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II

(Non-legislative acts)

INTERNATIONAL AGREEMENTS

Notice concerning the provisional application of the Agreement between the European Union, Iceland, the Principality of Liechtenstein and the Kingdom of Norway on an EEA Financial Mechanism 2009-2014

The Agreement between the European Union, Iceland, the Principality of Liechtenstein and the Kingdom of Norway on an EEA Financial Mechanism 2009-2014 ⁽¹⁾, signed in Brussels on 28 July and 19 August 2010, is provisionally applicable, by virtue of Article 3, third paragraph of the Agreement, since 1 January 2011.

⁽¹⁾ OJ L 291, 9.11.2010, p. 4.

COUNCIL DECISION**of 15 February 2011****on the conclusion of the Interim Partnership Agreement between the European Community, of the one part, and the Pacific States, of the other part**

(2011/144/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 207, in conjunction with Article 218(6)(a)(iii) and 218(6)(a)(v) thereof,

Having regard to the proposal from the European Commission,

Having regard to the consent of the European Parliament,

Whereas:

- (1) On 12 June 2002, the Council authorised the Commission to open negotiations to conclude Economic Partnership Agreements with ACP countries.
- (2) Negotiations for an Interim Partnership Agreement (hereinafter referred to as the 'interim EPA') were concluded on 23 November 2007 with Papua New Guinea and the Republic of the Fiji Islands.
- (3) The interim EPA has not yet been concluded. Following the entry into force of the Treaty of Lisbon, the procedure to be followed to that end is laid down in Article 218 of the Treaty on the Functioning of the European Union.
- (4) The interim EPA should be concluded on behalf of the European Union,

Article 1

The Interim Partnership Agreement between the European Community, of the one part, and the Pacific States, of the other part, is hereby approved on behalf of the European Union.

Article 2

The President of the Council shall give the notification referred to in Article 76(2) of the interim EPA on behalf of the Union.

Article 3

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

Article 4

This Decision shall be published in the *Official Journal of the European Union*.

The date of entry into force of the Agreement shall be published in the *Official Journal of the European Union*.

Done at Brussels, 15 February 2011.

For the Council
The President
MATOLCSY Gy.

REGULATIONS

COMMISSION REGULATION (EU) No 221/2011

of 4 March 2011

concerning the authorisation of 6-phytase (EC 3.1.3.26) produced by *Aspergillus oryzae* DSM 14223 as a feed additive for salmonids (holder of authorisation DSM Nutritional Products Ltd represented by DSM Nutritional products Sp. Z o.o)

(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 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition⁽¹⁾, and in particular Article 9(2) thereof,

Whereas:

- (1) Regulation (EC) No 1831/2003 provides for the authorisation of additives for use in animal nutrition and for the grounds and procedures for granting such authorisation.
- (2) In accordance with Article 7 of Regulation (EC) No 1831/2003, an application was submitted for the authorisation of the enzyme preparation 6-phytase (EC 3.1.3.26) produced by *Aspergillus oryzae* DSM 14223. That application was accompanied by the particulars and documents required pursuant to Article 7(3) of Regulation (EC) No 1831/2003.
- (3) The application concerns the authorisation of 6-phytase (EC 3.1.3.26) produced by *Aspergillus oryzae* DSM 14223 as a feed additive for salmonids, to be classified in the additive category 'zootechnical additives'.
- (4) Its use was also provisionally authorised for salmonids by Commission Regulation (EC) No 521/2005⁽²⁾.
- (5) New data were submitted in support of the application for the authorisation of 6-phytase (EC 3.1.3.26) produced by *Aspergillus oryzae* DSM 14223 for salmonids. The European Food Safety Authority ('the Authority')

concluded in its opinion of 10 November 2010⁽³⁾ that, under the proposed conditions of use, 6-phytase (EC 3.1.3.26) produced by *Aspergillus oryzae* DSM 14223 does not have an adverse effect on animal health, human health or the environment, and that its use can improve the phosphorus utilisation. The Authority does not consider that there is a need for specific requirements of post-market monitoring. It also verified the report on the method of analysis of the feed additive in feed submitted by the European Union Reference Laboratory for Feed Additives set up by Regulation (EC) No 1831/2003.

- (6) The assessment of 6-phytase (EC 3.1.3.26) produced by *Aspergillus oryzae* DSM 14223 shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the use of this preparation should be authorised as specified in the Annex to this Regulation.
- (7) In the interest of clarity, the entry on 6-phytase (EC 3.1.3.26) produced by *Aspergillus oryzae* DSM 14223 in Regulation (EC) No 521/2005 should be deleted.
- (8) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS REGULATION:

Article 1

The preparation specified in the Annex, belonging to the additive category 'zootechnical additives' and to the functional group 'digestibility enhancers', is authorised as an additive in animal nutrition, subject to the conditions laid down in that Annex.

Article 2

In Regulation (EC) No 521/2005, Article 2 and Annex II are deleted.

⁽¹⁾ OJ L 268, 18.10.2003, p. 29.

⁽²⁾ OJ L 84, 2.4.2005, p. 3.

⁽³⁾ *The EFSA Journal* 2010; 8(12):1915.

Article 3

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

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

Done at Brussels, 4 March 2011.

