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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.

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⁽¹⁾ Text with EEA relevance

II

(Non-legislative acts)

REGULATIONS

COMMISSION REGULATION (EU) No 317/2013

of 8 April 2013

amending the Annexes to Regulations (EC) No 1983/2003, (EC) No 1738/2005, (EC) No 698/2006, (EC) No 377/2008 and (EU) No 823/2010 as regards the International Standard Classification of Education**(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EC) No 1177/2003 of the European Parliament and of the Council of 16 June 2003 concerning Community statistics on income and living conditions (EU-SILC) ⁽¹⁾, and in particular Article 15 thereof,Having regard to Council Regulation (EC) No 530/1999 of 9 March 1999 concerning structural statistics on earnings and on labour costs ⁽²⁾, and in particular Article 11 thereof,Having regard to Council Regulation (EC) No 577/98 of 9 March 1998 on the organisation of a labour force sample survey in the Community ⁽³⁾, and in particular Article 4 thereof,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 ⁽⁴⁾, and in particular Article 6(1) thereof,

Whereas:

- (1) The introduction of an updated classification system is central to the Commission's ongoing efforts to maintain the relevance of European statistics, by taking into account developments and changes in the area of education.
- (2) The United Nations Educational, Scientific and Cultural Organization (Unesco) has revised the version of the International Standard Classification of Education (ISCED) used hitherto (ISCED 1997) with the aim of ensuring that it is consistent with developments in the policies and structures of education and training.

- (3) The international comparability of educational statistics requires that the Member States and the Union institutions use classifications of education which 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) The establishment of a revised International Standard Classification of Education makes it necessary to amend various references to ISCED, ISCED 97 and ISCED 1997 as well as to amend a number of relevant instruments.

- (5) It is therefore necessary to amend accordingly the following Regulations: Commission Regulation (EC) No 1983/2003 of 7 November 2003 implementing Regulation (EC) No 1177/2003 of the European Parliament and of the Council concerning Community statistics on income and living conditions (EU-SILC) as regards the list of target primary variables ⁽⁵⁾; Commission Regulation (EC) No 1738/2005 of 21 October 2005 amending Regulation (EC) No 1916/2000 as regards the definition and transmission of information on the structure of earnings ⁽⁶⁾; Commission Regulation (EC) No 698/2006 of 5 May 2006 implementing Council Regulation (EC) No 530/1999 as regards quality evaluation of structural statistics on labour costs and earnings ⁽⁷⁾; Commission Regulation (EC) No 377/2008 of 25 April 2008 implementing Council Regulation (EC) No 577/98 on the organisation of a labour force sample survey in the Community as regards the codification to be used for data transmission from 2009 onwards, the use of a subsample for the collection of data on structural variables and the definition of the reference quarters ⁽⁸⁾; Commission Regulation (EU) No 823/2010 of 17 September 2010 implementing Regulation (EC) No 452/2008 of the European Parliament and of the

⁽¹⁾ OJ L 165, 3.7.2003, p. 1.⁽²⁾ OJ L 63, 12.3.1999, p. 10.⁽³⁾ OJ L 77, 14.3.1998, p. 3.⁽⁴⁾ OJ L 145, 4.6.2008, p. 227.⁽⁵⁾ OJ L 298, 17.11.2003, p. 34.⁽⁶⁾ OJ L 279, 22.10.2005, p. 32.⁽⁷⁾ OJ L 121, 6.5.2006, p. 30.⁽⁸⁾ OJ L 114, 26.4.2008, p. 57.

Council concerning the production and development of statistics on education and lifelong learning, as regards statistics on the participation of adults in lifelong learning ⁽¹⁾.

- (6) The measures provided for in this Regulation are in accordance with the opinion of the European Statistical System Committee,

HAS ADOPTED THIS REGULATION:

Article 1

Amendment to Regulation (EC) No 1983/2003

Footnote No 19 in the Annex to Regulation (EC) No 1983/2003 is replaced by the following:

‘ISCED 2011: International standard classification of education 2011.’.

Article 2

Amendment to Regulation (EC) No 1738/2005

Regulation (EC) No 1738/2005 is amended as follows:

- (1) ‘ISCED 97’ is replaced by ‘ISCED 2011’ throughout the Annexes;

- (2) variable 2.5 of Annex I is replaced by the following:

‘*Educational attainment level (ISCED 2011)*’;

- (3) variable 2.5 of Annex II is replaced by the following:

‘*Educational attainment level (ISCED 2011)*’

This variable concerns the highest level of education successfully completed, which the employee has received according to the International Standard Classification of Education, 2011 version (ISCED 2011). The expression “level successfully completed” must be associated with

obtaining a certificate or a diploma, when there is certification. In cases where there is no certification, successful completion must be associated with full attendance.

Groups of codes to be used are defined in the Implementing Arrangements of the SES survey.’.

Article 3

Amendment to Regulation (EC) No 698/2006

Regulation (EC) No 698/2006 is amended as follows:

In Section 2.1(2) of the Annex, the reference to ‘level of education (ISCED 0 to 6)’ is replaced by ‘Educational attainment level (ISCED 2011 levels 0 to 8)’.

Article 4

Amendment to Regulation (EC) No 377/2008

Regulation (EC) No 377/2008 is amended as follows:

Annex III is amended in accordance with Annex I to this Regulation.

Article 5

Amendment to Regulation (EU) No 823/2010

Regulation (EU) No 823/2010 is amended as follows:

Annexes I and II are amended in accordance with Annex II to this Regulation.

Article 6

This Regulation shall enter into force on the 20th day following that of its publication in the *Official Journal of the European Union*.

It shall apply as from the reference year starting on 1 January 2014.

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

Done at Brussels, 8 April 2013.

For the Commission

The President

José Manuel BARROSO

⁽¹⁾ OJ L 246, 18.9.2010, p. 33.

