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<sup>(1)</sup> Text with EEA relevance

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<sup>(1)</sup> Text with EEA relevance

## I

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

## REGULATIONS

**COMMISSION REGULATION (EC) No 583/2008****of 20 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 <sup>(1)</sup>, 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 21 June 2008.

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

Done at Brussels, 20 June 2008.

*For the Commission*

Jean-Luc DEMARTY

*Director-General for Agriculture and  
Rural Development*

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<sup>(1)</sup> OJ L 350, 31.12.2007, p. 1.

## ANNEX

**to Commission Regulation of 20 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 <sup>(1)</sup>	Standard import value
0702 00 00	MA	41,8
	MK	34,1
	TR	59,0
	ZZ	45,0
0707 00 05	JO	151,2
	MK	24,1
	TR	134,5
	ZZ	103,3
0709 90 70	TR	101,1
	ZZ	101,1
0805 50 10	AR	109,6
	EG	120,2
	TR	135,6
	US	99,2
	ZA	103,7
	ZZ	113,7
0808 10 80	AR	169,1
	BR	88,0
	CL	103,6
	CN	91,0
	NZ	118,7
	US	91,0
	UY	58,3
	ZA	97,1
	ZZ	102,1
0809 10 00	IL	89,8
	TR	193,8
	US	236,6
	ZZ	173,4
0809 20 95	TR	388,7
	US	379,0
	ZZ	383,9
0809 30 10, 0809 30 90	EG	182,1
	US	191,8
	ZZ	187,0
0809 40 05	IL	121,3
	TR	131,9
	ZZ	126,6

<sup>(1)</sup> 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 584/2008

of 20 June 2008

**implementing Regulation (EC) No 2160/2003 of the European Parliament and of the Council as regards a Community target for the reduction of the prevalence of *Salmonella enteritidis* and *Salmonella typhimurium* in turkeys**

(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 2160/2003 of the European Parliament and of the Council of 17 November 2003 on the control of salmonella and other specified food-borne zoonotic agents<sup>(1)</sup> and, in particular Article 4(1) and Article 13 thereof,

Whereas:

- (1) The purpose of Regulation (EC) No 2160/2003 is to ensure that proper and effective measures are taken to detect and control salmonella and other zoonotic agents at all relevant stages of production, processing and distribution, particularly at the level of primary production, in order to reduce their prevalence and the risk they pose to public health.
- (2) Regulation (EC) No 2160/2003 provides for a Community target to be established for the reduction of the prevalence of all salmonella serotypes with public health significance in turkeys at the level of primary production. Such reduction is important in view of the strict measures which are to apply to fresh meat from infected flocks of turkeys in accordance with that Regulation, as from 12 December 2010. In particular, fresh poultrymeat, including meat of turkeys, may not be placed on the market for human consumption unless it meets the following criterion: 'salmonella absence in 25 grams'.
- (3) Regulation (EC) No 2160/2003 provides that the Community target is to include a numerical expression of the maximum percentage of epidemiological units remaining positive and/or the minimum percentage of reduction in the number of epidemiological units remaining positive, the maximum time limit within which the target must be achieved and the definition of the testing schemes necessary to verify achievement of the target. It is also to include a definition, where relevant, of serotypes with public health significance.
- (4) Regulation (EC) No 2160/2003 provides that experience gained under existing national control measures and information forwarded to the Commission or to the European Food Safety Authority under existing Community requirements, in particular in the framework of information provided for in Directive 2003/99/EC of the European Parliament and of the Council of 17 November 2003 on the monitoring of zoonoses and zoonotic agents<sup>(2)</sup>, and in particular Article 5 thereof, should be taken into account when setting the Community target.
- (5) Regulation (EC) No 2160/2003 provides that, when defining each Community target, the Commission shall provide an analysis of its expected costs and benefits. However, by way of derogation, the Community target for turkey, covering *Salmonella enteritidis* and *Salmonella typhimurium* may be established for a transitional period without such analysis.
- (6) Comparable data on the prevalence of the salmonella serotypes in flocks of turkeys in Member States have therefore been collected in accordance with Commission Decision 2006/662/EC of 29 September 2006 concerning a financial contribution from the Community towards a baseline survey on the prevalence of salmonella in turkeys to be carried out in the Member States<sup>(3)</sup>.
- (7) Regulation (EC) No 2160/2003 provides that for a transitional period of three years, the Community target for turkeys is to cover only *Salmonella enteritidis* and *Salmonella typhimurium*. Other serotypes with public health significance may be considered after that period.
- (8) In order to verify progress on the achievement of the Community target, it is necessary to provide for repeated sampling of flocks of turkeys in this Regulation.
- (9) In accordance with Article 15 of Regulation (EC) No 2160/2003, the European Food Safety Authority (EFSA) was consulted on the setting of the Community target for turkeys.

<sup>(1)</sup> OJ L 325, 12.12.2003, p. 1. Regulation as last amended by Commission Regulation (EC) No 1237/2007 (OJ L 280, 24.10.2007, p. 5).

<sup>(2)</sup> OJ L 325, 12.12.2003, p. 31. Directive as amended by Council Directive 2006/104/EC (OJ L 363, 20.12.2006, p. 352).

<sup>(3)</sup> OJ L 272, 3.10.2006, p. 22.

- (10) The Task Force on Zoonoses Data Collection of the EFSA adopted on 28 April 2008 a Report on the Analysis of the baseline survey on the prevalence of salmonella in flocks of turkeys in the EU, 2006-2007, Part A: Salmonella prevalence estimates.
- (11) In accordance with Commission Regulation (EC) No 646/2007 of 12 June 2007 implementing Regulation (EC) No 2160/2003 of the European Parliament and of the Council as regards a Community target for the reduction of *Salmonella enteritidis* and *Salmonella typhimurium* in broilers and repealing Regulation (EC) No 1091/2005<sup>(1)</sup>, at least two pairs of boot/sock swabs shall be taken to sample flocks of broilers for salmonella. New scientific evidence demonstrates the using a combination of one pair of boot/sock swabs with a dust sample is at least as sensitive as sampling by taking two pairs of boot/sock swabs. Therefore, this combination should be allowed as alternative sampling method and Regulation (EC) No 646/2007 should be amended accordingly.
- (12) 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

##### Community target

1. The Community target, as referred to in Article 4(1) of Regulation (EC) No 2160/2003, for the reduction of *Salmonella enteritidis* and *Salmonella typhimurium* in turkeys ('Community target') shall be:
- (a) a reduction of the maximum percentage of fattening turkey flocks remaining positive of *Salmonella enteritidis* and *Salmonella typhimurium* to 1 % or less by 31 December 2012; and
- (b) a reduction of the maximum percentage of adult breeding turkey flocks remaining positive of *Salmonella enteritidis* and *Salmonella typhimurium* to 1 % or less by 31 December 2012.

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

Done at Brussels, 20 June 2008.

However, for Member States with less than 100 flocks of adult breeding or fattening turkeys, the Community target shall be that no more than one flock of adult breeding or fattening turkeys may remain positive by 31 December 2012.

2. The testing scheme necessary to verify progress in the achievement of the Community target is set out in the Annex.

3. The Commission shall consider a review of the target and the testing scheme set out in the Annex based on the experience gained in 2010 being the first year of the national control programmes as referred to in Article 5(1) of Regulation (EC) No 2160/2003.

#### Article 2

##### Amendment to Regulation (EC) No 646/2007

In the Annex to Regulation (EC) No 646/2007, the following paragraphs are added:

1. at the end of point 2:

'Alternatively, the competent authority may decide that one pair of boot swabs shall be taken, covering 100 % of the area of the house if combined with a dust sample, collected from multiple places throughout the house from surfaces with visible presence of dust.'

2. after the second paragraph of point 3(1):

'The dust sample shall preferably be analysed separately. However, the competent authority may decide to pool it with the pair of boot/sock swabs for analysis.'

#### Article 3

##### Entry into force and applicability

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

Articles 1(1) and (3), and 2 shall apply from 1 July 2008 and Article 1(2) shall apply from 1 January 2010.

For the Commission

Androulla VASSILIOU

Member of the Commission

<sup>(1)</sup> OJ L 151, 13.6.2007, p. 21.

## ANNEX

**Testing scheme necessary to verify the achievement of the Community target as referred to in Article 1(2)****1. Frequency and status of sampling**

- (a) The sampling frame shall cover all flocks of fattening and breeding turkeys covered by the scope of Regulation (EC) No 2160/2003.
- (b) Flocks of turkeys shall be sampled on the initiative of the food business operator and by the competent authority.
- (i) Sampling of flocks of fattening and breeding turkeys on the initiative of the food business operator shall take place in accordance with Article 5(3) of Regulation (EC) No 2160/2003 within three weeks before the birds are moved to the slaughterhouse. The results remain only valid until maximum six weeks after sampling and therefore repeated sampling of the same flock might be required.
- (ii) Additionally, sampling of flocks of breeding turkeys on the initiative of the food business operator shall take place:
- in rearing flocks: at day-old, at four weeks of age and two weeks before moving to the laying phase or laying unit,
  - in adult flocks: at least every third week during the laying period at the holding or at the hatchery.
- (iii) Sampling by the competent authority shall include at least:
- once a year, all flocks on 10 % of holdings with at least 250 adult breeding turkeys between 30 and 45 weeks of age but including in any case all holdings where *Salmonella enteritidis* or *Salmonella typhimurium* was detected during the previous 12 months and all holdings with elite, great grand parents and grand parent breeding turkeys; this sampling may also take place at the hatchery,
  - all flocks on holdings in case of detection of *Salmonella enteritidis* or *Salmonella typhimurium* from samples taken at the hatchery by food business operators or within the frame of official controls, to investigate the origin of infection,
  - once a year, all flocks on 10 % of the holdings with at least 500 fattening turkeys, but in any case:
    - all flocks on the holding when one flock tested positive for *Salmonella enteritidis* or *Salmonella typhimurium* in samples taken by the food business operator, unless the meat of the turkeys in the flocks is destined for industrial heat treatment or another treatment to eliminate salmonella, and
    - all flocks on the holding when one flock tested positive for *Salmonella enteritidis* or *Salmonella typhimurium* during the previous round in samples taken by the food business operator, and
    - each time the competent authority considers it necessary.

A sampling carried out by the competent authority may replace the sampling on the initiative of the food business operator.

**2. Sampling protocol****2.1. Sampling at the hatchery**

Sampling shall occur at the hatchery in accordance with the provisions laid down in point 2.2.1 of the Annex to Regulation (EC) No 1003/2005 <sup>(1)</sup>.

**2.2. Sampling at the holding****2.2.1. Breeding turkeys**

Samples shall be taken in accordance with the provisions laid down in point 2.2.2 of the Annex to Regulation (EC) No 1003/2005.

<sup>(1)</sup> OJ L 170, 1.7.2005, p. 12.



### 2.2.2. Fattening turkeys

At least two pairs of boot/sock swabs shall be taken. For free range flocks of turkeys, samples shall only be collected in the area inside the house. All boot/sock swabs must be pooled into one sample.

