

Official Journal

of the European Union

L 158

English edition

Legislation

Volume 51

18 June 2008

Contents

I Acts adopted under the EC Treaty/Euratom Treaty whose publication is obligatory

REGULATIONS

- Commission Regulation (EC) No 551/2008 of 17 June 2008 establishing the standard import values for determining the entry price of certain fruit and vegetables 1
- ★ **Commission Regulation (EC) No 552/2008 of 17 June 2008 amending Regulations (EC) No 2430/1999, (EC) No 2380/2001 and (EC) No 1289/2004 as regards the terms of the authorisations of certain additives for use in animal nutrition ⁽¹⁾ 3**
- ★ **Commission Regulation (EC) No 553/2008 of 17 June 2008 amending Annex VII to Regulation (EC) No 999/2001 of the European Parliament and of the Council laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies ⁽¹⁾ 5**
- ★ **Commission Regulation (EC) No 554/2008 of 17 June 2008 concerning the authorisation of 6-phytase (Quantum Phytase) as a feed additive ⁽¹⁾ 14**

DIRECTIVES

- ★ **Commission Directive 2008/60/EC of 17 June 2008 laying down specific purity criteria concerning sweeteners for use in foodstuffs (Codified version) ⁽¹⁾ 17**
- ★ **Commission Directive 2008/61/EC of 17 June 2008 establishing the conditions under which certain harmful organisms, plants, plant products and other objects listed in Annexes I to V to Council Directive 2000/29/EC may be introduced into or moved within the Community or certain protected zones thereof, for trial or scientific purposes and for work on varietal selections (Codified version) 41**

Price: EUR 18

⁽¹⁾ Text with EEA relevance

(Continued overleaf)

EN

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

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

II Acts adopted under the EC Treaty/Euratom Treaty whose publication is not obligatory

DECISIONS

Council

2008/451/EC:

- ★ **Council Decision of 16 June 2008 adjusting the allowances provided for in Decision 2003/479/EC and Decision 2007/829/EC concerning the rules applicable to national experts and military staff on secondment to the General Secretariat of the Council** 56

Commission

2008/452/EC:

- ★ **Commission Decision of 6 June 2008 amending Decision 2007/27/EC adopting certain transitional measures concerning deliveries of raw milk to processing establishments and the processing of this milk in Romania with regard to the requirements of Regulation (EC) No 852/2004 and (EC) No 853/2004 of the European Parliament and of the Council (notified under document number C(2008) 2404) ⁽¹⁾** 58

2008/453/EC:

- ★ **Commission Decision of 10 June 2008 amending Decision 2006/139/EC as regards an authority approved for keeping a herdbook or register for the porcine species in the United States (notified under document number C(2008) 2472) ⁽¹⁾** 60

RECOMMENDATIONS

Commission

2008/454/EC:

- ★ **Commission Recommendation of 30 May 2008 on risk reduction measures for the substances sodium chromate, sodium dichromate and 2,2',6,6'-tetrabromo-4,4'-isopropylidenediphenol (tetrabromobisphenol A) (notified under document number C(2008) 2256) ⁽¹⁾** 62

2008/455/EC:

- ★ **Commission Recommendation of 30 May 2008 on risk reduction measures for the substances chromium trioxide, ammonium dichromate and potassium dichromate (notified under document number C(2008) 2326) ⁽¹⁾** 65



⁽¹⁾ Text with EEA relevance

I

(Acts adopted under the EC Treaty/Euratom Treaty whose publication is obligatory)

REGULATIONS

COMMISSION REGULATION (EC) No 551/2008**of 17 June 2008****establishing the standard import values for determining the entry price of certain fruit and vegetables**

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Commission Regulation (EC) No 1580/2007 of 21 December 2007 laying down implementing rules of Council Regulations (EC) No 2200/96, (EC) No 2201/96 and (EC) No 1182/2007 in the fruit and vegetable sector ⁽¹⁾, and in particular Article 138(1) thereof,

Whereas:

- (1) 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 the Annex thereto.

- (2) In compliance with the above criteria, the standard import values must be fixed at the levels set out in the Annex to this Regulation,

HAS ADOPTED THIS REGULATION:

Article 1

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

Article 2

This Regulation shall enter into force on 18 June 2008.

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

Done at Brussels, 17 June 2008.

For the Commission

Jean-Luc DEMARTY

*Director-General for Agriculture and
Rural Development*

⁽¹⁾ OJ L 350, 31.12.2007, p. 1.

ANNEX

to Commission Regulation of 17 June 2008 establishing the 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	41,9
	MK	40,3
	TR	57,1
	ZZ	46,4
0707 00 05	JO	151,2
	MK	35,8
	TR	83,4
	ZZ	90,1
0709 90 70	TR	103,3
	ZZ	103,3
0805 50 10	AR	121,9
	EG	120,2
	US	91,7
	ZA	131,5
	ZZ	116,3
0808 10 80	AR	101,8
	BR	86,7
	CL	95,1
	CN	92,0
	MK	63,0
	NZ	114,9
	US	112,7
	UY	59,9
	ZA	86,7
	ZZ	90,3
0809 10 00	IL	124,0
	TR	184,2
	ZZ	154,1
0809 20 95	TR	421,2
	US	405,5
	ZZ	413,4
0809 30 10, 0809 30 90	EG	182,1
	US	239,8
	ZZ	211,0
0809 40 05	IL	190,0
	TR	223,9
	ZZ	207,0

⁽¹⁾ Country nomenclature as fixed by Commission Regulation (EC) No 1833/2006 (OJ L 354, 14.12.2006, p. 19). Code 'ZZ' stands for 'of other origin'.

COMMISSION REGULATION (EC) No 552/2008**of 17 June 2008****amending Regulations (EC) No 2430/1999, (EC) No 2380/2001 and (EC) No 1289/2004 as regards the terms of the authorisations of certain additives for use in animal nutrition****(Text with EEA relevance)**

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

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 13(3) thereof,

Whereas:

(1) Alpharma (Belgium) BVBA has submitted an application under Article 13(3) of Regulation (EC) No 1831/2003 proposing to change the name of the holder of the authorisation as regards Commission Regulations (EC) No 2430/1999⁽²⁾, (EC) No 2380/2001⁽³⁾ and (EC) No 1289/2004⁽⁴⁾. Those Regulations authorise the use of certain additives. The authorisations are linked to the holder of the authorisation.

(2) In the case of the additives robenidine hydrochloride 66 g/kg (Cycostat 66G) and maduramicin ammonium alpha 1 g/100g (Cygro 1 %) listed in Annex I to Regulation (EC) No 2430/1999 the holder of the authorisation is Roche Vitamins Europe Ltd.

(3) In the case of additives maduramicin ammonium alpha 1 g/100g (Cygro 1 %) listed in the Annex to Regulation (EC) No 2380/2001 and decoquinat 60,6 g/kg (Deccox) listed in the Annex to Regulation (EC) No 1289/2004 the holder of the authorisation is Alpharma AS.

(4) The applicant claims that Alpharma (Belgium) BVBA is the legal successor of the holders of the authorisations

referred to in recitals 2 and 3. With the application Alpharma (Belgium) BVBA has submitted appropriate documents showing that the marketing rights for those additives have been transferred to Alpharma (Belgium) BVBA together with additional supporting documents from the original holders as named in those authorisations.

(5) The proposed change of the terms of the authorisations is purely administrative in nature and does not entail a fresh assessment of the additives concerned. The European Food Safety Authority was informed of the application.

(6) To allow the applicant to exploit its marketing rights under the name of Alpharma (Belgium) BVBA, it is necessary to change the terms of the authorisations.

(7) Regulations (EC) No 2430/1999, (EC) No 2380/2001 and (EC) No 1289/2004 should therefore be amended accordingly.

(8) It is appropriate to provide for a transitional period during which existing stocks may be used up.

(9) 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

1. In Annex I to Regulation (EC) No 2430/1999, in column 2 of the entry for E758 and E770, the words 'Roche Vitamins Europe Ltd' are replaced by the words 'Alpharma (Belgium) BVBA'.

2. In the Annex to Regulation (EC) No 2380/2001, in column 2 of the entry for E770, the words 'Alpharma AS' are replaced by the words 'Alpharma (Belgium) BVBA'.

⁽¹⁾ OJ L 268, 18.10.2003, p. 29. Regulation as amended by Commission Regulation (EC) No 378/2005 (OJ L 59, 5.3.2005, p. 8).

⁽²⁾ OJ L 296, 17.11.1999, p. 3. Regulation as last amended by Regulation (EC) No 1519/2007 (OJ L 335, 20.12.2007, p. 15).

⁽³⁾ OJ L 321, 6.12.2001, p. 18.

⁽⁴⁾ OJ L 243, 15.7.2004, p. 15.

3. In the Annex to Regulation (EC) No 1289/2004, in column 2 of the entry for E756, the words 'Alpharma AS' are replaced by the words 'Alpharma (Belgium) BVBA'.

Article 2

Existing stocks which are in conformity with the provisions applicable before the entry into force of this Regulation may continue to be placed on the market and used until 30 September 2008.

Article 3

This Regulation shall enter into force on the 20th 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, 17 June 2008.

For the Commission
Androulla VASSILIOU
Member of the Commission

COMMISSION REGULATION (EC) No 553/2008**of 17 June 2008****amending Annex VII to Regulation (EC) No 999/2001 of the European Parliament and of the Council laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies****(Text with EEA relevance)**

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Regulation (EC) No 999/2001 of the European Parliament and of the Council of 22 May 2001 laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies ⁽¹⁾, and in particular Article 23 thereof,

Whereas:

- (1) Regulation (EC) No 999/2001 lays down rules for the monitoring of transmissible spongiform encephalopathies in bovine, ovine and caprine animals and for eradication measures to be carried out following confirmation of a transmissible spongiform encephalopathy (TSE) in ovine and caprine animals.
- (2) Annex VII to Regulation (EC) No 999/2001 lays down the eradication measures to be carried out following confirmation of an outbreak of TSE in ovine and caprine animals.
- (3) Although TSE has been known to be present in ovine and caprine animals for over two hundred years, there is no evidence of any relationship between outbreaks of TSE in those animals and outbreaks of TSE in humans. Nevertheless, in 2000 the Commission introduced a comprehensive set of measures for the monitoring, prevention, control and eradication of TSE in ovine and caprine animals, on the basis of the limited scientific knowledge available at that time, and in order to ensure that sourcing from ovine and caprine animals' materials is as safe as possible.
- (4) Those measures are aimed at gathering as much data as possible on the prevalence of TSE other than bovine spongiform encephalopathy (BSE) in ovine and caprine animals, and on possible links with BSE and transmissibility to humans. The measures are also aimed at reducing as much as possible the occurrence of TSE.

The measures include the removal of specified risk materials, an extensive active monitoring programme, measures applicable to flocks infected with TSE and voluntary breeding schemes to increase resistance to TSE in the ovine population. Since the introduction of such measures and with the information obtained from active surveillance programmes carried out in the Member States, no epidemiological link has ever been established between TSE, other than BSE, in ovine and caprine animals and TSE in humans.

- (5) Article 7 of Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety ⁽²⁾ provides that in specific circumstances where, following an assessment of available information, the possibility of harmful effects on health is identified but scientific uncertainty persists, provisional risk management measures necessary to ensure a high level of health protection may be adopted, pending further scientific information for a more comprehensive risk assessment. It also stipulates that such measures must be proportionate and no more restrictive of trade than is required to achieve the high level of health protection sought, regard being had to technical and economic feasibility and other factors regarded as legitimate in the matter under consideration. The measures are to be reviewed within a reasonable period of time.
- (6) On 8 March 2007 the European Food Safety Authority (EFSA) adopted an opinion on certain aspects related to the risk of TSE in ovine and caprine animals ⁽³⁾. In that opinion, EFSA concluded that 'there is no evidence for an epidemiological or molecular link between classical and/or atypical scrapie and TSEs in humans. The BSE agent is the only TSE agent identified as zoonotic. However, in view of their diversity it is currently not possible to exclude transmissibility to humans of other animal TSE agents'. It also concluded that 'current discriminatory tests as described in the Community legislation to be used for discrimination between scrapie and BSE appear, up to now, to be reliable for the differentiation of BSE from classical and atypical scrapie. However, at the current stage of scientific knowledge, neither their diagnostic sensitivity nor their specificity can be assumed to be perfect'.

⁽¹⁾ OJ L 147, 31.5.2001, p. 1. Regulation as last amended by Commission Regulation (EC) No 357/2008 (OJ L 111, 23.4.2008, p. 3).

⁽²⁾ OJ L 31, 1.2.2002, p. 1. Regulation as last amended by Commission Regulation (EC) No 202/2008 (OJ L 60, 5.3.2008, p. 17).

⁽³⁾ The EFSA Journal (2007), 466, 1-10.

- (7) Following that opinion and in the framework of the Communication from the Commission — TSE Road map of 15 July 2005 ⁽¹⁾, and in line with the SANCO work programme 2006-07 on TSEs of 21 November 2006 ⁽²⁾, Commission Regulation (EC) No 727/2007 of 26 June 2007 amending Annexes I, III, VII and X to Regulation (EC) No 999/2001 of the European Parliament and of the Council laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies ⁽³⁾ was adopted. The amendments made to Regulation (EC) No 999/2001 by Regulation (EC) No 727/2007 were aimed at adjusting the measures initially taken as regards TSE in ovine and caprine animals, to take account of updated scientific evidence. Regulation (EC) No 999/2001, as amended by Regulation (EC) No 727/2007, therefore discontinued the obligation to cull the entire flock and provided for certain alternative measures to culling in the event of confirmation of an outbreak of TSE in a holding of ovine or caprine animals and where the presence of bovine spongiform encephalopathy (BSE) had been excluded. In particular, taking into account the fact that the sector for ovine and caprine animals is different across the Community, Regulation (EC) No 999/2001, as amended by Regulation (EC) No 727/2007, introduced the possibility for Member States to apply alternative policies, as laid down in Regulation (EC) No 727/2007, depending on the specific characteristics of the sector in each Member State.
- (8) On 17 July 2007, in Case T-257/07, France brought an action against the European Commission before the Court of First Instance of the European Communities, applying for the partial annulment of point 2.3(b)(iii), point 2.3(d) and point 4 of Chapter A of Annex VII to Regulation (EC) No 999/2001, as amended by Regulation (EC) No 727/2007, in particular regarding the measures to be applied to TSE-affected flocks, or alternatively the entire annulment of that Regulation. In its Order of 28 September 2007 ⁽⁴⁾, the Court suspended the application of those provisions pending delivery of a final judgment.
- (9) In the Order of 28 September 2007, the Commission's assessment of the available scientific data on the possible risks was questioned. Accordingly, the Commission subsequently asked EFSA to assist it in clarifying the two main premises on which Regulation (EC) No 727/2007 was based. Firstly, the absence of any scientific evidence demonstrating that any TSE agent, other than BSE, may be considered to be a zoonotic agent. Secondly, the possibility to distinguish through molecular and biological tests between BSE and other animal TSE in ovine and caprine animals. On 24 January 2008, EFSA adopted the scientific and technical clarification ⁽⁵⁾, as regards the interpretation of some facets of the conclusions of its Opinion of 8 March 2007, which had been taken into account for the adoption of Regulation (EC) No 727/2007.
- (10) As regards the transmissibility of TSE, EFSA confirmed that:
- in ovine animals, no TSE agents other than those causing Classical Scrapie and Atypical Scrapie have been identified,
 - in caprine animals, no TSE agents other than those causing BSE, Classical Scrapie and Atypical Scrapie have been identified,
 - the operational term 'BSE' covers a TSE of bovine animals that could be caused by at least three distinct TSE agents with heterogeneous biological properties,
 - the operational term 'Classical Scrapie' covers a TSE of ovine and caprine animals caused by several TSE agents with heterogeneous biological properties,
 - the operational term 'Atypical Scrapie' covers a TSE of ovine and caprine animals that differs from Classical Scrapie. Currently, it is a subject for debate whether it is caused by one or more TSE agents.
- (11) However, EFSA cannot exclude transmissibility to humans of other TSE agents other than BSE as:
- experimental transmissions to primate and to transgenic mouse models expressing the human PrP gene are currently used to evaluate the potential capacity of a TSE agent to cross the human species barrier,
 - TSE agents other than the Classical BSE agent from three field TSE cases (two Classical Scrapie cases and one L type BSE case) have been demonstrated to cross the modelled human species barrier,
 - some limitations to these models have to be considered, including the uncertainty of how well they represent the human species barrier and the uncertainty of how well the experimental inoculation route employed represents exposure under natural conditions.