For the Commission
The President
José Manuel BARROSO

ANNEX

Identification number of the additive	Name of the holder of authorisation	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisation
						Units of activity/kg of complete feedingstuff with a moisture content of 12 %			
Category of zootechnical additives. Functional group: digestibility enhancers									
4a1641(i)	DSM Nutritional Products Ltd represented by DSM Nutritional products Sp. Z o.o	6-phytase (EC 3.1.3.26)	<p><i>Additive composition</i> Preparation of 6-phytase produced by <i>Aspergillus oryzae</i> DSM 14223 having a minimum activity of: liquid form: 20 000 FYT ⁽¹⁾/g</p> <p><i>Characterisation of the active substance</i> 6-phytase produced by <i>Aspergillus oryzae</i> DSM 14223</p> <p><i>Analytical method</i> ⁽²⁾ Colorimetric method based on reaction of vanadomolybdate on inorganic phosphate produced by action of 6-phytase produced by <i>Aspergillus oryzae</i> DSM 14223 on a phytate-containing substrate (sodium phytate) at pH 5,5 and 37 °C, quantified against a standard curve from inorganic phosphate.</p>	Salmonids	—	750 FYT	—	<p>1. In the directions for use of the additive and premixture, indicate the storage temperature, storage life, and stability to pelleting.</p> <p>2. For use in feed containing more than 0,23 % phytin-bound phosphorus.</p> <p>3. For safety: breathing protection, glasses and gloves shall be used during handling.</p>	25 March 2021

⁽¹⁾ One FYT is the amount of enzyme that releases 1 µmol of inorganic phosphate from sodium phytate per minute under reaction conditions with a phytate concentration of 5,0 mM at pH 5,5 and a temperature of 37 °C during 30 minutes incubation.

⁽²⁾ Details of the analytical methods are available at the following address of the European Union Reference Laboratory for Feed Additives: www.irmm.jrc.be/crl-feed-additives

COMMISSION REGULATION (EU) No 222/2011**of 3 March 2011****laying down exceptional measures as regards the release of out-of-quota sugar and isoglucose on the Union market at reduced surplus levy during marketing year 2010/2011**

THE EUROPEAN COMMISSION,

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

Having regard to Council Regulation (EC) No 1234/2007 of 22 October 2007 establishing a common organisation of agricultural markets and on specific provisions for certain agricultural products (Single CMO Regulation) ⁽¹⁾ and in particular Article 64(2) and Article 187, in conjunction with Article 4 thereof,

Whereas:

- (1) The world market prices for sugar have been at a constant high level since the beginning of the 2010/2011 marketing year. Forecasts of world market prices based on the New York's sugar futures exchange market for the terms of March, May and July 2011 further indicate a constant high world market price.
- (2) The cumulated negative difference between availability and utilisation of sugar and isoglucose over the last two marketing years is estimated at 1,0 million tonnes, and would result in the lowest level of ending stocks in the EU since the implementation of the 2006 reform of the sugar sector. Any further shortfall of imports threatens to seriously disrupt the availability of supply on the Union sugar market and to further deteriorate in the absence of measures for the sector.
- (3) Exports from African, Caribbean and Pacific (ACP) countries and Least Developed Countries (LDCs) to the European Union are not expected to increase in the short run.
- (4) On the other hand, a good harvest in some parts of the Union has led to the production of sugar in excess of the quota set out in Article 56 of Regulation (EC) No 1234/2007. Part of this sugar should be made available to the sugar market of the Union in order to partially satisfy demand and to avoid excessive price increases. The available quantity of sugar in excess of the quota is estimated at 0,5 million tonnes. This estimate takes into account contractual commitments of sugar producers in respect of certain industrial uses provided for in Article 62 of Regulation (EC) No 1234/2007, and the quantities for which export licences have already been issued.
- (5) Article 64(2) of Regulation (EC) No 1234/2007 empowers the Commission to fix the surplus levy on sugar and isoglucose produced in excess of the quota at a sufficiently high level in order to avoid the accumulation of surplus quantities. Article 3(1) of Commission Regulation (EC) No 967/2006 of 29 June 2006 laying down detailed rules for the application of Council Regulation (EC) No 318/2006 as regards sugar production in excess of the quota ⁽²⁾ has fixed that levy at EUR 500 per tonne.
- (6) The extraordinarily low supply of sugar on the internal market in the 2010/2011 marketing year may allow the Commission to exceptionally fix the surplus levy at zero for a limited quantity of sugar produced in excess of the quota, without any risk of accumulation of quantities.
- (7) As Regulation (EC) No 1234/2007 fixes quotas for both sugar and isoglucose, a similar measure should apply for an appropriate quantity of isoglucose produced in excess of the quota because the latter product is, to some extent, a commercial substitute for sugar. In order to preserve the balance between the two sweeteners, the appropriate quantity of out of quota isoglucose to be released on the internal market should be established on the basis of the relation of the quotas for each of the two products fixed in Annex VI to Regulation (EC) No 1234/2007.
- (8) Sugar and isoglucose producers should apply to the competent authorities of the Member States for certificates allowing them to sell certain quantities, produced above the quota limit, on the Union market.
- (9) Fixing upper limits of the quantities for which each producer can apply in one application period and restricting the certificates to products of the applicant's own available production, should prevent speculative actions within the system created by this Regulation.
- (10) Applications should only be possible until the end of June and should only be valid for a short period of time. This should encourage a rapid availability of the quantities on the Union market.

⁽¹⁾ OJ L 299, 16.11.2007, p. 1.⁽²⁾ OJ L 176, 30.6.2006, p. 22.