In flocks with less than 100 turkeys, where it is not possible to use boot/sock swabs as access to the houses is not possible, they may be replaced by hand drag swabs, where the boot swabs or socks are worn over gloved hands and rubbed over surfaces contaminated with fresh faeces, or if not feasible, by other sampling techniques for faeces fit for the intended purpose.

Before putting on the boot/sock swabs, their surface shall be moistened with maximum recovery diluents (MRD: 0,8 % sodium chloride, 0,1 % peptone in sterile deionised water), or sterile water or any other diluent approved by the national reference laboratory referred to in Article 11 of Regulation (EC) No 2160/2003. The use of farm water containing antimicrobials or additional disinfectants shall be prohibited. The recommended way to moisten boot swabs shall be to pour the liquid inside before putting them on. Alternatively, boot swabs or socks may be autoclaved with diluents within autoclave bags or jars before use. Diluents may also be applied after boots are put on using a spray or wash bottle.

It shall be ensured that all sections in a house are represented in the sampling in a proportionate way. Each pair should cover about 50 % of the area of the house.

Alternatively, the competent authority may decide that one pair of boot swabs shall be taken, covering 100 % of the area of the house if combined with a dust sample, collected from multiple places throughout the house from surfaces with visible presence of dust.

On completion of sampling the boot/sock swabs shall be carefully removed so as not to dislodge adherent material. Boot swabs may be inverted to retain material. They shall be placed in a bag or pot and labelled.

The competent authority shall supervise education of the food business operators to guarantee the correct application of the sampling protocol.

In the case of sampling by the competent authority because of suspicion salmonella infection in a flock on that holding and in any other case considered appropriate, the competent authority shall satisfy itself by conducting further tests as appropriate so that the results of examinations for salmonella in flocks of turkeys are not affected by the use of antimicrobials in those flocks.

Where the presence of *Salmonella enteritidis* and *Salmonella typhimurium* is not detected but antimicrobials or bacterial growth inhibitory effect are detected it shall be considered as an infected flock of turkeys for the purpose of the Community target referred to in Article 1(2).

## 3. Examination of the samples

### 3.1. Transport and preparation of the samples

Samples shall preferably be sent by express mail or courier to the laboratories referred to in Articles 11 and 12 of Regulation (EC) No 2160/2003, within 24 hours after collection. If not sent within 24 hours, they shall be stored refrigerated. At the laboratory samples shall be kept refrigerated until examination, which shall be started within 48 hours following receipt and within 96 hours after sampling.

The pair(s) of boot/sock swabs shall be carefully unpacked to avoid dislodging adherent faecal material, pooled and placed in 225 ml buffered peptone water (BPW) which has been pre-warmed to room temperature. The boot/sock swabs shall be fully immersed in BPW and therefore more BPW may be added if necessary.

The dust sample shall preferably be analysed separately. However, the competent authority may decide to pool it with the pair of boot/sock swabs for analysis.

The sample shall be swirled to fully saturate it and culture shall be continued by using the detection method in point 3.2.

Other samples (e.g. from hatcheries) shall be prepared in accordance with the provisions laid down in point 2.2.2 of the Annex to Regulation (EC) No 1003/2005.

If ISO standards on the preparation of faeces for the detection of salmonella are agreed on, they shall be applied and replace the provisions on the preparation of samples set out in this point.

### 3.2. *Detection method*

The detection method recommended by the Community reference laboratory (CRL) for salmonella in Bilthoven, the Netherlands, shall be used.

That method is described in the Annex D of ISO 6579 (2002): 'Detection of salmonella spp. in animal faeces and in samples of the primary production stage'. The latest version of Annex D shall be used.

In that detection method, a semi-solid medium (modified semi-solid Rappaport-Vassiladis medium, MSRV) is used as the single selective enrichment medium.

### 3.3. *Serotyping*

At least one isolate from each positive sample shall be serotyped, following the Kaufmann-White scheme.

### 3.4. *Alternative methods*

With regard to samples taken on the initiative of the food business operator, the methods of analysis provided for in Article 11 of Regulation (EC) No 882/2004 <sup>(1)</sup>, may be used instead of the methods for the preparation of samples, detection methods and serotyping provided for in points 3.1, 3.2 and 3.3 of this Annex, if validated in accordance with EN/ISO 16140/2003.

### 3.5. *Storage of strains*

Laboratories shall guarantee that at least one isolated strain of salmonella spp. per house and per year can be collected by the competent authority and stored for possible future phage typing or anti-microbial susceptibility testing, using the normal methods for culture collection, which must ensure integrity of the strains for a minimum of two years.

## 4. **Results and reporting**

### 4.1. *Detection of Salmonella enteritidis and/or Salmonella typhimurium*

The laboratory shall immediately report each detection of *Salmonella enteritidis* and/or *Salmonella typhimurium* to the competent authority and give holding and flock references.

### 4.2. *Calculation of prevalence for the verification of the Community target*

A flock of turkeys shall be considered positive for the purpose of verifying the achievement of the Community target, where the presence of *Salmonella enteritidis* and/or *Salmonella typhimurium* (other than vaccine strains) was detected in the flock at any occasion.

Positive flocks of turkeys shall be counted only once per round, irrespective of the number of sampling and testing operations and only be reported in the year of the first positive sampling.

The prevalence shall be calculated separately for flocks of fattening turkeys and flocks of adult breeding turkeys.

<sup>(1)</sup> OJ L 165, 30.4.2004, p. 1, corrected version OJ L 191, 28.5.2004, p. 1.

#### 4.3. Annual reporting

The annual reporting shall include:

- (a) the total number of flocks of fattening and adult breeding turkeys sampled by the competent authority or by the food business operator;
- (b) the total number of flocks infected with *Salmonella enteritidis* or *Salmonella typhimurium*, of fattening and adult breeding turkeys;
- (c) all serotypes of salmonella isolated (including other than *Salmonella enteritidis* and *Salmonella typhimurium*) and the number of flocks infected per serotype;
- (d) explanations of the results, in particular concerning exceptional cases.

The results and any additional relevant information shall be reported as part of the report on trends and sources provided for in Article 9(1) of Directive 2003/99/EC <sup>(1)</sup>.

#### 4.4. Additional information

At least the following information shall be made available from each flock of turkeys tested for analysis at national level or by the European Food Safety Authority at its request:

- (a) sample taken by the competent authority or by the food business operator;
- (b) holding reference, remaining unique in time;
- (c) house reference, remaining unique in time;
- (d) month of sampling.

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<sup>(1)</sup> OJ L 325, 12.12.2003, p. 31.

**COMMISSION REGULATION (EC) No 585/2008**  
**of 19 June 2008**  
**establishing a prohibition of fishing for cod in Kattegat by vessels flying the flag of Sweden**

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EC) No 2371/2002 of 20 December 2002 on the conservation and sustainable exploitation of fisheries resources under the Common Fisheries Policy <sup>(1)</sup>, and in particular Article 26(4) thereof,

Having regard to Council Regulation (EEC) No 2847/93 of 12 October 1993 establishing a control system applicable to common fisheries policy <sup>(2)</sup>, and in particular Article 21(3) thereof,

Whereas:

- (1) Council Regulation (EC) No 40/2008 of 16 January 2008 fixing for 2008 the fishing opportunities and associated conditions for certain fish stocks and groups of fish stocks applicable in Community waters and for Community vessels, in waters where catch limitations are required <sup>(3)</sup>, lays down quotas for 2008.
- (2) According to the information received by the Commission, catches of the stock referred to in the Annex to this Regulation by vessels flying the flag of or registered in the Member State referred to therein have exhausted the quota allocated for 2008.

- (3) It is therefore necessary to prohibit fishing for that stock and its retention on board, transshipment and landing,

HAS ADOPTED THIS REGULATION:

*Article 1*

**Quota exhaustion**

The fishing quota allocated to the Member State referred to in the Annex to this Regulation for the stock referred to therein for 2008 shall be deemed to be exhausted from the date set out in that Annex.

*Article 2*

**Prohibitions**

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

*Article 3*

**Entry into force**

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

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

Done at Brussels, 19 June 2008.

*For the Commission*

Fokion FOTIADIS

*Director-General for Fisheries and Maritime Affairs*

<sup>(1)</sup> OJ L 358, 31.12.2002, p. 59. Regulation as last amended by Regulation (EC) No 865/2007 (OJ L 192, 24.7.2007, p. 1).

<sup>(2)</sup> OJ L 261, 20.10.1993, p. 1. Regulation as last amended by Regulation (EC) No 1967/2006 (OJ L 409, 30.12.2006, p. 11), as corrected by OJ L 36, 8.2.2007, p. 6.

<sup>(3)</sup> OJ L 19, 23.1.2008, p. 1.

## ANNEX

No	10/T&Q
Member State	SWE
Stock	COD/03AS
Species	Cod ( <i>Gadus morhua</i> )
Area	Kattegat
Date	19.5.2008

## DIRECTIVES

## DIRECTIVE 2008/54/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 17 June 2008

**amending Council Directive 95/50/EC on uniform procedures for checks on the transport of dangerous goods by road, as regards the implementing powers conferred on the Commission**

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 71 thereof,

Having regard to the proposal from the Commission,

Having regard to the opinion of the European Economic and Social Committee <sup>(1)</sup>,

After consulting the Committee of the Regions,

Acting in accordance with the procedure laid down in Article 251 of the Treaty <sup>(2)</sup>,

Whereas:

(1) Council Directive 95/50/EC <sup>(3)</sup> provides that certain measures are to be adopted in accordance with Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission <sup>(4)</sup>.

(2) Decision 1999/468/EC has been amended by Decision 2006/512/EC, which introduced the regulatory procedure with scrutiny for the adoption of measures of general scope and designed to amend non-essential elements of a basic instrument adopted in accordance with the procedure laid down in Article 251 of the Treaty, *inter alia*, by deleting some of those elements or by supplementing the instrument with new non-essential elements.

(3) In accordance with the statement by the European Parliament, the Council and the Commission <sup>(5)</sup> concerning Decision 2006/512/EC, for the regulatory procedure with scrutiny to be applicable to instruments adopted in accordance with the procedure laid down in Article 251 of the Treaty which are already in force, those instruments must be adjusted in accordance with the applicable procedures.

(4) In particular the Commission should be empowered to adapt the Annexes to Directive 95/50/EC to scientific and technical progress. Since those measures are of general scope and are designed to amend non-essential elements of Directive 95/50/EC, they must be adopted in accordance with the regulatory procedure with scrutiny provided for in Article 5a of Decision 1999/468/EC.

(5) Directive 95/50/EC should therefore be amended accordingly.