⁽¹⁾ COM(2005) 322 final.

⁽²⁾ SEC(2006) 1527.

⁽³⁾ OJ L 165, 27.6.2007, p. 8.

⁽⁴⁾ OJ C 283, 24.11.2007, p. 28.

⁽⁵⁾ Scientific Report of the Panel on Biological Hazards on a request from the European Commission on 'Scientific and technical clarification in the interpretation and consideration of some facets of the conclusions of its Opinion of 8 March 2007 on certain aspects related to the risk of Transmissible Spongiform Encephalopathies (TSEs) in ovine and caprine animals'. The EFSA Journal (2008), 626, 1-11.

- (12) It appears from EFSA's clarifications that the biodiversity of the disease agents in ovine and caprine animals is an important element which does not make it possible to exclude transmissibility to humans and that that diversity increases the likelihood of one of the TSE agents being transmissible. However, EFSA acknowledges that there is no scientific evidence of any direct link between TSE in ovine and caprine animals, other than BSE, and TSE in humans. The EFSA viewpoint that transmissibility to humans of TSE agents in ovine or caprine animals cannot be excluded is based on experimental studies on human species barrier and animal models (primates and mice). Those models, however, do not take into account genetic characteristics of humans which have a major influence on relative susceptibility to prion diseases. They also have limitations when extrapolating results to natural conditions, in particular regarding how well they represent the human species barrier and the uncertainty of how well the experimental inoculation route employed represents exposure under natural conditions. On that basis, it may be considered that although a risk of transmissibility to humans of TSE agents in ovine or caprine animals cannot be excluded, that risk would be extremely low, taking into account the fact that the evidence of transmissibility is based on experimental models which do not represent the natural conditions related to the real human species barrier and the real routes of infection.
- (13) As regards the discriminatory tests, EFSA confirmed that:
- based on the limited data available, the discriminatory tests as implemented at European Union level are practicable tools for screening of field TSE cases, as referred to in point 3.2(c) of Chapter C of Annex X to Regulation (EC) No 999/2001, fulfilling the objective of rapid and reproducible identification of TSE cases that have a signature compatible with Classical BSE agent,
 - those discriminatory tests cannot be considered to be perfect because of the current lack of understanding of both the true biodiversity of TSE agents in ovine and caprine animals and how the agents interact in case of co-infection.
- (14) Following a request by the Commission for clarification as to whether the absence of statistically sufficient data on the performance of the tests is compensated by the procedure in place, which includes a ring trial with additional molecular testing methods in different laboratories and an evaluation by an expert panel chaired by the Community Reference Laboratory for TSEs, EFSA explained that:
- despite consistent performance in ring trials employing samples from experimental ovine BSE cases, there is uncertainty on about their performance in the field because of the lack of detection of natural BSE in ovine or caprine animals,
 - TSE positive cases go through the full discriminatory process, including bioassay, only when biochemical discriminatory testing is compatible with BSE signature; therefore, data obtained through this process cannot be used for the evaluation of the sensitivity or the specificity of the discriminatory tests,
 - increasing the number of negative results during TSE discriminatory testing of ovine or caprine animals cannot compensate for the absence of statistically sufficient data on the performance of the tests.
- (15) EFSA acknowledged that the discriminatory tests established in Regulation (EC) No 999/2001 are practicable tools fulfilling the objective of rapid and reproducible identification of TSE cases that have a signature compatible with the classical BSE agent. Given the absence of scientific evidence of co-infection of BSE and other TSE agents in ovine or caprine animals in natural conditions, and given that the prevalence of BSE in ovine, if present, or caprine animals is very low and therefore the possibility of co-infection would be even lower, the number of BSE cases missed in ovine and caprine animals would be extremely low. Therefore, although the discriminatory tests cannot be considered to be perfect, it is appropriate to consider them as a suitable tool for the purposes of the TSE eradication objectives pursued by Regulation (EC) No 999/2001.
- (16) In its Opinion of 25 January 2007 ⁽¹⁾, EFSA gave an estimation of the likely prevalence of BSE in ovine animals. The Authority concluded that in high-risk countries there is a rate of less than 0,3 to 0,5 cases of BSE per 10 000 healthy slaughtered animals. EFSA also stated that in the European Union 'there is a 95 % confidence that the number of cases is equal to or below four cases per million sheep; at a 99 % confidence level, the number becomes equal to or below six cases per million. Since no BSE case has yet to be confirmed in sheep, the most likely prevalence is zero'. Since the introduction in 2005 of the discriminatory tests procedure, as set out in point 3.2(c) of Chapter C of Annex X to Regulation (EC) No 999/2001, 2 798 discriminatory tests have been carried out in TSE-affected ovine animals and 265 discriminatory tests have been carried out in TSE-affected caprine animals and none of them have been confirmed as BSE-like.
- ⁽¹⁾ Opinion of the Scientific Panel on Biological Hazards on a request from the European Commission on the quantitative risk assessment on the residual BSE risk in sheep meat and meat products, The EFSA Journal (2007) 442, 1-44.

- (17) A high level of protection of human life and health is assured in the pursuit of Community policies. Community measures governing food and feed must be based on an appropriate assessment of the possible risks for human and animal health and must, taking into account existing scientific evidence, maintain or, if scientifically justified, increase the level of protection of human and animal health. It is impossible, however, to consider the complete elimination of risk as a realistic objective for any risk management decision in matters regarding food safety, where the cost and benefits of risk-reducing measures have to be carefully weighed in order to ensure the measure's proportionality. It is the role and responsibility of the risk manager to decide the acceptable level of risk, taking into account all the elements present in a scientific risk assessment.
- (18) The Commission, in its role as risk manager on EU level, is responsible for establishing the acceptable level of risk and adopting measures that are the most appropriate for maintaining a high level of protection of public health. It has reviewed and assessed the most recent scientific information as regards the transmissibility of TSE to humans. It has assessed any risk that is present as being currently very low.
- (19) The measures set out in Annex VII to Regulation (EC) No 999/2001 should therefore be reassessed in order to ensure that they do not impose a burden on the Member States and economic operators that is not appropriate to the level of risk involved and disproportionate to the objective pursued.
- (20) The measures laid down in Annex VII to Regulation (EC) No 999/2001 should therefore be amended in order to make it possible for Member States to dispense with the requirement of total or partial herd culling if a TSE case is detected in ovine or caprine animals.
- (21) Regulation (EC) No 999/2001 should therefore be amended accordingly.
- (22) 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*
- Annex VII to Regulation (EC) No 999/2001 is amended in accordance with the Annex to this Regulation.
- Article 2*
- This Regulation shall enter into force on the 60th 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, 17 June 2008.

For the Commission
Androulla VASSILIOU
Member of the Commission

ANNEX

In Annex VII to Regulation (EC) No 999/2001, Chapter A is replaced by the following:

‘CHAPTER A

Measures following confirmation of the presence of a TSE

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

(a) in the case of bovine animals:

- all other ruminants on the holding of the animal in which the disease was confirmed,
- where the disease was confirmed in a female animal, its progeny born within two years prior to, or after, clinical onset of the disease,
- all animals of the cohort of the animal in which the disease was confirmed,
- the possible origin of the disease,
- other animals on the holding of the animal in which the disease was confirmed or on other holdings which may have become infected by the TSE agent or been exposed to the same feed or contamination source,
- the movement of potentially contaminated feedingstuffs, of other material or any other means of transmission, which may have transmitted the TSE agent to or from the holding in question;

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

- all ruminants other than ovine and caprine animals on the holding of the animal in which the disease was confirmed,
- insofar as they are identifiable, the parents, and in the case of females all embryos, ova and the last progeny of the female animal in which the disease was confirmed,
- all other ovine and caprine animals on the holding of the animal in which the disease was confirmed in addition to those referred to in the second indent,
- the possible origin of the disease and the identification of other holdings on which there are animals, embryos or ova which may have become infected by the TSE agent or been exposed to the same feed or contamination source,
- the movement of potentially contaminated feedingstuffs, other material or any other means of transmission, which may have transmitted the TSE agent to or from the holding in question.

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

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

- not to kill and destroy animals of the cohort referred to in the third indent of point 1(a) if evidence has been provided that such animals did not have access to the same feed as the affected animal,
- to defer the killing and destruction of animals in the cohort referred to in the third indent of point 1(a) until the end of their productive life, provided that they are bulls continuously kept at a semen collection centre and it can be ensured that they are completely destroyed following death.

2.2. If a TSE is suspected in an ovine or caprine animal on a holding in a Member State, all other ovine and caprine animals from that holding shall be placed under official movement restriction until the results of the examination are available. If there is evidence that the holding where the animal was present when the TSE was suspected is not likely to be the holding where the animal could have been exposed to a TSE, the competent authority may decide that other holdings or only the holding of exposure shall be placed under official control depending on the epidemiological information available.

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

- (a) if BSE cannot be excluded after the results of a ring trial carried out in accordance with the procedure set out in Annex X, Chapter C, point 3.2(c), the killing and complete destruction of all animals, embryos and ova identified by the inquiry referred to in the second to fifth indents of point 1(b);
- (b) if BSE is excluded in accordance with the procedure set out in Annex X, Chapter C, point 3.2(c), pursuant to the decision of the competent authority:

either

- (i) the killing and complete destruction of all animals, embryos and ova identified by the inquiry referred to in the second and third indents of point 1(b). The conditions set out in point 3 shall apply to the holding;

or

- (ii) the killing and complete destruction of all animals, embryos and ova identified by the inquiry referred to in the second and third indents of point 1(b), with the exception of:

- breeding rams of the ARR/ARR genotype,
- breeding ewes carrying at least one ARR allele and no VRQ allele and, where such breeding ewes are pregnant at the time of the inquiry, the lambs subsequently born, if their genotype meets the requirements of this subparagraph,
- sheep carrying at least one ARR allele which are intended solely for slaughter,
- if the competent authority so decides, sheep and goats less than three months old which are intended solely for slaughter.

The conditions set out in point 3 shall apply to the holding;

or

- (iii) a Member State may decide not to kill and destroy the animals, identified by the inquiry referred to in the second and third indents of point 1(b) where it is difficult to obtain replacement ovine animals of a known genotype or where the frequency of the ARR allele within the breed or holding is low, or where it is deemed necessary in order to avoid inbreeding, or based on a reasoned consideration of all the epidemiological factors. The conditions set out in point 4 shall apply to the holding;
- (c) by way of derogation from the measures set out in point (b), and only where the TSE case confirmed on a holding is an atypical scrapie case, the Member State may decide to apply the measures laid down in point 5;
- (d) Member States may decide:
 - (i) to replace the killing and complete destruction of all animals referred to in b(i) by slaughtering for human consumption;
 - (ii) to replace the killing and complete destruction of animals referred to in b(ii) by slaughtering for human consumption provided that:
 - the animals are slaughtered within the territory of the concerned Member State,

- all animals which are over 18 months of age or have more than two permanent incisors erupted through the gum and are slaughtered for human consumption shall be tested for the presence of TSE in accordance with the laboratory methods set out in Annex X, Chapter C, point 3.2 (b);
 - (e) the prion protein genotype of ovine animals, up to a maximum of 50, killed and destroyed or slaughtered for human consumption in accordance with points (b)(i) and (iii) shall be determined;
 - (f) where the frequency of the ARR allele within the breed or holding is low, or where it is deemed necessary in order to avoid inbreeding, a Member State may decide to delay the destruction of animals as referred to in point 2.3 (b)(i) and (ii) for up to five breeding years.
- 2.4. If the infected animal has been introduced from another holding, a Member State may decide, based on the history of the case, to apply eradication measures in the holding of origin in addition to, or instead of, the holding in which the infection was confirmed; in the case of land used for common grazing by more than one flock, Member States may decide to limit the application of those measures to a single flock, based on a reasoned consideration of all the epidemiological factors; where more than one flock is kept on a single holding, Member States may decide to limit the application of the measures to the flock in which the TSE has been confirmed, provided it has been verified that the flocks have been kept isolated from each other and that the spread of infection between the flocks through either direct or indirect contact is unlikely.
3. Following the application on a holding of the measures referred to in point 2.3 (a) and (b)(i) and (ii):
- 3.1. Only the following animals may be introduced to the holding(s):
- (a) male sheep of the ARR/ARR genotype;
 - (b) female sheep carrying at least one ARR allele and no VRQ allele;
 - (c) caprine animals, provided that:
 - (i) no ovine animals for breeding other than those of the genotypes referred to in points (a) and (b) are present on the holding;
 - (ii) thorough cleaning and disinfection of all animal housing on the premises has been carried out following destocking.
- 3.2. Only the following ovine germinal products may be used in the holding(s):
- (a) semen from rams of the ARR/ARR genotype;
 - (b) embryos carrying at least one ARR allele and no VRQ allele.
- 3.3. Movement of the animals from the holding shall be subject to the following conditions:
- (a) movement of ARR/ARR sheep from the holding shall not be subject to any restriction;
 - (b) sheep carrying only one ARR allele may be moved from the holding only to go directly for slaughter for human consumption or for the purposes of destruction; however,
 - ewes carrying one ARR allele and no VRQ allele may be moved to other holdings which are restricted following the application of measures in accordance with point 2.3 (b)(ii) or 4,
 - if the competent authority so decides, lambs and kids may be moved to one other holding solely for the purposes of fattening prior to slaughter; the holding of destination shall not contain any ovine or caprine animals other than those being fattened prior to slaughter, and shall not dispatch live ovine or caprine animals to other holdings, except for direct slaughter within the territory of the concerned Member State;

- (c) caprine animals may be moved provided that the holding is subjected to intensified TSE monitoring, including the testing of all caprine animals which are over the age of 18 months and:
 - (i) are slaughtered for human consumption at the end of their productive lives; or
 - (ii) have died or been killed on the holding, and meet the conditions set out in Annex III, Chapter A, Part II, point 3;
 - (d) if the Member State so decides, lambs and kids less than three months old may be moved from the holding to go directly for slaughter for human consumption.
- 3.4. The restrictions set out in points 3.1, 3.2 and 3.3 shall continue to apply to the holding for a period of two years from:
- (a) the date of attainment of ARR/ARR status by all ovine animals on the holding; or
 - (b) the last date when any ovine or caprine animal was kept on the premises; or
 - (c) the date when the intensified TSE monitoring set out in 3.3 (c) commenced; or
 - (d) the date when all breeding rams on the holding are of ARR/ARR genotype and all breeding ewes carry at least one ARR allele and no VRQ allele, provided that during the two-year period, negative results are obtained from TSE testing of the following animals over the age of 18 months:
 - an annual sample of ovine animals slaughtered for human consumption at the end of their productive lives in accordance with the sample size referred to in the Table in Annex III, Chapter A, Part II, point 5, and
 - all ovine animals referred to in Annex III, Chapter A, Part II, point 3 which have died or been killed on the holding.
4. Following the application on a holding of the measures set out in point 2.3 (b)(iii) and for a period of two breeding years following the detection of the last TSE case:
- (a) all ovine and caprine animals on the holding shall be identified;
 - (b) all ovine and caprine animals on the holding, may be moved only within the territory of the concerned Member State for slaughter for human consumption or for the purposes of destruction; all animals over the age of 18 months slaughtered for human consumption shall be tested for the presence of TSE in accordance with the laboratory methods laid down in Annex X, Chapter C, point 3.2(b);
 - (c) the competent authority shall ensure that embryos and ova are not dispatched from the holding;
 - (d) only the semen from rams of the ARR/ARR genotype and embryos carrying at least one ARR allele and no VRQ allele may be used in the holding;
 - (e) all ovine and caprine animals which are over the age of 18 months which have died or been killed on the holding shall be subject to TSE testing;
 - (f) only male sheep of the ARR/ARR genotype and female ovine animals from holdings where no TSE cases have been detected or from flocks fulfilling the conditions set out in point 3.4 may be introduced in the holding;
 - (g) only caprine animals from holdings where no TSE cases have been detected or from flocks fulfilling the conditions of point 3.4 may be introduced in the holding;
 - (h) all ovine and caprine animals in the holding shall be subject to common grazing restrictions to be determined by the competent authority, based on a reasoned consideration of all the epidemiological factors;

- (i) by way of derogation of point (b) if the competent authority so decides, lambs and kids may be moved to another holding within the same Member State solely for the purposes of fattening prior to slaughter; provided that the holding of destination shall not contain any ovine or caprine animals other than those being fattened prior to slaughter, and shall not dispatch live ovine or caprine animals to other holdings, except for direct slaughter within the territory of the concerned Member State.
5. Following the application of the derogation provided for in point 2.3 (c) the following measures shall apply:
- (a) either the killing and complete destruction of all animals, embryos and ova identified by the inquiry referred to in the second and third indents of point 1(b). Member States may decide to determine the prion protein genotype of ovine animals which have been killed and destroyed;
 - (b) or, for a period of two breeding years following the detection of the last TSE case, at least the following measures:
 - (i) all ovine and caprine animals in the holding shall be identified;
 - (ii) the holding must be subject to intensified TSE monitoring for a period of two years, including the testing of all ovine and caprine animals which are over the age of 18 months and slaughtered for human consumption and all ovine and caprine animals over the age of 18 which have died or been killed on the holding;
 - (iii) the competent authority shall ensure that live ovine and caprine animals, embryos and ova from the holding are not dispatched to other Member States or third countries.
6. Member States applying the measures set out in point 2.3(b)(iii) or the derogations provided for in points 2.3(c) and (d) shall notify to the Commission an account of the conditions and criteria used for granting them. Where additional TSE cases are detected in flocks where derogations are applied, the conditions for granting such derogations shall be reassessed.'
-

COMMISSION REGULATION (EC) No 554/2008

of 17 June 2008

concerning the authorisation of 6-phytase (Quantum Phytase) as a feed additive

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

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 preparation set out in the Annex to this Regulation. That application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.
- (3) The application concerns authorisation of the enzyme preparation 6-phytase (Quantum Phytase) produced by *Pichia pastoris* (DSM 15927) as a feed additive for chickens for fattening, laying hens, turkeys for fattening, ducks for fattening and piglets (weaned), to be classified in the additive category 'zootechnical additives'.
- (4) The European Food Safety Authority (the Authority) concluded in its opinion adopted on 1 February 2007

and on 30 January 2008⁽²⁾ that the enzyme preparation 6-phytase (Quantum Phytase) produced by *Pichia pastoris* (DSM 15927) does not have an adverse effect on animals, consumers, or the environment and that it is efficacious in improving digestibility of feedingstuffs, based on the data provided by the applicant. It further concluded that the product is a mild irritant and a dermal sensitiser and that it may be a potential respiratory sensitiser. 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 Community Reference Laboratory set up by Regulation (EC) No 1831/2003.

