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Legislation

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Contents

[1] Text with EEA relevance

(Continued overleaf)

EN

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

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

Contents (continued)

EN

[1] Text with EEA relevance

I

(Acts whose publication is obligatory)

COUNCIL REGULATION (EC) No 374/2005

of 28 February 2005

amending Regulation (EC) No 2007/2000 introducing exceptional trade measures for countries and territories participating in or linked to the European Union's stabilisation and association process

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 133 thereof,

Having regard to the proposal from the Commission,

Whereas:

(1) Under Regulation (EC) No 2007/2000 [1], the Community has extended duty-free access to imports from the countries concerned of most agricultural goods, including sugar.

(2) In the case of sugar, the duty-free access for unlimited quantities has created an incentive for western Balkan production at levels that are unsustainable in view of foreseeable developments.

(3) The modification of the import regime for each of the western Balkan countries, while allowing the respect of present trade concessions will prepare their sector for the adjustments needed to perform within a realistic and economically sustainable environment.

(4) Regulation (EC) No 2007/2000 should be amended to clarify that preferential Community wine imports from the western Balkans benefit only from tariff quotas, rather than unlimited duty-free access, under the autonomous measures,

HAS ADOPTED THIS REGULATION:

Article 1

Regulation (EC) No 2007/2000 is hereby amended as follows:

1. Article 1 shall be amended as follows:

(a) paragraph 1 shall be replaced by the following:

'1. Subject to the special provisions laid down in Articles 3 and 4, products originating in Albania, Bosnia and Herzegovina and Serbia and Montenegro, including Kosovo, other than those of heading Nos 0102, 0201, 0202, 1604, 1701, 1702 and 2204 of the Combined Nomenclature, shall be admitted for import into the Community without quantitative restrictions or measures having equivalent effect and with exemption from customs duties and charges having equivalent effect.'

(b) the following paragraph shall be added:

'3. Imports of sugar products under heading Nos 1701 and 1702 of the Combined Nomenclature originating in Albania, Bosnia and Herzegovina and Serbia and Montenegro, including Kosovo, shall benefit from concessions provided for in Article 4.';

2. the following paragraph 4 shall be added to Article 4:

'4. Imports of sugar products under heading Nos 1701 and 1702 of the Combined Nomenclature originating in Albania, Bosnia and Herzegovina and Serbia and Montenegro, including Kosovo, shall be subject to the following annual duty-free tariff quotas:

(a) 1 000 tonnes (net weight) for sugar products originating in Albania;

(b) 12 000 tonnes (net weight) for sugar products originating in Bosnia and Herzegovina;

(c) 180 000 tonnes (net weight) for sugar products originating in Serbia and Montenegro, including Kosovo.';

[1] OJ L 240, 23.9.2000, p. 1. Regulation as last amended by Regulation (EC) No 607/2003 (OJ L 86, 3.4.2003, p. 18).

3. Article 6 shall be amended as follows:

(a) the title shall be replaced by the following:

'Implementation of tariff quotas for "baby beef" and sugar'.

(b) the following subparagraph shall be added:

'The detailed rules for implementing the tariff quotas for sugar products under heading Nos 1701 and 1702 shall be determined by the Commission in accordance with the procedure laid down in Article 42(2) of Regulation (EC) No 1260/2001 of 19 June 2001 on the common organisation of the markets in the sugar sector (*).

(*) OJ L 178, 30.6.2001, p. 1. Regulation as last amended by Commission Regulation (EC) No 39/2004 (OJ L 6, 10.1.2004, p. 16).'

Article 2

This Regulation shall enter into force on 1 July 2005.

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

Done at Brussels, 28 February 2005.

For the Council
The President
F. BODEN

COMMISSION REGULATION (EC) No 375/2005

of 4 March 2005

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 3223/94 of 21 December 1994 on detailed rules for the application of the import arrangements for fruit and vegetables [1], and in particular Article 4(1) thereof,

Whereas:

(1) Regulation (EC) No 3223/94 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 4 of Regulation (EC) No 3223/94 shall be fixed as indicated in the Annex hereto.