(6) Since the amendments made to Directive 95/50/EC by this Directive are technical in nature and concern committee procedure only, they do not need to be transposed by the Member States. It is therefore not necessary to lay down provisions to that effect,

HAVE ADOPTED THIS DIRECTIVE:

## Article 1

## Amendments

Article 9a and 9b of Directive 95/50/EC shall be replaced by the following:

## ‘Article 9a

The Commission shall adapt the Annexes to scientific and technical progress in the fields covered by this Directive, in particular to take account of amendments to Directive 94/55/EC. Those measures, designed to amend non-essential elements of this Directive, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 9b(2).

<sup>(1)</sup> OJ C 44, 16.2.2008, p. 52.

<sup>(2)</sup> Opinion of the European Parliament of 15 January 2008 (not yet published in the Official Journal) and Council Decision of 14 May 2008.

<sup>(3)</sup> OJ L 249, 17.10.1995, p. 35. Directive as last amended by Commission Directive 2004/112/EC (OJ L 367, 14.12.2004, p. 23).

<sup>(4)</sup> OJ L 184, 17.7.1999, p. 23. Decision as amended by Decision 2006/512/EC (OJ L 200, 22.7.2006, p. 11).

<sup>(5)</sup> OJ C 255, 21.10.2006, p. 1.

*Article 9b*

1. The Commission shall be assisted by the Committee on the Transport of Dangerous Goods set up by Article 9 of Directive 94/55/EC.

2. Where reference is made to this paragraph, Article 5a(1) to (4) and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.'

*Article 2***Entry into force**

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

*Article 3***Addressees**

This Directive is addressed to the Member States.

Done at Strasbourg, 17 June 2008.

*For the European Parliament*

*The President*

H.-G. PÖTTERING

*For the Council*

*The President*

J. LENARČIČ

## COMMISSION DIRECTIVE 2008/62/EC

of 20 June 2008

**providing for certain derogations for acceptance of agricultural landraces and varieties which are naturally adapted to the local and regional conditions and threatened by genetic erosion and for marketing of seed and seed potatoes of those landraces and varieties**

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to Council Directive 2002/57/EC of 13 June 2002 on the marketing of seed of oil and fibre plants <sup>(6)</sup>, and in particular Article 27(1)(b) thereof,

Having regard to the Treaty establishing the European Community,

Whereas:

Having regard to Council Directive 66/401/EEC of 14 June 1966 on the marketing of fodder plant seed <sup>(1)</sup>, and in particular Article 22a(1)(b) thereof,

Having regard to Council Directive 66/402/EEC of 14 June 1966 on the marketing of cereal seed <sup>(2)</sup>, and in particular Article 22a(1)(b) thereof,

Having regard to Council Directive 2002/53/EC of 13 June 2002 on the common catalogue of varieties of agricultural plant species <sup>(3)</sup>, and in particular Article 4(6), Article 20(2) and Article 21 thereof,

Having regard to Council Directive 2002/54/EC of 13 June 2002 on the marketing of beet seed <sup>(4)</sup>, and in particular Article 30(1)(b) thereof,

Having regard to Council Directive 2002/56/EC of 13 June 2002 on the marketing of seed potatoes <sup>(5)</sup>, and in particular Article 10(1) and Article 27(1)(b) thereof,

(1) The questions of biodiversity and the conservation of plant genetic resources have grown in importance in recent years, as shown by different developments at international and Community level. Examples include Council Decision 93/626/EEC of 25 October 1993 concerning the conclusion of the Convention on Biological Diversity <sup>(7)</sup>, Council Decision 2004/869/EC of 24 February 2004 concerning the conclusion, on behalf of the European Community, of the International Treaty on Plant Genetic Resources for Food and Agriculture <sup>(8)</sup>, Council Regulation (EC) No 870/2004 of 24 April 2004 establishing a Community programme on the conservation, characterisation, collection and utilisation of genetic resources in agriculture and repealing Regulation (EC) No 1467/94 <sup>(9)</sup> and Council Regulation (EC) No 1698/2005 of 20 September 2005 on support for rural development by the European Agricultural Fund for Rural Development (EAFRD) <sup>(10)</sup>. Specific conditions should be established under the Community legislation governing the marketing of seed of agricultural plants, namely Directives 66/401/EEC, 66/402/EEC, 2002/53/EC, 2002/54/EC, 2002/56/EC and 2002/57/EC, in order to take account of these issues.

(2) In order to ensure in situ conservation and the sustainable use of plant genetic resources, landraces and varieties which are naturally adapted to local and regional conditions and threatened by genetic erosion (conservation varieties) should be grown and marketed even where they do not comply with the general requirements as regards the acceptance of varieties and the marketing of seed and seed potatoes. In order to achieve that objective it is necessary to provide for derogations as regards the acceptance of conservation varieties, for inclusion in the national catalogues of varieties of agricultural plant species as well as for the production and marketing of seed and seed potatoes of those varieties.

<sup>(1)</sup> OJ L 125, 11.7.1966, p. 2298/66. Directive as last amended by Commission Directive 2007/72/EC (OJ L 329, 14.12.2007, p. 37).

<sup>(2)</sup> OJ L 125, 11.7.1966, p. 2309/66. Directive as last amended by Commission Directive 2006/55/EC (OJ L 159, 13.6.2006, p. 13).

<sup>(3)</sup> OJ L 193, 20.7.2002, p. 1. Directive as last amended by Regulation (EC) No 1829/2003 of the European Parliament and of the Council (OJ L 268, 18.10.2003, p. 1).

<sup>(4)</sup> OJ L 193, 20.7.2002, p. 12. Directive as last amended by Directive 2004/117/EC (OJ L 14, 18.1.2005, p. 18).

<sup>(5)</sup> OJ L 193, 20.7.2002, p. 60. Directive as last amended by Commission Decision 2005/908/EC (OJ L 329, 16.12.2005, p. 37).

<sup>(6)</sup> OJ L 193, 20.7.2002, p. 74. Directive as last amended by Directive 2004/117/EC.

<sup>(7)</sup> OJ L 309, 13.12.1993, p. 1.

<sup>(8)</sup> OJ L 378, 23.12.2004, p. 1.

<sup>(9)</sup> OJ L 162, 30.4.2004, p. 18.

<sup>(10)</sup> OJ L 277, 21.10.2005, p. 1. Regulation as last amended by Regulation (EC) No 146/2008 (OJ L 46, 21.2.2008, p. 1).



- (3) Those derogations should concern the substantive requirements for the acceptance of a variety and the procedural requirements provided for in Commission Directive 2003/90/EC of 6 October 2003 setting out implementing measures for the purposes of Article 7 of Council Directive 2002/53/EC as regards the characteristics to be covered as a minimum by the examination and the minimum conditions for examining certain varieties of agricultural plant species <sup>(1)</sup>.
- (4) Member States should, in particular, be authorised to adopt their own provisions as regards distinctness, stability and uniformity. These provisions should, as regards distinctness and stability, at least be based on the characteristics listed in the technical questionnaire to be completed by the applicant in connection with the application for the variety acceptance as referred to in Annexes I and II to Directive 2003/90/EC. Where uniformity is established on the basis of off-types, the provisions should be based on defined standards.
- (5) The procedural requirements should be provided for under which a variety may be accepted without official examination. Furthermore, as regards the denomination, it is necessary to provide for certain derogations from the requirements laid down in Directive 2002/53/EC and Commission Regulation (EC) No 930/2000 of 4 May 2000 establishing implementing rules as to the suitability of the denominations of varieties of agricultural plant species and vegetable species <sup>(2)</sup>.
- (6) As regards the production and marketing of seed and seed potatoes of conservation varieties, a derogation from official certification should be provided for.
- (7) To ensure that the marketing of seed and seed potatoes of conservation varieties takes place in the context of the conservation of plant genetic resources, restrictions should be provided for, in particular regarding the region of origin. In order to contribute to the conservation in situ and to the sustainable use of those varieties, Member States should have the possibility to approve additional regions where seed exceeding the quantities necessary to ensure the conservation of the variety concerned in its region of origin may be marketed provided that those additional regions are comparable as regards natural and semi-natural habitats. To ensure that the link with the region of origin is preserved, this should not apply where a Member State has approved additional regions of production.
- (8) Maximum quantities should be fixed for the marketing of each conservation variety within one species and a total quantity for all conservation varieties within one species together. To make sure that these quantities are respected, Member States should require producers to notify the quantities of conservation varieties they intend to produce and should allocate the quantities to producers.
- (9) The traceability of seed and seed potatoes should be ensured through appropriate sealing and labelling requirements.
- (10) To ensure that the rules provided for in this Directive are correctly applied, seed crops should be monitored, seed should be tested and official post control carried out. Amounts of seed of conservation varieties placed on the market should be reported by the suppliers to the Member States and by the Member States to the Commission.
- (11) After three years the Commission should assess whether the measures provided for in this Directive, in particular the provisions concerning quantitative restrictions, are effective.
- (12) The measures provided for in this Directive are in accordance with the opinion of the Standing Committee on Seeds and Propagating Material for Agriculture, Horticulture and Forestry,

HAS ADOPTED THIS DIRECTIVE:

## CHAPTER I

### SUBJECT MATTER AND DEFINITIONS

#### Article 1

##### Subject matter

1. As regards the agricultural species covered by Directives 66/401/EEC, 66/402/EEC, 2002/54/EC, 2002/56/EC and 2002/57/EC, this Directive lays down certain derogations in relation to the conservation in situ and the sustainable use of plant genetic resources through growing and marketing:

- (a) for acceptance for inclusion in the national catalogues of varieties of agricultural plant species, as provided for in Directive 2002/53/EC, of landraces and varieties which are naturally adapted to the local and regional conditions and threatened by genetic erosion;

<sup>(1)</sup> OJ L 254, 8.10.2003, p. 7. Directive as last amended by Directive 2007/48/EC (OJ L 195, 27.7.2007, p. 29).

<sup>(2)</sup> OJ L 108, 5.5.2000, p. 3. Regulation as last amended by Regulation (EC) No 920/2007 (OJ L 201, 2.8.2007, p. 3).

(b) for the marketing of seed and seed potatoes of such landraces and varieties.

2. Unless otherwise provided in this Directive, Directives 66/401/EEC, 66/402/EEC, 2002/53/EC, 2002/54/EC, 2002/56/EC and 2002/57/EC shall apply.

## Article 2

### Definitions

For the purposes of this Directive the following definitions shall apply:

(a) 'conservation in situ' means the conservation of genetic material in its natural surroundings and, in the case of cultivated plant species, in the farmed environment where they have developed their distinctive properties;

(b) 'genetic erosion' means loss of genetic diversity between and within populations or varieties of the same species over time, or reduction of the genetic basis of a species due to human intervention or environmental change;

(c) 'landrace' means a set of populations or clones of a plant species which are naturally adapted to the environmental conditions of their region;

(d) 'seed' means seed and seed potatoes, unless seed potatoes are expressly excluded.

## CHAPTER II

### ACCEPTANCE OF CONSERVATION VARIETIES

## Article 3

### Conservation variety

Member States may accept in the national catalogues of varieties of agricultural plant species the landraces and varieties referred to in Article 1(1)(a) subject to the requirements provided for in Articles 4 and 5. Such landraces or varieties shall be referred to in the common catalogue of varieties of agricultural plant species as 'conservation varieties'.

