The procedures with regard to the product documentation should also ensure that all products intended to be placed on the market or put into service, regardless of their trade name, are covered by the declarations of conformity of the manufacturer and that these are contained in and are compatible with the technical documentation. Notified bodies should verify the correct execution of these procedures by sampling the product documentation of individual devices.

9. Notified bodies should verify that the manufacturer's procedures aiming at the fulfilment of procedural legal requirements, in particular with regard to determining the appropriate class and conformity assessment procedure, are

([1]) See first sentence of Section 3.2 of Annex 2 to Directive 90/385/EEC, first sentence of Section 3.2 of Annex II to Directive 93/42/EEC and first sentence of Section 3.2 of Annex IV to Directive 98/79/EC.

([2]) See first sentence of Section 3.2 of Annex 5 to Directive 90/385/EEC, first sentence of Section 3.2 of Annex V and first sentence of Section 3.2 of Annex VI to Directive 93/42/EEC and first sentence of Section 3.2 of Annex VII to Directive 98/79/EC.

up-to-date, complete, consistent and correct. These procedures should take account of the necessity to provide data in order to allow the notified bodies to respect their consultation obligations for certain devices referred to in Section 1 of Annex I.

10. Notified bodies should verify that the manufacturer's procedures aiming at the fulfilment of device related legal requirements, are up-to-date, complete, consistent and correct. They should verify that the procedures on the risk management are in conformity with the legal requirements contained in Part I (general requirements) of Annex 1 to Directive 90/385/EEC, in Part I of Annex I to Directive 93/42/EEC and in Part A of Annex I to Directive 98/79/EC and that the procedures cover among others the aspects listed in Section 4 of Annex I to this Recommendation. They should verify the correct execution of these procedures by sampling the product documentation of individual devices.

11. In case of manufacturers of medical devices other than *in vitro* diagnostic devices, notified bodies should verify that the manufacturer's procedures on clinical evaluations and on the post-market clinical follow-up are complete and correct and that these are correctly implemented. To that end, they should examine clinical evaluations and the post-market clinical follow-up for some of the device types covered by the application, applying the principles described in Section 5 of Annex I to this Recommendation. They should verify the correct execution of these procedures by sampling the product documentation of individual devices.

12. In case of manufacturers of *in vitro* diagnostic medical devices, notified bodies should verify the manufacturer's working procedures on performance evaluations, on the identification of certified reference materials or reference measurement procedures to allow for metrological traceability. They should verify the correct execution of these procedures by sampling the product documentation of individual devices.

13. Notified bodies should verify that the procedures regarding the design and product development, including any change control procedures, are appropriate to ensure the compliance of the devices.

14. Notified bodies should verify that the manufacturer controls the manufacturing environment and processes so as to ensure the conformity of the devices with the legal requirements. Notified bodies should pay special attention to critical processes such as design control, establishment of material specifications, purchasing and control of incoming material or components, assembling, software validation, sterilisation, batch-release, packaging, and product quality control, regardless of whether they are subcontracted or not.

15. Notified bodies should verify the manufacturer's system ensuring traceability of materials and components, from the entry into the manufacturer's, suppliers' or subcontractors' premises to the delivery of the final product. In particular where risks might be caused by the exchange of raw materials, notified bodies should check the coherence between the quantity of produced or purchased crucial raw material or components approved for the design and the quantity of finished products.

16. Notified bodies should verify that experience gained in the post-production phase, in particular user complaints and vigilance data, is systematically collected and evaluated for the devices covered by the application of the manufacturer and that the necessary improvement of the devices or of their production has been initiated. They should in particular verify that the manufacturer has in place distributor, user or patient related business processes which are suitable for providing information indicating the need for reviewing the design of the device, its manufacturing or the quality system.

17. Notified bodies should verify that the documentation and records with regard to the quality system and its changes, the procedure of management review, and the respective documentation control are up-to-date, consistent, complete, correct and properly structured.

18. At each annual surveillance audit, the notified bodies should verify that the manufacturer correctly applies the approved quality management system and the post-market surveillance plan.

19. The notified body should clearly document the conclusions of its assessment and it should be clearly evidenced how the conclusions are taken into account as part of the notified body's decision making process.

General advice in case of outsourcing of the production via subcontractors or suppliers

Critical subcontractors or crucial suppliers may be suppliers of suppliers or even suppliers further down the supply chain. Notified bodies should refrain from signing arrangements with manufacturers unless they receive access to all critical subcontractors and crucial suppliers and thus to all sites where the devices or its crucial components are produced, regardless of the length of the contractual chain between the manufacturer and the subcontractor or supplier.

Notified bodies should note that manufacturers:

(a) have to fulfil their obligations themselves regardless of any partial or total outsourcing of the production via subcontractors or suppliers;

(b) do not fulfil their obligation to have at their disposal the full technical documentation and/or of a quality system by referring to the technical documentation of a subcontractor or supplier and/or to their quality system;

(c) should integrate the quality system of critical subcontractors and of crucial suppliers with their quality system;

(d) need to control the quality of services provided and of components supplied and the quality of production thereof regardless of the length of the contractual chain between the manufacturer and the subcontractor or supplier.