ANNEX I

Amendment to Regulation (EC) No 377/2008

- (1) In Annex III the instructions for the codification of the variables 'HATLEVEL', 'HATFIELD', and 'HATYEAR' shall be replaced by the following:

Name	Column	Periodicity	Code	Description	Filter/Remarks
'HATLEVEL	197/199	QUARTERLY		<i>Educational attainment level ⁽¹⁾</i>	Everybody aged 15 years or more
			000	No formal education or below ISCED 1	
			100	ISCED 1	
			200	ISCED 2 (incl. ISCED 3 programmes of duration less than 2 years)	
			302	ISCED 3 programme duration of 2 years and more, sequential (i.e. access to next ISCED 3 programme only)	
			303	ISCED 3 programme duration of 2 years and more, terminal or access to ISCED 4 only	
			304	ISCED 3 with access to ISCED 5, 6 or 7	
			300	ISCED 3 programme of duration of 2 years and more, without possible distinction of access to other ISCED levels	
			400	ISCED 4	
			500	ISCED 5	
			600	ISCED 6	
			700	ISCED 7	
			800	ISCED 8	
			999	Not applicable (child less than 15 years)	
			blank	No answer	
HATYEAR	200/203	YEARLY		<i>Year when this level was successfully completed</i>	HATLEVEL = 100-800
				The four digits of year when highest level of education was successfully completed are entered	
			9999	Not applicable (HATLEVEL ≠ 100 to 800)	
			blank	No answer	

Name	Column	Periodicity	Code	Description	Filter/Remarks
HATVOC	204	QUARTERLY		<i>Orientation of this level</i>	HATLEVEL = 300 to 400 and
			1	General	(15 ≤ AGE ≤ 34 or
			2	Vocational	(AGE > 34 and REFYEAR – HATYEAR ≤ 15))
			9	Not applicable (HATLEVEL ≠ 300 to 400 or (AGE > 34 and REFYEAR – HATYEAR > 15))	
HATFIELD	205/208	YEARLY	blank	No answer	
				<i>Field of this level</i>	HATLEVEL = 300 to 800 and
			0000-9998	<i>Level 1 of the classification of fields of education and training</i> ⁽²⁾	(15 ≤ AGE ≤ 34 or
			9999	Not applicable (HATLEVEL ≠ 300 to 800 or (AGE > 34 and REFYEAR – HATYEAR > 15))	(AGE > 34 and REFYEAR – HATYEAR ≤ 15))
			blank	No answer	

⁽¹⁾ Highest level of education successfully completed as defined by ISCED 2011, coding based on ISCED mappings to be delivered to Eurostat.

⁽²⁾ Or subdivisions of the classification of fields of education and training.

- (2) In Annex III the variable 'EDUCFILD' and the instructions for the codification of the variable 'EDUCLEVL' shall be replaced by the following:

Name	Column	Periodicity	Code	Description	Filter/Remarks
'EDUCLEVL	209	QUARTERLY		<i>Level of this education</i> ⁽¹⁾	EDUCSTAT = 1 or 3
			1	ISCED 1	
			2	ISCED 2	
			3	ISCED 3	
			4	ISCED 4	
			5	ISCED 5	
			6	ISCED 6	
			7	ISCED 7	
			8	ISCED 8	
			9	Not applicable (EDUCSTAT ≠ 1 or 3)	
EDUCVOC	210	QUARTERLY	blank	No answer	EDUCLEVL = 3 to 4
				<i>Orientation of this education</i>	
			1	General	

Name	Column	Periodicity	Code	Description	Filter/Remarks
			2	Vocational	
			9	Not applicable (EDUCLEVL ≠ 3 to 4)	
			blank	No answer	

(¹) Coding based on ISCED mappings to be delivered to Eurostat.'

ANNEX II

Amendment to Regulation (EU) No 823/2010

- (1) In Annex I the instructions for the codification of the variables 'HATLEVEL', 'HATFIELD', 'HATYEAR', 'HATVOC', 'HATOTHER', 'HATOTHER_LEVEL', 'HATOTHER_VOC', 'HATOTHER_FIELD', 'HATCOMP' and 'HATCOMPHIGH' shall be replaced by the following:

Variable name and status	Code	Description	Filter
HATLEVEL		EDUCATIONAL ATTAINMENT LEVEL <i>(Highest level of education successfully completed as defined by ISCED 2011, coding based on ISCED mappings to be delivered to Eurostat)</i>	Everybody
	000	No formal education or below ISCED 1	
	100	ISCED 1	
	200	ISCED 2 (incl. ISCED 3 programmes of duration less than 2 years)	
	302	ISCED 3 programme duration of 2 years and more, sequential (i.e. access to next ISCED 3 programme only)	
	303	ISCED 3 programme duration of 2 years and more, terminal or access to ISCED 4 only	
	304	ISCED 3 with access to ISCED 5, 6 or 7	
	300	ISCED 3 programme of duration of 2 years and more, without possible distinction of access to other ISCED levels	
	400	ISCED 4	
	500	ISCED 5	
	600	ISCED 6	
	700	ISCED 7	
	800	ISCED 8	
	- 1	No answer	
HATFIELD		FIELD OF THE HIGHEST LEVEL OF EDUCATION SUCCESSFULLY COMPLETED	HATLEVEL = 300 to 800
	0000-9998	<i>Level 1 of the classification of fields of education and training (1)</i> <i>(1) or subdivisions of the classification of fields of education and training, details provided in the Adult Education Survey Manual referred to in Article 6</i>	
	- 1	No answer	
	- 2	Not applicable (HATLEVEL ≠ 300 to 800)	
HATYEAR		YEAR WHEN HIGHEST LEVEL OF EDUCATION WAS SUCCESSFULLY COMPLETED	HATLEVEL ≠ 000, - 1
	four digits	<i>The four digits of the year when highest level of education or training was successfully completed are entered</i>	