- (5) The assessment of that preparation shows that the conditions for authorisation, provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the use of that preparation should be authorised, as a digestibility enhancer, as specified in the Annex to this Regulation. Measures should be provided for the protection of users from the risks identified in the opinion of the Authority.
- (6) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS REGULATION:

Article 1

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

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

⁽¹⁾ OJ L 268, 18.10.2003, p. 29. Regulation as amended by Commission Regulation (EC) No 378/2005 (OJ L 59, 5.3.2005, p. 8).

⁽²⁾ Scientific Opinion of the Panel on Additives and Products or Substances used in Animal Feed (FEEDAP) and of the Panel on Genetically Modified Organisms (GMO) on 'Safety and efficacy of the product Quantum Phytase 5000 L and Quantum Phytase 2500 D (6-phytase) as a feed additive for chickens for fattening, laying hens, turkeys for fattening, ducks for fattening and piglets (weaned)'. The EFSA Journal (2008) 627, pp. 1-27.

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

Done at Brussels, 17 June 2008.

For the Commission
Androulla VASSILIOU
Member of the Commission

ANNEX

Identification number of the additive	Name of the holder of authorisation	Additive (Trade name)	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 feedstuff with a moisture content of 12 %			
Category of zootechnical additives. Functional group: digestibility enhancers									
4a5	AB Enzyme GmbH	6-phytase EC 3.1.3.26 (Quantum Phytase 2500 D Quantum Phytase 5000 L)	<i>Additive composition</i> 6-phytase produced by <i>Pichia pastoris</i> (DSM 15927) having a minimum activity of: Solid form: 2 500 FTU/g ⁽¹⁾ Liquid form: 5 000 FTU/ml <i>Characterisation of the active substance</i> 6-phytase produced by <i>Pichia pastoris</i> (DSM 15927) <i>Analytical method</i> ⁽²⁾ Colorimetric method based on reaction of vanadomolybdate on organic phosphate produced by reaction on a phytate-containing substrate (sodium phosphate) at pH 5,5 and 37 °C.	Chickens for fattening	—	500 FTU	—	1. In the directions for use of the additive and premixture, indicate the storage temperature, storage life, and stability to pelleting 2. Recommended dose per kilogram of complete feedingstuff: — chickens for fattening: 500-2 500 FTU — laying hens: 2 000 FTU — ducks for fattening: 250-2 000 FTU — turkeys for fattening: 1 000-2 700 FTU — piglets (weaned): 100-2 500 FTU 3. For use in compound feed containing more than 0,25 % phytin-bound phosphorus 4. For use in weaned piglets until approximately 35 kg 5. For safety: breathing protection glasses and gloves shall be used during handling	8.7.2018
				Laying hens	—	2 000 FTU	—		
				Ducks for fattening	—	250 FTU	—		
				Turkeys for fattening	—	1 000 FTU	—		
				Piglets (weaned)	—	100 FTU	—		

⁽¹⁾ 1 FTU is the amount of enzyme which liberates 1 micromole of inorganic phosphate per minute from sodium phytate at pH 5.5 and 37 °C.

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

⁽¹⁾ 1 FTU is the amount of enzyme which liberates 1 micromole of inorganic phosphate per minute from sodium phytate at pH 5,5 and 37 °C.

⁽²⁾ Details of the analytical methods are available at the following address of the Community Reference Laboratory: www.irmm.jrc.be/crt/feed-additives

DIRECTIVES

COMMISSION DIRECTIVE 2008/60/EC

of 17 June 2008

laying down specific purity criteria concerning sweeteners for use in foodstuffs

(Text with EEA relevance)

(Codified version)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Directive 89/107/EEC of 21 December 1988 on the approximation of the laws of the Member States concerning food additives authorized for use in foodstuffs intended for human consumption ⁽¹⁾, and in particular Article 3(3)(a) thereof,

Whereas:

(1) Commission Directive 95/31/EC of 5 July 1995 laying down specific criteria of purity concerning sweeteners for use in foodstuffs ⁽²⁾ has been substantially amended several times ⁽³⁾. In the interest of clarity and rationality the said Directive should be codified.

(2) It is necessary to establish purity criteria for all sweeteners mentioned in European Parliament and Council Directive 94/35/EC of 30 June 1994 on sweeteners for use in foodstuffs ⁽⁴⁾.

(3) It is necessary to take into account the specifications and analytical techniques for sweeteners as set out in the *Codex Alimentarius* as drafted by the Joint FAO/WHO Expert Committee on Food Additives (JECFA).

⁽¹⁾ OJ L 40, 11.2.1989, p. 27. Directive as last amended by Regulation (EC) No 1882/2003 of the European Parliament and of the Council (OJ L 284, 31.10.2003, p. 1).

⁽²⁾ OJ L 178, 28.7.1995, p. 1. Directive as last amended by Directive 2006/128/EC (OJ L 346, 9.12.2006, p. 6).

⁽³⁾ See Annex II, Part A.

⁽⁴⁾ OJ L 237, 10.9.1994, p. 3. Directive as last amended by Directive 2006/52/EC (OJ L 204, 26.7.2006, p. 10).

(4) Food additives prepared by production methods or starting materials significantly different from those evaluated by the Scientific Committee for Food or different from those mentioned in this Directive should be submitted for safety evaluation by the European Food Safety Authority with emphasis on the purity criteria.

(5) The measures provided for in this Directive are in line with the opinion of the Standing Committee on the Food Chain and Animal Health.

(6) This Directive should be without prejudice to the obligations of the Member States relating to the time-limits for transposition into national law of the Directives set out in Annex II, Part B,

HAS ADOPTED THIS DIRECTIVE:

Article 1

The purity criteria referred to in Article 3(3)(a) of Directive 89/107/EEC for sweeteners mentioned in Directive 94/35/EC are set out in Annex I to this Directive.

Article 2

Directive 95/31/EC, as amended by the Directives listed in Annex II, Part A, is repealed, without prejudice to the obligations of the Member States relating to the time-limits for transposition into national law of the Directives set out in Annex II, Part B.

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

Article 3

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

Article 4

This Directive is addressed to the Member States.

Done at Brussels, 17 June 2008.

For the Commission

The President

José Manuel BARROSO

ANNEX I

E 420 (i) — SORBITOL

Synonyms	D-glucitol, D-sorbitol
Definition	
Chemical name	D-glucitol
Einecs	200-061-5
Chemical formula	$C_6H_{14}O_6$
Relative molecular mass	182,17
Assay	Content not less than 97 % of total glycitols and not less than 91 % of D-sorbitol on dry weight basis. Glycitols are compounds with the structural formula $CH_2OH-(CHOH)_n-CH_2OH$, where 'n' is an integer
Description	White hygroscopic powder, crystalline powder, flakes or granules having a sweet taste
Identification	
A. Solubility	Very soluble in water, slightly soluble in ethanol
B. Melting range	88 to 102 °C
C. Sorbitol monobenzylidene derivative	To 5 g of the sample add 7 ml of methanol, 1 ml of benzaldehyde and 1 ml of hydrochloric acid. Mix and shake in a mechanical shaker until crystals appear. Filter with the aid of suction, dissolve the crystals in 20 ml of boiling water containing 1 g of sodium bicarbonate, filter while hot, cool the filtrate, filter with suction, wash with 5 ml of methanol-water mixture (1 in 2) and dry in air. The crystals so obtained melt between 173 and 179 °C
Purity	
Water content	Not more than 1 % (Karl Fischer method)
Sulphated ash	Not more than 0,1 % expressed on dry weight basis
Reducing sugars	Not more than 0,3 % expressed as glucose on dry weight basis
Total sugars	Not more than 1 % expressed as glucose on dry weight basis
Chlorides	Not more than 50 mg/kg expressed on dry weight basis
Sulphates	Not more than 100 mg/kg expressed on dry weight basis
Nickel	Not more than 2 mg/kg expressed on dry weight basis
Arsenic	Not more than 3 mg/kg expressed on dry weight basis
Lead	Not more than 1 mg/kg expressed on dry weight basis
Heavy metals	Not more than 10 mg/kg expressed as Pb on dry weight basis

E 420 (ii) — SORBITOL SYRUP**Synonyms**

D-glucitol syrup

Definition

Chemical name

Sorbitol syrup formed by hydrogenation of glucose syrup is composed of D-sorbitol, D-mannitol and hydrogenated saccharides.

The part of the product which is not D-sorbitol is composed mainly of hydrogenated oligosaccharides formed by the hydrogenation of glucose syrup used as raw material (in which case the syrup is non-crystallising) or mannitol. Minor quantities of glycitols where $n \leq 4$ may be present. Glycitols are compounds with the structural formula $\text{CH}_2\text{OH}-(\text{CHOH})_n-\text{CH}_2\text{OH}$, where 'n' is an integer

Einecs

270-337-8

Assay

Content not less than 69 % total solids and not less than 50 % of D-sorbitol on the anhydrous basis

Description

Clear colourless and sweet-tasting aqueous solution

Identification

A. Solubility

Miscible with water, with glycerol, and with propane-1,2-diol

B. Melting range

To 5 g of the sample add 7 ml of methanol, 1 ml of benzaldehyde and 1 ml of hydrochloric acid. Mix and shake in a mechanical shaker until crystals appear. Filter with the aid of suction, dissolve the crystals in 20 ml of boiling water containing 1 g of sodium bicarbonate, filter while hot. Cool the filtrate filter with suction, wash with 5 ml of methanol-water mixture (1 in 2) and dry in air. The crystals so obtained melt between 173 and 179 °C

Purity

Water content

Not more than 31 % (Karl Fischer method)

Sulphated ash

Not more than 0,1 % expressed on dry weight basis

Reducing sugars

Not more than 0,3 % expressed as glucose on dry weight basis

Chlorides

Not more than 50 mg/kg expressed on dry weight basis

Sulphates

Not more than 100 mg/kg expressed on dry weight basis

Nickel

Not more than 2 mg/kg expressed on dry weight basis

Arsenic

Not more than 3 mg/kg expressed on dry weight basis

Lead

Not more than 1 mg/kg expressed on dry weight basis

Heavy metals

Not more than 10 mg/kg expressed as Pb on dry weight basis

E 421 — MANNITOL

(I) MANNITOL

Synonyms

D-mannitol

Definition

Manufactured by catalytic hydrogenation of carbohydrate solutions containing glucose and/or fructose

Chemical name

D-mannitol

Einecs

200-711-8

Chemical formula

$C_6H_{14}O_6$

Molecular weight

182,2

Assay

Content not less than 96,0 % D-mannitol and not more than 102 % on the dried basis

Description

White, odourless, crystalline powder

Identification

A. Solubility

Soluble in water, very slightly soluble in ethanol, practically insoluble in ether

B. Melting range

Between 164 and 169 °C

C. Thin layer chromatography

Passes test

D. Specific rotation

$[\alpha]^{20}_D$: + 23 ° to + 25 ° (borate solution)

E. pH

Between 5 and 8

Add 0,5 ml of a saturated solution of potassium chloride to 10 ml of a 10 % w/v solution of the sample, then measure the pH

Purity

Loss on drying

Not more than 0,3 % (105 °C, four hours)

Reducing sugars

Not more than 0,3 % (as glucose)

Total sugars

Not more than 1 % (as glucose)

Sulphated ash

Not more than 0,1 %

Chlorides

Not more than 70 mg/kg

Sulphate

Not more than 100 mg/kg

Nickel

Not more than 2 mg/kg

Lead

Not more than 1 mg/kg

(II) MANNITOL MANUFACTURED BY FERMENTATION**Synonyms**

D-mannitol

Definition

Manufactured by discontinuous fermentation under aerobic conditions using a conventional strain of the yeast *Zygosaccharomyces rouxii*

Chemical name

D-mannitol

Einecs	200-711-8
Chemical formula	C ₆ H ₁₄ O ₆
Molecular weight	182,2
Assay	Not less than 99 % on the dried basis
Description	White, odourless crystalline powder
Identification	
A. Solubility	Soluble in water, very slightly soluble in ethanol, practically insoluble in ether
B. Melting range	Between 164 and 169 °C
C. Thin layer chromatography	Passes test
D. Specific rotation	[α] ²⁰ _D : + 23 ° to + 25 ° (borate solution)
E. pH	Between 5 and 8 Add 0,5 ml of a saturated solution of potassium chloride to 10 ml of a 10 % w/v solution of the sample, then measure the pH
Purity	
Arabitol	Not more than 0,3 %
Loss on drying	Not more than 0,3 % (105 °C, four hours)
Reducing sugars	Not more than 0,3 % (as glucose)
Total sugars	Not more than 1 % (as glucose)
Sulphated ash	Not more than 0,1 %
Chlorides	Not more than 70 mg/kg
Sulphate	Not more than 100 mg/kg
Lead	Not more than 1 mg/kg
Aerobic mesophilic bacteria	Not more than 10 ³ /g
Coliforms	Absent in 10 g
<i>Salmonella</i>	Absent in 10 g
<i>E. Coli</i>	Absent in 10 g
<i>Staphylococcus aureus</i>	Absent in 10 g
<i>Pseudomonas aeruginosa</i>	Absent in 10 g
Moulds	Not more than 100/g
Yeasts	Not more than 100/g

E 950 — ACESULFAME K

Synonyms	Acesulfame potassium, potassium salt of 3,4-dihydro-6-methyl-1,2,3-oxathiazin-4-one,2,2-dioxide
Definition	
Chemical name	6-methyl-1,2,3-oxathiazin-4(3H)-one-2,2-dioxide potassium salt
Einecs	259-715-3
Chemical formula	C ₄ H ₄ KNO ₄ S
Molecular weight	201,24
Assay	Content not less than 99 % of C ₄ H ₄ KNO ₄ S on the anhydrous basis
Description	Odourless, white, crystalline powder. Approximately 200 times as sweet as sucrose
Identification	
A. Solubility	Very soluble in water, very slightly soluble in ethanol
B. Ultraviolet absorption	Maximum 227 ± 2 nm for a solution of 10 mg in 1 000 ml of water
C. Positive test for potassium	Passes test (test the residue obtained by igniting 2 g of the sample)
D. Precipitation test	Add a few drops of a 10 % solution of sodium cobalt nitrite to a solution of 0,2 g of the sample in 2 ml of acetic acid and 2 ml of water. A yellow precipitate is produced
Purity	
Loss on drying	Not more than 1 % (105 °C, two hours)
Organic impurities	Passes test for 20 mg/kg of UV active components
Fluoride	Not more than 3 mg/kg
Lead	Not more than 1 mg/kg