## Article 4

### Substantive requirements

1. In order to be accepted as a conservation variety, a landrace or variety referred to in Article 1(1)(a) shall present an interest for the conservation of plant genetic resources.

2. By way of derogation from Article 1(2) of Directive 2003/90/EC, Member States may adopt their own provisions as regards distinctness, stability and uniformity of conservation varieties.

In such cases Member States shall ensure that for distinctness and stability at least the characteristics shall apply which are referred to in:

(a) the technical questionnaires associated with the test protocols of the Community Plant Variety Office (CPVO) listed in Annex I to Directive 2003/90/EC, which applies to those species, or

(b) the technical questionnaires of the guidelines of the International Union for the Protection of New Varieties of Plants (UPOV) listed in Annex II to Directive 2003/90/EC, which applies to those species.

For the assessment of uniformity, Directive 2003/90/EC shall apply.

However, if the uniformity level is established on the basis of off-types, a population standard of 10 % and an acceptance probability of at least 90 % shall be applied.

## Article 5

### Procedural requirements

By way of derogation from the first sentence of Article 7(1) of Directive 2002/53/EC, no official examination shall be required if the following information is sufficient for the decision on the acceptance of the conservation varieties:

(a) the description of the conservation variety and its denomination;

(b) the results of unofficial tests;

(c) knowledge gained from practical experience during cultivation, reproduction and use, as notified by the applicant to the Member State concerned;

(d) other information, in particular from the plant genetic resource authorities or from organisations recognised for this purpose by the Member States.

## Article 6

**Exclusion of acceptance**

A conservation variety shall not be accepted for inclusion in the national catalogues of varieties if:

- (a) it is already listed in the common catalogue of varieties of agricultural plant species as a variety other than a conservation variety, or it was deleted from the common catalogue within the last two years, or within the last two years from the expiry of the period granted under Article 15(2) of Directive 2002/53/EC, or
- (b) it is protected by a Community plant variety right as provided for in Council Regulation (EC) No 2100/94 <sup>(1)</sup>, or by a national plant variety right, or an application for such a right is pending.

## Article 7

**Denomination**

1. With respect to denominations of conservation varieties which were known before 25 May 2000, Member States may permit derogations from Regulation (EC) No 930/2000, except where such derogations would violate prior rights of a third party which is protected under Article 2 of that Regulation.
2. Notwithstanding Article 9(2) of Directive 2002/53/EC, Member States may accept more than one name for a variety if the names concerned are historically known.

## Article 8

**Region of origin**

1. When a Member State accepts a conservation variety, it shall identify the region or regions in which the variety has historically been grown and to which it is naturally adapted, hereinafter 'region of origin'. It shall take into account information from plant genetic resource authorities or from organisations recognised for that purpose by the Member States.

Where the region of origin is located in more than one Member States, it shall be identified by all Member States concerned by common accord.

2. The Member State or Member States performing the identification of the region of origin shall notify the identified region to the Commission.

<sup>(1)</sup> OJ L 227, 1.9.1994, p. 1.

## Article 9

**Maintenance**

Member States shall ensure that a conservation variety must be maintained in its region of origin.

## CHAPTER III

**SEED PRODUCTION AND MARKETING**

## Article 10

**Certification**

1. By way of derogation from the certification requirements provided for in Article 3(1) of Directive 66/401/EEC, Article 3(1) of Directive 66/402/EEC, Article 3(1) of Directive 2002/54/EC, Article 3(1) of Directive 2002/56/EC and Article 3(1) of Directive 2002/57/EC, Member States may provide that seed of a conservation variety may be placed on the market if it complies with paragraphs 2, 3 and 4 of this Article.

2. The seed shall descend from seed produced according to well defined practices for maintenance of the variety.

3. The seed, except seed of *Oryza sativa*, shall comply with the requirements for certification of certified seed provided for in Directives 66/401/EEC, 66/402/EEC, 2002/54/EC, 2002/56/EC and 2002/57/EC, with the exception of the requirements in respect of minimum varietal purity and the requirements concerning official examination or examination under official supervision.

Seed of *Oryza sativa* shall comply with the requirements for certification of 'certified seed, second generation' provided for in Directive 66/402/EEC, with the exception of the requirements in respect of minimum varietal purity and the requirements concerning official examination or examination under official supervision.

The seed shall have sufficient varietal purity.

4. As regards seed potatoes, Member States may provide that Article 10 of Directive 2002/56/EC concerning the size shall not apply.

## Article 11

**Region of seed production**

1. Member States shall ensure that seed of a conservation variety may only be produced in the region of origin.

If the conditions for certification provided for in Article 10(3) cannot be fulfilled in that region, due to a specific environmental problem, Member States may approve additional regions for seed production taking into account information from plant genetic resource authorities or from organisations recognised for this purpose by the Member States. However, seed produced in those additional regions may be used exclusively in the regions of origin.

2. Member States shall notify to the Commission and to the other Member States the additional regions which they intend to approve for seed production pursuant to paragraph 1.

The Commission and the other Member States may, within 20 working days from receipt of those notifications, request the matter to be referred to the Standing Committee on Seeds and Propagating Material for Agriculture, Horticulture and Forestry. A decision shall be taken in accordance with Article 22a(1)(b) of Directive 66/401/EEC, Article 22a(1)(b) of Directive 66/402/EEC, Article 4(6), Article 20(2) and Article 21 of Directive 2002/53/EC, Article 30(1)(b) of Directive 2002/54/EC, Article 10(1) and Article 27(1)(b) of Directive 2002/56/EC and Article 27(1)(b) of Directive 2002/57/EC, as appropriate, to lay down, if necessary, restrictions or conditions for the designation of such regions.

If neither the Commission nor other Member States make a request under the second subparagraph, the Member State in question may approve the additional regions for seed production as notified.

## Article 12

### Seed testing

1. Member States shall ensure that tests are carried out to check that seed of conservation varieties complies with the certification requirements provided for in Article 10(3).

Such tests shall be carried out in accordance with current international methods, or, where such methods do not exist, in accordance with any appropriate methods.

2. For the tests referred to in paragraph 1, Member States shall ensure that samples are drawn from homogeneous lots. They shall ensure that the rules on lot weight and sample weight provided for in Article 7(2) of Directive 66/401/EEC, Article 7(2) of Directive 66/402/EEC, Article 9(2) of Directive 2002/54/EC and Article 9(2) of Directive 2002/57/EC are applied.

## Article 13

### Marketing conditions

1. Member States shall ensure that seed of a conservation variety may only be marketed subject to the following conditions:

(a) it has been produced in its region of origin or in a region referred to in Article 11;

(b) marketing takes place in its region of origin.

2. By way of derogation from paragraph 1(b), a Member State may approve additional regions in its own territory for the marketing of seed of a conservation variety provided that those regions are comparable to the region of origin as regards the natural and semi-natural habitats of that variety.

Where Member States approve such additional regions, they shall ensure that the amount of seed necessary for the production of at least the quantity of seed referred to in Article 14 is reserved to conserve the variety in its region of origin.

The Member States shall inform the Commission and the other Member States of the approval of such additional regions.

3. Where a Member State approves additional regions for seed production in accordance with Article 11, it shall not use the derogation provided for in paragraph 2 of this Article.

## Article 14

### Quantitative restrictions

Each Member State shall ensure that, for each conservation variety, the quantity of seed marketed does not exceed 0,5 % of the seed of the same species used in that Member State in one growing season, or a quantity necessary to sow 100 ha, whichever is the greater quantity. For the species *Pisum sativum*, *Triticum* spp., *Hordeum vulgare*, *Zea mays*, *Solanum tuberosum*, *Brassica napus* and *Helianthus annuus*, that percentage shall not exceed 0,3 %, or a quantity necessary to sow 100 ha, whichever is the greater quantity.

However, the total quantity of seed of conservation varieties marketed in each Member State shall not exceed 10 % of the seed of the species concerned used yearly in the Member State. In cases where this leads to a quantity lower than necessary to sow 100 ha, the maximum amount of seed of the species concerned used yearly in the Member State may be increased so that to reach the quantity necessary to sow 100 ha.

*Article 15***Application of quantitative restrictions**

1. Member States shall ensure that producers notify them before the beginning of each production season of the size and the location of the area for the seed production.

2. If, based on the notifications referred to in paragraph 1, the quantities laid down in Article 14 are likely to be exceeded, Member States shall allocate to each producer concerned the quantity it may market in the respective production season.

*Article 16***Monitoring of seed crops**

Member States shall ensure by official monitoring that the seed crops of a conservation variety comply with the provisions of this Directive, paying particular attention to the variety, locations of the seed production and quantities.

*Article 17***Sealing of packages and containers**

1. Member States shall ensure that seed of conservation varieties may be marketed only in closed packages or containers bearing a sealing device.

2. Seed packages and containers shall be sealed by the supplier in such a manner that they cannot be opened without damaging the sealing system or leaving evidence of tampering on the supplier's label, or on the package or container.

3. In order to ensure sealing in accordance with paragraph 2, the sealing system shall comprise at least the label or the affixing of a seal.

*Article 18***Labelling**

Member States shall ensure that packages or containers of seed of conservation varieties bear a supplier's label or a printed or stamped notice including the following information:

- (a) the words 'EC rules and standards';
- (b) the name and address of the person responsible for affixing the labels or his identification mark;
- (c) the year of sealing expressed as: 'sealed...' (year), or, except for seed potatoes, the year of the last sampling for the purposes of the last testing of germination expressed as: 'sampled...' (year);

(d) the species;

(e) the denomination of the conservation variety;

(f) the words 'conservation variety';

(g) the region of origin;

(h) where the region of seed production is different from the region of origin, the indication of the region of seed production;

(i) the reference number of the lot given by the person responsible for affixing the labels;

(j) the declared net or gross weight, or, except for seed potato, declared number of seeds;

(k) where weight is indicated and granulated pesticides, pelleting substances or other solid additives are used, the nature of the chemical treatment or additive and the approximate ratio between the weight of clusters of pure seeds and the total weight, except for seed potatoes.

*Article 19***Official post control**

The Member States shall ensure that seed is subject to official post control by random inspections to verify its varietal identity and varietal purity.

## CHAPTER IV

**GENERAL AND FINAL PROVISIONS***Article 20***Reporting**

The Member States shall ensure that suppliers operating in their territory report for each production season the amount of seed of each conservation variety placed on the market.

The Member States shall report on request to the Commission and to the other Member States the amount of seed of each conservation variety placed on the market in their territory.

*Article 21***Notification of the recognised organisations of plant genetic resources**

Member States shall notify to the Commission the recognised organisations referred to in Articles 5(d), 8(1) and 11(1).

*Article 22***Evaluation**

By 31 December 2011 the Commission shall evaluate the implementation of Articles 4, 13(2), 14 and 15.