- (11) With their application, sugar producers should commit themselves to pay the minimum price for sugar beet used to produce the quantity of sugar for which they apply.
- (12) The competent authorities of the Member States should notify the Commission of the applications received.
- (13) The Commission should ensure that certificates are granted only within the quantitative limits fixed in this Regulation. Therefore, if necessary, the Commission should be able to fix an allocation coefficient applicable to the applications received.
- (14) Member States should immediately inform the applicants whether their application was fully or partially granted.
- (15) Account taken that the release on the Union market of quantities in excess of the certificates delivered is subject to the surplus levy set out in Article 64(2) of Regulation (EC) No 1234/2007, it is appropriate to provide that any applicant not fulfilling his commitment to release on the Union market the quantity covered by a certificate delivered to him, should also pay an amount of EUR 500 per tonne, for reasons of consistency, and to prevent abuse of the exceptional release of out-of-quota sugar and isoglucose on the Union market during marketing year 2010/2011.
- (16) The measures provided for in this Regulation are in accordance with the opinion of the Management Committee for the Common Organisation of Agricultural Markets,

HAS ADOPTED THIS REGULATION:

Article 1

Temporary reduction of the surplus levy

By way of derogation from Article 3(1) of Regulation (EC) No 967/2006, the amount of the surplus levy for a maximum quantity of 500 000 tonnes of sugar in white sugar equivalent and 26 000 tonnes of isoglucose in dry matter, produced in excess of the quota fixed in Annex VI to Regulation (EC) No 1234/2007 and released on the Union market in the marketing year 2010/2011, shall be fixed at EUR 0 per tonne.

Article 2

Application for certificates

1. In order to benefit from the conditions specified in Article 1, sugar and isoglucose producers shall apply for a certificate.
2. Applicants may be only undertakings producing beet and cane sugar or isoglucose, which are approved in accordance

with Article 57 of Regulation (EC) No 1234/2007 and have been allocated a production quota for the 2010/2011 marketing year, in accordance with Article 56 of that Regulation.

3. Each applicant may submit one application for each product per week.

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

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

(a) they shall indicate:

- (i) the name, address and VAT number of the applicant; and
- (ii) the quantities applied for, expressed in tonnes of white sugar equivalent and tonnes of isoglucose in dry matter;

(b) the quantity of sugar applied for shall not exceed the quantity of out-of-quota sugar production that the applicant declared in storage in his latest notification done in accordance with Article 21(1) of Commission Regulation (EC) No 952/2006 ⁽²⁾. That quantity shall be reduced by the quantities covered by unused certificates and export licences that were already issued to the applicant under this Regulation or under Commission Regulation (EC) No 397/2010 ⁽³⁾. The quantity of isoglucose applied for shall not exceed 10 % of the isoglucose quota allocated to the applicant;

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

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

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

⁽¹⁾ OJ L 13, 19.1.2000, p. 12.

⁽²⁾ OJ L 178, 1.7.2006, p. 39.

⁽³⁾ OJ L 115, 8.5.2010, p. 26.

*Article 3***Submission of applications**

Applications for certificates shall be submitted each week, from Monday to Friday, 1 p.m. (Brussels time) starting from the first Monday after the entry into force of this Regulation until 24 June 2011.

*Article 4***Transmission of applications by the Member States**

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

2. The competent authority shall notify the Commission on Monday at the latest, by fax or electronic mail, of the admissible applications submitted during the preceding week. Member States that received no applications but have sugar or isoglucose quota allocated to them in marketing year 2010/2011, shall also send their nil returns notifications to the Commission within the same time limit.

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

*Article 5***Exceeded limits**

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

- (a) fix an allocation coefficient, which the Member States shall apply to the quantities covered by each notified certificate application;
- (b) reject applications not yet notified;
- (c) close the period for submitting the applications.

*Article 6***Issue of certificates**

1. Without prejudice to Article 5, every week from Monday to Friday at the latest, the competent authorities of the Member States shall issue certificates for the applications notified to the Commission, in accordance with Article 4(2), during the preceding week.

A template of the certificate is set out in the Annex to this Regulation.

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

*Article 7***Validity of certificates**

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

*Article 8***Transferability of certificates**

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

*Article 9***Monitoring**

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

2. Before the end of the second month following the month during which the certificate was issued, each applicant shall submit to the competent authorities of the Member States proof that all quantities covered by his certificate were released on the Union market. Quantities covered by the certificate but not released on the Union market for reasons other than *force majeure*, shall be subject to payment of an amount of EUR 500/tonne. Member States shall communicate the quantities released on the Union market to the Commission.

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

*Article 10***Entry into force**

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

It shall expire on 30 June 2012.

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

Done at Brussels, 3 March 2011.

For the Commission
The President
 José Manuel BARROSO

ANNEX

(Model for the certificate referred to in Article 6(1))

CERTIFICATE

for the reduction, for the 2010/2011 marketing year, of the levy provided for in Article 3 of Regulation (EC) No 967/2006

Member State:

Quota holder:

Product:	
Quantities applied:	
Quantities issued:	

For the marketing year 2010/2011, the levy referred to in Article 3 of Regulation (EC) No 967/2006 shall not apply to the quantities issued of this certificate, subject to the respect of the rules laid down in Commission Regulation (EU) No 222/2011, in particular in Article 2(4)(c)

Signature of the Competent authority of the Member State

Date of issue

This certificate shall be valid until the end of the month following the month of issue

COMMISSION IMPLEMENTING REGULATION (EU) No 223/2011**of 4 March 2011****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 Regulation (EC) No 1580/2007 of 21 December 2007 laying down implementing rules for Council Regulations (EC) No 2200/96, (EC) No 2201/96 and (EC) No 1182/2007 in the fruit and vegetable sector ⁽²⁾, and in particular Article 138(1) thereof,

Whereas:

Regulation (EC) No 1580/2007 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 XV, Part A thereto,

HAS ADOPTED THIS REGULATION:

Article 1

The standard import values referred to in Article 138 of Regulation (EC) No 1580/2007 are fixed in the Annex hereto.

Article 2

This Regulation shall enter into force on 5 March 2011.

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

Done at Brussels, 4 March 2011.