E 951 — ASPARTAME

Synonyms	Aspartyl phenylalanine methyl ester
Definition	
Chemical name	N-L-α-(Aspartyl-L-phenylalanine-1-methyl ester, 3-amino-N-(α-carbo-methoxy-phenethyl)-succinamic acid-N-methyl ester
Einecs	245-261-3
Chemical formula	C ₁₄ H ₁₈ N ₂ O ₅
Relative molecular mass	294,31
Assay	Not less than 98 % and not more than 102 % of C ₁₄ H ₁₈ N ₂ O ₅ on the anhydrous basis

Description	White, odourless, crystalline powder having a sweet taste. Approximately 200 times as sweet as sucrose
Identification	
Solubility	Slightly soluble in water and in ethanol
Purity	
Loss on drying	Not more than 4,5 % (105 °C, four hours)
Sulphated ash	Not more than 0,2 % expressed on dry weight basis
pH	Between 4,5 and 6,0 (1 in 125 solution)
Transmittance	The transmittance of a 1 % solution in 2N hydrochloric acid, determined in a 1-cm cell at 430 nm with a suitable spectrophotometer, using 2N hydrochloric acid as a reference, is not less than 0,95, equivalent to an absorbance of not more than approximately 0,022
Specific rotation	$[\alpha]_D^{20}$: + 14,5 to + 16,5 ° Determine in a 4 in 100/15 N formic acid solution within 30 minutes after preparation of the sample solution
Arsenic	Not more than 3 mg/kg expressed on dry weight basis
Lead	Not more than 1 mg/kg expressed on dry weight basis
Heavy metals	Not more than 10 mg/kg expressed as Pb on dry weight basis
5-Benzyl-3,6-dioxo-2-piperazineacetic acid	Not more than 1,5 % expressed on dry weight basis

E 952 — CYCLAMIC ACID AND ITS Na AND Ca SALTS**(I) CYCLAMIC ACID**

Synonyms	Cyclohexylsulphamic acid, cyclamate
Definition	
Chemical name	Cyclohexanesulphamic acid, cyclohexylaminosulphonic acid
Einecs	202-898-1
Chemical formula	$C_6H_{13}NO_3S$
Relative molecular mass	179,24
Assay	Cyclohexylsulphamic acid contains not less than 98 % and not more than the equivalent of 102 % of $C_6H_{13}NO_3S$, calculated on the anhydrous basis
Description	A practically colourless, white crystalline powder with a sweet-sour taste. Approximately 40 times as sweet as sucrose
Identification	
A. Solubility	Soluble in water and in ethanol

B. Precipitation test	Acidify a 2 % solution with hydrochloric acid, add 1 ml of an approximately molar solution of barium chloride in water and filter if any haze or precipitate forms. To the clear solution add 1 ml of a 10 % solution of sodium nitrite. A white precipitate forms.
Purity	
Loss on drying	Not more than 1 % (105 °C, one hour)
Selenium	Not more than 30 mg/kg expressed as selenium on dry weight basis
Lead	Not more than 1 mg/kg expressed on dry weight basis
Heavy metals	Not more than 10 mg/kg expressed as Pb on dry weight basis
Arsenic	Not more than 3 mg/kg expressed on dry weight basis
Cyclohexylamine	Not more than 10 mg/kg expressed on dry weight basis
Dicyclohexylamine	Not more than 1 mg/kg expressed on dry weight basis
Aniline	Not more than 1 mg/kg expressed on dry weight basis
(II) SODIUM CYCLAMATE	
Synonyms	Cyclamate, sodium salt of cyclamic acid
Definition	
Chemical name	Sodium cyclohexanesulphamate, sodium cyclohexylsulphamate
Einecs	205-348-9
Chemical formula	$C_6H_{12}NNaO_3S$ and the dihydrate form $C_6H_{12}NNaO_3S \cdot 2H_2O$
Relative molecular mass	201,22 calculated on the anhydrous form 237,22 calculated on the hydrated form
Assay	Not less than 98 % and not more than 102 % on the dried basis Dihydrate form: not less than 84 % on the dried basis
Description	White, odourless crystals or crystalline powder. Approximately 30 times as sweet as sucrose
Identification	
Solubility	Soluble in water, practically insoluble in ethanol
Purity	
Loss on drying	Not more than 1 % (105 °C, one hour) Not more than 15,2 % (105 °C, two hours) for the dihydrate form
Selenium	Not more than 30 mg/kg expressed as selenium on dry weight basis
Arsenic	Not more than 3 mg/kg expressed on dry weight basis
Lead	Not more than 1 mg/kg expressed on dry weight basis
Heavy metals	Not more than 10 mg/kg expressed as Pb on dry weight basis

Cyclohexylamine	Not more than 10 mg/kg expressed on dry weight basis
Dicyclohexylamine	Not more than 1 mg/kg expressed on dry weight basis
Aniline	Not more than 1 mg/kg expressed on dry weight basis
(III) CALCIUM CYCLAMATE	
Synonyms	Cyclamate, calcium salt of cyclamic acid
Definition	
Chemical name	Calcium cyclohexanesulphamate, calcium cyclohexylsulphamate
Einecs	205-349-4
Chemical formula	$C_{12}H_{24}CaN_2O_6S_2 \cdot 2H_2O$
Relative molecular mass	432,57
Assay	Not less than 98 % and not more than 101 % on the dried basis
Description	White, colourless crystals or crystalline powder. Approximately 30 times as sweet as sucrose
Identification	
Solubility	Soluble in water, sparingly soluble in ethanol
Purity	
Loss on drying	Not more than 1 % (105 °C, one hour) Not more than 8,5 % (140 °C, four hours) for the dihydrate form
Selenium	Not more than 30 mg/kg expressed as selenium on dry weight basis
Arsenic	Not more than 3 mg/kg expressed on dry weight basis
Lead	Not more than 1 mg/kg expressed on dry weight basis
Heavy metals	Not more than 10 mg/kg expressed as Pb on dry weight basis
Cyclohexylamine	Not more than 10 mg/kg expressed on dry weight basis
Dicyclohexylamine	Not more than 1 mg/kg expressed on dry weight basis
Aniline	Not more than 1 mg/kg expressed on dry weight basis
E 953 — ISOMALT	
Synonyms	Hydrogenated isomaltulose, hydrogenated palatinose.

Definition

Chemical name	Isomalt is a mixture of hydrogenated mono- and disaccharides whose principal components are the disaccharides: 6-O- α -D-Glucopyranosyl-D-sorbitol (1,6-GPS) and 1-O- α -D-Glucopyranosyl-D-mannitol dihydrate (1,1-GPM)
Chemical formula	6-O- α -D-Glucopyranosyl-D-sorbitol: $C_{12}H_{24}O_{11}$ 1-O- α -D-Glucopyranosyl-D-mannitol dihydrate: $C_{12}H_{24}O_{11} \cdot 2H_2O$
Relative molecular mass	6-O- α -D-Glucopyranosyl-D-sorbitol: 344,32 1-O- α -D-Glucopyranosyl-D-mannitol dihydrate: 380,32
Assay	Content not less than 98 % of hydrogenated mono- and disaccharides and not less than 86 % of the mixture of 6-O- α -D-Glucopyranosyl-D-sorbitol and 1-O- α -D-Glucopyranosyl-D-mannitol dihydrate determined on the anhydrous basis.

Description

Odourless, white, slightly hygroscopic, crystalline mass.

Identification

A. Solubility	Soluble in water, very slightly soluble in ethanol.
B. Thin layer chromatography	Examine by thin layer chromatography using a plate coated with an approximately 0,2 mm layer of chromatographic silica gel. The principal spots in the chromatogram are those of 1,1-GPM and 1,6-GPS.

Purity

Water content	Not more than 7 % (Karl Fischer Method)
Sulphated ash	Not more than 0,05 % expressed on dry weight basis
D-Mannitol	Not more than 3 %
D-Sorbitol	Not more than 6 %
Reducing sugars	Not more than 0,3 % expressed as glucose on dry weight basis
Nickel	Not more than 2 mg/kg expressed on dry weight basis
Arsenic	Not more than 3 mg/kg expressed on dry weight basis
Lead	Not more than 1 mg/kg expressed on dry weight basis
Heavy metals (as Pb)	Not more than 10 mg/kg expressed on dry weight basis.

E 954 — SACCHARIN AND ITS Na, K AND Ca SALTS**(I) SACCHARIN****Definition**

Chemical name	3-Oxo-2,3-dihydrobenzo(d)isothiazol-1,1-dioxide
---------------	---

Einecs	201-321-0
Chemical formula	$C_7H_5NO_3S$
Relative molecular mass	183,18
Assay	Not less than 99 % and not more than 101 % of $C_7H_5NO_3S$ on the anhydrous basis
Description	White crystals or a white crystalline powder, odourless or with a faint, aromatic odour, having a sweet taste even in very dilute solutions. Approximately between 300 and 500 times as sweet as sucrose
Identification	
Solubility	Slightly soluble in water, soluble in basic solutions, sparingly soluble in ethanol
Purity	
Loss on drying	Not more than 1 % (105 °C, two hours)
Melting range	226 to 230 °C
Sulphated ash	Not more than 0,2 % expressed on dry weight basis
Benzoic and salicylic acid	To 10 ml of a 1 in 20 solution, previously acidified with five drops of acetic acid, add three drops of an approximately molar solution of ferric chloride in water. No precipitate or violet colour appears
o-Toluenesulphonamide	Not more than 10 mg/kg expressed on dry weight basis
p-Toluenesulphonamide	Not more than 10 mg/kg expressed on dry weight basis
Benzoic acid p-sulphonamide	Not more than 25 mg/kg expressed on dry weight basis
Readily carbonisable substances	Absent
Arsenic	Not more than 3 mg/kg expressed on dry weight basis
Selenium	Not more than 30 mg/kg expressed on dry weight basis
Lead	Not more than 1 mg/kg expressed on dry weight basis
(II) SODIUM SACCHARIN	
Synonyms	Saccharin, sodium salt of saccharin
Definition	
Chemical name	Sodium o-benzosulphimide, sodium salt of 2,3-dihydro-3-oxobenzisulphonazole, oxobenzisulphonazole, 1,2-benzisothiazolin-3-one-1, 1-dioxide sodium salt dihydrate
Einecs	204-886-1
Chemical formula	$C_7H_4NNaO_3S \cdot 2H_2O$

Relative molecular mass	241,19
Assay	Not less than 99 % and not more than 101 % of $C_7H_4NNaO_3S$ on the anhydrous basis
Description	White crystals or a white crystalline efflorescent powder, odourless or with a faint odour, having an intensely sweet taste, even in very dilute solutions. Approximately between 300 and 500 times as sweet as sucrose in dilute solutions
Identification	
Solubility	Freely soluble in water, sparingly soluble in ethanol
Purity	
Loss on drying	Not more than 15 % (120 °C, four hours)
Benzoic and salicylic acid	To 10 ml of a 1 in 20 solution, previously acidified with five drops of acetic acid, add three drops of an approximately molar solution of ferric chloride in water. No precipitate or violet colour appears
<i>o</i> -Toluenesulphonamide	Not more than 10 mg/kg expressed on dry weight basis
<i>p</i> -Toluenesulphonamide	Not more than 10 mg/kg expressed on dry weight basis
Benzoic acid <i>p</i> -sulphonamide	Not more than 25 mg/kg expressed on dry weight basis
Readily carbonisable substances	Absent
Arsenic	Not more than 3 mg/kg expressed on dry weight basis
Selenium	Not more than 30 mg/kg expressed on dry weight basis
Lead	Not more than 1 mg/kg expressed on dry weight basis
(III) CALCIUM SACCHARIN	
Synonyms	Saccharin, calcium salt of saccharin
Definition	
Chemical name	Calcium <i>o</i> -benzosulphimide, calcium salt of 2,3-dihydro-3-oxobenzo-sulphonazole, 1,2-benzisothiazolin-3-one-1,1-dioxide calcium salt hydrate (2:7)
Einecs	229-349-9
Chemical formula	$C_{14}H_8CaN_2O_6S_2 \cdot 3\frac{1}{2}H_2O$
Relative molecular mass	467,48
Assay	Not less than 95 % of $C_{14}H_8CaN_2O_6S_2$ on the anhydrous basis
Description	White crystals or a white crystalline powder, odourless or with a faint odour, having an intensely sweet taste, even in very dilute solutions. Approximately between 300 and 500 times as sweet as sucrose in dilute solutions

Identification

Solubility

Freely soluble in water, soluble in ethanol

Purity

Loss on drying

Not more than 13,5 % (120 °C, four hours)

Benzoic and salicylic acid

To 10 ml of a 1 in 20 solution, previously acidified with five drops of acetic acid, add three drops of an approximately molar solution of ferric chloride in water. No precipitate or violet colour appears

o-Toluenesulphonamide

Not more than 10 mg/kg expressed on dry weight basis

p-Toluenesulphonamide

Not more than 10 mg/kg expressed on dry weight basis

Benzoic acid *p*-sulphonamide

Not more than 25 mg/kg expressed on dry weight basis

Readily carbonisable substances

Absent

Arsenic

Not more than 3 mg/kg expressed on dry weight basis

Selenium

Not more than 30 mg/kg expressed on dry weight basis

Lead

Not more than 1 mg/kg expressed on dry weight basis

(IV) POTASSIUM SACCHARIN**Synonyms**

Saccharin, potassium salt of saccharin

Definition

Chemical name

Potassium *o*-benzosulphimide, potassium salt of 2,3-dihydro-3-oxobenzisoxsulphonazole, potassium salt of 1,2-benzisothiazolin-3-one-1,1-dioxide monohydrate

Einecs

Chemical formula

 $C_7H_4KNO_3S \cdot H_2O$

Relative molecular mass

239,77

Assay

Not less than 99 % and not more than 101 % of $C_7H_4KNO_3S$ on the anhydrous basis**Description**

White crystals or a white crystalline powder, odourless or with a faint odour, having an intensely sweet taste, even in very dilute solutions. Approximately between 300 and 500 times as sweet as sucrose

Identification

Solubility

Freely soluble in water, sparingly soluble in ethanol

Purity

Loss on drying

Not more than 8 % (120 °C, four hours)

Benzoic and salicylic acid	To 10 ml of a 1 in 20 solution, previously acidified with five drops of acetic acid, add three drops of an approximately molar solution of ferric chloride in water. No precipitate or violet colour appears
<i>o</i> -Toluenesulphonamide	Not more than 10 mg/kg expressed on dry weight basis
<i>p</i> -Toluenesulphonamide	Not more than 10 mg/kg expressed on dry weight basis
Benzoic acid <i>p</i> -sulphonamide	Not more than 25 mg/kg expressed on dry weight basis
Readily carbonisable substances	Absent
Arsenic	Not more than 3 mg/kg expressed on dry weight basis
Selenium	Not more than 30 mg/kg expressed on dry weight basis
Lead	Not more than 1 mg/kg expressed on dry weight basis

E 955 — SUCRALOSE**Synonyms**

4,1',6'-Trichlorogalactosucrose

Definition

Chemical name	1,6-Dichloro-1,6-dideoxy- β -D-fructofuranosyl-4-chloro-4-deoxy- α -D-galactopyranoside
Einecs	259-952-2
Chemical formula	$C_{12}H_{19}Cl_3O_8$
Molecular weight	397,64
Assay	Content not less than 98 % and not more than 102 % $C_{12}H_{19}Cl_3O_8$ calculated on an anhydrous basis.

Description

White to off-white, practically odourless, crystalline powder.