Article 2

This Regulation shall enter into force on 5 March 2005.

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

Done at Brussels, 4 March 2005.

For the Commission

J. M. SILVA RODRÍGUEZ

Director-General for Agriculture and Rural Development

[1] OJ L 337, 24.12.1994, p. 66. Regulation as last amended by Regulation (EC) No 1947/2002 (OJ L 299, 1.11.2002, p. 17).

ANNEX

to Commission Regulation of 4 March 2005 establishing the standard import values for determining the entry price of certain fruit and vegetables

(EUR/100 kg)

CN code	Third country code (1)	Standard import value
0702 00 00	052	107,2
	204	82,9
	212	123,3
	624	182,8
	999	124,1
0707 00 05	052	168,5
	068	159,6
	204	139,6
	999	155,9
0709 10 00	220	24,0
	999	24,0
0709 90 70	052	181,5
	204	149,3
	999	165,4
0805 10 20	052	59,3
	204	49,9
	212	52,8
	220	52,0
	421	41,6
	624	61,4
	999	52,8
0805 50 10	052	66,5
	220	76,3
	624	51,0
	999	64,6
0808 10 80	388	81,1
	400	112,5
	404	71,0
	508	77,7
	512	53,6
	528	71,0
	720	66,6
	999	76,2
0808 20 50	052	208,3
	388	70,0
	400	92,1
	512	85,3
	528	65,6
	720	45,1
	999	94,4

(1) Country nomenclature as fixed by Commission Regulation (EC) No 2081/2003 (OJ L 313, 28.11.2003, p. 11). Code '999' stands for 'of other origin'.

COMMISSION REGULATION (EC) No 376/2005

of 4 March 2005

suspending the buying-in of butter in certain Member States

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EC) No 1255/1999 of 17 May 1999 on the common organisation of the market in milk and milk products [1],

Having regard to Commission Regulation (EC) No 2771/1999 of 16 December 1999 laying down detailed rules for the application of Council Regulation (EC) No 1255/1999 as regards intervention on the market in butter and cream [2], and in particular Article 2 thereof,

Whereas:

(1) Article 2 of Regulation (EC) No 2771/1999 lays down that buying-in is to be opened or suspended by the Commission in a Member State, as appropriate, once it is observed that, for two weeks in succession, the market price in that Member State is below or equal to or above 92 % of the intervention price.

(2) Commission Regulation (EC) No 337/2005 [3] establishes the most recent list of Member States in which intervention is suspended. This list must be adjusted as a result of the market prices communicated by France and the United Kingdom pursuant to Article 8 of Regulation (EC) No 2771/1999. In the interests of clarity, the list in question should be replaced and Regulation (EC) No 337/2005 should be repealed,

HAS ADOPTED THIS REGULATION:

Article 1

Buying-in of butter as provided for in Article 6(1) of Regulation (EC) No 1255/1999 is hereby suspended in Belgium, the Czech Republic, Denmark, Cyprus, Hungary, Malta, Greece, Luxembourg, the Netherlands, Austria, Slovakia, Slovenia, Finland and Sweden.

Article 2

Regulation (EC) No 337/2005 is hereby repealed.

Article 3

This Regulation shall enter into force on 5 March 2005.

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

Done at Brussels, 4 March 2005.

For the Commission
Mariann FISCHER BOEL
Member of the Commission

[1] OJ L 160, 26.6.1999, p. 48. Regulation as last amended by Commission Regulation (EC) No 186/2004 (OJ L 29, 3.2.2004, p. 6).

[2] OJ L 333, 24.12.1999, p. 11. Regulation as last amended by Regulation (EC) No 2250/2004 (OJ L 381, 28.12.2004, p. 25).

[3] OJ L 53, 26.2.2005, p. 24.