Variable name and status	Code	Description	Filter
	- 1	No answer	
	- 2	Not applicable (HATLEVEL = 000, - 1)	
HATVOC		ORIENTATION OF THE HIGHEST LEVEL OF EDUCATION SUCCESSFULLY COMPLETED	HATLEVEL = 300 to 400 and (REFYEAR - HATYEAR) ≤ 20
	1	General education	
	2	Vocational education	
	- 1	No answer	
	- 2	Not applicable (HATLEVEL ≠ 300 to 400 or (REFYEAR - HATYEAR) > 20)	
HATOTHER (optional)		OTHER FORMAL EDUCATION OR TRAINING SUCCESSFULLY COMPLETED IN ANOTHER FIELD THAN "HATLEVEL"	HATLEVEL = 300 to 800 and (REFYEAR - HATYEAR) ≤ 20
	1	Yes	
	2	No	
	- 1	No answer	
	- 2	Not applicable (HATLEVEL ≠ 300 to 800 or (REFYEAR - HATYEAR) > 20)	
HATOTHER_LEVEL (optional)		Level of the formal education programme	HATOTHER = 1
	300-800	Coded as HATLEVEL	
	- 1	No answer	
	- 2	Not applicable (HATOTHER ≠ 1)	
HATOTHER_VOC (optional)		Orientation of the formal education programme	HATOTHER = 1 and HATOTHER_LEVEL = 300 to 400
	1-2	Coded as HATVOC	
	- 1	No answer	
	- 2	Not applicable (HATOTHER ≠ 1 or HATOTHER_LEVEL ≠ 300 to 400)	
HATOTHER_FIELD (optional)		Field of the formal education programme	HATOTHER = 1 and HATOTHER_LEVEL = 300 to 800
	0000-9998	Coded as HATFIELD	
	- 1	No answer	
	- 2	Not applicable (HATOTHER ≠ 1 or HATOTHER_LEVEL ≠ 300 to 800)	
HATCOMP (optional)		PROCEDURE OF RECOGNITION OF SKILLS and COMPETENCES UNDERTAKEN	Everybody
	1	Yes, certification obtained	
	2	Yes, procedure ongoing	
	3	No	
	- 1	No answer	

Variable name and status	Code	Description	Filter
HATCOMPHIGH (optional)		RECOGNITION OF SKILLS and COMPETENCES ALLOWS ACCESS TO A higher formal education programme than the level mentioned in "HATLEVEL"	HATCOMP = 1,2 and HATLEVEL ≠ 000, - 1
	1	Yes	
	2	No	
	- 1	No answer	
	- 2	Not applicable (HATCOMP ≠ 1,2 or HATLEVEL = 000, - 1)	

- (2) In Annex I the instructions for the codification of the variables 'DROPHIGH', 'DROPLEVEL' and 'DROPVOC' shall be replaced by the following:

Variable name and status	Code	Description	Filter
'DROPHIGH		FORMAL education ABANDONED, higher than the level mentioned in "HATLEVEL" but NOT COMPLETED	HATLEVEL ≠ 000, - 1 and (REFYEAR - HATYEAR) ≤ 20
	1	Yes	
	2	No	
	- 1	No answer	
	- 2	Not applicable (HATLEVEL = 000, - 1 or (REFYEAR - HATYEAR) > 20)	
DROPLEVEL		Level of the FORMAL education not completed (as defined by ISCED 2011)	DROPHIGH = 1
	200	ISCED 2 (incl. ISCED 3 programmes of duration less than 2 years)	
	302	ISCED 3 programme duration of 2 years and more, sequential (i.e. access to next ISCED 3 programme only)	
	303	ISCED 3 programme duration of 2 years and more, terminal or access to ISCED 4 only	
	304	ISCED 3 with access to ISCED 5, 6 or 7	
	300	ISCED 3 programme of duration of 2 years and more, without possible distinction of access to other ISCED levels	
	400	ISCED 4	
	500	ISCED 5	
	600	ISCED 6	
	700	ISCED 7	
	800	ISCED 8	
	- 1	No answer	
	- 2	Not applicable (DROPHIGH ≠ 1)	

Variable name and status	Code	Description	Filter
DROPVOC (optional)		Orientation of the FORMAL education not completed	$\text{DROPLEVEL} = 300 \text{ to } 400 \text{ and } (\text{REFYEAR} - \text{HATYEAR}) \leq 20$
	1	General education	
	2	Vocational education	
	- 1	No answer	
	- 2	Not applicable ($\text{DROPLEVEL} \neq 300 \text{ to } 400$ or $(\text{REFYEAR} - \text{HATYEAR}) > 20$)	

- (3) In Annex I the instructions for the codification of the variables 'FEDLEVEL', 'FEDFIELD' and 'FEDVOC' shall be replaced by the following:

Variable name and status	Code	Description	Filter
FEDLEVEL		Level of the most recent FORMAL education activity (as defined by ISCED 2011)	$\text{FEDNUM} \geq 1$
	100	ISCED 1	
	200	ISCED 2 (incl. ISCED 3 programmes of duration less than 2 years)	
	302	ISCED 3 programme duration of 2 years and more, sequential (i.e. access to next ISCED 3 programme only)	
	303	ISCED 3 programme duration of 2 years and more, terminal or access to ISCED 4 only	
	304	ISCED 3 with access to ISCED 5, 6 or 7	
	300	ISCED 3 programme of duration of 2 years and more, without possible distinction of access to other ISCED levels	
	400	ISCED 4	
	500	ISCED 5	
	600	ISCED 6	
	700	ISCED 7	
	800	ISCED 8	
	- 2	Not applicable ($\text{FEDNUM} = 0$)	
FEDFIELD		Field of the most recent FORMAL education activity	$\text{FEDNUM} \geq 1$ and $\text{FEDLEVEL} = 300 \text{ to } 800$
	0000-9998	Level 1 of the classification of fields of education and training (1) (1) or subdivisions of the classification of fields of education and training, details provided in the Adult Education Survey Manual referred to in Article 6	
	- 1	No answer	
	- 2	Not applicable ($\text{FEDNUM} = 0$ or $\text{FEDLEVEL} \neq 300 \text{ to } 800$)	

Variable name and status	Code	Description	Filter
FEDVOC		Orientation of the most recent FORMAL education activity	FEDLEVEL = 300 to 400
	1	<i>General education</i>	
	2	<i>Vocational education</i>	
	– 1	<i>No answer</i>	
	– 2	<i>Not applicable (FEDLEVEL ≠ 300 to 400)</i>	

- (4) In Annex II, 'sample and precision requirements', in paragraph 3, the indicator 'participation rate (%) in non-formal education and training by highly educated persons (ISCED level 5-6)' shall be replaced by 'participation rate (%) in non-formal education and training by highly educated persons (ISCED levels 5-8)'.