Identification

A. Solubility	Freely soluble in water, methanol and ethanol Slightly soluble in ethyl acetate
B. Infrared absorption	The infrared spectrum of a potassium bromide dispersion of the sample exhibits relative maxima at similar wave numbers as those shown in the reference spectrum obtained using a sucralose reference standard.
C. Thin layer chromatography	The main spot in the test solution has the same R_f value as that of the main spot of standard solution A referred to in the test for other chlorinated disaccharides. This standard solution is obtained by dissolving 1,0g of sucralose reference standard in 10 ml of methanol.
D. Specific rotation	$[\alpha]_D^{20} + 84,0^\circ$ to $+ 87,5^\circ$ calculated on the anhydrous basis (10 % w/v solution)

Purity

Water	Not more than 2,0 % (Karl Fischer method)
Sulphated ash	Not more than 0,7 %
Other chlorinated disaccharides	Not more than 0,5 %
Chlorinated monosaccharides	Not more than 0,1 %
Triphenylphosphine oxide	Not more than 150 mg/kg
Methanol	Not more than 0,1 %
Lead	Not more than 1 mg/kg

E 957 — THAUMATIN**Synonyms****Definition**

Chemical name	Thaumatococcus daniellii (Benth) and consists essentially of the proteins thaumatin I and thaumatin II together with minor amounts of plant constituents derived from the source material
Einecs	258-822-2
Chemical formula	Polypeptide of 207 amino acids
Relative molecular mass	Thaumatococcus I 22209 Thaumatococcus II 22293
Assay	Not less than 16 % nitrogen on the dried basis equivalent to not less than 94 % proteins (N × 5,8)

Description

Odourless, cream-coloured powder with an intensely sweet taste. Approximately 2 000 to 3 000 times as sweet as sucrose

Identification

Solubility	Very soluble in water, insoluble in acetone
------------	---

Purity

Loss on drying	Not more than 9 % (105 °C to constant weight)
Carbohydrates	Not more than 3 % expressed on dry weight basis
Sulphated ash	Not more than 2 % expressed on dry weight basis

Aluminium	Not more than 100 mg/kg expressed on dry weight basis
Arsenic	Not more than 3 mg/kg expressed on dry weight basis
Lead	3 mg/kg expressed on dry weight basis
Microbiological criteria	Total aerobic microbial count: Max 1 000/g <i>E. Coli</i> : absent in 1 g

E 959 — NEOHESPERIDINE DIHYDROCHALCONE

Synonyms

Neohesperidin dihydrochalcone, NHDC, hesperetin dihydrochalcone-4'- β -neohesperidoside, neohesperidin DC

Definition

Chemical name	2-O- α -L-rhamnopyranosyl-4'- β -D-glucopyranosyl hesperetin dihydrochalcone; obtained by catalytic hydrogenation of neohesperidin
Einecs	243-978-6
Chemical formula	C ₂₈ H ₃₆ O ₁₅
Relative molecular mass	612,6
Assay	Content not less than 96 % on the dried basis

Description

Off-white, odourless, crystalline powder having a characteristic, intensive sweet taste. Approximately between 1 000 and 1 800 times as sweet as sucrose

Identification

A. Solubility	Freely soluble in hot water, very slightly soluble in cold water, practically insoluble in ether and benzene
B. Ultraviolet absorption maximum	282 to 283 nm for a solution of 2 mg in 100 ml methanol
C. Neu's test	Dissolve about 10 mg of neohesperidine DC in 1 ml methanol, add 1 ml of a 1 % 2-aminoethyl diphenyl borate methanolic solution. A bright yellow colour is produced

Purity

Loss on drying	Not more than 11 % (105 °C, three hours)
Sulphated ash	Not more than 0,2 % expressed on dry weight basis
Arsenic	Not more than 3 mg/kg expressed on dry weight basis
Lead	Not more than 2 mg/kg expressed on dry weight basis
Heavy metals	Not more than 10 mg/kg expressed as Pb on dry weight basis

E 962 — SALT OF ASPARTAME-ACESULFAME

Synonyms	Aspartame-acesulfame, Aspartame-acesulfame salt
Definition	The salt is prepared by heating an approximately 2:1 ratio (w/w) of aspartame and acesulfame K in solution at acidic pH and allowing crystallisation to occur. The potassium and moisture are eliminated. The product is more stable than aspartame alone.
Chemical name	6-Methyl-1,2,3-oxathiazine-4(3H)-one-2,2-dioxide salt of L-phenylalanyl-2-methyl-L- α -aspartic acid
Chemical formula	$C_{18}H_{23}O_9N_3S$
Molecular weight	457,46
Assay	63,0 % to 66,0 % aspartame (dry basis) and 34,0 % to 37,0 % acesulfame (acid form on a dry basis)
Description	A white, odourless, crystalline powder.
Identification	
A. Solubility	Sparingly soluble water; slightly soluble in ethanol
B. Transmittance	The transmittance of a 1 % solution in water determined in a 1 cm cell at 430 nm with a suitable spectrophotometer using water as a reference, is not less than 0,95, equivalent to an absorbance of not more than approximately 0,022.
C. Specific rotation	$[\alpha]^{20}_D + 14,5^\circ$ to $+ 16,5^\circ$ Determine at a concentration of 6,2 g in 100 ml formic acid (15N) within 30 min of preparation of the solution. Divide the calculated specific rotation by 0,646 to correct for the aspartame content of the salt of aspartame-acesulfame
Purity	
Loss on drying	Not more than 0,5 % (105 °C, four hours)
5-Benzyl-3,6-dioxo-2-piper-azineacetic acid	Not more than 0,5 %
Lead	Not more than 1 mg/kg

E 965 (i) — MALTITOL

Synonyms	D-Maltitol, hydrogenated maltose
Definition	
Chemical name	(α)-D-Glucopyranosyl-1,4-D-glucitol
Einecs	209-567-0
Chemical formula	$C_{12}H_{24}O_{11}$

Relative molecular mass	344,31
Assay	Content not less than 98 % D-maltitol $C_{12}H_{24}O_{11}$ on the anhydrous basis
Description	Sweet tasting, white crystalline powder
Identification	
A. Solubility	Very soluble in water, slightly soluble in ethanol
B. Melting range	148 to 151 °C
C. Specific rotation	$[\alpha]_D^{20} = + 105,5^\circ$ to $+ 108,5^\circ$ (5 % w/v solution)
Purity	
Water content	Not more than 1 % (Karl Fischer method)
Sulphated ash	Not more than 0,1 % expressed on dry weight basis
Reducing sugars	Not more than 0,1 % expressed as glucose on dry weight basis
Chlorides	Not more than 50 mg/kg expressed on dry weight basis
Sulphates	Not more than 100 mg/kg expressed on dry weight basis
Nickel	Not more than 2 mg/kg expressed on dry weight basis
Arsenic	Not more than 3 mg/kg expressed on dry weight basis
Lead	Not more than 1 mg/kg expressed on dry weight basis

E 965 (ii) — MALTITOL SYRUP

Synonyms	Hydrogenated high-maltose-glucose syrup, hydrogenated glucose syrup
Definition	A mixture consisting of mainly maltitol with sorbitol and hydrogenated oligo- and polysaccharides. It is manufactured by the catalytic hydrogenation of high maltose-content glucose syrup or by the hydrogenation of its individual components followed by blending. The article of commerce is supplied both as a syrup and as a solid product.
Assay	Content not less than 99 % of total hydrogenated saccharides on the anhydrous basis and not less than 50 % of maltitol on the anhydrous basis
Description	Colourless and odourless, clear viscous liquids or white crystalline masses
Identification	
A. Solubility	Very soluble in water, slightly soluble in ethanol
B. Thin layer chromatography	Passes test

Purity

Water	Not more than 31 % (Karl Fischer)
Reducing sugars	Not more than 0,3 % (as glucose)
Sulphated ash	Not more than 0,1 %
Chlorides	Not more than 50 mg/kg
Sulphate	Not more than 100 mg/kg
Nickel	Not more than 2 mg/kg
Lead	Not more than 1 mg/kg

E 966 — LACTITOL**Synonyms**

Lactit, lactositol, lactobiosit

Definition

Chemical name	4-O-β-D-Galactopyranosyl-D-glucitol
Einecs	209-566-5
Chemical formula	C ₁₂ H ₂₄ O ₁₁
Relative molecular mass	344,32
Assay	Not less than 95 % on the dry weight basis

Description

Sweet-tasting crystalline powders or colourless solutions. Crystalline products occur in anhydrous, monohydrate and dihydrate forms

Identification

A. Solubility	Very soluble in water
B. Specific rotation	$[\alpha]_D^{20} = + 13^\circ$ to $+ 16^\circ$ calculated on the anhydrous basis (10 % w/v aqueous solution)

Purity

Water content	Crystalline products; not more than 10,5 % (Karl Fischer method)
Other polyols	Not more than 2,5 % on the anhydrous basis
Reducing sugars	Not more than 0,2 % expressed as glucose on dry weight basis
Chlorides	Not more than 100 mg/kg expressed on dry weight basis
Sulphates	Not more than 200 mg/kg expressed on dry weight basis
Sulphated ash	Not more than 0,1 % expressed on dry weight basis

Nickel	Not more than 2 mg/kg expressed on dry weight basis
Arsenic	Not more than 3 mg/kg expressed on dry weight basis
Lead	Not more than 1 mg/kg expressed on dry weight basis

E 967 — XYLITOL**Synonyms**

Xylitol

Definition

Chemical name	D-xylitol
Einecs	201-788-0
Chemical formula	$C_5H_{12}O_5$
Relative molecular mass	152,15
Assay	Not less than 98,5 % as xylitol on the anhydrous basis

Description

White, crystalline powder, practically odourless with a very sweet taste

Identification

A. Solubility	Very soluble in water, sparingly soluble in ethanol
B. Melting range	92 to 96 °C
C. pH	5 to 7 (10 % w/v aqueous solution)

Purity

Loss on drying	Not more than 0,5 %. Dry 0,5 g of sample in a vacuum over phosphorus at 60 °C for four hours
Sulphated ash	Not more than 0,1 % expressed on dry weight basis
Reducing sugars	Not more than 0,2 % expressed as glucose on dry weight basis
Other polyhydric alcohols	Not more than 1 % expressed on dry weight basis
Nickel	Not more than 2 mg/kg expressed on dry weight basis
Arsenic	Not more than 3 mg/kg expressed on dry weight basis
Lead	Not more than 1 mg/kg expressed on dry weight basis
Heavy metals	Not more than 10 mg/kg expressed as Pb on dry weight basis
Chlorides	Not more than 100 mg/kg expressed on dry weight basis
Sulphates	Not more than 200 mg/kg expressed on dry weight basis

E 968 — ERYTHRITOL

Synonyms	Meso-erythritol, tetrahydroxybutane, erythrite
Definition	Obtained by fermentation of carbohydrate source by safe and suitable food grade osmophilic yeasts such as <i>Moniliella pollinis</i> or <i>Trichosporonoides megachilensis</i> , followed by purification and drying
Chemical name	1,2,3,4-Butanetetrol
Einecs	205-737-3
Chemical formula	C ₄ H ₁₀ O ₄
Molecular weight	122,12
Assay	Not less than 99 % after drying
Description	White, odourless, non-hygroscopic, heat-stable crystals with a sweetness of approximately 60-80 % that of sucrose.
Identification	
A. Solubility	Freely soluble in water, slightly soluble in ethanol, insoluble in diethyl ether.
B. Melting range	119-123 °C
Purity	
Loss on drying	Not more than 0,2 % (70 °C, six hours, in a vacuum desiccator)
Sulphated ash	Not more than 0,1 %
Reducing substances	Not more than 0,3 % expressed as D-glucose
Ribitol and glycerol	Not more than 0,1 %
Lead	Not more than 0,5 mg/kg

ANNEX II

PART A

Repealed Directive with list of its successive amendments

(referred to in Article 2)

Commission Directive 95/31/EC	(OJ L 178, 28.7.1995, p. 1)
Commission Directive 98/66/EC	(OJ L 257, 19.9.1998, p. 35)
Commission Directive 2000/51/EC	(OJ L 198, 4.8.2000, p. 41)
Commission Directive 2001/52/EC	(OJ L 190, 12.7.2001, p. 18)
Commission Directive 2004/46/EC	(OJ L 114, 21.4.2004, p. 15)
Commission Directive 2006/128/EC	(OJ L 346, 9.12.2006, p. 6)

PART B

List of time-limits for transposition into national law

(referred to in Article 2)

Directive	Time-limit for transposition
95/31/EC	1 July 1996 ⁽¹⁾
98/66/EC	1 July 1999
2000/51/EC	30 June 2001
2001/52/EC	30 June 2002
2004/46/EC	1 April 2005
2006/128/EC	15 February 2008

⁽¹⁾ According to Article 2(2) of Directive 95/31/EC, products put on the market or labelled before 1 July 1996 which do not comply with this Directive may be marketed until stocks are exhausted.

ANNEX III

Correlation table

Directive 95/31/EC	This Directive
Article 1(1)	Article 1
Article 1(2)	—
Article 2	—
—	Article 2
Article 3	Article 3
Article 4	Article 4
Annex	Annex I
—	Annex II
—	Annex III

COMMISSION DIRECTIVE 2008/61/EC

of 17 June 2008

establishing the conditions under which certain harmful organisms, plants, plant products and other objects listed in Annexes I to V to Council Directive 2000/29/EC may be introduced into or moved within the Community or certain protected zones thereof, for trial or scientific purposes and for work on varietal selections

(Codified version)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

or moved within the Community or certain protected zones thereof unless the relevant special requirements indicated in that Annex are met.

Having regard to the Treaty establishing the European Community,

Having regard to Council Directive 2000/29/EC of 8 May 2000 on protective measures against the introduction into the Community of organisms harmful to plants or plant products and against their spread within the Community ⁽¹⁾, and in particular Articles 3(8), 4(5), 5(5) and 13b(4) thereof,

Whereas:

(1) Commission Directive 95/44/EC of 26 July 1995 establishing the conditions under which certain harmful organisms, plants, plant products and other objects listed in Annexes I to V to Council Directive 77/93/EEC may be introduced into or moved within the Community or certain protected zones thereof, for trial or scientific purposes and for work on varietal selections ⁽²⁾ has been substantially amended ⁽³⁾. In the interests of clarity and rationality the said Directive should be codified.

(2) Under the provisions of Directive 2000/29/EC, harmful organisms listed in its Annexes I and II, whether singly or associated with the relevant plants or plant products listed in Annex II to that Directive, may not be introduced into and spread by movement within the Community or certain protected zones thereof.

(3) Under Directive 2000/29/EC, plants, plant products and other objects listed in its Annex III may not be introduced into the Community or into certain protected zones thereof.

(4) Plants, plant products and other objects listed in Annex IV to Directive 2000/29/EC may not be introduced into

(5) Plants, plant products and other objects listed in Annex V, Part B to Directive 2000/29/EC coming from third countries may not be introduced into the Community unless they comply with the standards and requirements laid down in that Directive and are accompanied by an official phytosanitary certificate ensuring such compliance and are, moreover, inspected on an official basis for compliance with these provisions.

(6) However, Articles 3(8), 4(5), 5(5) and 13b(4) of Directive 2000/29/EC provide for those rules not to apply to the introduction and movement of such harmful organisms, plants, plant products and other objects, for trial or scientific purposes and for work on varietal selections, under conditions which shall be determined at Community level.

(7) Therefore, it is necessary to determine the conditions which must be satisfied in the case of such introductions or movements, in order to ensure that there is no risk of harmful organisms spreading.

(8) The conditions laid down for material under Council Regulation (EC) No 338/97 of 9 December 1996 on the protection of species of wild fauna and flora by regulating trade therein ⁽⁴⁾ and under Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC ⁽⁵⁾, and other more specific Community provisions regarding endangered species of wild fauna and flora and genetically modified organisms, are not affected by this Directive.

(9) The measures provided for in this Directive are in accordance with the opinion of the Standing Committee on Plant Health.

⁽¹⁾ OJ L 169, 10.7.2000, p. 1. Directive as last amended by Commission Directive 2007/41/EC (OJ L 169, 29.6.2007, p. 51).

⁽²⁾ OJ L 184, 3.8.1995, p. 34. Directive as amended by Directive 97/46/EC (OJ L 204, 31.7.1997, p. 43).

⁽³⁾ See Annex IV, Part A.

⁽⁴⁾ OJ L 61, 3.3.1997, p. 1. Regulation as last amended by Commission Regulation (EC) No 318/2008 (OJ L 95, 8.4.2008, p. 3).

⁽⁵⁾ OJ L 106, 17.4.2001, p. 1. Directive as last amended by Directive 2008/27/EC (OJ L 81, 20.3.2008, p. 45).

- (10) This Directive should be without prejudice to the obligations of the Member States relating to the time-limits for transposition into national law of the Directives set out in Annex IV, Part B,

HAS ADOPTED THIS DIRECTIVE:

Article 1

1. Member States shall ensure that for any activity for trial or scientific purposes and for work on varietal selections, hereinafter referred to as 'the activities', which would involve the use of harmful organisms, plants, plant products and other objects pursuant to Article 3(8), 4(5), 5(5) or 13b(4) of Directive 2000/29/EC, hereinafter referred to as 'the material', an application shall be submitted to the responsible official bodies prior to the introduction into, or movement within, any Member State or relevant protected zones thereof, of any such material.