*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 350, 31.12.2007, 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	IL	122,2
	MA	49,6
	TN	92,7
	TR	97,6
	ZZ	90,5
0707 00 05	TR	163,5
	ZZ	163,5
0709 90 70	MA	33,5
	TR	132,7
	ZZ	83,1
0805 10 20	EG	55,5
	IL	67,8
	MA	56,2
	TN	51,2
	TR	66,0
	ZA	37,9
	ZZ	55,8
0805 50 10	EG	36,5
	MA	45,9
	TR	55,6
	ZZ	46,0
0808 10 80	CA	126,3
	CL	90,0
	CN	104,6
	MK	54,8
	US	102,6
	ZZ	95,7
0808 20 50	AR	87,4
	CL	85,9
	CN	57,6
	US	96,8
	ZA	111,2
	ZZ	87,8

⁽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'.

DIRECTIVES

COMMISSION DIRECTIVE 2011/27/EU

of 4 March 2011

amending Council Directive 91/414/EEC to include oryzalin as active substance and amending Decision 2008/934/EC

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market ⁽¹⁾, and in particular Article 6(1) thereof,

Whereas:

(1) Commission Regulations (EC) No 451/2000 ⁽²⁾ and (EC) No 1490/2002 ⁽³⁾ lay down the detailed rules for the implementation of the third stage of the programme of work referred to in Article 8(2) of Directive 91/414/EEC and establish a list of active substances to be assessed, with a view to their possible inclusion in Annex I to Directive 91/414/EEC. That list included oryzalin.

(2) In accordance with Article 11e of Regulation (EC) No 1490/2002 the notifier withdrew its support of the inclusion of that active substance in Annex I to Directive 91/414/EEC within 2 months from receipt of the draft assessment report. Consequently, Commission Decision 2008/934/EC of 5 December 2008 concerning the non-inclusion of certain active substances in Annex I to Council Directive 91/414/EEC and the withdrawal of authorisations for plant protection products containing these substances ⁽⁴⁾ was adopted on the non-inclusion of oryzalin.

(3) Pursuant to Article 6(2) of Directive 91/414/EEC the original notifier (hereinafter 'the applicant') submitted a new application requesting the accelerated procedure to be applied, as provided for in Articles 14 to 19 of Commission Regulation (EC) No 33/2008 of 17 January 2008 laying down detailed rules for the application of Council Directive 91/414/EEC as regards a regular and an accelerated procedure for the assessment of active substances which were part of the programme of work referred to in Article 8(2) of that Directive but have not been included into its Annex I ⁽⁵⁾.

(4) The application was submitted to France, which had been designated rapporteur Member State by Regulation (EC) No 1490/2002. The time period for the accelerated procedure was respected. The specification of the active substance and the supported uses are the same as were the subject of Decision 2008/934/EC. That application also complies with the remaining substantive and procedural requirements of Article 15 of Regulation (EC) No 33/2008.

(5) France evaluated the additional data submitted by the applicant and prepared an additional report. It communicated that report to the European Food Safety Authority (hereinafter 'the Authority') and to the Commission on 17 August 2009. The Authority communicated the additional report to the other Member States and the applicant for comments and forwarded the comments it had received to the Commission. In accordance with Article 20(1) of Regulation (EC) No 33/2008 and at the request of the Commission, the Authority presented its conclusion on oryzalin to the Commission on 6 August 2010 ⁽⁶⁾. The draft assessment report, the additional report and the conclusion of the Authority were reviewed by the Member States and the Commission within the Standing Committee on the Food Chain and Animal Health and finalised on 28 January 2011 in the format of the Commission review report for oryzalin.

⁽¹⁾ OJ L 230, 19.8.1991, p. 1.

⁽²⁾ OJ L 55, 29.2.2000, p. 25.

⁽³⁾ OJ L 224, 21.8.2002, p. 23.

⁽⁴⁾ OJ L 333, 11.12.2008, p. 11.

⁽⁵⁾ OJ L 15, 18.1.2008, p. 5.

⁽⁶⁾ European Food Safety Authority; Conclusion on the peer review of the pesticide risk assessment of the active substance oryzalin. EFSA Journal 2010; 8(9):1707. [59 pp.]. doi:10.2903/j.efsa.2010.1707. Available online: www.efsa.europa.eu