COMMISSION REGULATION (EC) No 377/2005

of 4 March 2005

repealing Regulation (EC) No 72/2005 suspending the preferential customs duties and re-establishing the Common Customs Tariff duty on imports of uniflorous (bloom) carnations originating in the West Bank and the Gaza Strip

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EEC) No 4088/87 of 21 December 1987 fixing conditions for the application of preferential customs duties on imports of certain flowers originating in Cyprus, Israel, Jordan, Morocco and the West Bank and the Gaza Strip [1], and in particular Article 5 (2)(b) thereof;

Whereas:

(1) Following Council Decision 2005/4/EC of 22 December 2004 on the conclusion of the Agreement in the form of an Exchange of Letters between the European Community and the Palestine Liberation Organisation (PLO) for the benefit of the Palestinian Authority of the West Bank and the Gaza Strip concerning reciprocal liberalisation measures and the replacement of Protocols 1 and 2 to the EC-Palestinian Authority Interim Association Agreement [2], it is no longer necessary, since 1 January 2005, to set minimum entry prices for roses and carnations imported from the West Bank and the Gaza Strip since the scheme of preferential customs duties will apply to all imports within the quota ceiling.

(2) None the less, these prices were calculated, and the calculations led to the adoption of Commission Regulation (EC) No 72/2005 [3].

(3) It is therefore necessary to re-establish the preferential customs duties introduced by Council Regulation (EC) No 747/2001 of 9 April 2001 providing for the management of Community tariff quotas and of reference quantities for products eligible for preferences by virtue of agreements with certain Mediterranean countries and repealing Regulations (EC) No 1981/94 and (EC) No 934/95 [4].

(4) Regulation (EC) No 72/2005 should therefore be repealed with effect from its date of entry into force, since the customs duties collected under this Regulation can be reimbursed under Council Regulation (EEC) No 2913/92 of 12 October 1992 establishing the Community Customs Code [5] and Commission Regulation (EEC) No 2454/93 of 2 July 1993 laying down provisions for the implementation of Council Regulation (EEC) No 2913/92 establishing the Community Customs Code [6].

(5) The Commission must take these measures in between the meetings of the Management Committee for Live Plants,

HAS ADOPTED THIS REGULATION:

Article 1

Regulation (EC) No 72/2005 is hereby repealed with effect from 18 January 2005.

Article 2

This Regulation shall enter into force on 5 March 2005.

[1] OJ L 382, 31.12.1987, p. 22. Regulation as last amended by Regulation (EC) No 1300/1997 (OJ L 177, 5.7.1997, p. 1).
[2] OJ L 2, 5.1.2005, p. 4.
[3] OJ L 14, 18.1.2005, p. 13.
[4] OJ L 109, 19.4.2001, p. 2. Regulation as last amended by Commission Regulation (EC) No 2279/2004 (OJ L 396, 31.12.2004, p. 38).
[5] OJ L 302, 19.10.1992, p. 1. Regulation as last amended by the 2003 Act of Accession.
[6] OJ L 253, 11.10.1993, p. 1. Regulation as last amended by Regulation (EC) No 2286/2003 (OJ L 343, 31.12.2003, p. 1).

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

Done at Brussels, 4 March 2005.

For the Commission
J. M. SILVA RODRÍGUEZ
Director-General for Agriculture and Rural Development

COMMISSION REGULATION (EC) No 378/2005

of 4 March 2005

on detailed rules for the implementation of Regulation (EC) No 1831/2003 of the European Parliament and of the Council as regards the duties and tasks of the Community Reference Laboratory concerning applications for authorisations of feed additives

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition [1], and in particular the first subparagraph of Article 7(4) and the third subparagraph of Article 21 thereof,

Whereas:

(1) Regulation (EC) No 1831/2003 lays down rules for the placing on the market and use of feed additives in animal nutrition. It provides that any person seeking an authorisation for a feed additive or a new use of a feed additive is to submit an application for authorisation to the Commission in accordance with that Regulation (the application).

(2) Regulation (EC) No 1831/2003 provides for a Community reference laboratory (the CRL) to carry out certain duties and tasks set out in Annex II to that Regulation. It also provides that the Joint Research Centre of the Commission is to be the CRL and that it may be assisted by a consortium of national reference laboratories to perform the duties and tasks set out in that Annex.