2. The application referred to in paragraph 1, shall specify at least the following:

- (a) the name and address of the person responsible for the activities;
- (b) the scientific name or names of the material, including the harmful organism concerned, where appropriate;
- (c) the type of material;
- (d) the quantity of material;
- (e) the place of origin of the material, with appropriate documentary evidence for material to be introduced from a third country;
- (f) the duration, nature and objectives of the activities envisaged, including, at least, a resumé of the work and a specification for trial or scientific purposes or work on varietal selections;
- (g) the address and description of the specific site or sites for quarantine containment and, where appropriate, for testing;
- (h) the place of first storage or of first planting, as appropriate, after the material has been officially released, where appropriate;
- (i) the proposed method of destruction or treatment of material on completion of the approved activities, where appropriate;
- (j) the proposed point of entry into the Community for material to be introduced from a third country.

Article 2

1. Member States, on receipt of the application referred to in Article 1, shall approve the activities concerned, if it is established that the general conditions laid down in Annex I are satisfied.

Member States shall withdraw the said approval at any time if it is established that the conditions laid down in Annex I cease to be met.

2. Following the approval of the activities referred to in paragraph 1, Member States shall approve the introduction into or movement within the Member State or relevant protected zones of the material referred to in the application, provided that such material is accompanied in all cases by a letter of authority for such introduction or movement of harmful organisms, plants, plant products and other objects for trial or scientific purposes and for work on varietal selections, hereinafter referred to as a 'letter of authority', conforming to the model set out in Annex II and issued by the responsible official body of the Member State in which the activities are to be undertaken, and

- (a) in the case of material originating in the Community:
 - (i) where the place of origin is in another Member State, the accompanying letter of authority shall be officially endorsed by the Member State of origin for movement of the material under quarantine containment conditions; and
 - (ii) for those plants, plant products and other objects listed in Annex V, Part A to Directive 2000/29/EC, the material shall also be accompanied by a plant passport issued in accordance with Article 10 of Directive 2000/29/EC, on the basis of the examination carried out pursuant to Article 6 of that Directive for compliance with the provisions laid down therein, other than those relating to any harmful organism in respect of which the activities have been approved under the first subparagraph of paragraph 1 of this Article. The plant passport shall contain the following statement: 'This material is moved under Directive 2008/61/EC'.

In cases where the address of the specific site or sites for quarantine containment is located in another Member State, the Member State responsible for issuing the plant passport shall issue a plant passport only on the basis of information regarding the approval referred to in the first subparagraph of paragraph 1 of this Article received officially from the Member State responsible for the approval of the activities, and on the assurance that quarantine containment conditions shall be applied during movement of the material; and

(b) in the case of material introduced from a third country:

- (i) Member States shall ensure that the letter of authority is issued on the basis of appropriate documentary evidence as regards the place of origin of the material; and
- (ii) for plants, plant products and other objects listed in Annex V, Part B to Directive 2000/29/EC the material shall also be accompanied wherever possible by a phytosanitary certificate issued in the country of origin in accordance with Article 13(1) of Directive 2000/29/EC, on the basis of the examination carried out pursuant to Article 6 of that Directive for compliance with the provisions laid down therein, other than those relating to any harmful organism in respect of which the activities have been approved under the first subparagraph of paragraph 1 of this Article.

The certificate shall, under 'Additional declaration', contain the following indication: 'This material is imported under Directive 2008/61/EC'. The relevant harmful organism or organisms shall also be specified, where appropriate.

In all cases Member States shall ensure that the material is held under quarantine containment conditions during the said introduction or movement, and is moved directly and immediately to the site or sites specified in the application.

3. The responsible official body shall monitor the approved activities and shall ensure that:

- (a) the quarantine containment conditions and other general conditions specified in accordance with Annex I are complied with throughout the duration of the activities, by examination of the premises and activities at appropriate times;
- (b) the following procedures are applied according to the type of approved activities:
 - (i) for plants, plant products or other objects intended for release from quarantine:

— the plants, plant products or other objects shall not be released without approval by the responsible official body, hereinafter referred to as 'official release'. Prior to official release, the plants, plant products or other objects shall have been subject to quarantine measures, including testing, and must

have been found free by such measures from any harmful organism, unless it is identified as one which is known to occur in the Community and is not listed in Directive 2000/29/EC,

- the quarantine measures, including testing, shall be carried out by scientifically trained staff of that body or of any officially approved body, and shall be carried out in accordance with the provisions laid down in Annex III to this Directive for the plants, plant products and other objects specified,
- any plants, plant products or other objects which have not been found free, by such measures, from harmful organisms as specified in the first indent, and any other plants, plant products or other objects with which they have been in contact or which may have become contaminated shall be destroyed or subjected to an appropriate treatment or quarantine measure aimed at eradicating the relevant harmful organisms; the provisions of (ii), second indent shall apply accordingly;

- (ii) for all other material (including harmful organisms), at the end of the duration of the approved activities, and for all material found to be contaminated during the activities:

- the material (including the harmful organisms and any contaminated material) and any other plants, plant products or other objects with which it has been in contact or which may have become contaminated shall be destroyed, sterilised or otherwise treated in a manner to be specified by the responsible official body, and
- the premises and facilities at which the activities in question have been undertaken shall be sterilised or otherwise cleaned, as necessary, in a manner to be specified by the responsible official body;

- (c) any contamination of the material by harmful organisms listed in Directive 2000/29/EC and any other harmful organism considered a risk to the Community by the responsible official body and detected during the activity shall be notified immediately to the responsible official body by the person responsible for the activities, along with notification of any event resulting in the escape of such organisms into the environment.

4. Member States shall ensure that for activities utilising plants, plant products and other objects listed in Annex III to Directive 2000/29/EC and not covered by Part A, Sections I, II and III of Annex III to this Directive, appropriate quarantine measures, including testing, shall be carried out. These quarantine measures shall be notified to the Commission and to the other Member States. The details of such quarantine measures shall be completed and inserted in Annex III to this Directive once the necessary technical information is available.

Article 3

1. Before 1 September each year, Member States shall send to the Commission and to the other Member States a list, with quantities, of the introductions and movements of material approved under this Directive during the preceding period of one year ending on 30 June, and of any contamination by harmful organisms of such material, which has been confirmed under the quarantine measures, including testing, carried out under Annex III during the same period.

2. Member States shall cooperate administratively through the authorities established or designated pursuant to Article 1(4) of Directive 2000/29/EC, with regard to the provision of details of the quarantine containment conditions and measures imposed for activities approved under this Directive.

Article 4

Member States shall immediately communicate to the Commission all provisions of national law which they adopt

in the field covered by this Directive. The Commission shall inform the other Member States thereof.

Article 5

Directive 95/44/EC, as amended by the Directive listed in Annex IV, Part A, is repealed, without prejudice to the obligations of the Member States relating to the time-limits for transposition into national law of the Directives set out in Annex IV, Part B.

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

Article 6

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

Article 7

This Directive is addressed to the Member States.

Done at Brussels, 17 June 2008.

For the Commission

The President

José Manuel BARROSO

ANNEX I

1. For the purposes of Article 2(1) of this Directive the following general conditions shall apply:
 - the nature and objectives of the activities for which the material is to be introduced or moved shall have been examined by the responsible official body and found to comply with the concept of trial or scientific purposes and for work on varietal selections provided for under Directive 2000/29/EC,
 - the quarantine containment conditions of the premises and facilities at the site or sites at which the activities are to be undertaken shall have been inspected for compliance with the provisions laid down in point 2 and approved by the responsible official body,
 - the responsible official body shall limit the quantity of material to an amount that is adequate for the approved activities and in any case the amount shall not exceed quantities which have been determined having regard to available quarantine containment facilities,
 - the scientific and technical qualifications of the personnel by whom the activities are to be undertaken shall have been examined and approved by the responsible official body.
2. For the purposes of point 1, the quarantine containment conditions of the premises and facilities at the site or sites at which the activities are to be undertaken shall be sufficient to ensure a safe handling of the material such that any harmful organisms of concern are contained and the risk of spreading such harmful organisms eliminated. For each activity specified in the application, the risk of spread of the harmful organisms held under quarantine containment conditions shall be determined by the responsible official body, having regard to the type of material and the activity envisaged, and to the biology of the harmful organisms, the means of their dispersal, the interaction with the environment and other relevant factors relating to the risk posed by the material concerned. As a result of the assessment of the risk, the responsible official body shall consider and lay down as appropriate:
 - (a) the following quarantine measures concerning the premises, facilities and working procedures:
 - physical isolation from all other plant/harmful organism material, including consideration of control of vegetation in surrounding areas,
 - designation of a contact person responsible for the activities,
 - restricted access to the premises and facilities and to the surrounding area, as appropriate, to named personnel only,
 - appropriate identification of the premises and facilities indicating the type of activities and the personnel responsible,
 - maintenance of a register of the activities performed and a manual of operating procedures, including procedures in the event of escape of harmful organisms from containment,
 - appropriate security and alarm systems,
 - appropriate control measures to prevent the introduction into and the spread within the premises of harmful organisms,
 - controlled procedures for sampling and for transfer between premises and facilities, of the material,
 - controlled waste, soil and water disposal, as appropriate,
 - appropriate hygiene and disinfection procedures and facilities for personnel, structures and equipment,
 - appropriate measures and facilities for disposal of experimental material,
 - appropriate indexing (including testing) facilities and procedures; and

(b) further quarantine measures according to the specific biology and epidemiology of the type of material involved and the activities approved:

- maintenance in facilities with separate chamber 'double door' access to personnel,
 - maintenance under negative air pressure,
 - maintenance in escape-proof containers with appropriate mesh size and other barriers e.g. water barrier for mites, closed soil containers for nematodes, electric insect traps,
 - maintenance in isolation from other harmful organisms and material, e.g. viruliferous plant food material, host material,
 - maintenance of material for breeding in breeding cages with manipulation devices,
 - no interbreeding of the harmful organisms with indigenous strains or species,
 - avoidance of continuous culture of the harmful organisms,
 - maintenance under conditions that strictly control the multiplication of the harmful organism, e.g. under an environmental regime such that diapause does not occur,
 - maintenance in such a way that no spread by propagules can occur, e.g. air streams should be avoided,
 - procedures to check the purity of cultures of the harmful organisms for freedom from parasites and other harmful organisms,
 - appropriate control programmes for the material to eliminate possible vectors,
 - for *in vitro* activities, handling of the material under sterile conditions: equipping the laboratory for the performance of aseptic procedures,
 - maintenance of harmful organisms spread by vectors under conditions such that there is no spread via the vector e.g. controlled mesh size, containment of soil,
 - seasonal isolation to ensure the activities are done during periods of low plant health risk.
-

ANNEX II

**Model Letter of Authority for the introduction and/or movement of harmful organisms, plants, plant products
and other objects for trial or scientific purposes and for work on varietal selections**

EUROPEAN COMMUNITIES

LETTER OF AUTHORITY

1. Name and address of consignor/plant protection organisation of the country of origin	Letter of Authority for the introduction and/or movement of harmful organisms, plants, plant products and other objects for trial or scientific purposes and for work on varietal selections (Issued under Directive 2008/61/EC)	
2. Name and address of person responsible for the approved activities		
4. Address and description of the specific site or sites for quarantine containment	3. Name of the responsible official body of the Member State of issue	
	5. Place of origin (documentary evidence attached for material originating in a third country)	
7. Declared point of entry for material introduced from a third country	6. Plant passport number: or Phytosanitary certificate number:	
8. Scientific name(s) of the material, including the harmful organisms concerned		9. Quantity of material
10. Type of material		
11. Additional declaration This material is [introduced into]/[moved within] ⁽¹⁾ the Community under Directive 2008/61/EC ⁽¹⁾ delete if not applicable		
12. Additional information		
13. Endorsement by the responsible official body of the Member State of origin of the material Place of endorsement: Date: Name and signature of authorised officer:	14. Stamp of the responsible official body of issue Place of issue: Date: Name and signature of authorised officer:	

Original dimensions reduced by 10 %.

ANNEX III

**QUARANTINE MEASURES INCLUDING TESTING ON PLANTS, PLANT PRODUCTS AND OTHER OBJECTS
INTENDED FOR RELEASE FROM QUARANTINE**

PART A

For certain plants, plant products and other objects listed in Annex III to Directive 2000/29/EC

Section I: Plants of *Citrus* L., *Fortunella* Swingle, *Poncirus* Raf. and their hybrids, other than fruit and seeds

1. The plant material, as appropriate, shall be subjected to appropriate therapy procedures as laid down in FAO/IPGRI Technical Guidelines.
2. The plant material, following the therapy procedures carried out pursuant to point 1, shall be subjected to indexing procedures in its entirety. All plant material including indexing plants, shall be held at the approved facilities under the quarantine containment conditions laid down in Annex I. Plant material intended for approval for official release shall be held under conditions conducive to a normal cycle of vegetative growth and be subjected to visual inspection for signs and symptoms of harmful organisms including all relevant harmful organisms listed in Directive 2000/29/EC, on arrival and subsequently, at appropriate times, during the period of the indexing procedures.
3. For the purposes of point 2, the plant material shall be indexed for harmful organisms (tested for and identified) according to the following procedures:
 - 3.1. The testing shall use appropriate laboratory methods and, where appropriate, indicator plants, including *Citrus sinensis* (L.) Osbeck, *C. aurantiifolia* Christm. Swing, *C. medica* L., *C. reticulata* Blanco and *Sesamum* L., in order to detect at least the following harmful organisms:
 - (a) Citrus greening bacterium
 - (b) Citrus variegated chlorosis
 - (c) Citrus mosaic virus
 - (d) Citrus tristeza virus (all isolates)
 - (e) Citrus vein enation woody gall
 - (f) Leprosis
 - (g) Naturally spreading psorosis
 - (h) *Phoma tracheiphila* (Petri) Kanchaveli & Gikashvili
 - (i) Satsuma dwarf virus
 - (j) *Spiroplasma citri* Saglio *et al.*
 - (k) Tatter leaf virus
 - (l) Witches' broom (MLO)
 - (m) *Xanthomonas campestris* (all strains pathogenic to *Citrus*).
 - 3.2. For diseases such as Blight and Blight-like for which there are no short-term indexing procedures the plant material must be subjected upon arrival to shoot-tip grafting onto seedling stock grown under sterile culture as set out in FAO/IPGRI Technical Guidelines, and the resulting plants subjected to therapy procedures according to point 1.

4. The plant material subjected to the visual inspections referred to in point 2 and on which signs and symptoms of harmful organisms have been observed shall be subjected to an investigation including testing where necessary, to determine, as far as possible, the identity of the harmful organisms causing the signs and symptoms.

Section II: Plants of *Cydonia* Mill., *Malus* Mill., *Prunus* L. and *Pyrus* L. and their hybrids and *Fragaria* L., intended for planting, other than seeds

1. The plant material, as appropriate, shall be subjected to appropriate therapy procedures as laid down in FAO/IPGRI Technical Guidelines.
2. The plant material, following the therapy procedures carried out pursuant to point 1, shall be subjected to indexing procedures in its entirety. All plant material including indexing plants, shall be held at the approved facilities under the quarantine containment conditions laid down in Annex I. Plant material intended for approval for official release shall be held under conditions conducive to a normal cycle of vegetative growth and be subjected to visual inspection for signs and symptoms of harmful organisms including all relevant harmful organisms listed in Directive 2000/29/EC, on arrival and subsequently, at appropriate times, during the period of the indexing procedures.
3. For the purposes of point 2 the plant material shall be indexed for harmful organisms (tested for and identified) according to the following procedures:
 - 3.1. In the case of *Fragaria* L., irrespective of the country of origin of the plant material, the testing shall use appropriate laboratory methods and, where appropriate, indicator plants, including *Fragaria vesca*, *F. virginiana* and *Chenopodium* spp. for the detection of at least the following harmful organisms:
 - (a) Arabis mosaic virus
 - (b) Raspberry ringspot virus
 - (c) Strawberry crinkle virus
 - (d) Strawberry latent 'C' virus
 - (e) Strawberry latent ringspot virus
 - (f) Strawberry mild yellow edge virus
 - (g) Strawberry vein banding virus
 - (h) Strawberry witches' broom mycoplasma
 - (i) Tomato black ring virus
 - (j) Tomato ringspot virus
 - (k) *Colletotrichum acutatum* Simmonds
 - (l) *Phytophthora fragariae* Hickman var. *fragariae* Wilcox & Duncan
 - (m) *Xanthomonas fragariae* Kennedy & King.
 - 3.2. In the case of *Malus* Mill.:
 - (i) where the plant material originates from a country which is not known to be free of any of the following harmful organisms:
 - (a) Apple proliferation mycoplasma; or
 - (b) Cherry rasp leaf virus (American),

the testing shall use appropriate laboratory methods and, where appropriate, indicator plants for the detection of the relevant harmful organisms, and

- (ii) irrespective of the country of origin of the plant material, the testing shall use appropriate laboratory methods and, where appropriate, indicator plants for the detection of at least the following harmful organisms:

- (a) Tobacco ringspot virus
- (b) Tomato ringspot virus
- (c) *Erwinia amylovora* (Burr.) Winsl. *et al.*

3.3. In the case of *Prunus* L., as appropriate for each *Prunus* species:

- (i) where the plant material originates from a country which is not known to be free of any of the following harmful organisms:

- (a) Apricot chlorotic leafroll mycoplasma;
- (b) Cherry rasp leaf virus (American); or
- (c) *Pseudomonas syringae* pv. *persicae* (Prunier *et al.*) Young *et al.*,

the testing shall use appropriate laboratory methods and, where appropriate, indicator plants for the detection of the relevant harmful organisms; and

- (ii) irrespective of the country of origin of the plant material, the testing shall use appropriate laboratory methods and, where appropriate, indicator plants for the detection of at least the following harmful organisms:

- (a) Little cherry pathogen (non-European isolates)
- (b) Peach mosaic virus (American)
- (c) Peach phony rickettsia
- (d) Peach rosette mosaic virus
- (e) Peach rosette mycoplasma
- (f) Peach X-disease mycoplasma
- (g) Peach yellows mycoplasma
- (h) Plum line pattern virus (American)
- (i) Plum pox virus
- (j) Tomato ringspot virus
- (k) *Xanthomonas campestris* pv. *pruni* (Smith) Dye.