COMMISSION REGULATION (EU) No 318/2013**of 8 April 2013****adopting the programme of ad-hoc modules, covering the years 2016 to 2018, for the labour force sample survey provided for by Council Regulation (EC) No 577/98****(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

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

Having regard to Council Regulation (EC) No 577/98 of 9 March 1998 on the organisation of a labour force sample survey in the Community ⁽¹⁾, and in particular Article 4(2) thereof,

Whereas:

- (1) In accordance with Regulation (EC) No 577/98, it is necessary to specify the elements of the programme of ad-hoc modules covering the years 2016 to 2018.
- (2) The Europe 2020 strategy and its flagship initiative 'Youth on the Move' call for further information on the situation of young people on the labour market. The 2011 Commission Communication on a 'Youth Opportunities Initiative' ⁽²⁾ encourages action at European level in several priority fields linked to getting a first job.
- (3) Based on the Communication concerning a 'Small Business Act' ⁽³⁾, the 2012 Commission Communication

'Towards a job-rich recovery' ⁽⁴⁾, which forms part of the Employment Package, encourages job creation specifically through promoting and supporting self-employment.

- (4) The strategy for equality between women and men, covering the period 2010-2015 ⁽⁵⁾, includes measures for reconciliation between work and family life as a means of achieving equal economic independence for women and men.
- (5) The measures provided for in this Regulation are in accordance with the opinion of the European Statistical System Committee,

HAS ADOPTED THIS REGULATION:

Article 1

The programme of ad-hoc modules for the labour force sample survey, covering the years 2016 to 2018, as set out in the Annex, is hereby adopted.

*Article 2*This Regulation shall enter into force on the seventh 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, 8 April 2013.

*For the Commission**The President*

José Manuel BARROSO

⁽¹⁾ OJ L 77, 14.3.1998, p. 3.⁽²⁾ Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions — Youth Opportunities Initiative, adopted on 20 December 2011 — COM(2011) 933 final.⁽³⁾ Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions — 'Think Small First' — A 'Small Business Act' for Europe, adopted on 25 June 2008 — COM(2008) 394 final.⁽⁴⁾ Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions — 'Towards a job-rich recovery', adopted on 18 April 2012 — COM(2012) 173 final.⁽⁵⁾ Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions — Strategy for equality between women and men 2010-2015, adopted on 21 September 2010 — COM(2010) 491.

ANNEX

LABOUR FORCE SURVEY**Multiannual programme of ad-hoc modules****1. YOUNG PEOPLE ON THE LABOUR MARKET**

List of variables: to be defined before December 2014.

Reference period: 2016. Member States may provide data for all 52 weeks or for the second quarter of the year.

Member States and regions concerned: All.

Sample: the ad-hoc module sample should fulfil the requirements of Annex I, point 4, to Commission Regulation (EC) No 377/2008 ⁽¹⁾, i.e. the sample used to collect information on ad-hoc modules must also provide information on structural variables.

Transmission of the results: before 31 March 2017.

2. SELF-EMPLOYMENT

List of variables: to be defined before December 2015.

Reference period: 2017. Member States may provide data for all 52 weeks or for the second quarter of the year.

Member States and regions concerned: All.

Sample: the ad-hoc module sample should fulfil the requirements of Annex I, point 4, to Regulation (EC) No 377/2008, i.e. the sample used to collect information on ad-hoc modules must also provide information on structural variables.

Transmission of the results: before 31 March 2018.

3. RECONCILIATION BETWEEN WORK AND FAMILY LIFE

List of variables: to be defined before December 2016.

Reference period: 2018. Member States may provide data for all 52 weeks or for the second quarter of the year.

Member States and regions concerned: All.

Sample: the ad-hoc module sample should fulfil the requirements of Annex I, point 4, to Regulation (EC) No 377/2008, i.e. the sample used to collect information on ad-hoc modules must also provide information on structural variables.

Transmission of the results: before 31 March 2019.

⁽¹⁾ OJ L 114, 26.4.2008, p. 57.

COMMISSION IMPLEMENTING REGULATION (EU) No 319/2013**of 8 April 2013****derogating, for the marketing year 2012/13, from Article 63(2)(a) of Council Regulation (EC) No 1234/2007 as regards the dates for communicating the carry forward of surplus sugar**

THE EUROPEAN COMMISSION,

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

Having regard to Council Regulation (EC) No 1234/2007 of 22 October 2007 establishing a common organisation of agricultural markets and on specific provisions for certain agricultural products (Single CMO Regulation) ⁽¹⁾, and in particular point (c) of Article 85 in conjunction with Article 4 thereof,

Whereas:

- (1) According to Article 63(2)(a) of Regulation (EC) No 1234/2007, undertakings which decide to carry forward all or part of their production in excess of quota have to inform Member States concerned about the decision. That information has to be submitted before a date to be determined by each Member State, within the time limits provided for by that Article.
- (2) In order to facilitate the supply of the out-of-quota sugar on the Union market, thereby allowing undertakings to respond to unforeseen changes in demand in the early months of the marketing year 2012/13, it is necessary to give Member States the possibility to determine dates within larger time limits than those provided for in Article 63(2)(a) of Regulation (EC) No 1234/2007.

- (3) It is therefore appropriate to derogate from Article 63(2)(a) of Regulation (EC) No 1234/2007 in respect to the marketing year 2012/13.

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

HAS ADOPTED THIS REGULATION:

Article 1

By way of derogation from Article 63(2)(a) of Regulation (EC) No 1234/2007, for the marketing year 2012/13, the undertakings which, in accordance with Article 63(1) of that Regulation, have decided to carry forward quantities of surplus sugar, shall inform the Member State concerned before a date to be determined by Member States between 1 February and 15 August 2013.

Article 2

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

It shall apply until 30 September 2013.

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

Done at Brussels, 8 April 2013.

For the Commission

The President

José Manuel BARROSO

⁽¹⁾ OJ L 299, 16.11.2007, p. 1.

COMMISSION IMPLEMENTING REGULATION (EU) No 320/2013**of 8 April 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 multi-lateral 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, 8 April 2013.