*Article 23***Transposition**

1. Member States shall bring into force, by 30 June 2009 at the latest, the laws, regulations and administrative provisions necessary to comply with this Directive. They shall forthwith communicate to the Commission the text of those provisions and a correlation table between those provisions and this Directive.

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

2. Member States shall communicate to the Commission the text of the main provisions of national law which they adopt in the field covered by this Directive.

*Article 24***Entry into force**

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

*Article 25***Addressees**

This Directive is addressed to the Member States.

Done at Brussels, 20 June 2008.

*For the Commission*  
Androulla VASSILIOU  
*Member of the Commission*



**COMMISSION DIRECTIVE 2008/63/EC**  
**of 20 June 2008**  
**on competition in the markets in telecommunications terminal equipment**  
(Text with EEA relevance)  
(Codified version)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community, and in particular Article 86(3) thereof,

Whereas:

- (1) Commission Directive 88/301/EEC of 16 May 1988 on competition in the markets in telecommunications terminal equipment<sup>(1)</sup> has been substantially amended<sup>(2)</sup>. In the interests of clarity and rationality the said Directive should be codified.
- (2) In all the Member States, telecommunications were, either wholly or partly, a State monopoly generally granted in the form of special or exclusive rights to one or more bodies responsible for providing and operating the network infrastructure and related services. Those rights, however, often used to go beyond the provision of network utilisation services and used to extend to the supply of user terminal equipment for connection to the network. The last decades have seen considerable technical developments in networks, and the pace of development has been especially striking in the area of terminal equipment.
- (3) Member States have, in response to technical and economic developments, reviewed their grant of special or exclusive rights in the telecommunications sector. The proliferation of types of terminal equipment and the possibility of the multiple use of terminals means that users must be allowed a free choice between the various types of equipment available if they are to benefit fully from the technological advances made in the sector.
- (4) The existence of exclusive rights has the effect of restricting the free movement of telecommunications terminal equipment either as regards the importation and marketing of terminal equipment (including satellite equipment), because certain products are not marketed, or as regards the connection, bringing into service or maintenance because, taking into account the

characteristics of the market and in particular the diversity and technical nature of the products, a monopoly has no incentive to provide these services in relation to products which it has not marketed or imported, nor to align its prices on costs, since there is no threat of competition from new entrants on the market. Taking into account the fact that in most equipment markets there is typically a large range of telecommunication equipment, any special right which directly or indirectly limits the number of the undertakings authorised to import, market, connect, bring into service and maintain such equipment, is liable to have the same kind of effect as the grant of exclusive rights. Such exclusive or special rights constitute measures having equivalent effect to quantitative restrictions incompatible with Article 28 of the Treaty. Thus it is necessary to abolish all existing exclusive rights in the importation, marketing, connection, bringing into service and maintenance of terminal and telecommunications equipment, as well as those rights having comparable effects — that is to say, all special rights except those consisting in legal or regulatory advantages conferred on one or more undertakings and affecting only the ability of other undertakings to engage in any of the abovementioned activities in the same geographical area under substantially equivalent conditions.

- (5) The special or exclusive rights relating to terminal equipment are exercised in such a way as, in practice, to disadvantage equipment from other Member States, notably by preventing users from freely choosing the equipment that best suits their needs in terms of price and quality, regardless of its origin. The exercise of these rights is therefore not compatible with Article 31 of the Treaty in all the Member States.
- (6) The provision of installation and maintenance services is a key factor in the purchasing or rental of terminal equipment. The retention of exclusive rights in this field would be tantamount to retention of exclusive marketing rights. Such rights must therefore also be abolished if the abolition of exclusive importing and marketing rights is to have any practical effect.
- (7) The maintenance of terminal equipment is a service within the meaning of Article 50 of the Treaty. The service in question, which cannot from a commercial point of view be dissociated from the marketing of the equipment terminals, must be provided freely in accordance with Article 49 of the Treaty and in particular when provided by qualified operators.

<sup>(1)</sup> OJ L 131, 27.5.1988, p. 73. Directive as amended by Directive 94/46/EC (OJ L 268, 19.10.1994, p. 15).

<sup>(2)</sup> See Annex II, Part A.

- (8) The situation in the market continues to produce infringements of the competition rules laid down by the Treaty and to affect adversely the development of trade to such an extent as would be contrary to the interests of the Community. Stronger competition in the terminal equipment market requires the introduction of transparent technical specifications which meet the essential requirements mentioned in Directive 1999/5/EC of the European Parliament and of the Council of 9 March 1999 on radio equipment and telecommunications terminal equipment and the mutual recognition of their conformity <sup>(1)</sup> and allow the free movement of terminal equipment. In turn, such transparency necessarily entails the publication of technical specifications.
- (9) Special or exclusive rights to import and market terminal equipment give rise to a situation which is contrary to the objective of Article 3(g) of the Treaty, which provides for the institution of a system ensuring that competition in the internal market is not distorted, and requires a fortiori that competition must not be eliminated. Member States have an obligation under Article 10 of the Treaty to abstain from any measure which could jeopardise the attainment of the objectives of the Treaty, including Article 3(g). The exclusive rights must therefore be regarded as incompatible with Article 82 of the Treaty in conjunction with Article 3 thereof, and the grant or maintenance of such rights by a Member State is prohibited under Article 86(1) of the Treaty.
- (10) To enable users to have access to the terminal equipment of their choice, it is necessary to know and make transparent the characteristics of the interface points of the public network to which the terminal equipment is to be connected. Member States must therefore ensure that the characteristics are published and that users have access to interface points of the public network.
- (11) To be able to market their products, manufacturers of terminal equipment must know what technical specifications they must satisfy. Member States should therefore formalise and publish the specifications, which they must notify to the Commission in draft form, in accordance with Directive 98/34/EC of the European Parliament and of the Council of 22 June 1998 laying down a procedure for the provision of information in the field of technical standards and regulations <sup>(2)</sup>. The specifications may be extended to products imported from other Member States only in so far as they are necessary to ensure conformity with the essential requirements specified in Article 3 of Directive 1999/5/EC that can legitimately be required under Community law. Member States must, in any event, comply with Articles 28 and 30 of the Treaty,
- under which an importing Member State must allow terminal equipment legally manufactured and marketed in another Member State.
- (12) To ensure that type-approval specifications are applied transparently, objectively and without discrimination monitoring applications cannot be entrusted to a competitor in the terminal equipment market in view of the obvious conflict of interest. Member States should therefore ensure that the responsibility for monitoring is assigned to a body independent of the operator of the network and of any other competitor in the market in question.
- (13) 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

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

1. 'terminal equipment' means:
  - (a) equipment directly or indirectly connected to the interface of a public telecommunications network to send, process or receive information; in either case (direct or indirect), the connection may be made by wire, optical fibre or electromagnetically; a connection is indirect if equipment is placed between the terminal and the interface of the network;
  - (b) satellite earth station equipment;
2. 'satellite earth station equipment' means equipment which is capable of being used for the transmission only ('transmit-only'), or for the transmission and reception ('transmit/receive'), or for the reception only ('receive-only') of radio communication signals by means of satellites or other space-based systems;
3. 'undertaking' means a public or private body, to which a Member State grants special or exclusive rights for the importation, marketing, connection, bringing into service of telecommunications terminal equipment and/or maintenance of such equipment;

<sup>(1)</sup> OJ L 91, 7.4.1999, p. 10. Directive as amended by Regulation (EC) No 1882/2003 (OJ L 284, 31.10.2003, p. 1).

<sup>(2)</sup> OJ L 204, 21.7.1998, p. 37. Directive as last amended by Council Directive 2006/96/EC (OJ L 363, 20.12.2006, p. 81).



4. 'special rights' means rights that are granted by a Member State to a limited number of undertakings, through any legislative, regulatory or administrative instrument, which, within a given geographical area:

- (a) limits to two or more the number of such undertakings, otherwise than according to objective, proportional and non-discriminatory criteria; or
- (b) designates, otherwise than according to the criteria referred to in point (a), several competing undertakings; or
- (c) confers on any undertaking or undertakings, otherwise than according to the criteria referred to in points (a) and (b), any legal or regulatory advantages which substantially affect the ability of any other undertaking to import, market, connect, bring into service and/or maintain telecommunication terminal equipment in the same geographical area under substantially equivalent conditions.

#### Article 2

Member States which have granted special or exclusive rights to undertakings shall ensure that all exclusive rights are withdrawn, as well as those special rights which:

- (a) limit to two or more the number of undertakings, otherwise than according to objective, proportional and non-discriminatory criteria; or
- (b) designate, otherwise than according to the criteria referred to in point (a), several competing undertakings.

They shall inform the Commission of the measures taken or draft legislation introduced to that end.

#### Article 3

Member States shall ensure that economic operators have the right to import, market, connect, bring into service and maintain terminal equipment.

However, Member States may:

- (a) in the case of satellite earth station equipment, refuse to allow such equipment to be connected to the public telecommunications network or to be brought into service where it does not satisfy the relevant common technical regulations adopted in pursuance of Directive 1999/5/EC or, in the absence thereof, the essential requirements laid down in Article 3 of that Directive; in the absence of common technical rules of harmonised regulatory

conditions, national rules shall be proportionate to those essential requirements and shall be notified to the Commission in accordance with Directive 98/34/EC where that Directive so requires;

- (b) in the case of other terminal equipment, refuse to allow such equipment to be connected to the public telecommunications network where it does not satisfy the relevant common technical regulations adopted in pursuance of Directive 1999/5/EC or, in the absence thereof, the essential requirements laid down in Article 3 of that Directive;
- (c) require economic operators to possess the technical qualifications needed to connect, bring into service and maintain terminal equipment on the basis of objective, non-discriminatory and publicly available criteria.

#### Article 4

Member States shall ensure that users have access to new public network interface points and that the physical characteristics of these points are published by users of the telecommunications public network.

#### Article 5

Member States shall ensure that all specifications for terminal equipment are formalised and published.

Member States shall notify those technical specifications in draft form to the Commission in accordance with Directive 98/34/EC.

#### Article 6

Member States shall ensure that in monitoring the specifications referred to in Article 5, the application is entrusted to a body independent of public or private undertakings offering goods and/or services in the telecommunications sector.

#### Article 7

Member States shall provide the Commission at the end of each year with a report allowing it to monitor compliance with the provisions of Articles 2, 3, 4, and 6.

An outline of the report is set out in Annex I.

#### Article 8

Directive 88/301/EEC, as amended by the Directive 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 10*

This Directive is addressed to the Member States.

Done at Brussels, 20 June 2008.

*Article 9*

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

*For the Commission*

*The President*

José Manuel BARROSO

## ANNEX I

**Outline of the report referred to in Article 7****Implementation of Article 2**

Terminal equipment for which legislation is being or has been modified.

By category of terminal equipment:

- date of adoption of the measure, or
- date of introduction of the bill, or
- date of entry into force of the measure.

**Implementation of Article 3**

- terminal equipment, the connection and/or commissioning of which has been restricted,
- technical qualifications required, giving reference of their publication.