(3) In accordance with Regulation (EC) No 1831/2003, it is necessary to adopt detailed rules for implementing Annex II to that Regulation, including practical conditions for the duties and tasks of the CRL and to amend that Annex accordingly.

(4) In addition, the samples to be provided in the application, in accordance with Regulation (EC) No 1831/2003, should meet specific requirements in view of the duties and tasks of the CRL.

(5) It is necessary to establish a precise timing for the delivery of the evaluation report from the CRL to the European Food Safety Authority (the Authority) in order to ensure that the procedures provided for in Regulation (EC) No 1831/2003 can be met.

(6) The CRL should be authorised to charge a fee to applicants towards the costs of supporting the duties and tasks of the CRL and the consortium of national reference laboratories.

(7) National reference laboratories should be part of the consortium of laboratories assisting the CRL only if they meet specific requirements in order to properly perform the duties and tasks laid down in Regulation (EC) No 1831/2003. Member States should be permitted to apply to the Commission for the designation of such laboratories.

(8) In order to ensure the effective functioning of the consortium, it is necessary to appoint a rapporteur laboratory to carry out an initial assessment of the method(s) of analysis of each individual application and to establish clearly the duties and tasks of the rapporteur laboratories and the other laboratories participating in the consortium.

(9) It is necessary to establish special procedures for the cases where the data in the application are insufficient concerning testing or validation of the method(s) of analysis.

(10) In the interests of stability and efficacy and also in order to make the consortium operational, it is necessary to appoint the national reference laboratories participating in the consortium.

(11) The relations between the members of the consortium should be defined by contract between them. In this context the CRL may develop guidance for applicants and for the laboratories participating in the consortium.

(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,

[1] OJ L 268, 18.10.2003, p. 29.

HAS ADOPTED THIS REGULATION:

CHAPTER I

GENERAL PROVISIONS

Article 1

Subject matter and scope

This Regulation lays down detailed rules for the implementation of Regulation (EC) No 1831/2003 as regards:

(a) applications for authorisation of a feed additive or for a new use of a feed additive as provided for in Article 4(1) of that Regulation (the application); and

(b) the duties and tasks of the Community Reference Laboratory (the CRL).

Article 2

Definitions

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

(a) 'reference sample' means a representative sample of the feed additive, as referred to in Article 7(3)(f) of Regulation (EC) No 1831/2003, which is the object of an application;

(b) 'method of analysis' means the procedure for the determination of the active substance(s) of the feed additive in feedingstuffs, and where appropriate, of its residue(s) or metabolite(s) in food, as referred to in Article 7(3)(c) of the Regulation (EC) No 1831/2003;

(c) 'evaluation of the method of analysis' means the thorough assessment of the protocol of the method of analysis as described in the application, including, if appropriate, literature research but not necessarily any experimental work;

(d) 'testing of a method of analysis' means the application of the method of analysis in a laboratory and comparison of results with those described in the application;

(e) 'validation of a method of analysis' means the process of proving that a method of analysis is fit for the intended purpose, by an intercomparison study according to ISO 5725-1 to 6 or other internationally harmonised guidelines for validation of methods by intercomparison study;

(f) 'feed test material' means a feedingstuff sample or premixture sample with or without the inclusion of the feed additive which is the object of the application, to be used for experimental studies on the method of analysis for the determination of the feed additive in feedingstuffs and/or premixtures;

(g) 'food test material' means a food sample derived from an animal that has been fed with feedingstuffs with or without the inclusion of the feed additive which is the object of the application, to be used for experimental studies on the method of analysis for the determination of the feed additive in the residue(s) or metabolite(s).

Article 3

Reference samples

1. Any person making an application shall send reference samples:

(a) in a form in which the feed additive is intended to be placed on the market by the applicant; or

(b) that are suitable to be converted easily in a form in which the feed additive is intended to be placed on the market by the applicant.

2. The three reference samples shall be accompanied by a written statement by the applicant that the fee provided for in Article 4(1) has been paid.