*For the Commission,
On behalf of the President,
José Manuel SILVA RODRÍGUEZ
Director-General for Agriculture and
Rural Development*

⁽¹⁾ OJ L 299, 16.11.2007, p. 1.

⁽²⁾ OJ L 157, 15.6.2011, p. 1.

ANNEX

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

(EUR/100 kg)		
CN code	Third country code ⁽¹⁾	Standard import value
0702 00 00	MA	63,6
	TN	101,8
	TR	127,7
	ZZ	97,7
0707 00 05	JO	194,1
	MA	116,3
	TR	137,2
	ZZ	149,2
0709 93 10	MA	91,2
	TR	120,7
	ZZ	106,0
0805 10 20	EG	51,7
	IL	71,8
	MA	75,7
	TN	65,6
	TR	65,2
	ZZ	66,0
0805 50 10	TR	74,3
	ZZ	74,3
0808 10 80	AR	106,7
	BR	93,9
	CL	112,0
	CN	78,6
	MK	31,3
	US	275,4
	UY	106,8
	ZA	113,1
	ZZ	114,7
0808 30 90	AR	115,0
	CL	134,2
	CN	85,2
	TR	204,5
	US	182,0
	ZA	118,6
	ZZ	139,9

⁽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 5 April 2013

appointing a Spanish member of the Committee of the Regions

(2013/171/EU)

THE COUNCIL OF THE EUROPEAN UNION,

HAS ADOPTED THIS DECISION:

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 305 thereof,

Having regard to the proposal of the Spanish Government,

Whereas:

(1) On 22 December 2009 and on 18 January 2010, the Council adopted Decisions 2009/1014/EU ⁽¹⁾ and 2010/29/EU ⁽²⁾ appointing the members and alternate members of the Committee of the Regions for the period from 26 January 2010 to 25 January 2015.

(2) A member's seat on the Committee of the Regions has become vacant following the end of the term of office of Mr Juan Ignacio ZOIDO ÁLVAREZ,

Article 1

The following is hereby appointed as member to the Committee of the Regions for the remainder of the current term of office, which runs until 25 January 2015:

— Mr Iñigo de la SERNA HERNÁIZ, *Alcalde de Santander*.

Article 2

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

Done at Brussels, 5 April 2013.

For the Council

The President

E. GILMORE

⁽¹⁾ OJ L 348, 29.12.2009, p. 22.

⁽²⁾ OJ L 12, 19.1.2010, p. 11.

RECOMMENDATIONS

COMMISSION RECOMMENDATION

of 5 April 2013

on a common framework for a unique device identification system of medical devices in the Union

(Text with EEA relevance)

(2013/172/EU)

THE EUROPEAN COMMISSION,

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

Whereas:

- (1) Traceability of medical devices throughout the whole supply chain contributes to patient safety by facilitating vigilance, market surveillance and transparency in this sector.
- (2) The current regulatory framework for medical devices does not include specific provisions on traceability. Therefore, a recommendation paving the way to a reinforced regulatory approach on traceability of medical devices is needed.
- (3) The proposal from the European Commission for a regulation of the European Parliament and of the Council on medical devices, and amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 ⁽¹⁾ adopted on 26 September 2012, and the proposal from the European Commission for a regulation of the European Parliament and of the Council on *in vitro* diagnostic medical devices ⁽²⁾ adopted on 26 September 2012, include provisions on traceability of medical devices and *in vitro* diagnostic medical devices, in order to improve patient health and safety.
- (4) The Council conclusions on innovation in the medical device sector ⁽³⁾ of 6 June 2011 invites the Commission and Member States to pay particular attention to interoperability and safety issues related to the integration of medical devices in e-Health systems, especially personal health systems.
- (5) Significant efforts are being made at international level towards a globally harmonised approach on traceability and to establish a globally accepted unique device identification (UDI) system for medical devices.
- (6) UDI mechanisms, based on different national and/or regional traceability requirements, have already been developed and there is a risk that further diverging UDI mechanisms may be developed at these levels.
- (7) In future certain information contained in the UDI code could feed the Electronic Health Record according to Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare ⁽⁴⁾ and the Digital Agenda for Europe ⁽⁵⁾,

HAS ADOPTED THIS RECOMMENDATION:

1. INTRODUCTION

Purpose of the Recommendation

1. Traceability is currently not regulated by the medical device directives ⁽⁶⁾ while it is addressed in some cases at national and/or regional level. The differences and incompatibility between the traceability mechanisms may weaken and compromise the efficiency of the systems put in place.
2. In addition, the development of different national and/or regional unique device identification mechanisms would oblige manufacturers to adapt their products to each mechanism in order to fulfil traceability obligations.

⁽¹⁾ COM(2012) 542 final

⁽²⁾ COM(2012) 541 final.

⁽³⁾ OJ C 202, 8.7.2011, p. 7.

⁽⁴⁾ OJ L 88, 4.4.2011, p. 45.

⁽⁵⁾ <http://ec.europa.eu/digital-agenda/>

⁽⁶⁾ Council Directive 90/385/EEC (OJ L 189, 20.7.1990, p. 17), Council Directive 93/42/EEC (OJ L 169, 12.7.1993, p. 1), Directive 98/79/EC of the European Parliament and of the Council (OJ L 331, 7.12.1998, p. 1).

3. The best way to ensure effective traceability of medical devices in the Union is to develop a UDI system harmonised at European level. The ongoing revision process of the current Directives on medical devices should empower the Commission to adopt detailed traceability requirements.

4. In the meantime, should Member States decide to develop their own UDI mechanisms it is essential that these are made compatible with each other and with the future UDI system of the Union. This is important in order to avoid the risk of incompatible and divergent systems frustrating the objectives of the internal market and to facilitate the introduction of a harmonized UDI system of the Union.

5. This Recommendation does not aim to define all the aspects of the UDI system. It should be taken as a tool to facilitate the compatibility of the traceability mechanisms established at national and/or regional level and to pave the way to the mandatory implementation of an internationally compatible UDI system of the Union.