- (6) It has appeared from the various examinations made that plant protection products containing oryzalin may be expected to satisfy, in general, the requirements laid down in Article 5(1)(a) and (b) of Directive 91/414/EEC, in particular with regard to the uses which have been examined and detailed in the Commission review report. It is therefore appropriate to include oryzalin in Annex I, in order to ensure that in all Member States the authorisations of plant protection products containing this active substance can be granted in accordance with the provisions of that Directive.
- (7) Without prejudice to that conclusion, it is appropriate to obtain further information on certain specific points. Article 6(1) of Directive 91/414/EEC provides that inclusion of a substance in Annex I may be subject to conditions. Therefore, it is necessary that the specification of the technical material, as commercially manufactured, be confirmed by appropriate analytical data, including information on the relevance of the impurities, which for confidentiality reasons are referred to as impurities 2, 6, 7, 9, 10, 11, 12. The relevance of the test material used in the toxicity dossiers should be confirmed in view of the specification of the technical material and information confirming the risk assessment for aquatic organisms should be requested. Provided that oryzalin becomes classified under Regulation (EC) No 1272/2008 of the European Parliament and of the Council ⁽¹⁾ as 'suspected of causing cancer', the Member States concerned shall request the submission of further information confirming the relevance of the metabolites OR13 ⁽²⁾ and OR15 ⁽³⁾, and the corresponding groundwater risk assessment.
- (8) A reasonable period should be allowed to elapse before an active substance is included in Annex I in order to permit Member States and the interested parties to prepare themselves to meet the new requirements which will result from the inclusion.
- (9) Without prejudice to the obligations defined by Directive 91/414/EEC as a consequence of including an active substance in Annex I, Member States should be allowed a period of 6 months after inclusion to review existing authorisations of plant protection products containing oryzalin to ensure that the requirements laid down by Directive 91/414/EEC, in particular in its Article 13 and the relevant conditions set out in Annex I, are satisfied. Member States should vary, replace or withdraw, as appropriate, existing authorisations, in accordance with the provisions of Directive 91/414/EEC. By derogation from the above deadline, a longer period should be provided for the submission and
- assessment of the complete Annex III dossier of each plant protection product for each intended use in accordance with the uniform principles laid down in Directive 91/414/EEC.
- (10) The experience gained from previous inclusions in Annex I to Directive 91/414/EEC of active substances assessed in the framework of Commission Regulation (EEC) No 3600/92 of 11 December 1992 laying down the detailed rules for the implementation of the first stage of the programme of work referred to in Article 8(2) of Council Directive 91/414/EEC concerning the placing of plant protection products on the market ⁽⁴⁾ has shown that difficulties can arise in interpreting the duties of holders of existing authorisations in relation to access to data. In order to avoid further difficulties it therefore appears necessary to clarify the duties of the Member States, especially the duty to verify that the holder of an authorisation demonstrates access to a dossier satisfying the requirements of Annex II to that Directive. However, this clarification does not impose any new obligations on Member States or holders of authorisations compared to the directives which have been adopted until now amending Annex I.
- (11) It is therefore appropriate to amend Directive 91/414/EEC accordingly.
- (12) Decision 2008/934/EC provides for the non-inclusion of oryzalin and the withdrawal of authorisations for plant protection products containing that substance by 31 December 2011. It is necessary to delete the line concerning oryzalin in the Annex to that Decision.
- (13) It is therefore appropriate to amend Decision 2008/934/EC accordingly.
- (14) The measures provided for in this Directive are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS DIRECTIVE:

Article 1

Annex I to Directive 91/414/EEC is amended as set out in the Annex to this Directive.

Article 2

The line concerning oryzalin in the Annex to Decision 2008/934/EC is deleted.

⁽¹⁾ OJ L 353, 31.12.2008, p. 1.

⁽²⁾ 2-ethyl-7-nitro-1-propyl-1H-benzimidazole-5-sulfonamide.

⁽³⁾ 2-ethyl-7-nitro-1H-benzimidazole-5-sulfonamide.

⁽⁴⁾ OJ L 366, 15.12.1992, p. 10.

Article 3

Member States shall adopt and publish by 30 November 2011 at the latest the laws, regulations and administrative provisions necessary to comply with this Directive. They shall forthwith communicate to the Commission the text of those provisions and a correlation table between those provisions and this Directive.

They shall apply those provisions from 1 December 2011.

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

Article 4

1. Member States shall in accordance with Directive 91/414/EEC, where necessary, amend or withdraw existing authorisations for plant protection products containing oryzalin as an active substance by 30 November 2011.

By that date they shall in particular verify that the conditions in Annex I to that Directive relating to oryzalin are met, with the exception of those identified in part B of the entry concerning that active substance, and that the holder of the authorisation has, or has access to, a dossier satisfying the requirements of Annex II to that Directive in accordance with the conditions of Article 13 of that Directive.

2. By way of derogation from paragraph 1, for each authorised plant protection product containing oryzalin as either the only active substance or as one of several active substances all of which were listed in Annex I to Directive 91/414/EEC by 31 May 2011 at the latest, Member States shall re-evaluate the product in accordance with the uniform principles provided for in Annex VI to Directive 91/414/EEC, on the basis of a dossier

satisfying the requirements of Annex III to that Directive and taking into account part B of the entry in Annex I to that Directive concerning oryzalin. On the basis of that evaluation, they shall determine whether the product satisfies the conditions set out in Article 4(1)(b), (c), (d) and (e) of Directive 91/414/EEC.

Following that determination Member States shall:

- (a) in the case of a product containing oryzalin as the only active substance, where necessary, amend or withdraw the authorisation by 31 May 2015 at the latest; or
- (b) in the case of a product containing oryzalin as one of several active substances, where necessary, amend or withdraw the authorisation by 31 May 2015 or by the date fixed for such an amendment or withdrawal in the respective Directive or Directives which added the relevant substance or substances to Annex I to Directive 91/414/EEC, whichever is the latest.

Article 5

This Directive shall enter into force on 1 June 2011.

Article 6

This Directive is addressed to the Member States.

Done at Brussels, 4 March 2011.

For the Commission
The President
José Manuel BARROSO

ANNEX

The following entry shall be added at the end of the table in Annex I to Directive 91/414/EEC:

No	Common Name, Identification Numbers	IUPAC Name	Purity (*)	Entry into force	Expiration of inclusion	Specific provisions
'334	Oryzalin CAS No: 19044-88-3 CIPAC No: 537	3,5-dinitro-N4,N4-dipropylsulfanilamide	≥ 960 g/kg N-nitrosodipropylamine: ≤ 0,1 mg/kg Toluene: ≤ 4 g/kg	1 June 2011	31 May 2021	<p>PART A</p> <p>Only uses as herbicide may be authorised.</p> <p>PART B</p> <p>For the implementation of the uniform principles of Annex VI the conclusions of the review report on oryzalin, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 28 January 2011, shall be taken into account.</p> <p>In this overall assessment Member States shall pay particular attention to:</p> <ol style="list-style-type: none"> 1. the operator safety and ensure that conditions of use include the application of adequate personal protective equipment; 2. the protection of aquatic organisms and non-target plants; 3. the protection of groundwater, where the active substance is applied in regions with vulnerable soil and/or climatic conditions; 4. the risk to herbivorous birds and mammals; 5. the risk to bees, in the flowering season. <p>Conditions of authorisation shall include risk mitigation measures, where appropriate.</p> <p>The Member States concerned shall carry out monitoring programmes to verify potential groundwater contamination from the metabolites OR13 (2-ethyl-7-nitro-1-propyl-1H-benzimidazole-5-sulfonamide) and OR15 (2-ethyl-7-nitro-1H-benzimidazole-5-sulfonamide) in vulnerable zones, where appropriate. The Member States concerned shall request the submission of confirmatory information as regards:</p>