ANNEX III

Unannounced audits

1. Notified bodies should carry out unannounced audits at least once every third year. Notified bodies should increase the frequency of unannounced audits if the devices bear a high risk, if the devices of the type in question are frequently non-compliant or if specific information provides reasons to suspect non-conformities of the devices or of their manufacturer. The timing of the unannounced audits should be unpredictable. As a general principle an unannounced audit should not take less than one day and should be executed by at least two auditors.

2. Notified bodies may, instead of or in addition to visiting the manufacturer, visit one of the premises of the manufacturer's critical subcontractors or crucial suppliers if this is likely to ensure more efficient control. This applies in particular if the main part of the design development, manufacturing, testing or another crucial process is located with the subcontractor or supplier.

3. Within the context of such unannounced audits, the notified bodies should check a recently produced adequate sample, preferably a device taken from the ongoing manufacturing process, for its conformity with the technical documentation and with legal requirements. The check of the conformity of the device should include the verification of the traceability of all critical components and materials and of the manufacturer's traceability system. The check should encompass a file review and, if necessary in order to establish the conformity, a test of the device.

   To prepare the test, notified bodies should request from the manufacturer all the relevant technical documentation including previous test protocols and results. The test should be undertaken in accordance with the testing procedure defined by the manufacturer in the technical documentation which has to be validated by the notified body. The test may also be performed by the manufacturer, its critical subcontractor or crucial supplier under observation of the notified body.

4. Notified bodies in charge of product assessment [1] should, in addition to the steps foreseen in Sections 1, 2 and 3, sample devices belonging to at least three different device types and, where the manufacturer produces more than 99 device types, devices belonging to at least every hundredth type at the end of the production chain or in the manufacturer's warehouse with a view of testing the conformity of the device types. Variants containing a technical difference which might affect safety or performance of the device should be counted as a separate device type. Dimensional size variants should not be regarded as different types unless specific risks are linked to the dimension. These samples should be tested by the notified bodies or by qualified personnel under their observation on their own premises, or on the manufacturer's premises, or on the premises of the manufacturer's critical subcontractor or crucial supplier or in external laboratories. Sampling criteria and testing procedures should be defined in advance. In particular if a sampling in the manufacturer's premises is not possible, notified bodies should take samples from the market, if necessary with support by the competent authorities, or should perform testing on a device installed at a customer location. To prepare the test, notified bodies should request from the manufacturer relevant technical documentation including final batch testing reports, previous test protocols and results.

5. Notified bodies in charge of verifying the quality system of the manufacturer [2] should, in addition to the steps foreseen in Sections 1, 2 and 3, verify whether the manufacturing activity ongoing at the time of the unannounced audit is in line with the manufacturer's documentation relevant for the manufacturing activity and that both are in conformity with legal requirements. In addition, these notified bodies should check in more detail at least two critical processes such as design control, establishment of material specifications, purchasing and control of incoming material or components, assembling, sterilisation, batch-release, packaging, or product quality control. Amongst the suitable critical processes, notified bodies should select one which has a high likelihood of non-conformity and one which is particularly safety relevant.

General advice with regard to contractual arrangements between the notified body and the manufacturer for the organisation of unannounced audits

In order to ensure that notified bodies are in a position to perform unannounced audits, some modalities, such as the following ones, should be considered.

Unannounced audits in premises of the manufacturer or its critical subcontractors or crucial suppliers should be foreseen in the contractual arrangements between the notified bodies and the manufacturers. If a visa is needed to visit the country where the manufacturer is located, the contractual arrangements should contain, as an annex, an invitation to visit the

[1] According to Section 2(a) and Annex I to this Recommendation.
[2] According to Section 2(b) and Annex II to this Recommendation.

manufacturer at any time and an invitation which leaves the date of signature and the date of visit open (to be filled-in by the notified body). The contractual arrangements should also contain, as an annex, similar invitations issued by the critical subcontractors or crucial suppliers.

The contractual arrangements should foresee that the manufacturers continuously inform the notified bodies on the periods when devices falling under the notified bodies' certificates will not be manufactured. The contractual arrangements should authorise the notified bodies to end the contract as soon as their permanent unannounced access to the premises of the manufacturer or its critical subcontractors or crucial suppliers is no longer assured.

The contractual arrangements should furthermore cover the measures to be taken by notified bodies to ensure the security of their auditors. The contractual arrangements should provide for a financial compensation for the unannounced audits including, where applicable, the device acquisition, its testing and security arrangements.

NOTICE TO READERS

Council Regulation (EU) No 216/2013 of 7 March 2013 on the electronic publication of the *Official Journal of the European Union*

In accordance with Council Regulation (EU) No 216/2013 of 7 March 2013 on the electronic publication of the *Official Journal of the European Union* (OJ L 69, 13.3.2013, p. 1), as of 1 July 2013, only the electronic edition of the Official Journal shall be considered authentic and shall have legal effect.

Where it is not possible to publish the electronic edition of the Official Journal due to unforeseen and exceptional circumstances, the printed edition shall be authentic and shall have legal effect in accordance with the terms and conditions set out in Article 3 of Regulation (EU) No 216/2013.

NOTE TO READERS — WAY OF REFERRING TO ACTS

As of 1 July 2013 the way of referring to acts has changed.

During a transitional period this new practice will coexist with the previous one.

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