3. The applicant shall supply feed and/or food test materials related to the samples if requested by the CRL.

Article 4

Fees

1. The CRL shall charge the applicant a fee of EUR 3 000 for each application (the fee).

2. The CRL shall use the fees towards supporting the costs of the duties and tasks as set out in Annex II to Regulation (EC) No 1831/2003, and in particular those referred to in 2.1, 2.2 and 2.3 of that Annex.

3. The amount of the fee mentioned in paragraph 1 may be adapted once a year in accordance with the procedure referred to in Article 22(2) of Regulation (EC) No 1831/2003. The adaptation shall take into account the experience gained during the operation of this Regulation and in particular the possibility of fixing different fees for different types of applications.

Article 5

Evaluation reports by the CRL

1. The CRL shall submit a full evaluation report to the European Food Safety Authority (the Authority) for each application within three months from the date of receipt of a valid application as referred to in Article 8(1) of Regulation (EC) No 1831/2003 and the payment of the fee. However, if the CRL considers that the application is very complex, it may extend that period by an additional month. The CRL shall inform the Commission, the Authority and the applicant where the period is extended.

2. The evaluation report provided for in paragraph 1 shall include in particular:

(a) an evaluation indicating if the methods of analysis in the data submitted in the application are suitable to be used for official controls;

(b) an indication if testing of a method of analysis is considered necessary;

(c) an indication if a validation of a method of analysis by an intercomparison study is considered necessary.

CHAPTER II

NATIONAL REFERENCE LABORATORIES

Article 6

National reference laboratories

1. The CRL shall be assisted by a consortium of national reference laboratories (the consortium) for the duties and tasks set out in 2.2, 2.4 and 3 of Annex II to Regulation (EC) No 1831/2003.

2. The consortium is open to national reference laboratories which comply with the requirements set out in Annex I. The laboratories listed in Annex II are hereby appointed national reference laboratories to take part in the consortium.

3. The members of the consortium, including the CRL, shall enter into a contract to define the relations between them, particularly in financial matters. In particular, the contract may provide that the CRL is to distribute a share of the fees it receives to the other members of the consortium. Subject to this contract, the CRL may issue guidance to the members of the consortium as provided for in Article 12.

4. Any Member State may submit requests to the Commission for the designation of further national reference laboratories to take part in the consortium. If it considers that such laboratories comply with the requirements set out in Annex I, the Commission shall amend the list in Annex II in accordance with the procedure referred to in Article 22(2) of Regulation (EC) No 1831/2003. The same procedure shall apply if a Member State wishes to withdraw one of its national reference laboratories from the consortium. The contractual arrangements between the members of the consortium shall be adjusted to reflect any changes to the consortium.

Article 7

Rapporteur laboratories

1. The CRL shall appoint one laboratory to act as rapporteur laboratory for each application (the rapporteur laboratory).

However, the CRL may also act as rapporteur laboratory for applications.

2. When appointing a rapporteur laboratory, the CRL shall take into account the expertise, experience and workload of the laboratory.

3. The laboratories shall send comments to the rapporteur laboratory within 20 days from the date of receipt of the initial evaluation report provided for in Article 8(a).

Article 8

Duties and tasks of rapporteur laboratories

The rapporteur laboratories shall be responsible for:

(a) drafting an initial evaluation report concerning the data submitted in each application and submitting it for comments to the other laboratories;

(b) compiling the comments received from the other laboratories and preparing a revised evaluation report;

(c) submitting the revised evaluation report to the CRL in sufficient time to allow the CRL to submit its full evaluation report to the Authority within the deadline referred to in Article 5(1).

Article 9

Duties and tasks of the laboratories participating in the consortium

1. The laboratories participating in the consortium shall be responsible for contributing to the initial evaluation report prepared by the rapporteur laboratory by sending comments to the rapporteur laboratory within 20 days of the reception of the initial report.

2. Each laboratory shall communicate to the CRL by 30 January each year an estimate of the number of applications for which the laboratory considers itself able to carry out the tasks of rapporteur laboratory for that year. The CRL shall make available annually to all the laboratories a compilation of the estimates provided.