Scope of the Recommendation

6. This Recommendation applies to medical devices, active implantable medical devices (other than devices which are custom-made or intended for clinical investigations) and *in vitro* diagnostic medical devices (other than those manufactured in health institutions and for performance evaluation), including their accessories.

International activity on UDI

7. At international level, in 2008 the Global Harmonization Task Force (GHTF) ⁽¹⁾ set up an ad hoc working group with the purpose of developing an internationally coordinated approach on UDI.

8. This group, gathering industry and regulators, was chaired by the European Commission and ceased its activity in September 2011, when the GHTF adopted a guidance ⁽²⁾ document on a 'Unique Device Identification (UDI) System for Medical Devices'.

9. The work of the GHTF towards a further harmonisation of the medical device regulatory framework is being carried

out under the auspice of the International Medical Device Regulators Forum (IMDRF) ⁽³⁾.

10. This Recommendation is aligned to the approach developed at international level.

European activity on UDI

11. In 2010, the European Commission set up a European UDI ad hoc Working Group, within the regulatory framework established by the directives on medical devices, in order to develop a coordinated approach, taking into account the progress made at both national and international level.

12. The aim of the group is threefold:

(a) first, it is intended to encourage contributions and monitor the reaction of Competent Authorities to the work carried out at international level;

(b) second, it encourages the sharing of views and information on national initiatives developed by Member States and search for common solutions;

(c) thirdly, it facilitates the convergence with the future Union legislation of national initiatives developed by Member States.

2. RATIONALE

13. The primary objectives of a UDI system are patient safety ⁽⁴⁾ enhancement and patient care optimisation. It pursues these objectives by:

(a) improving incident reporting;

(b) facilitating efficient recalls and other field safety corrective actions (FSCA);

(c) facilitating efficient post market actions by national competent authorities;

(d) enabling queries in numerous data systems;

(e) reducing the likelihood of medical errors linked to misuse of the device.

⁽¹⁾ The 'Global Harmonization Task Force (GHTF)' is a voluntary international group of representatives from medical device regulatory authorities and trade associations from Europe, the United States of America (USA), Canada, Japan and Australia. GHTF was conceived in 1992 in an effort to respond to the growing need for international harmonisation in the regulation of medical devices. The GHTF mission ended in December 2012.

⁽²⁾ www.imdrf.org/docs/ghrf/final/steering-committee/technical-docs/ghrf-sc-n2r3-2011-unique-device-identification-system-110916.pdf

⁽³⁾ The 'International Medical Device Regulators Forum (IMDRF)' was conceived in February 2011 as a forum to discuss future directions in medical device regulatory harmonisation. It is a voluntary group of medical device regulators from Australia, Brazil, Canada, China (observer), European Union, Japan, Russia (observer) and the United States who have come together to build on the strong foundational work of the 'Global Harmonization Task Force on Medical Devices (GHTF)'. The 'World Health Organization (WHO)' participates in the IMDRF as an observer.

⁽⁴⁾ Patient safety is understood as the avoidance, prevention and amelioration of adverse outcomes or injuries stemming from the processes of health care. These events include 'errors', 'deviations', 'accidents'. Safety emerges from the interaction of the components of the system; it does not reside in a person, device or department. Improving safety depends on learning how safety emerges from the interactions of the components. Patient safety is a subset of health care quality.

14. The establishment of a UDI system could also support the achievement of other objectives such as the fight against counterfeiting, better distribution control, stock management and reimbursement issues.

15. However, the objectives referred to in paragraph 14 should be seen as possible positive consequences of the UDI system.

Improvement of incident reporting

16. The use of a UDI is expected to improve incident reporting and offers the opportunity to gather all the incidents related to one medical device at Union level and, in case of an internationally accepted and compatible UDI, at international level. This will increase the potential for comparing results associated with each specific medical device.

Efficient recalls and other field safety corrective actions

17. The attribution of a unique identifier to a specific device and its use along the distribution chain (global use) will allow the unambiguous identification of the device itself.

18. For traceability to be ensured, it is not sufficient that every manufacturer has developed its own traceability mechanism. The lack of a Union system used all along the supply chain could lead to negative outcomes inasmuch as each actor of the distribution chain might modify the coding developed by the manufacturer. This might give rise to errors in the encoding of medical devices which would in turn endanger the traceability of devices in case of FSCA. The use of the same coding language improves the tracking and tracing of medical devices.

Efficient post market actions by national competent authorities

19. A UDI system helps specifically to target identified products.

20. In addition, it will provide an opportunity to ensure coordinated reactions by Member States.

Queries in numerous data systems

21. By using the same UDI in different data systems (both at regulatory and health institutions level) queries will become more efficient and it will be easier to perform searches in order to aggregate information. At the moment, this approach is not possible because each data system has its own identification tool.

Reduction of medical errors

22. It might be expected that, by using identification mechanisms, the number of cases where medical devices have been incorrectly selected will be reduced.

3. DEFINITIONS

For the purposes of this Recommendation the following definitions apply:

(a) 'medical device' means any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, including the software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application, intended by the manufacturer to be used for human beings for the purpose of:

- diagnosis, prevention, monitoring, treatment or alleviation of disease,
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap,
- investigation, replacement or modification of the anatomy or of a physiological process,
- control of conception,

and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means ⁽¹⁾;

(b) 'active implantable medical device' means any active medical device which is intended to be totally or partially introduced, surgically or medically, into the human body or by medical intervention into a natural orifice, and which is intended to remain after the procedure ⁽²⁾;

(c) 'in vitro diagnostic medical device' means any medical device which is a reagent, reagent product, calibrator, control material, kit, instrument, apparatus, equipment or system, whether used alone or in combination, intended by the manufacturer to be used *in vitro* for the examination of specimens, including blood and tissue donations, derived from the human body, solely or principally for the purpose of providing information:

- concerning a physiological or pathological state, or
- concerning a congenital abnormality, or
- to determine the safety and compatibility with potential recipients, or
- to monitor therapeutic measures.

⁽¹⁾ Article 1(2)(a) of Directive 93/42/EEC.

⁽²⁾ Article 1(2)(c) of Directive 90/385/EEC.