3.4. In the case of *Cydonia* Mill. and *Pyrus* L. irrespective of the country of origin of the plant material, testing by appropriate laboratory methods, and, where appropriate, indicator plants, for detection of at least the following harmful organisms:

- (a) *Erwinia amylovora* (Burr.) Winsl. *et al.*
- (b) Pear decline mycoplasma.

4. The plant material subjected to the visual inspections referred to in point 2 and on which signs and symptoms of harmful organisms have been observed shall be subject to an investigation including testing where necessary, to determine, as far as possible, the identity of the harmful organisms causing the signs and symptoms.

Section III: Plants of *Vitis* L., other than fruits

1. The plant material shall be subjected, as appropriate, to appropriate therapy procedures, as laid down in FAO/IPGRI Technical Guidelines.
2. The plant material, following the therapy procedures carried out pursuant to point 1, shall be subjected to indexing procedures in its entirety. All plant material including indexing plants, shall be held at the approved facilities under the quarantine containment conditions laid down in Annex I. Plant material intended for approval for official release shall be held under conditions conducive to a normal cycle of vegetative growth and shall be subjected to visual inspection for signs and symptoms of harmful organisms including those of *Daktulosphaira vitifoliae* (Fitch) and of all other relevant harmful organisms listed in Directive 2000/29/EC, on arrival and subsequently, at appropriate times, during the period of the indexing procedures.
3. For the purposes of point 2 the plant material shall be indexed for harmful organisms (tested for and identified) according to the following procedures:
 - 3.1. Where the plant material originates in a country which is not known to be free of the following harmful organisms:
 - (i) A j i n a s h i k a d i s e a s e

The testing shall use an appropriate laboratory method. In the event of a negative result, the plant material shall be indexed on the vine variety Koshu and kept under observation during at least two cycles of vegetation.
 - (ii) G r a p e v i n e s t u n t v i r u s

The testing shall use appropriate indicator plants, including the vine variety Campbell Early, and observation shall take place during one year.
 - (iii) S u m m e r m o t t l e

The testing shall use appropriate indicator plants, including the vine varieties Sideritis, Cabernet-Franc and Mission.
 - 3.2. Irrespective of the country of origin of the plant material, the testing shall use appropriate laboratory methods and, where appropriate, indicator plants for the detection of at least the following harmful organisms:
 - (a) B l u e b e r r y l e a f m o t t l e v i r u s
 - (b) G r a p e v i n e F l a v e s c e n c e d o r é e M L O a n d o t h e r g r a p e v i n e y e l l o w s
 - (c) P e a c h r o s e t t e m o s a i c v i r u s
 - (d) T o b a c c o r i n g s p o t v i r u s
 - (e) T o m a t o r i n g s p o t v i r u s (s t r a i n ' y e l l o w v e i n ' a n d o t h e r s t r a i n s)
 - (f) *Xylella fastidiosa* (Well & Raju)
 - (g) *Xylophilus ampelinus* (Panagopoulos) Willems *et al.*
4. The plant material subjected to the visual inspections referred to in point 2 and on which signs and symptoms of harmful organisms have been observed shall be subjected to an investigation including testing where necessary, to determine, as far as possible, the identity of the harmful organisms causing the signs and symptoms.

Section IV: Plants of stolon- or tuber-forming species of *Solanum* L. or their hybrids, intended for planting

1. The plant material, as appropriate, shall be subjected to the therapy procedures as laid down in FAO/IPGRI Technical Guidelines.

2. Each unit of the plant material, following the therapy procedures carried out pursuant to point 1, shall be subjected to indexing procedures. All plant material, including indexing plants, shall be held at the approved facilities under the quarantine containment conditions laid down in Annex I. Plant material intended for approval for official release shall be held under conditions conducive to a normal cycle of vegetative growth and be subjected to visual inspection for signs and symptoms of harmful organisms including all relevant harmful organisms listed in Directive 2000/29/EC and potato yellow vein disease, on arrival and subsequently, at regular intervals until senescence, during the period of the indexing procedures.
3. The indexing procedures referred to in point 2 shall follow the technical provisions set out in point 5, in order to detect at least the following harmful organisms:

— B a c t e r i a

- (a) *Clavibacter michiganensis* (Smith) Davis *et al.* ssp. *sepedonicus* (Spieckermann et Kotthoff) Davis *et al.*;
- (b) *Ralstonia solanacearum* (Smith) Yabuuchi *et al.*

— V i r u s e s a n d v i r u s - l i k e o r g a n i s m s

- (a) Andean potato latent virus,
- (b) Potato black ringspot virus,
- (c) Potato spindle tuber viroid,
- (d) Potato yellowing alfamovirus,
- (e) Potato virus T,
- (f) Andean potato mottle virus,
- (g) Common potato viruses A, M, S, V, X and Y (including Y^o, Yⁿ and Y^c) and potato leaf roll virus.

However, in the case of true seed of potato, the indexing procedures shall be carried out in order to detect at least the viruses and virus-like organisms listed above at (a) to (e).

4. The plant material subjected to the visual inspections referred to in point 2 and on which signs and symptoms of harmful organisms have been observed shall be subjected to an investigation including testing where necessary, to determine, as far as possible, the identity of the harmful organisms causing the signs and symptoms.
5. The technical provisions referred to in point 3 shall be as follows:

— B a c t e r i a

1. For tubers, test the heel end of each tuber. The standard sample size shall be 200 tubers. However, the procedure can be applied for samples with less than 200 tubers.
2. For young plants and cuttings, including micro-plants, test the lower sections of the stem and, where appropriate, the roots, for each unit of the plant material.
3. For testing of progeny tubers, or of stem bases for non-tuber forming species, one normal cycle of vegetative growth after the testing referred to in points 1 and 2, is recommended.
4. For the material referred to in point 1, the testing method for *Clavibacter michiganensis* (Smith) Davis *et al.* ssp. *sepedonicus* (Spieckermann et Kotthoff) Davis *et al.* shall be the Community method set out in Annex I to Council Directive 93/85/EEC ⁽¹⁾. For the material referred to in point 2, this testing method could be applied.
5. For the material referred to in point 1, the testing method for *Ralstonia solanacearum* (Smith) Yabuuchi *et al.* shall be the test scheme set out in Annex II to Council Directive 98/57/EC ⁽²⁾. For the material referred to in point 2, this testing method could be applied.

⁽¹⁾ OJ L 259, 18.10.1993, p. 1. Directive as amended by Commission Directive 2006/56/EC (OJ L 182, 4.7.2006, p. 1).

⁽²⁾ OJ L 235, 21.8.1998, p. 1. Directive as amended by Commission Directive 2006/63/EC (OJ L 206, 27.7.2006, p. 36).

— Viruses and virus-like organisms, other than potato spindle tuber viroid

1. The minimum testing for vegetative material (tubers, young plants and cuttings, including micro-plants) shall include a serological test done at or near flowering for each of the specified list of harmful organisms other than potato spindle tuber viroid, and followed by a biological test of material testing negative in the serological test. For Potato leaf roll virus, two serological tests shall be done.
2. The minimum testing for true seed shall be a serological test or a biological test if no serological test is available. Retesting of a proportion of negative samples and testing of borderline results by another method is highly recommended.
3. The serological and biological testing referred to in points 1 and 2 shall be done on glasshouse grown plants, sampled from at least two positions on every stem, including a young fully expanded leaflet at the top of each stem and an older leaflet from a midway position; each stem shall be sampled because of possible non-systemic infection. In the case of the serological testing, no bulking of leaflets from separate plants shall be done, unless the bulking rate has been validated for the method of use; leaflets from each stem may however be bulked to make up the sample from each plant. In the case of the biological testing, the maximum bulking is up to five plants with inoculation of a minimum of duplicate indicator plants.
4. The appropriate indicator plants to be used for the biological testing referred to in points 1 and 2 shall be those listed by the European and Mediterranean Plant Protection Organization (EPPO), or other officially approved indicator plants, which have been shown to detect the viruses.
5. Only material which has been directly tested shall be released from quarantine. Where eye indexing has been done, only the progeny of the tested eye may be released. The tuber should not be released because of possible problems with non-systemic infection.

— Potato spindle tuber viroid

1. For all material, glasshouse grown plants shall be tested, as soon as they are well established but prior to flowering and pollen production. Testing on tuber sprouts/*in vitro* plants/small seedlings shall only be regarded as a preliminary test.
2. Samples shall be taken from a fully expanded leaflet at the top of each stem of the plant.
3. All material for testing shall be grown at temperatures not less than 18 °C (preferably at temperatures higher than 20 °C) and with at least a 16-hour photo-period.
4. Testing shall be by radioactive or non-radioactive labelled cDNA or RNA-probes, return-PAGE (with silver staining) or RT-PCR.
5. The maximum bulking rate for probes and return-PAGE is 5. Use of this or higher bulking rates must be validated.

PART B

For plants, plant products and other objects listed in Annexes II and IV to Directive 2000/29/EC

1. The official quarantine measures shall include appropriate inspection or testing for the relevant harmful organisms listed in Annexes I and II to Directive 2000/29/EC and shall be carried out in respect of the special requirements laid down in Annex IV to Directive 2000/29/EC for specific harmful organisms, as appropriate. In respect of such special requirements the methods used for the quarantine measures shall be those laid down in Annex IV to Directive 2000/29/EC or other equivalent officially approved measures.
 2. The plants, plant products and other objects must be found free, according to the provisions of point 1, from the relevant harmful organisms specified in Annexes I, II and IV to Directive 2000/29/EC for those plants, plant products and other objects.
-

ANNEX IV

PART A

Repealed Directive with its amendment

(referred to in Article 5)

Commission Directive 95/44/EC

(OJ L 184, 3.8.1995, p. 34)

Commission Directive 97/46/EC

(OJ L 204, 31.7.1997, p. 43)

PART B

List of time-limits for transposition into national law

(referred to in Article 5)

Directive	Time-limit for transposition
95/44/EC	1 February 1996
97/46/EC	1 January 1998

ANNEX V

Correlation table

Directive 95/44/EC	This Directive
Article 1(1)	Article 1(1)
Article 1(2), introductory sentence	Article 1(2), introductory sentence
Article 1(2), first indent	Article 1(2)(a)
Article 1(2), second indent	Article 1(2)(b)
Article 1(2), third indent	Article 1(2)(c)
Article 1(2), fourth indent	Article 1(2)(d)
Article 1(2), fifth indent	Article 1(2)(e)
Article 1(2), sixth indent	Article 1(2)(f)
Article 1(2), seventh indent	Article 1(2)(g)
Article 1(2), eighth indent	Article 1(2)(h)
Article 1(2), ninth indent	Article 1(2)(i)
Article 1(2), tenth indent	Article 1(2)(j)
Articles 2 and 3	Articles 2 and 3
Article 4(1)	—
Article 4(2)	Article 4
—	Article 5
Article 5	Article 6
Article 6	Article 7
Annexes I, II and III	Annexes I, II and III
—	Annex IV
—	Annex V

II

(Acts adopted under the EC Treaty/Euratom Treaty whose publication is not obligatory)

DECISIONS

COUNCIL

COUNCIL DECISION

of 16 June 2008

adjusting the allowances provided for in Decision 2003/479/EC and Decision 2007/829/EC concerning the rules applicable to national experts and military staff on secondment to the General Secretariat of the Council

(2008/451/EC)

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Union, and in particular Article 28(1) thereof,

Having regard to the Treaty establishing the European Community, and in particular Article 207(2) thereof,

Having regard to Decision 2003/479/EC ⁽¹⁾, and in particular Article 15(7) thereof,

Having regard to Decision 2007/829/EC ⁽²⁾, and in particular Article 15(6) thereof,

Whereas:

(1) Article 15(7) of Decision 2003/479/EC and Article 15(6) of Decision 2007/829/EC provide that the daily and monthly allowances shall be adjusted each year without retroactive effect on the basis of the adaptation of the basic salaries of Community officials in Brussels and Luxembourg.

(2) The Council, through Regulation (EC, Euratom) No 420/2008 of 14 May 2008 adjusting with effect from

1 July 2007 the remuneration and pensions of officials and other servants of the European Communities ⁽³⁾ and the correction coefficients applied thereto, adopted an adjustment of 1,4 % to the remuneration and pensions of Community officials,

HAS DECIDED AS FOLLOWS:

Article 1

1. In Article 15(1) of Decision 2003/479/EC and Article 15(1) of Decision 2007/829/EC, the amounts EUR 29,44 and EUR 117,74 shall be replaced by EUR 29,85 and EUR 119,39 respectively.

2. In Article 15(2) of Decision 2003/479/EC and in Article 15(2) of Decision 2007/829/EC the table shall be replaced by the following:

'Distance between place of recruitment and place of secondment (in km)	Amount in EUR
0-150	0,00
> 150	76,74
> 300	136,42
> 500	221,71
> 800	358,14
> 1 300	562,80
> 2 000	673,67'

⁽¹⁾ Council Decision 2003/479/EC of 16 June 2003 concerning the rules applicable to national experts and military staff on secondment to the General Secretariat of the Council (OJ L 160, 28.6.2003, p. 72). Decision as repealed by Decision 2007/829/EC.

⁽²⁾ Council Decision 2007/829/EC of 5 December 2007 concerning the rules applicable to national experts and military staff on secondment to the General Secretariat of the Council (OJ L 327, 13.12.2007, p. 10).

⁽³⁾ OJ L 127, 15.5.2008, p. 1.

3. In Article 15(4) of Decision 2003/479/EC the amount EUR 29,44 shall be replaced by EUR 29,85.

Article 2

This Decision shall take effect on the first day of the month following that of its adoption.

Done at Luxembourg, 16 June 2008.

For the Council

The President

D. RUPEL

COMMISSION

COMMISSION DECISION

of 6 June 2008

amending Decision 2007/27/EC adopting certain transitional measures concerning deliveries of raw milk to processing establishments and the processing of this milk in Romania with regard to the requirements of Regulation (EC) No 852/2004 and (EC) No 853/2004 of the European Parliament and of the Council

(notified under document number C(2008) 2404)

(Text with EEA relevance)

(2008/452/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to the Treaty of Accession of Bulgaria and Romania,

Having regard to the Act of Accession of Bulgaria and Romania, and in particular Article 42 thereof,

Whereas:

(1) Commission Decision 2007/27/EC ⁽¹⁾ sets out lists of milk processing establishments in Romania that comply with the structural requirements laid down in Regulation (EC) No 852/2004 of the European Parliament and of the Council ⁽²⁾ (compliant establishments) and are authorized to receive and process raw milk which is not in compliance with Regulation (EC) No 853/2004 of the European Parliament and of the Council ⁽³⁾ (non-compliant milk).

(2) Chapter I of the Annex to Decision 2007/27/EC lists compliant establishments authorised to receive and process without separation compliant and non-compliant milk while Chapter II of that Annex lists compliant establishments authorised to receive and process separately compliant and non-compliant milk.

(3) Five establishments listed in Chapter I of the Annex to Decision 2007/27/EC have chosen to process only compliant milk. One establishment has ceased its activities. Those establishments should therefore be deleted from the list in Chapter I of that Annex.

(4) Furthermore, three other establishments have completed their upgrading plan and are now in full compliance with Community legislation. Those establishments should therefore be deleted from the list of establishments in transition. Those establishments process compliant and non-compliant milk without separation and should be added to the list in Chapter I of the Annex to Decision 2007/27/EC.