**Implementation of Article 4**

- references of publications in which the physical characteristics are specified,
- number of existing public network interface points,
- number of public network interface points now accessible.

**Implementation of Article 6**

- independent body or bodies appointed.
-

## ANNEX II

## PART A

**Repealed Directive with its successive amendment**

(referred to in Article 8)

Commission Directive 88/301/EEC

(OJ L 131, 27.5.1988, p. 73)

Commission Directive 94/46/EC

(OJ L 268, 19.10.1994, p. 15)

## PART B

**List of time limits for transposition into national law**

(referred to in Article 8)

Directive	Time limit for transposition
88/301/EEC	—
94/46/EC	8 August 1995

## ANNEX III

## Correlation table

Directive 88/301/EEC	This Directive
Article 1, introductory words	Article 1, introductory words
Article 1, first indent, first and second sentences	Article 1, point (1)(a)
Article 1, first indent, last sentence	Article 1, point (1)(b)
Article 1, second indent	Article 1, point (3)
Article 1, third indent, introductory words	Article 1, point (4), introductory words
Article 1, third indent, first sub-indent	Article 1, point (4)(a)
Article 1, third indent, second sub-indent	Article 1, point (4)(b)
Article 1, third indent, third sub-indent	Article 1, point (4)(c)
Article 1, fourth indent	Article 1, point (2)
Article 2	Article 2
Article 3, first sentence	Article 3, first paragraph
Article 3, second sentence	Article 3, second paragraph, introductory sentence
Article 3, first indent	Article 3, second paragraph, point (a)
Article 3, second indent	Article 3, second paragraph, point (b)
Article 3, third indent	Article 3, second paragraph, point (c)
Article 4, first paragraph	Article 4
Article 4, second paragraph	—
Article 5(1)	—
Article 5(2), first sentence	Article 5, first paragraph
Article 5(2), second sentence	Article 5, second paragraph
Article 6	Article 6
Article 8	—
Article 9	Article 7
Article 10	—
—	Article 8
—	Article 9
Article 11	Article 10
Annex I	—
Annex II	Annex I
—	Annex II
—	Annexe III

## DECISIONS ADOPTED JOINTLY BY THE EUROPEAN PARLIAMENT AND THE COUNCIL

### DECISION No 586/2008/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 17 June 2008

**amending Decision No 896/2006/EC establishing a simplified regime for the control of persons at the external borders based on the unilateral recognition by the Member States of certain residence permits issued by Switzerland and Liechtenstein for the purpose of transit through their territory**

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 62(2)(a) thereof,

Having regard to the proposal from the Commission,

Acting in accordance with the procedure laid down in Article 251 of the Treaty <sup>(1)</sup>,

Whereas:

(1) Decision No 896/2006/EC <sup>(2)</sup> establishes common rules on unilateral recognition by the Member States of certain residence permits issued by Switzerland and Liechtenstein allowing a simplified regime for the control at the external borders of third country nationals who hold these documents.

(2) As a result of the two-step implementation of the Schengen *acquis*, those Member States that joined the European Union on 1 May 2004 were required, as from that date, to issue national visas to third country nationals who hold a residence permit issued by Switzerland and Liechtenstein and who are subject to a visa obligation under Council Regulation (EC) No 539/2001 of 15 March 2001 listing the third countries whose nationals must be in possession of visas when crossing the external borders and those whose nationals are exempt from that requirement <sup>(3)</sup>. That requirement created additional administrative burdens on the consulates of those Member States in Switzerland and Liechtenstein.

(3) However, it did not appear necessary for Member States to require that category of persons to hold a visa for the purpose of transit, as they represent a low illegal immigration risk for the Member States.

(4) Considering that the same reasoning applies to Bulgaria and Romania, the simplified regime introduced by Decision No 896/2006/EC should be extended to Bulgaria and Romania.

(5) Such amendment of Decision No 896/2006/EC should allow Bulgaria and Romania, if they decide to apply Decision No 582/2008/EC of the European Parliament and of the Council of 17 June 2008 introducing a simplified regime for the control of persons at the external borders based on the unilateral recognition by Bulgaria, Cyprus and Romania of certain documents as equivalent to their national visas for the purposes of transit through their territories <sup>(4)</sup>, to recognise unilaterally the residence permits issued by Switzerland and Liechtenstein which are listed in the Annex to Decision No 896/2006/EC as equivalent to their national transit visas.

(6) Recognition should be limited to the purpose of transit through the territory of Bulgaria and Romania and should not affect the possibility for those two Member States to issue visas for short-term stay.

(7) The possibility for Bulgaria and Romania not to apply Decision No 896/2006/EC should be limited to the transitional period until the date to be determined by the Council in accordance with the second subparagraph of Article 4(2) of the 2005 Act of Accession.

<sup>(1)</sup> Opinion of the European Parliament of 31 January 2008 (not yet published in the Official Journal) and Council Decision of 5 June 2008.

<sup>(2)</sup> OJ L 167, 20.6.2006, p. 8.

<sup>(3)</sup> OJ L 81, 21.3.2001, p. 1. Regulation as last amended by Regulation (EC) No 1932/2006 (OJ L 405, 30.12.2006, p. 23).

<sup>(4)</sup> OJ L 161, 20.6.2008, p. 30.

- (8) The entry conditions laid down in Article 5(1) of Regulation (EC) No 562/2006 of the European Parliament and of the Council of 15 March 2006 establishing a Community Code on the rules governing the movement of persons across borders (Schengen Borders Code) <sup>(1)</sup> have to be fulfilled, with the exception of the condition laid down in Article 5(1)(b) thereof, insofar as this Decision sets up an equivalence regime between transit visas issued by Bulgaria and Romania and certain residence permits issued by Switzerland and Liechtenstein.
- (9) Since the objective of this Decision cannot be sufficiently achieved by the Member States as it directly affects the Community *acquis* on external borders and can therefore, by reason of the scale and effects of the action, be better achieved at Community level, the Community may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty. In accordance with the principle of proportionality, as set out in that Article, this Decision does not go beyond what is necessary in order to achieve that objective.
- (10) As regards Iceland and Norway, this Decision constitutes a development of the provisions of the Schengen *acquis* within the meaning of the Agreement concluded by the Council of the European Union and the Republic of Iceland and the Kingdom of Norway concerning the association of those two States with the implementation, application and development of the Schengen *acquis* <sup>(2)</sup>, which fall within the area referred to in Article 1, point (A) of Council Decision 1999/437/EC of 17 May 1999 <sup>(3)</sup> on certain arrangements for the application of that Agreement
- (11) In accordance with Articles 1 and 2 of the Protocol on the Position of Denmark annexed to the Treaty on European Union and to the Treaty establishing the European Community, Denmark is not taking part in the adoption of this Decision and is not bound by it or subject to its application. Given that this Decision builds upon the Schengen *acquis* under the provisions of Title IV of Part Three of the Treaty establishing the European Community, Denmark shall, in accordance with Article 5 of the said Protocol, decide within a period of six months after the date of adoption of this Decision whether it will implement it in its national law.
- (12) This Decision constitutes a development of provisions of the Schengen *acquis* in which the United Kingdom does

not take part, in accordance with Council Decision 2000/365/EC of 29 May 2000 concerning the request of the United Kingdom of Great Britain and Northern Ireland to take part in some of the provisions of the Schengen *acquis* <sup>(4)</sup>; the United Kingdom is therefore not taking part in its adoption and is not bound by it or subject to its application.

- (13) This Decision constitutes a development of provisions of the Schengen *acquis* in which Ireland does not take part, in accordance with Council Decision 2002/192/EC of 28 February 2002 concerning Ireland's request to take part in some of the provisions of the Schengen *acquis* <sup>(5)</sup>. Ireland is therefore not taking part in its adoption and is not bound by it or subject to its application,

HAVE ADOPTED THIS DECISION:

#### Article 1

The following subparagraph shall be added to Article 2 of Decision No 896/2006/EC:

'If Bulgaria and Romania decide to apply Decision No 582/2008/EC of the European Parliament and of the Council of 17 June 2008 introducing a simplified regime for the control of persons at the external borders based on the unilateral recognition by Bulgaria, Cyprus and Romania of certain documents as equivalent to their national visas for the purposes of transit through their territories (\*), they may unilaterally recognise the residence permits listed in the Annex to this Decision as equivalent to their national transit visa until the date to be determined by the Council, in accordance with the second subparagraph of Article 4(2) of the 2005 Act of Accession.

(\*) OJ L 161, 20.6.2008, p. 30.'

#### Article 2

If Bulgaria and Romania decide to apply Decision No 896/2006/EC, they shall notify the Commission thereof within 10 working days of the date of entry into force of this Decision. The Commission shall publish the information communicated by them in the *Official Journal of the European Union*.

#### Article 3

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

<sup>(1)</sup> OJ L 105, 13.4.2006, p. 1.

<sup>(2)</sup> OJ L 176, 10.7.1999, p. 36.

<sup>(3)</sup> OJ L 176, 10.7.1999, p. 31.

<sup>(4)</sup> OJ L 131, 1.6.2000, p. 43.

<sup>(5)</sup> OJ L 64, 7.3.2002, p. 20.

*Article 4*

This Decision is addressed to the Member States in accordance with the Treaty establishing the European Community.

Done at Strasbourg, 17 June 2008.

*For the European Parliament*

*The President*

H.-G. PÖTTERING

*For the Council*

*The President*

J. LENARČIČ

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## II

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

## DECISIONS

## EUROPEAN PARLIAMENT AND COUNCIL

## DECISION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 5 June 2008

**on the mobilisation of the EU Solidarity Fund in accordance with point 26 of the Interinstitutional Agreement of 17 May 2006 between the European Parliament, the Council and the Commission on budgetary discipline and sound financial management**

(2008/469/EC)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Interinstitutional Agreement of 17 May 2006 between the European Parliament, the Council and the Commission on budgetary discipline and sound financial management <sup>(1)</sup>, and in particular point 26 thereof,

Having regard to Council Regulation (EC) No 1024/2002 of 11 November 2002 establishing the European Union Solidarity Fund <sup>(2)</sup>,

Having regard to the proposal from the Commission,

Whereas:

- (1) The European Union has created a European Union Solidarity Fund ('the Fund') to show solidarity with the population of regions struck by disasters.
- (2) The Interinstitutional Agreement of 17 May 2006 allows the mobilisation of the Fund within the annual ceiling of EUR 1 billion.
- (3) Regulation (EC) No 1024/2002 contains the provisions whereby the Fund may be mobilised.
- (4) Greece submitted an application to mobilise the Fund, concerning a disaster caused by forest fires in August 2007.

- (5) Slovenia submitted an application to mobilise the Fund, concerning a disaster caused by flooding in September 2007,

HAVE DECIDED AS FOLLOWS:

*Article 1*

For the general budget of the European Union for the financial year 2008, the European Union Solidarity Fund shall be mobilised to provide the sum of EUR 98 023 212 in commitment and payment appropriations.