CHAPTER III

TESTING AND VALIDATION OF METHODS OF ANALYSIS, REPORTING AND GUIDANCE

Article 10

Testing of methods of analysis and validation of methods of analysis

1. The CRL shall indicate in its evaluation report to the Authority, as provided for in Article 5(2), and shall inform the applicant and the Commission, if it considers that the following are necessary:

(a) testing of methods of analysis;

(b) validation of methods of analysis.

In doing so, the CRL shall provide the applicant with a document describing the work to be carried out through the consortium including a time schedule and an estimate of a special fee to be paid by the applicant. The applicant shall inform the CRL about his agreement to the document within 15 days of receipt of the communication.

2. The CRL shall supplement the report to the Authority, as provided for in Article 5(1), with an addendum concerning the outcome of the application of the procedure foreseen in paragraph 1 within 30 days of the availability to the CRL of the results of the testing and validation work.

Article 11

Reporting

The CRL shall be responsible for preparing an annual report on each year's activities carried out for the implementation of this Regulation and shall submit it to the Commission. The consortium shall contribute to this annual report.

The CRL may also organise an annual meeting with the consortium, in view of the establishment of the annual report.

Article 12

Guidance

1. The CRL may establish detailed guidance for applicants concerning:

(a) reference samples;

(b) the testing of methods of analysis, including in particular criteria about when such testing may be required;

(c) the validation of methods of analysis, including in particular criteria about when such validation may be required.

2. The CRL shall establish detailed guidance for laboratories, including criteria for appointing rapporteur laboratories.

CHAPTER IV

FINAL PROVISIONS

Article 13

Amendments to Regulation (EC) No 1831/2003

Paragraphs 2 and 3 of Annex II to Regulation (EC) No 1831/2003 are replaced by the text in Annex III to this Regulation.

Article 14

Entry into force

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

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

Done at Brussels, 4 March 2005.

For the Commission
Markos KYPRIANOU
Member of the Commission

ANNEX I

Requirements for laboratories participating, as referred to in Article 8

Laboratories participating in the consortium must satisfy the following minimum requirements:

(a) have been proposed as a national reference laboratory by a Member State for the purpose of taking part in the consortium referred to in Annex II to Regulation (EC) No 1831/2003;

(b) have suitable qualified staff that are adequately trained in analytical methods used for the feed additives on which they are involved;

(c) possess the equipment needed to carry out the analysis of feed additives, in particular the ones on which they are carrying tasks under this Regulation;

(d) have an adequate administrative infrastructure;

(e) have sufficient data-processing capacity to produce technical reports and to enable rapid communication with the other laboratories participating in the consortium;

(f) provide assurance that their staff respect the confidential aspects of issues, results or communications involved in the handling of applications for authorisation submitted in accordance with Regulation (EC) No 1831/2003 and in particular the information referred to in Article 18 of that Regulation;

(g) have sufficient knowledge of international standards and practices in laboratory work;

(h) must be accredited, or being in the process of accreditation according to international standards such as ISO 17025.

ANNEX II

Community reference laboratory and consortium of national reference laboratories, as referred to in Article 6(2)

COMMUNITY REFERENCE LABORATORY

Joint Research Centre of the European Commission. Institute for Reference Materials and Measurements, Geel, Belgium.

NATIONAL REFERENCE LABORATORIES OF THE MEMBER STATES

Belgique/België

— Federaal Voedingslabo Tervuren (FAVV), Tervuren,

— Vlaamse Instelling voor Technogisch Onderzoek (VITO), Mol;

Česká republika

— Central Inst. Superv. Test. Agriculture, Ústřední kontrolní a zkušební ústav zemědělský (ÚKZÚZ), Praha;

Danmark

— Plantedirektoratets Laboratorium, Lyngby;

Deutschland

— Schwerpunktlabor Futtermittel des Bayerischen Landesamtes für Gesundheit und Lebensmittelsicherheit (LGL). Oberschleißheim;

— Landwirtschaftliche Untersuchungs- und Forschungsanstalt (LUFA) Speyer. Speyer;

— Sächsische Landesanstalt für Landwirtschaft. Fachbereich 8 — Landwirtschaftliches Untersuchungswesen. Leipzig;

— Thüringer Landesanstalt für Landwirtschaft (TLL). Abteilung Untersuchungswesen. Jena;

Eesti

— Põllumajandusuuringute Keskus (PMK), Jääkide ja saasteainete labor, Saku, Harjumaa,

— Põllumajandusuuringute Keskus (PMK), Taimse materjali analüüsi labor, Saku, Harjumaa;

España

— Laboratorio Arbitral Agroalimentario, Ministerio de Agricultura, Pesca y Alimentación, Madrid.