Specimen receptacles are considered to be *in vitro* diagnostic medical devices. 'Specimen receptacles' are those devices, whether vacuum-type or not, specifically intended by their manufacturers for the primary containment and preservation of specimens derived from the human body for the purpose of *in vitro* diagnostic examination.

Products for general laboratory use are not *in vitro* diagnostic medical devices unless such products, in view of their characteristics, are specifically intended by their manufacturer to be used for *in vitro* diagnostic examination ⁽¹⁾;

- (d) 'traceability' means the ability to trace the history, application or location of that which is under consideration;
- (e) 'unique device identification — UDI' means a series of numeric or alphanumeric characters that is created through an internationally accepted device identification and coding standard and allows the unambiguous identification of specific medical devices on the market. The UDI comprises the device identifier and production identifier;
- (f) 'device identifier' means a unique numeric or alphanumeric code specific to a manufacturer and a device model;
- (g) 'production identifier' means a unique numeric or alphanumeric code that identifies data related to the unit of device production;
- (h) 'UDI carrier' means the way in which the unique device identification is conveyed by means of the Automatic Identification and Data Capture ⁽²⁾ (AIDC) and, if applicable, its human readable interpretation (HRI);
- (i) 'UDI electronic system' means a central repository/database storing device identifier codes and related/associated identifying information of specific devices placed on the Union market;
- (j) 'human readable interpretation' means a legible format of the data characters encoded in the AIDC symbol;
- (k) 'direct part mark' means any technology which can be used to fix a symbol on the surface of an item

(e.g. producing two different surface conditions by laser etching, moulding, peening or other technologies like ink jet printing or flexography);

- (l) 'manufacturer' means the natural or legal person with responsibility for the design, manufacture, packaging and labelling of a device before it is placed on the market under his own name, regardless of whether these operations are carried out by that person himself or on his behalf by a third party ⁽³⁾;
- (m) 'authorised representative' means any natural or legal person established within the Union who, explicitly designated by the manufacturer, acts and may be addressed by authorities and bodies in the Community instead of the manufacturer with regard to the latter's obligations under the relevant Community legislation ⁽⁴⁾;
- (n) 'importer' means any natural or legal person established within the Union who places a device from a third country on the Union market ⁽⁵⁾;
- (o) 'distributor' means any natural or legal person in the supply chain, other than the manufacturer or the importer, who makes a device available on the market ⁽⁶⁾;
- (p) 'economic operators' means the manufacturer, the authorised representative, the importer and the distributor ⁽⁷⁾;
- (q) 'health institution' means an organisation whose primary purpose is the care or treatment of patients and/or the promotion of public health;
- (r) 'user' means the person, either professional or lay, who uses a device.

4. RISK BASED APPROACH

- 23. Should Member States intend to establish a UDI system they should follow a risk based approach in accordance with the classification of the device.
- 24. The UDI system should be implemented gradually, starting from highest risk class devices which should be the first to respect the condition to bear the UDI.

UDI type

- 25. The UDI should comprise two parts, a device identifier and a production identifier.

⁽¹⁾ Article 1(2)(b) of Directive 98/79/EC.

⁽²⁾ The Automatic Identification and Data Capture refers to the methods for automatically identifying objects, collecting data about them, and entering the data directly into computer systems.

⁽³⁾ Article 1(2)(f) of Directive 93/42/EEC.

⁽⁴⁾ Article 1(2)(j) of Directive 93/42/EEC.

⁽⁵⁾ Article 2(5) of Regulation (EC) No 765/2008 of the European Parliament and of the Council (OJ L 218, 13.8.2008, p.30).

⁽⁶⁾ Article 2(6) of Regulation (EC) No 765/2008.

⁽⁷⁾ Article 2(7) of Regulation (EC) No 765/2008.

26. The device identifier should contain static information ⁽¹⁾ specific to a manufacturer and a device model and is also used as the 'access key' to information stored in a UDI database.
27. The production identifier should contain dynamic information ⁽²⁾ identifying data related to the unit of device production and determine the level of traceability to be achieved.
28. UDI should appear in both human readable format (human readable version composed of a series of numeric or alphanumeric characters) and in a format that can be read by an AIDC technology and conveyed via a carrier.
29. If there are significant constraints limiting the use of both AIDC and HRI on the label, the AIDC format should be favoured. However, certain environments or use situations, such as home care, may warrant the use of HRI over AIDC.
30. Member States should monitor that differentiation between the different classes of devices is based exclusively on the type of production identifier (dynamic information) in accordance with paragraph 31.
31. As a general rule, the information provided by the production identifier (dynamic information) should vary according to the different risk classes as follows ⁽³⁾:
- expiration date and/or manufacturing date for class I,
 - lot/batch number for class IIa,
 - lot/batch number for class IIb,
 - lot/batch number or serial number ⁽⁴⁾ for class III.
32. Where appropriate, manufacturers may choose a production identifier (dynamic information) applicable to a higher class than the device in question.

⁽¹⁾ This information does not vary from one to another device of the same specific model.

⁽²⁾ This information varies according to the different way the production process is controlled (by expiration/manufacturing date, lot/batch number or serial number).

⁽³⁾ In accordance with international guidance, possible exceptions and/or exemptions to the general rule, based on the device class, should be taken into account.

⁽⁴⁾ The serial number allows the identification of the individual device unit.

UDI application

33. As a general rule, UDI should be applied to every packaging level for all classes of devices ⁽⁵⁾.
34. UDI carrier (AIDC and HRI representation of the UDI) should be on the label of the device, its package, or on the device itself (direct part mark), and on all higher levels of packaging ⁽⁶⁾.

5. CONDITIONS TO BE FULFILLED BY ECONOMIC OPERATORS, HEALTH INSTITUTIONS AND PROFESSIONAL USERS

35. In order to achieve the objectives of the UDI system, while developing their own national UDI mechanisms, the economic operators and health institutions should store through the distribution chain information related to both the device identifier (static information) and the production identifier (dynamic information). Health institutions and, where feasible, professional users should use this information in their reporting of incidents. This will, in particular, allow a more efficient action in case of recall or withdrawal of products.
36. Information related to the device identifier (static information) should be collected into the national UDI databases.
37. Once the future European databank on medical devices (Eudamed) is established, information related to device identifier (static information) will be centralised at European level via a European UDI electronic system which will be part of the future Eudamed.
38. As regards information related to production identifier (dynamic information), it should not be sent to the national UDI databases and will not be included in the European UDI electronic system.