*Article 2*

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

Done at Strasbourg, 5 June 2008.

For the European Parliament  
The President  
H.-G. PÖTTERING

For the Council  
The President  
J. LENARČIČ

<sup>(1)</sup> OJ C 139, 14.6.2006, p. 1. Agreement as last amended by Decision 2008/371/EC of the European Parliament and of the Council (OJ L 128, 16.5.2008, p. 8).

<sup>(2)</sup> OJ L 311, 14.11.2002, p. 3.

# COMMISSION

## COMMISSION DECISION

of 7 May 2008

**concerning the provisional prohibition of the use and sale in Austria of genetically modified maize (*Zea mays* L. line T25) pursuant to Directive 2001/18/EC of the European Parliament and of the Council**

(notified under document number C(2008) 1715)

(Only the German text is authentic)

(Text with EEA relevance)

(2008/470/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

market of genetically modified organisms which have not been completed by 17 October 2002 are subject to Directive 2001/18/EC.

Having regard to the Treaty establishing the European Community,

Having regard to 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 <sup>(1)</sup>, and in particular the first subparagraph of Article 18(1) thereof,

(4) On 8 May 2000 Austria informed the Commission of its decision to prohibit provisionally the use and sale of *Zea mays* L. line T25 for all uses and gave reasons for that decision in accordance with Article 16(1) of Directive 90/220/EEC.

After consulting the European Food Safety Authority,

(5) Products derived from *Zea mays* L. line T25 (starch and all its derivatives, crude and refined oil, all heat-processed or fermented products obtained from *Zea mays* L. line T25, as well as feed produced from *Zea mays* L. line T25) are authorised under Regulation (EC) No 258/97 of the European Parliament and of the Council <sup>(4)</sup> and Regulation (EC) No 1829/2003 of the European Parliament and of the Council <sup>(5)</sup>. These uses are not subject to the safeguard clause notified by Austria.

Whereas:

(1) By Commission Decision 98/293/EC of 22 April 1998 concerning the placing on the market of genetically modified maize (*Zea mays* L. line T25), pursuant to Council Directive 90/220/EEC <sup>(2)</sup> it was decided that consent was to be given for the placing on the market of that product.

(2) On 3 August 1998 the French authorities granted such consent. The consent covers all uses of the product, namely import, processing into food and feed products and cultivation.

(3) Pursuant to Article 35(1) of Directive 2001/18/EC which replaced Council Directive 90/220/EEC <sup>(3)</sup>, procedures in respect of notifications concerning the placing on the

(6) The Scientific Committee on Plants concluded on 20 July 2001 that the information submitted by Austria did not constitute new relevant scientific evidence which had not been taken into account during the original evaluation of the dossier and which would occasion a review of that Committee's original opinion on this product.

(7) On 9 January 2004, as well as on 9 and 17 February 2004, Austria submitted to the Commission additional information in support of its national measures concerning maize line T25.

<sup>(1)</sup> 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).

<sup>(2)</sup> OJ L 131, 5.5.1998, p. 30.

<sup>(3)</sup> OJ L 117, 8.5.1990, p. 15. Directive as last amended by Commission Directive 97/35/EC (OJ L 169, 27.6.1997, p. 72).

<sup>(4)</sup> OJ L 43, 14.2.1997, p. 1. Regulation as last amended by Regulation (EC) No 1882/2003 (OJ L 284, 31.10.2003, p. 1).

<sup>(5)</sup> OJ L 268, 18.10.2003, p. 1. Regulation as last amended by Regulation (EC) No 298/2008 (OJ L 97, 9.4.2008, p. 64).

- (8) In accordance with Article 28(1) of Directive 2001/18/EC, the Commission consulted the European Food Safety Authority (EFSA), as established by Regulation (EC) No 178/2002 of the European Parliament and of the Council<sup>(1)</sup>, under which it has replaced the relevant scientific committees.
- (9) The EFSA concluded on 8 July 2004<sup>(2)</sup> that the information submitted by Austria did not constitute new scientific evidence sufficient to invalidate the environmental risk assessment of maize line T25, justifying a prohibition of the use and sale of that product in Austria.
- (10) Since, under the circumstances, there was no reason to consider that the product constituted a risk to human health or the environment, the Commission submitted on 29 November 2004 a draft Decision, requesting Austria to repeal its provisional safeguard measure, for consideration by the Committee established under Article 30 of Directive 2001/18/EC, in accordance with the procedure laid down in Article 30(2) of that Directive.
- (11) However, that Committee did not deliver an opinion and, in accordance with Article 5(4) of Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission<sup>(3)</sup>, the Commission submitted to the Council a proposal relating to the measures to be taken.
- (12) On 24 June 2005, in accordance with Article 5(6) of Decision 1999/468/EC, the Council, acting by qualified majority, rejected this proposal.
- (13) The Council, in its declaration, stated that 'there is still a degree of uncertainty in relation to the national safeguard measures on the market of [the] genetically modified maize variet[y] [...] T25' and called on the Commission 'to gather further evidence on the GMO in question and further assess, whether the measure taken by [Austria] aimed at suspending as a temporary precautionary measure [its] placing on the market [is] justified and, whether the authorisation of such [an] organism still meets the safety requirements of Directive 2001/18/EC'.
- (14) In November 2005, the EFSA was consulted again by the Commission as to whether there was any scientific reason to believe that the continued placing on the market of T25 maize was likely to cause any adverse effects to human health or the environment under the conditions of consent. In particular, the EFSA was requested to take account of any further scientific information that had arisen subsequent to the previous scientific opinion concerning the safety of this GMO.
- (15) In its opinion of 29 March 2006<sup>(4)</sup>, EFSA concluded that there is no reason to believe that the continued placing on the market of T25 maize is likely to cause any adverse effects for human and animal health or the environment under the conditions of its consent.
- (16) In accordance with Article 5(6) of Decision 1999/468/EC, the Commission submitted a proposal to the Council requesting Austria to repeal its safeguard measure.
- (17) In accordance with Article 5(6) of Decision 1999/468/EC, the Environment Council, on 18 December 2006, indicated its opposition by qualified majority, to the proposal.
- (18) In its Decision, the Council referred to the environmental risk assessment as provided in the Directive 2001/18/EC and indicated that 'the different agricultural structures and regional ecological characteristics in the European Union need to be taken into account in a more systematic manner in the environmental risk assessment'.
- (19) In accordance with Article 5(6) of Decision 1999/468/EC the Commission submitted an amended proposal in order to take into account the Council Decision of 18 December 2006 which refers only to the environmental aspects of the Austrian safeguard clause, namely cultivation aspects.
- (20) Austria has initiated work to collect any relevant scientific evidence on these aspects, which in the view of Austria justifies provisionally the maintenance of the safeguard clause, in particular in reference to 'the different agricultural structures and regional ecological characteristics' as indicated in recital 3 of the above mentioned Council decision. In accordance with Article 23 of Directive 2001/18/EC, Austria is invited to provide the Commission with all the scientific evidence that it has collected as well as any new risk assessment as soon as it is completed and inform all Member States thereof.

<sup>(1)</sup> 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).

<sup>(2)</sup> Opinion of the Scientific Panel on Genetically Modified Organisms on a request from the Commission related to the Austrian invoke of Article 23 of Directive 2001/18/EC, The EFSA Journal (2004) 78, 1-13.

<sup>(3)</sup> OJ L 184, 17.7.1999, p. 23. Decision as amended by Decision 2006/512/EC (OJ L 200, 22.7.2006, p. 11).

<sup>(4)</sup> Opinion of the Scientific Panel on Genetically Modified Organisms on a request from the Commission related to genetically modified crops (Bt176 maize, MON810 maize, T25 maize, Topas 19/2 oilseed rape and Ms1xRf1 oilseed rape) subject to safeguard clauses invoked according to Article 16 of Directive 90/220/EEC, The EFSA Journal (2006) 338, pp. 1-15.

- (21) On the basis of Austria's submission and its scientific assessment, the Commission will act in accordance with Article 23 of Directive 2001/18/EC on these aspects of the Austrian measure.
- (22) The food and feed safety aspects of *Zea mays* L. line T25 covered by the consent granted under Directive 90/220/EEC (including import and processing) are identical throughout Europe and have been assessed by the EFSA, which concluded that this product is unlikely to cause any adverse effects for human and animal health.
- (23) The Commission proposal takes into account only food and feed aspects of the Austrian prohibition namely the prohibition on import and processing of unprocessed kernels as source materials for further processing or for direct food or feed use.
- (24) Under these circumstances Austria should repeal its safeguard measures at least with regard to import and processing into food and feed of *Zea mays* L. line T25.
- (25) The measures provided for in this Decision are not in accordance with the opinion of the Committee established under Article 30 of Directive 2001/18/EC and the Commission therefore submitted to the Council a proposal relating to these measures. Since on the expiry of the period laid down in Article 30(2) of Directive 2001/18/EC, the Council had neither adopted the proposed measures nor indicated its opposition to them, in accordance with Article 5(6) of Decision

1999/468/EC, the measures should be adopted by the Commission,

HAS ADOPTED THIS DECISION:

*Article 1*

The measures taken by Austria to prohibit the import and the processing into food and feed products of the *Zea mays* L. line T25, authorised for placing on the market by Decision 98/293/EC are not justified under Article 23 of Directive 2001/18/EC.

*Article 2*

Austria shall take the necessary steps to terminate the prohibition of import and processing into food and feed products of *Zea mays* L. line T25 at the latest 20 days after its notification.

*Article 3*

This Decision is addressed to the Republic of Austria.

Done at Brussels, 7 May 2008.

*For the Commission*

Stavros DIMAS

*Member of the Commission*

## RECOMMENDATIONS

## COMMISSION

## COMMISSION RECOMMENDATION

of 30 May 2008

**on risk reduction measures for the substances: trichloroethylene, benzene, and 2-methoxy-2-methylbutane (TAME)**

(notified under document number C(2008) 2271)

(Text with EEA relevance)

(2008/471/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 <sup>(1)</sup> 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 1179/94 <sup>(2)</sup> and (EC) No 2364/2000 <sup>(3)</sup> respectively concerning the first and the fourth list of priority substances as foreseen under Regulation (EEC) No 793/93:

— trichloroethylene,

— benzene,

— 2-methoxy-2-methylbutane (TAME).

(2) The rapporteur Member States designated pursuant to those Regulations 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 <sup>(4)</sup> 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 the Scientific 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 <sup>(5)</sup>.

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

<sup>(1)</sup> 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).

<sup>(2)</sup> OJ L 131, 26.5.1994, p. 3.

<sup>(3)</sup> OJ L 273, 26.10.2000, p. 5.

<sup>(4)</sup> OJ L 161, 29.6.1994, p. 3.

<sup>(5)</sup> OJ C 157, 21.6.2008, p. 1.