— Laboratori Agroalimentari, Departament d'Agricultura, Ramaderia i Pesca, Generalitat de Catalunya, Cabrils.

France

— Laboratoire de Rennes, direction générale de la concurrence, de la consommation et de la répression des fraudes (DGCCRF), Rennes;

Ireland

— The State Laboratory, Dublin;

Italia

— Istituto Superiore di Sanità. Dipartimento di Sanità alimentare ed animale, Roma.

— Centro di referenza nazionale per la sorveglianza ed il controllo degli alimenti per gli animali (CReAA), Torino.

Κύπρος

— Feedingstuffs Analytical Laboratory, Department of Agriculture, Nicosia;

Latvija

— Valsts veterinārmedicīnas diagnostikas centrs (VVMDC), Rīga;

Lietuvos

— Nacionalinė veterinarijos laboratorija, Vilnius,

— Klaipėdos apskrities VMVT laboratorija, Klaipėda;

Luxembourg

— Laboratoire de contrôle et d'essais — ASTA, Ettelbrück;

Magyarország

— Országos Mezőgazdasági Minősítő Intézet (OMMI) Központi Laboratórium, Budapest;

Nederland

— RIKILT- Instituut voor Voedselveiligheid, Wageningen,

— Rijkinstituut voor Volksgezondheid en Milieu (RIVM), Bilthoven;

Österreich

— Österreichische Agentur für Gesundheit und Ernährungssicherheit (AGES), Wien;

Polska

— Instytut Zootechniki w Krakowie, Krajowe Laboratorium Pasz, Lublin,

— Państwowy Instytut Weterynaryjny, Puławy;

Portugal

— Laboratório Nacional de Investigação Veterinária, Lisboa.

Slovenija

— Univerza v Ljubljani. Veterinarska fakulteta, Nacionalni veterinarski inštitut, Enota za patologijo prehrane in higieno okolja, Ljubljana,

— Kmetijski inštitut Slovenije, Ljubljana;

Slovensko

— Skúšobné laboratórium – oddelenie analýzy krmív, Ústredný kontrolný a skúšobný ústav poľnohospodársky, Bratislava.

Suomi/Finland

— Kasvintuotannon tarkastuskeskus/Kontrollcentralen för växtproduktion (KTTK). Vantaa/Vanda;

Sverige

— Foderavdelningen, Statens veterinärmedicinska anstalt (SVA), Uppsala.

United Kingdom

— The Laboratory of the Government Chemist, Teddington.

NATIONAL REFERENCE LABORATORIES OF EFTA COUNTRIES

Norway

— LabNett AS, Agricultural Chemistry Laboratory, Stjørdal.

ANNEX III

Text replacing paragraphs 2 and 3 of Annex II to Regulation (EC) No 1831/2003

'2. For the duties and tasks set out in this Annex, the CRL may be assisted by a consortium of national reference laboratories.

The CRL shall be responsible for:

2.1. the reception, storage and maintenance of the samples of the feed additive sent by the applicant as provided for in Article 7(3)(f);

2.2. evaluating the method of analysis of the feed additive, and of other relevant methods of analysis related to it, on the basis of the data provided in the application for authorisation of the feed additive as regards its suitability for official control in accordance with the requirements of the implementing rules referred to in Article 7(4) and (5) and the guidance of the Authority referred to in Article 7(6);

2.3. submitting a full evaluation report to the Authority on the results of the duties and tasks referred to in this Annex;

2.4. where necessary, the testing of the method(s) of analysis.