For the purpose of this Recommendation economic operators, health institutions and professional users should align with the following conditions.

Manufacturers

39. First, manufacturers should appropriately allocate a UDI (static and dynamic parts) to the medical devices they manufacture.
40. Second, they should provide the required data elements (see Annex) to be included in the UDI database.

⁽⁵⁾ In accordance with international guidance, possible exceptions and/or exemptions to the general rule, based on the device class, should be taken into account.

⁽⁶⁾ According to international guidance, pallets are not included in the notion of higher levels of packaging therefore UDI conditions do not apply to pallets.

41. Third, they should modify the labelling of their products in order to print the UDI code as far as practicable on the label of the device, its package, or on the device itself (direct part mark), and on all higher levels of packaging, as referred to in paragraph 34.
42. Fourth, they should keep an electronic record of both device identifier (static information) and production identifier (dynamic information).
43. Lastly, they should keep an electronic record of the economic operator, health institution or professional users to whom they have supplied each specific product.

Importers

44. First, importers should verify that the manufacturer has appropriately allocated a UDI (static and dynamic parts) to the product before they put it on the Union market. Where an importer considers or has reason to believe that this condition has not been fulfilled, he should not place the device on the Union market until it is brought into conformity.
45. Second, importers should not remove or modify the UDI, otherwise traceability will be impossible.
46. Third, they should ascertain whether the device has already been registered in the UDI database of the Member State where the device has been placed on the Union market.
47. If the device has already been registered, importers should verify that the device identifier (static information) on the product corresponds to that in the UDI database.
48. If the device has not yet been registered, the importers should align with the conditions concerning the registration of the information related to the device identifier (static information).
49. Fourth, they should keep an electronic record of both device identifier (static information) and production identifier (dynamic information).
50. Fifth, they should keep an electronic record of the economic operator who has supplied them with a device.
51. Lastly, they should keep electronic record of the economic operator, health institution or professional users to whom they have supplied the device.

Authorised representatives

52. Where a manufacturer who places a device on the market under his own name does not have a registered place of

business in a Member State, he should designate a single authorised representative in the Union. The designation must be effective at least for all devices of the same model.

53. The authorised representatives should have access, on request, to the record of both device identifier (static information) and production identifier (dynamic information) related to the product(s) for which he is appointed.

Distributors

54. First, before making a device available on the market distributors should verify that the manufacturer and, where applicable, the importer has appropriately allocated a UDI (static and dynamic parts) to the product. Where a distributor considers or has reason to believe that this condition has not been fulfilled, he should not make the device available on the Union market until it is brought into conformity.
55. Second, distributors should not remove or modify the UDI, otherwise traceability will be impossible.
56. Third, they should keep an electronic record of both device identifier (static information) and production identifier (dynamic information).
57. Fourth, they should keep an electronic record of the economic operator who has supplied them with a device.
58. Lastly, they should keep an electronic record of the economic operator, health institution or professional users to whom they have supplied a device.

Health institutions

59. First, health institutions should keep an electronic record of both device identifier (static information) and production identifier (dynamic information) of medical devices entering these organisations. Information related to both device identifier (static information) and production identifier (dynamic information) in respect of devices for which incidents are reported should be used by health institutions in their reporting of incidents.
60. Second, for certain medical devices, such as those used for high risk procedures and/or specifically intended to be used for high risk patients, a link should be established between the device used and the patient treated with it. Therefore, health institutions should keep a record of which device has been used on which patient.

61. Third, for certain devices such as implantable medical devices, health institutions should store both device identifier (static information) and production identifier (dynamic information) in the electronic patient record. Indeed, in case of recall, it should be possible to know exactly which medical device has been implanted to which patient.

Professional users

62. Where feasible, information related to both device identifier (static information) and production identifier (dynamic information) in respect of devices for which incidents are reported should be used by professional users in their reporting of incidents.

6. UDI NATIONAL DATABASES

Data elements

63. Member States who intend to establish a UDI system for medical devices are invited to build it on national UDI databases.

64. For the purpose of this Recommendation, Member States are invited to promote the use of the Extensible Markup Language (XML), as a common format for data exchange between UDI databases, and take into account relevant specifications and semantic standards existing in the area.

65. The data elements, which are listed in the Annex, should be introduced in UDI national databases and should correspond to the elements linked to the device identifier (static information).

Done at Brussels, 5 April 2013.

For the Commission

Tonio BORG

Member of the Commission

ANNEX

DATA ELEMENTS OF THE NATIONAL UDI DATABASES

National databases on UDI should include the following data elements:

- (a) quantity per package configuration;
 - (b) if applicable, alternative or additional identifier(s);
 - (c) the way how the device production is controlled (expiration date or manufacturing date, lot or batch number, serialisation number);
 - (d) if applicable, the unit of use device identifier (when a UDI is not assigned to the device at the level of its unit of use, a 'unit of use' device identifier shall be assigned to associate the use of a device with a patient);
 - (e) name and address of the manufacturer (as indicated on the label);
 - (f) if applicable, name and address of the authorised representative (as indicated on the label);
 - (g) Global Medical Device Nomenclature (GMDN) code or internationally recognised nomenclature code;
 - (h) if applicable, trade/brand name;
 - (i) if applicable, device model, reference, or catalogue number;
 - (j) if applicable, clinical size (including volume, length, gauge and diameter);
 - (k) additional product description (optional);
 - (l) if applicable, storage and/or handling conditions (as indicated on the label or in the instructions for use);
 - (m) if applicable, additional trade names of the device;
 - (n) labelled as single use device (y/n);
 - (o) if applicable, restricted number of reuses;
 - (p) device packaged sterile (y/n);
 - (q) need for sterilisation before use (y/n);
 - (r) labelled as containing latex (y/n);
 - (s) labelled as containing DEPH (y/n);
 - (t) URL for additional information, e.g. electronic instructions for use (optional);
 - (u) if applicable, critical warnings or contraindications.
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