No	Common Name, Identification Numbers	IUPAC Name	Purity (*)	Entry into force	Expiration of inclusion	Specific provisions
						<p>1. the specification of the technical material, as commercially manufactured, by appropriate analytical data, including information on the relevance of the impurities which for confidentiality reasons are referred to as impurities 2, 6, 7, 9, 10, 11, 12;</p> <p>2. the relevance of the test material used in the toxicity dossiers in view of the specification of the technical material;</p> <p>3. the risk assessment for aquatic organisms;</p> <p>4. the relevance of the metabolites OR13 and OR15, and the corresponding groundwater risk assessment, provided that oryzalin becomes classified under Regulation (EC) No 1272/2008 of the European Parliament and of the Council (OJ L 353, 31.12.2008, p. 1) as “suspected of causing cancer”.</p> <p>The Member States concerned shall ensure that the applicant submits to the Commission the information set out in points 1 and 2 by 1 December 2011, and the information set out in point 3 by 31 May 2013. The information set out in point 4 shall be submitted within 6 months of notification of a decision classifying oryzalin.’</p>

(*) Further details on identity and specification of active substance are provided in the review report.

COMMISSION DIRECTIVE 2011/28/EU**of 4 March 2011****amending Council Directive 91/414/EEC to include indolylbutyric acid as active substance and amending Commission Decision 2008/941/EC****(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

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

Having regard to Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market ⁽¹⁾, and in particular Article 6(1) thereof,

Whereas:

- (1) Commission Regulations (EC) No 1112/2002 ⁽²⁾ and (EC) No 2229/2004 ⁽³⁾ lay down the detailed rules for the implementation of the fourth stage of the programme of work referred to in Article 8(2) of Directive 91/414/EEC and establish a list of active substances to be assessed, with a view to their possible inclusion in Annex I to Directive 91/414/EEC. That list included indolylbutyric acid.
- (2) In accordance with Article 24e of Regulation (EC) No 2229/2004 the notifier withdrew its support of the inclusion of that active substance in Annex I to Directive 91/414/EEC within 2 months from receipt of the draft assessment report. Consequently, Commission Decision 2008/941/EC of 8 December 2008 concerning the non-inclusion of certain active substances in Annex I to Council Directive 91/414/EEC and the withdrawal of authorisations for plant protection products containing these substances ⁽⁴⁾ was adopted on the non-inclusion of indolylbutyric acid.
- (3) Pursuant to Article 6(2) of Directive 91/414/EEC the original notifier (hereinafter 'the applicant') submitted a new application requesting the application of the accelerated procedure provided for in Articles 14 to 19 of Commission Regulation (EC) No 33/2008 of 17 January 2008 laying down detailed rules for the application of Council Directive 91/414/EEC as regards a regular and an

accelerated procedure for the assessment of active substances which were part of the programme of work referred to in Article 8(2) of that Directive but have not been included into its Annex I ⁽⁵⁾.

- (4) The application was submitted to France, which had been designated rapporteur Member State by Regulation (EC) No 2229/2004. The time period for the accelerated procedure was respected. The specification of the active substance and the supported uses are the same as were the subject of Decision 2008/941/EC. That application also complies with the remaining substantive and procedural requirements of Article 15 of Regulation (EC) No 33/2008.
- (5) France evaluated the additional data submitted by the applicant and prepared an additional report. It communicated that report to the European Food Safety Authority (hereinafter 'the Authority') and to the Commission on 26 January 2010. The Authority communicated the additional report to the other Member States and the applicant for comments and forwarded the comments it had received to the Commission. In accordance with Article 20(1) of Regulation (EC) No 33/2008 and at the request of the Commission, the Authority presented its conclusion on indolylbutyric acid to the Commission on 3 September 2010 ⁽⁶⁾. The draft assessment report, the additional report and the conclusion of the Authority were reviewed by the Member States and the Commission within the Standing Committee on the Food Chain and Animal Health and finalised on 28 January 2011 in the format of the Commission review report for indolylbutyric acid.
- (6) It has appeared from the various examinations made that plant protection products containing indolylbutyric acid may be expected to satisfy, in general, the requirements laid down in Article 5(1)(a) and (b) of Directive 91/414/EEC, in particular with regard to the uses which have been examined and detailed in the Commission review report. It is therefore appropriate to include indolylbutyric acid in Annex I, in order to ensure that in all Member States the authorisations of plant protection products containing this active substance can be granted in accordance with the provisions of that Directive.

⁽¹⁾ OJ L 230, 19.8.1991, p. 1.

⁽²⁾ OJ L 168, 27.6.2002, p. 14.

⁽³⁾ OJ L 379, 24.12.2004, p. 13.

⁽⁴⁾ OJ L 335, 13.12.2008, p. 91.

⁽⁵⁾ OJ L 15, 18.1.2008, p. 5.