(5) Chapter I of the Annex to Decision 2007/27/EC should therefore be amended accordingly.

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

HAS ADOPTED THIS DECISION:

⁽¹⁾ OJ L 8, 13.1.2007, p. 45. Decision as amended by Decision 2007/557/EC (OJ L 212, 14.8.2007, p. 15).

⁽²⁾ OJ L 139, 30.4.2004, p. 1, as corrected by OJ L 226, 25.6.2004, p. 3.

⁽³⁾ OJ L 139, 30.4.2004, p. 55, as corrected by OJ L 226, 25.6.2004, p. 22. Regulation as last amended by Commission Regulation (EC) No 1243/2007 (OJ L 281, 25.10.2007, p. 8).

Article 1

Chapter I of the Annex to Decision 2007/27/EC is amended in accordance with the Annex to this Decision.

Article 2

This Decision is addressed to the Member States.

Done at Brussels, 6 June 2008.

For the Commission
Androulla VASSILIOU
Member of the Commission

ANNEX

Chapter I of the Annex to Decision 2007/27/EC is amended as follows:

(1) The following establishments are deleted:

4	L 52	SC Trinitrom SRL	Gepiu, județul Bihor, 417149
7	L 5	SC Ancal SRL	Saucenița, județul Botoșani, 717468
8	L 77	SC Milk Way Company SRL	Prigor, județul Caraș-Severin, 327305
9	L 74	SC Cremont SRL	Aghireșu, județul Cluj, 407005
10	L 42	SC Lacto Panait SRL	Crucea, județul Constanța, 907305
29	L 37	SC Magnolia Comlact SRL	Țapu, județul Sibiu, 556123

(2) The following establishments are added:

32	L 95	S.C. Marion Invest SRL	Crânguri, Jud. Dambovița, 137170
33	L 21	S.C. I.L. Mureș S.A.	Târgu Mureș, Jud. Mureș, 540390
34	L 96	S.C. Prod A.B.C. Company SRL	Grumăzești, Jud. Neamț, 617235

COMMISSION DECISION

of 10 June 2008

amending Decision 2006/139/EC as regards an authority approved for keeping a herdbook or register for the porcine species in the United States*(notified under document number C(2008) 2472)***(Text with EEA relevance)**

(2008/453/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Directive 94/28/EC of 23 June 1994 laying down the principles relating to the zootechnical and genealogical conditions applicable to imports from third countries of animals, their semen, ova and embryos, and amending Directive 77/504/EEC on pure-bred breeding animals of the bovine species ⁽¹⁾, and in particular Article 3(3) thereof,

Whereas:

- (1) Commission Decision 2006/139/EC of 7 February 2006 implementing Council Directive 94/28/EC as regards a list of authorities in third countries approved for the keeping of a herd book or register of certain animals ⁽²⁾ provides that Member States are authorised to import breeding animals of certain species, their semen, ova and embryos as 'pure-bred' or 'hybrid' only if they are entered or registered in a herd book or register kept by an authority listed in that Decision.
- (2) The United States have requested that one authority for the porcine species be added to the entries for that country in the Annex to Decision 2006/139/EC.
- (3) The United States have provided guarantees regarding compliance with the relevant requirements laid down in

Community legislation and, in particular in Directive 94/28/EC.

- (4) Annex to Decision 2006/139/EC should therefore be amended accordingly.
- (5) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on Zootechnics,

HAS ADOPTED THIS DECISION:

Article 1

The Annex to Decision 2006/139/EC is amended in accordance with the Annex to this Decision.

Article 2

This Decision shall apply from 1 June 2008.

Article 3

This Decision is addressed to the Member States.

Done at Brussels, 10 June 2008.

For the Commission

Androulla VASSILIOU

Member of the Commission⁽¹⁾ OJ L 178, 12.7.1994, p. 66.⁽²⁾ OJ L 54, 24.2.2006, p. 34.

ANNEX

Under the heading 'Species: porcine' of point VII of the Annex to Decision 2006/139/EC, the following entry is added:

PIC (Pig Improvement Company) North America

100 Bluegrass Commons Boulevard

Suite 2200

Hendersonville

TN 37075

Tel. (1-615) 265 27 00

Internet: <http://www.pic.com>

RECOMMENDATIONS

COMMISSION

COMMISSION RECOMMENDATION

of 30 May 2008

on risk reduction measures for the substances sodium chromate, sodium dichromate and 2,2',6,6'-tetrabromo-4,4'-isopropylidenediphenol (tetrabromobisphenol A)

*(notified under document number C(2008) 2256)***(Text with EEA relevance)**

(2008/454/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EEC) No 793/93 of 23 March 1993 on the evaluation and control of the risks of existing substances ⁽¹⁾ and in particular Article 11(2) thereof,

Whereas:

(1) In the framework of Regulation (EEC) No 793/93 the following substances have been identified as priority substances for evaluation in accordance with Commission Regulations (EC) No 143/97 ⁽²⁾ and (EC) No 2364/2000 ⁽³⁾ respectively concerning the third and fourth list of priority substances as foreseen under Regulation (EEC) No 793/93:

— sodium chromate,

— sodium dichromate,

— 2,2',6,6'-tetrabromo-4,4'-isopropylidenediphenol (Tetrabromobisphenol A).

(2) The Member States designated as rapporteurs pursuant to Regulations (EEC) No 793/93 and (EC) No 143/97 have completed the risk evaluation activities with regard to man and the environment for those substances in accordance with Commission Regulation (EC) No

1488/94 of 28 June 1994 laying down the principles for the assessment of risks to man and the environment of existing substances in accordance with Council Regulation (EEC) No 793/93 ⁽⁴⁾ and have suggested a strategy for limiting the risks.

(3) The Scientific Committee on Toxicity, Ecotoxicity and the Environment (SCTEE) and the Scientific Committee on Health and Environmental Risks (SCHER) have been consulted and have issued opinions with respect to the risk evaluations carried out by the rapporteurs. The opinions have been published on the website of those Committees.

(4) The results of the risk evaluation and further results of the strategies for limiting the risks are set out in the corresponding Commission Communication ⁽⁵⁾.

(5) It is appropriate, on the basis of that evaluation, to recommend certain risk reduction measures for certain substances.

(6) The risk reduction measures recommended for workers should be considered within the framework of the legislation for workers protection, which is considered to provide an adequate framework to limit the risks of the relevant substances to the extent needed.

(7) The risk reduction measures provided for in this recommendation are in accordance with the opinion of the Committee set up pursuant to Article 15(1) of Regulation (EEC) No 793/93,

⁽¹⁾ OJ L 84, 5.4.1993, p. 1. Regulation as amended by Regulation (EC) No 1882/2003 of the European Parliament and of the Council (OJ L 284, 31.10.2003, p. 1).

⁽²⁾ OJ L 25, 28.1.1997, p. 13.

⁽³⁾ OJ L 273, 26.10.2000, p. 5.

⁽⁴⁾ OJ L 161, 29.6.1994, p. 3.

⁽⁵⁾ OJ C 152, 18.6.2008, p. 11.

HEREBY RECOMMENDS:

SECTION 1

SODIUM CHROMATE

(CAS No 7775-11-3; Einecs No 231-889-5)

Risk reduction measures for workers (1) and the environment (2, 3, 4, 5 and 6)

1. Employers using chromium (VI) compounds for use in the manufacture of pigments and dyes, the formulation of metal treatment products, electrolytic metal plating, and as mordants in wool dyeing should take note of any sector-specific guidance developed at national level, based on the practical non-binding guidance, as provided for in Article 12(2) of Council Directive 98/24/EC ⁽¹⁾.
2. The competent authorities in the Member States concerned should lay down, in the permits issued under Directive 2008/1/EC of the European Parliament and of the Council ⁽²⁾, conditions, emission limit values or equivalent parameters or technical measures regarding chromium (VI), in order for the installations concerned to operate according to best available techniques (hereinafter BAT) taking into account the technical characteristic of the installations concerned, their geographical location and the local environmental conditions.
3. Member States should carefully monitor the implementation of BAT regarding chromium (VI) and report any important developments to the Commission in the framework of the exchange of information on BAT.
4. To facilitate permitting and monitoring under Directive 2008/1/EC chromium (VI) should be included in the ongoing work to develop guidance on BAT.
5. Local emissions to the environment should, where necessary, be controlled by national rules to ensure that no risk for the environment is expected.
6. For the water bodies where emissions of chromium (VI) may cause a risk, the relevant Member State(s) establish environmental quality standards (hereinafter EQS) and the

⁽¹⁾ OJ L 131, 5.5.1998, p. 11. Directive as modified by Directive 2007/30/EC of the European Parliament and of the Council (OJ L 165, 27.6.2007, p. 21).

⁽²⁾ OJ L 24, 29.1.2008, p. 8.

national pollution reduction measures to achieve those EQS in 2015 in accordance with Directive 2000/60/EC of the European Parliament and of the Council ⁽³⁾.

SECTION 2

SODIUM DICHROMATE

(CAS No 10588-01-9; Einecs No 234-190-3)

Risk reduction measures for workers (7) and the environment (8, 9, 10, 11 and 12)

7. Employers using chromium (VI) compounds for use in the manufacture of pigments and dyes, the formulation of metal treatment products, electrolytic metal plating, and as mordants in wool dyeing should take note of any sector-specific guidance developed at national level, based on the practical, non-binding guidance, as provided for in Article 12(2) of Directive 98/24/EC.
8. The competent authorities in the Member States concerned should lay down, in the permits issued under Directive 2008/1/EC, conditions, emission limit values or equivalent parameters or technical measures regarding chromium (VI), in order for the installations concerned to operate according to BAT taking into account the technical characteristic of the installations concerned, their geographical location and the local environmental conditions.
9. Member States should carefully monitor the implementation of BAT regarding chromium (VI) and report any important developments to the Commission in the framework of the exchange of information on BAT.
10. To facilitate permitting and monitoring under Directive 2008/1/EC, chromium (VI) should be included in the ongoing work to develop guidance on BAT.
11. Local emissions to the environment should, where necessary, be controlled by national rules to ensure that no risk for the environment is expected.
12. For the water bodies where emissions of chromium (VI) may cause a risk, the relevant Member State(s) establish EQS and the national pollution reduction measures to achieve those EQS in 2015 in accordance with Directive 2000/60/EC.

⁽³⁾ OJ L 327, 22.12.2000, p. 1. Directive as last amended by Directive 2008/32/EC (OJ L 81, 20.3.2008, p. 60).

SECTION 3

**2,2',6,6'-TETRABROMO-4,4'-ISOPROPYLIDENEDIPHENOL
(TETRABROMOBISPHENOL A)**

(CAS No 79-94-7; EINECS No 201-236-9)

Risk reduction measures for the environment (13, 14)

13. The competent authorities in the Member States concerned should lay down, in the permits issued under Directive 2008/1/EC, conditions, emission limit values or equivalent parameters or technical measures regarding TBBPA in order for the installations concerned to operate according to BAT taking into account the technical characteristic of the installations concerned, their geographical location and the local environmental conditions.

14. Local emissions to the environment of TBBPA should, where necessary, be controlled by national rules to ensure that no risk for the environment is expected.

SECTION 4

ADDRESSEES

15. This Recommendation is addressed to all sectors importing, producing, transporting, storing, formulating into a preparation or other processing, using, disposing or recovering the substances and to the Member States.

Done at Brussels, 30 May 2008.

For the Commission

Stavros DIMAS

Member of the Commission

COMMISSION RECOMMENDATION

of 30 May 2008

on risk reduction measures for the substances chromium trioxide, ammonium dichromate and potassium dichromate*(notified under document number C(2008) 2326)***(Text with EEA relevance)**

(2008/455/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EEC) No 793/93 of 23 March 1993 on the evaluation and control of the risks of existing substances ⁽¹⁾ and in particular Article 11(2) thereof,

Whereas:

(1) In the framework of Regulation (EEC) No 793/93 the following substances have been identified as priority substances for evaluation in accordance with Commission Regulation (EC) No 143/97 of 27 January 1997 concerning the third list of priority substances as foreseen under Council Regulation (EEC) No 793/93 ⁽²⁾:

— chromium trioxide,

— ammonium dichromate,

— potassium dichromate.

(2) The rapporteur Member State designated pursuant to that Regulation has completed the risk evaluation activities with regard to man and the environment for those substances in accordance with Commission Regulation (EC) No 1488/94 of 28 June 1994 laying down the principles for the assessment of risks to man and the environment of existing substances and has suggested a strategy for limiting the risks in accordance with Council Regulation (EEC) No 793/93 ⁽³⁾.

(3) The Scientific Committee on Toxicity, Ecotoxicity and the Environment (SCTEE) has been consulted and has issued opinions with respect to the risk evaluations carried out by the rapporteur. The opinions have been published on the website of the Scientific Committee.

(4) The results of the risk evaluation and further results of the strategies for limiting the risks are set out in the corresponding Commission Communication ⁽⁴⁾.

(5) It is appropriate, on the basis of that evaluation, to recommend certain risk reduction measures for certain substances.

(6) The risk reduction measures recommended for workers should be considered within the framework of the legislation for workers protection, which is considered to provide an adequate framework to limit the risks of the relevant substances to the extent needed.

(7) The risk reduction measures provided for in this recommendation are in accordance with the opinion of the Committee set up pursuant to Article 15(1) of Regulation (EEC) No 793/93,

HEREBY RECOMMENDS:

SECTION 1

CHROMIUM TRIOXIDE*(CAS No 1333-82-0; Eines No 215-607-8)***AMMONIUM DICHROMATE***(CAS No 7789-09-05; Eines No 232-143-1)***POTASSIUM DICHROMATE***(CAS No 7778-50-9; Eines No 231-906-6)***Risk reduction measures for workers (1) and the environment (2, 3, 4, 5, 6)**

1. Employers using chromium (VI) compounds for use in the manufacture of pigments and dyes, the formulation of metal treatment products, electrolytic metal plating, and as mordants in wool dyeing should take note of any sector-specific guidance developed at national level, based on the practical, non-binding guidance available from the Commission, as provided for in Article 12(2) of Council Directive 98/24/EC ⁽⁵⁾.

⁽¹⁾ OJ L 84, 5.4.1993, p. 1. Regulation as amended by Regulation (EC) No 1882/2003 of the European Parliament and of the Council (OJ L 284, 31.10.2003, p. 1).

⁽²⁾ OJ L 25, 28.1.1997, p. 13.

⁽³⁾ OJ L 161, 29.6.1994, p. 3.

⁽⁴⁾ OJ C 152, 18.6.2008, p. 1.

⁽⁵⁾ OJ L 131, 5.5.1998, p. 11. Directive as modified by Directive 2007/30/EC of the European Parliament and of the Council (OJ L 165, 27.6.2007, p. 21).

2. Competent authorities in the Member States concerned should lay down, in the permits issued under Directive 2008/1/EC ⁽¹⁾, conditions, emission limit values or equivalent parameters or technical measures regarding chromium (VI) compounds in order to operate according to the best available techniques (BAT) taking into account the technical characteristic of the installations concerned, their geographical location and the local environmental conditions.
 3. Member States should carefully monitor the implementation of BAT regarding chromium (VI) compounds and report any important developments to the Commission in the framework of the exchange of information on BAT.
 4. Local emissions to the environment should, where necessary, be controlled by national rules to ensure that no risk for the environment is expected.
 5. With particular regard to the on-site reduction of chromium (VI) compounds to Cr (III) tanning salts by plants involved in the tanning of hides and skins, it is recommended that in the next amendment of the BREF Document for plants involved in the tanning of hides and skins, appropriate references are included to indicate that the on-site reduction of chromium (VI) compounds for the production of chromium (III) tanning salts should not be considered as BAT.
 6. For the water bodies where emissions of chromium (VI) may cause a risk, the relevant Member State(s) establish environmental quality standards (EQS) and the national pollution reduction measures to achieve those EQS in 2015 in accordance with Directive 2000/60/EC of the European Parliament and of the Council ⁽²⁾.
- SECTION 2
- ADDRESSEES**
7. This Recommendation is addressed to all sectors importing, producing, transporting, storing, formulating into a preparation or other processing, using, disposing or recovering the substances and to the Member States.
- Done at Brussels, 30 May 2008.
- For the Commission*
Stavros DIMAS
For the Commission

⁽¹⁾ OJ L 24, 29.1.2008, p. 8.

⁽²⁾ OJ L 327, 22.12.2000, p. 1. Directive as last amended by Directive 2008/32/EC (OJ L 81, 20.3.2008, p. 60).