- (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,
4. To facilitate permitting and monitoring under Directive 2008/1/EC (Integrated Pollution Prevention and Control) benzene should be included in the ongoing work to develop guidance on 'Best Available Techniques' (BAT).
5. Exposure of microorganisms in industrial wastewater treatment plants should, where necessary, be controlled by national rules to ensure that no risk for the microorganisms and the environment is expected.

## SECTION 3

**2-METHOXY-2-METHYLBUTANE (TAME)**

(CAS No 994-05-8; Eines No 213-611-4)

**Risk reduction measures for the environment (6-11)**

6. The prevention of all anthropogenic inputs, including TAME, to groundwater is a key objective of current Community legislation<sup>(2)</sup>. It is recommended therefore that monitoring programmes be undertaken, where appropriate, in order to permit the early detection of groundwater contaminated by TAME.
7. It is further recommended that the best available techniques be widely applied for the construction and operation of petrol underground storage and distribution facilities at service stations. In this regard Member States should consider mandatory requirements especially for all service stations in groundwater recharge areas.
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 TAME in order for installations concerned 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.
9. Member States should carefully monitor the implementation of BAT regarding TAME and report any important developments to the Commission in the framework of the exchange of information on BAT.
10. Local emissions to the surface water should, where necessary, be controlled by national rules to ensure that no risk for the environment is expected.
11. The risk reduction measures recommended to protect the groundwater are considered sufficient to protect humans via the environment.

<sup>(2)</sup> Directive 2000/60/EC of the European Parliament and of the Council of 23 October 2000 establishing a framework for Community action in the field of water policy (OJ L 327, 22.12.2000, p. 1).

HEREBY RECOMMENDS:

## SECTION 1

**TRICHLOROETHYLENE**

(CAS No 79-01-6; Eines No 201-167-4)

**Risk reduction measures for workers (1)**

1. A voluntary agreement should be considered with the European Chlorinated Solvents Association on behalf of European producers of the substance, their distributors and customers, restricting the sale of the substance to purchasers who comply with the Charter for the safe use of trichloroethylene in metal cleaning. This Charter requires that users may only use trichloroethylene for metal cleaning in sealed or enclosed systems as defined in Part 4 of European Standard EN 12921, and is subject to third-party monitoring of compliance.

## SECTION 2

**BENZENE**

(CAS No 71-43-2; Eines No 200-753-7)

**Risk reduction measures for the environment (2, 3, 4 and 5)**

2. For the elimination of potential risks to industrial wastewater treatment plants at benzene production and/or processing sites it is recommended that competent authorities in the Member States concerned lay down conditions, emission limit values or equivalent parameters or technical measures regarding benzene in the permits issued under Council Directive 2008/1/EC of the European Parliament and of the Council<sup>(1)</sup> (Integrated Pollution Prevention and Control) in order to operate according to the best available techniques 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 benzene and report any important developments to the Commission in the framework of the exchange of information on BAT.

<sup>(1)</sup> OJ L 24, 29.1.2008, p. 8.

## SECTION 4

**ADDRESSEES**

12. 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*

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## COMMISSION RECOMMENDATION

of 30 May 2008

**on risk reduction measures for the substances 2,3-epoxypropyltrimethylammonium chloride (EPTAC), (3-chloro-2-hydroxypropyl) trimethylammonium chloride (CHPTAC) and hexachlorocyclopentadiene**

*(notified under document number C(2008) 2316)***(Text with EEA relevance)**

(2008/472/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 <sup>(1)</sup> 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 <sup>(2)</sup> and (EC) No 2364/2000 <sup>(3)</sup> respectively concerning the third and fourth list of priority substances as foreseen under Regulation (EEC) No 793/93:

— 2,3-epoxypropyltrimethylammonium chloride (EPTAC),

— (3-chloro-2-hydroxypropyl) trimethylammonium chloride (CHPTAC),

— hexachlorocyclopentadiene.

(2) The rapporteur Member States designated pursuant to those Regulations 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 <sup>(4)</sup> and have suggested a strategy for limiting the risks.

(3) The Scientific Committee on Health and Environmental Risks (SCHER) has been consulted and has issued opinions with respect to the risk evaluations carried

out by the rapporteurs. 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 <sup>(5)</sup>.

(5) It is appropriate, on the basis of that evaluation, to recommend certain risk reduction measures for certain substances. For the substances which are not specifically listed, there are no recommendations for the addressees of this Recommendation.

(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

**2,3-EPOXYPROPYLTRIMETHYLAMMONIUM CHLORIDE (EPTAC)***(CAS No 3033-77-0; EINECS No 221-221-0)***Risk reduction measures for workers (1) and the environment (2)**

1. Employers using EPTAC in manufacturing and as a cationisation agent in the cationisation of starches should take note of any sector specific guidance developed at national level based on the practical non-binding guidelines, drawn up by the Commission pursuant to Article 12(2) of Council Directive 98/24/EC <sup>(6)</sup> (Chemical Agents Directive).

<sup>(5)</sup> OJ C 157, 21.6.2008, p. 10.

<sup>(6)</sup> 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).

<sup>(1)</sup> 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).

<sup>(2)</sup> OJ L 25, 28.1.1997, p. 13.

<sup>(3)</sup> OJ L 273, 26.10.2000, p. 5.

<sup>(4)</sup> OJ L 161, 29.6.1994, p. 3.



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

#### SECTION 2

##### **(3-CHLORO-2-HYDROXYPROPYL) TRIMETHYLAMMONIUM CHLORIDE (CHPTAC)**

(CAS No 3327-22-8; Eines No 222-048-3)

##### **Risk reduction measures for workers (3) and the environment (4)**

3. Employers using CHPTAC as a cationisation agent in the cationisation of starches should take note of any sector specific guidance developed at national level based on the practical non-binding guidelines, drawn up by the Commission pursuant to Article 12(2) of Directive 98/24/EC.

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

#### SECTION 3

##### **ADDRESSEES**

5. 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 5 June 2008****concerning the limitation of the civil liability of statutory auditors and audit firms***(notified under document number C(2008) 2274)***(Text with EEA relevance)****(2008/473/EC)**

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community, and in particular Article 211, second indent, thereof,

audits of listed companies should be limited. However, any limitation on liability is not justified in cases of intentional breach of professional duties on the part of an auditor and should not apply in such cases. Nor should such a limitation prejudice the right of any injured party to be fairly compensated.

Whereas:

(1) Directive 2006/43/EC of the European Parliament and of the Council of 17 May 2006 on statutory audits of annual accounts and consolidated accounts, amending Council Directives 78/660/EEC and 83/349/EEC and repealing Council Directive 84/253/EEC <sup>(1)</sup> establishes a minimum harmonisation of statutory audit requirements. Pursuant to Article 31 of that Directive, the Commission is to report on the impact of the national liability rules for the carrying out of statutory audits on European capital markets and on the insurance conditions for statutory auditors and audit firms and to make recommendations if it considers it appropriate.

(2) Smooth functioning of capital markets requires sustainable audit capacity and a competitive market for audit services in which there is a sufficient choice of audit firms capable of conducting and willing to conduct statutory audits of companies the securities of which are admitted to trading on a regulated market of a Member State. However, increasing volatility in market capitalisation of companies has led to much higher liability risks, whilst access to insurance coverage against the risks associated with such audits has become increasingly limited.

(3) Since unlimited joint and several liability may deter audit firms and networks from entering the international audit market for listed companies in the Community, there is little prospect of new audit networks emerging which are in a position to conduct statutory audits of such companies.

(4) As a consequence, the liability of auditors and audit firms, including group auditors, carrying out statutory

(5) In view of the considerable variations between civil liability systems in the Member States, it is appropriate at this stage that each Member State be able to choose the method of limitation which it considers to be the most suitable for its civil liability system.

(6) Member States should accordingly be able to determine under national law a cap in respect of auditors' liability. Alternatively Member States should be able to establish under national law a system of proportionate liability according to which statutory auditors and audit firms are liable only to the extent of their contribution to the damage caused, without being jointly and severally liable with other parties. In the Member States where any claims against statutory auditors might be brought only by the audited company and not by individual shareholders or any other third parties, Member State should also be able to allow the company, its shareholders and the auditor to determine the limitation of the auditor's liability, subject to appropriate safeguards for investors in the company audited,

HEREBY RECOMMENDS:

**Subject matter**

1. This Recommendation concerns the civil liability of auditors and audit firms carrying out a statutory audit of the consolidated or annual accounts of a company which is registered in a Member State and the securities of which are admitted to trading on a regulated market in a Member State.

**Limitation of liability**

2. The civil liability of statutory auditors and of audit firms arising from a breach of their professional duties should be limited except in cases of intentional breach of duties by the statutory auditor or the audit firm.

<sup>(1)</sup> OJ L 157, 9.6.2006, p. 87. Directive as amended by Directive 2008/30/EC (OJ L 81, 20.3.2008, p. 53).

3. The limitation of liability should apply against the company audited and any third party entitled under national law to bring a claim for compensation.

4. Any limitation of civil liability should not prevent injured parties from being fairly compensated.

#### **Methods for limiting liability**

5. Member States should take measures to limit liability. For that purpose, it is recommended that any one or more of the following methods in particular be used:

(a) establishment of a maximum financial amount or of a formula allowing for the calculation of such an amount;

(b) establishment of a set of principles by virtue of which a statutory auditor or an audit firm is not liable beyond its actual contribution to the loss suffered by a claimant and is accordingly not jointly and severally liable with other wrongdoers;

(c) provision allowing any company to be audited and the statutory auditor or audit firm to determine a limitation of liability in an agreement.

6. Where liability is limited by agreement as referred to in point 5(c), Member States should ensure that all the following conditions are met:

(a) the agreement is subject to judicial review;

(b) with regard to the company to be audited, the limitation is decided collectively by the members of the administrative, management and supervisory bodies referred to in Article 50b of Council Directive 78/660/EEC <sup>(1)</sup>, or, in the case of a group audit, in Article 36a of Council Directive 83/349/EEC <sup>(2)</sup>, and such a decision is approved by the shareholders of the company to be audited;

(c) the limitation and any modification thereof are published in the notes to the accounts of the audited company.

7. Before adopting measures implementing any of the methods referred to in point 5(a), (b) or (c), or any other method limiting liability which complies with points 2, 3 and 4, a Member State should take into account the impact on financial markets and investors and on conditions for access to the market of statutory audit for listed companies, as well as the impact on audit quality, insurability of risks and the companies to be audited.

#### **Follow-up**

8. Member States are invited to inform the Commission of actions taken in light of this Recommendation by 5 June 2010.

#### **Addressees**

9. This Recommendation is addressed to the Member States

Done at Brussels, 5 June 2008.

*For the Commission*

Charlie McCREEVY

*Member of the Commission*

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<sup>(1)</sup> OJ L 222, 14.8.1978, p. 11. Directive as last amended by Directive 2006/46/EC of the European Parliament and of the Council (OJ L 224, 16.8.2006, p. 1).

<sup>(2)</sup> OJ L 193, 18.7.1983, p. 1. Directive as last amended by Directive 2006/99/EC (OJ L 363, 20.12.2006, p. 137).