⁽⁶⁾ European Food Safety Authority; Conclusion on the peer review of the pesticide risk assessment of the active substance indolylbutyric acid. EFSA Journal 2010;8(9):1720. [42 pp.] doi:10.2903/j.efsa.2010.1720. Available online: www.efsa.europa.eu/efsajournal.htm

- (7) Without prejudice to that conclusion, it is appropriate to obtain further information on certain specific points. Article 6(1) of Directive 91/414/EEC provides that inclusion of a substance in Annex I may be subject to conditions. Therefore, it is appropriate to require that the applicant submit further information confirming: the absence of clastogenicity potential of indolylbutyric acid, the vapour pressure of indolylbutyric acid and, consequently, an inhalation toxicity study, and the natural background concentration of indolylbutyric acid in the soil.
- (8) A reasonable period should be allowed to elapse before an active substance is included in Annex I in order to permit Member States and the interested parties to prepare themselves to meet the new requirements which will result from the inclusion.
- (9) Without prejudice to the obligations defined by Directive 91/414/EEC as a consequence of including an active substance in Annex I, Member States should be allowed a period of 6 months after inclusion to review existing authorisations of plant protection products containing indolylbutyric acid to ensure that the requirements laid down by Directive 91/414/EEC, in particular in its Article 13 and the relevant conditions set out in Annex I, are satisfied. Member States should vary, replace or withdraw, as appropriate, existing authorisations, in accordance with the provisions of Directive 91/414/EEC. By derogation from the above deadline, a longer period should be provided for the submission and assessment of the complete Annex III dossier of each plant protection product for each intended use in accordance with the uniform principles laid down in Directive 91/414/EEC.
- (10) The experience gained from previous inclusions in Annex I to Directive 91/414/EEC of active substances assessed in the framework of Commission Regulation (EEC) No 3600/92 of 11 December 1992 laying down the detailed rules for the implementation of the first stage of the programme of work referred to in Article 8(2) of Council Directive 91/414/EEC concerning the placing of plant protection products on the market⁽¹⁾ has shown that difficulties can arise in interpreting the duties of holders of existing authorisations in relation to access to data. In order to avoid further difficulties it therefore appears necessary to clarify the duties of the Member States, especially the duty to verify that the holder of an authorisation demonstrates access to a dossier satisfying the requirements of Annex II to that Directive. However, this clarification does not impose any new obligations on Member States or holders of authorisations compared to the Directives which have been adopted until now amending Annex I.
- (11) It is therefore appropriate to amend Directive 91/414/EEC accordingly.
- (12) Decision 2008/941/EC provides for the non-inclusion of indolylbutyric acid and the withdrawal of authorisation of plant protection products containing that substance by 31 December 2011. It is necessary to delete the line concerning indolylbutyric acid in the Annex to that Decision.
- (13) It is therefore appropriate to amend Decision 2008/941/EC accordingly.
- (14) The measures provided for in this Directive are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS DIRECTIVE:

Article 1

Annex I to Directive 91/414/EEC is amended as set out in the Annex to this Directive.

Article 2

The line concerning indolylbutyric acid in the Annex to Decision 2008/941/EC is deleted.

Article 3

Member States shall adopt and publish by 30 November 2011 at the latest the laws, regulations and administrative provisions necessary to comply with this Directive. They shall forthwith communicate to the Commission the text of those provisions and a correlation table between those provisions and this Directive.

They shall apply those provisions from 1 December 2011.

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

Article 4

1. Member States shall in accordance with Directive 91/414/EEC, where necessary, amend or withdraw existing authorisations for plant protection products containing indolylbutyric acid as an active substance by 30 November 2011.

By that date they shall in particular verify that the conditions in Annex I to that Directive relating to indolylbutyric acid are met, with the exception of those identified in part B of the entry concerning that active substance, and that the holder of the authorisation has, or has access to, a dossier satisfying the requirements of Annex II to that Directive in accordance with the conditions of Article 13 of that Directive.

⁽¹⁾ OJ L 366, 15.12.1992, p. 10.

2. By way of derogation from paragraph 1, for each authorised plant protection product containing indolylbutyric acid as either the only active substance or as one of several active substances all of which were listed in Annex I to Directive 91/414/EEC by 31 May 2011 at the latest, Member States shall re-evaluate the product in accordance with the uniform principles provided for in Annex VI to Directive 91/414/EEC, on the basis of a dossier satisfying the requirements of Annex III to that Directive and taking into account part B of the entry in Annex I to that Directive concerning indolylbutyric acid. On the basis of that evaluation, they shall determine whether the product satisfies the conditions set out in Article 4(1)(b), (c), (d) and (e) of Directive 91/414/EEC.

Following that determination Member States shall:

- (a) in the case of a product containing indolylbutyric acid as the only active substance, where necessary, amend or withdraw the authorisation by 31 May 2015 at the latest; or
- (b) in the case of a product containing indolylbutyric acid as one of several active substances, where necessary, amend or withdraw the authorisation by 31 May 2015 or by the date

fixed for such an amendment or withdrawal in the respective Directive or Directives which added the relevant substance or substances to Annex I to Directive 91/414/EEC, whichever is the latest.

Article 5

This Directive shall enter into force on 1 June 2011.

Article 6

This Directive is addressed to the Member States.

Done at Brussels, 4 March 2011.

For the Commission

The President

José Manuel BARROSO

ANNEX

The following entry shall be added at the end of the table in Annex I to Directive 91/414/EEC:

No	Common name, Identification numbers	IUPAC name	Purity (*)	Entry into force	Expiration of inclusion	Specific provisions
'333	Indolylbutyric acid CAS No 133-32-4 CIPAC No 830	4-(1H-indol-3-yl)butyric acid	≥ 994 g/kg	1 June 2011	31 May 2021	<p>PART A</p> <p>Only uses as plant growth regulator in ornamentals may be authorised.</p> <p>PART B</p> <p>For the implementation of the uniform principles of Annex VI, the conclusions of the review report on indolylbutyric acid, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 28 January 2011 shall be taken into account.</p> <p>In this overall assessment Member States shall pay particular attention to the operators and workers safety. Conditions of authorisation shall include the application of adequate personal protective equipment and risk mitigation measures to reduce the exposure.</p> <p>The Member States concerned shall request the submission of further information to confirm:</p> <ul style="list-style-type: none"> (a) the absence of clastogenicity potential of indolylbutyric acid; (b) the vapour pressure of indolylbutyric acid and, consequently, an inhalation toxicity study; (c) the natural background concentration of indolylbutyric acid in the soil. <p>The Member States concerned shall ensure that the applicant submits such confirmatory information to the Commission by 31 May 2013.'</p>

(*) Further details on identity and specification of active substance are provided in the review report.

ACTS ADOPTED BY BODIES CREATED BY INTERNATIONAL AGREEMENTS

DECISION No 1/2011 OF THE ACP-EU COMMITTEE OF AMBASSADORS

of 17 February 2011

concerning the status of Equatorial Guinea in relation to the amended ACP-EU Partnership Agreement

(2011/145/EU)

THE ACP-EU COMMITTEE OF AMBASSADORS,

Having regard to the Partnership Agreement between the members of the African, Caribbean and Pacific Group of States, of the one part, and the European Community and its Member States, of the other part, signed in Cotonou on 23 June 2000 ⁽¹⁾, as first amended in Luxembourg on 25 June 2005 ⁽²⁾ (hereinafter 'the ACP-EU Partnership Agreement') and as amended for the second time in Ouagadougou on 22 June 2010 ⁽³⁾ (hereinafter 'the amended ACP-EU Partnership Agreement') and in particular Article 15(3) and (4) thereof,

Having regard to Decision No 1/2005 of the ACP-EC Council of Ministers of 8 March 2005 concerning the adoption of the Rules of Procedure of the ACP-EC Council of Ministers ⁽⁴⁾ and in particular Article 8(3) thereof,

Whereas:

- (1) The ACP-EU Partnership Agreement entered into force on 1 July 2008 in accordance with Article 93(3) thereof. The amended ACP-EU Partnership Agreement has been provisionally applied since 31 October 2010.
- (2) Equatorial Guinea, which signed the ACP-EU Partnership Agreement on 25 June 2005, deposited an instrument of ratification with a reservation — an instrument that was rejected by the Union and its Member States in a letter of 19 December 2008. As a result, in accordance with Article 93(4) of the amended ACP-EU Partnership Agreement, the ratification is not valid.

⁽¹⁾ OJ L 317, 15.12.2000, p. 3.

⁽²⁾ Agreement amending the Partnership Agreement between the members of the African, Caribbean and Pacific Group of States, of the one part, and the European Community and its Member States, of the other part, signed in Cotonou on 23 June 2000 (OJ L 209, 11.8.2005, p. 27).

⁽³⁾ Agreement amending for the second time the Partnership Agreement between the members of the African, Caribbean and Pacific Group of States, of the one part, and the European Community and its Member States, of the other part, signed in Cotonou on 23 June 2000, as first amended in Luxembourg on 25 June 2005 (OJ L 287, 4.11.2010, p. 3).

⁽⁴⁾ OJ L 95, 14.4.2005, p. 44.

(3) Article 94 of the amended ACP-EU Partnership Agreement stipulates that any request for accession by a State is to be presented to, and approved by, the Council of Ministers.

(4) In May 2010, Equatorial Guinea presented a request for accession in accordance with Article 94 of the ACP-EU Partnership Agreement and a request for observer status, enabling it to participate in the joint institutions set up by the ACP-EU Partnership Agreement, until the accession procedure was completed.

(5) The observer status would be valid until 30 April 2011. Equatorial Guinea should deposit the Act of Accession with the Depositories of the amended ACP-EU Partnership Agreement, namely, the Secretariat General of the Council of the European Union and the Secretariat of the ACP States, no later than that date.

(6) In accordance with Article 15(4) of the ACP-EU Partnership Agreement, the Council of Ministers agreed in Ouagadougou on 21 June 2010 to give a mandate to the Committee of Ambassadors to take a decision on its behalf,

HAS ADOPTED THIS DECISION:

Article 1

Approval of request for accession and observer status

The request of Equatorial Guinea to accede to the Partnership Agreement between the members of the African, Caribbean and Pacific Group of States, of the one part, and the European Community and its Member States, of the other part, signed in Cotonou on 23 June 2000, as first amended in Luxembourg on 25 June 2005 and as amended for the second time in Ouagadougou on 22 June 2010 (hereinafter 'the amended ACP-EU Partnership Agreement') is hereby approved.

Equatorial Guinea shall have observer status until 30 April 2011 under the amended ACP-EU Partnership Agreement.

Equatorial Guinea shall deposit its Act of Accession with the Depositaries of the amended ACP-EU Partnership Agreement, namely, the Secretariat General of the Council of the European Union and the Secretariat of the ACP States, no later than that date.

Article 2

Entry into force

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

Done at Brussels, 17 February 2011.

*For the ACP-EU Council of Ministers
by the ACP-EU Committee of Ambassadors
The President
GYÖRKÖS P.*

CORRIGENDA**Corrigendum to Commission Decision 2009/564/EC of 9 July 2009 establishing the ecological criteria for the award of the Community eco-label for campsite service**

(Official Journal of the European Union L 196 of 28 July 2009)

On page 55:

for: '76. Used textiles, furniture and other products (up to 3 points)';

read: '76. Used textiles, furniture and other products (up to 2 points)'.

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