3. The CRL shall be responsible for coordination of the validation of the method(s) of analysis of the additive, in accordance with the procedure provided for in Article 10 of Regulation (EC) No 378/2005 (*). This task may involve the preparation of food or feed test material.

4. The CRL shall provide scientific and technical assistance to the Commission, especially in cases where Member States contest the results of analyses related to the duties and tasks referred to in this Annex, without prejudice to any role defined for it under Articles 11 and 32 of Regulation (EC) No 882/2004 of the European Parliament and of the Council (**).

5. On request by the Commission, the CRL may also be responsible for conducting special analytical or other related studies in a manner similar to the duties and tasks referred to in point 2. This may be the case, in particular, for existing products notified under Article 10 and included in the Register and for the period until an application for authorisation under Article 10(2) is submitted in accordance with Article 10(2).

6. The CRL shall be responsible for the overall coordination of the consortium of national reference laboratories. The CRL shall ensure that the relevant data concerning the applications are made available to the laboratories.

7. Without prejudice to the responsibilities of the Community reference laboratories laid down in Article 32 of Regulation (EC) No 882/2004, the CRL may create and maintain a database of methods of analysis available for control of feed additives and make it available to official control laboratories from Member States and other interested parties.

(*) OJ L 59, 5.3.2005, p. 8.
(**) OJ L 165, 30.4.2004, p. 1. Corrigendum OJ L 191, 28.5.2004, p. 1.'

COMMISSION REGULATION (EC) No 379/2005

of 4 March 2005

amending Regulation (EC) No 1168/1999 laying down marketing standards for plums

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EC) No 2200/96 of 28 October 1996 on the common organisation of the market in fruit and vegetables [1], and in particular Article 2(2) thereof,

Whereas:

(1) Commission Regulation (EC) No 537/2004 of 23 March 2004 adapting several regulations concerning the market of fresh fruit and vegetables by reason of the accession of the Czech Republic, Estonia, Cyprus, Latvia, Lithuania, Hungary, Malta, Poland, Slovenia and Slovakia to the European Union [2] added several varieties to the non-exhaustive list of large-fruited varieties of *Prunus domestica* by replacing the Appendix to the Annex to Commission Regulation (EC) No 1168/1999 [3]. However, the new Appendix does not contain the non-exhaustive list of large-fruited varieties of *Prunus salicina* it included before the amendment, following the recommendation of the United Nations Economic Commission for Europe to distinguish between varieties of *Prunus domestica* and those of *Prunus salicina*. In the interest of transparency on the world market, that list should be re-established.

(2) Regulation (EC) No 1168/1999 should therefore be amended accordingly.

(3) The measures provided for in this Regulation are in accordance with the opinion of the Management Committee for Fresh Fruit and Vegetables,

HAS ADOPTED THIS REGULATION:

Article 1

The Appendix to the Annex to Regulation (EC) No 1168/1999 is amended in accordance with the Annex to this Regulation.

Article 2

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

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

Done at Brussels, 4 March 2005.

For the Commission
Mariann FISCHER BOEL
Member of the Commission

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[1] OJ L 297, 21.11.1996, p. 1. Regulation as last amended by Commission Regulation (EC) No 47/2003 (OJ L 7, 11.1.2003, p. 64).
[2] OJ L 86, 24.3.2004, p. 9.
[3] OJ L 141, 4.6.1999, p. 5. Regulation as last amended by Regulation (EC) No 907/2004 (OJ L 163, 30.4.2004, p. 50).

ANNEX

The Appendix to the Annex to Regulation (EC) No 1168/1999 is amended as follows:

1. The title of the table is replaced by the following:

   '1. **Non-exhaustive list of large-fruited varieties of *Prunus domestica*'**

2. The following text is added:

   '2. **Non-exhaustive list of large-fruited varieties of *Prunus salicina***

Variety Cultivar and/or trade name	Synonyms
Allo	
Andy's Pride	
Angeleno	
Autumn Giant	
Autumn Pride	
Beaut Sun	
Beauty	Beaty
Bella di Barbiano	
Black Amber	
Black Beaut	
Black Gold	
Black Rosa	
Black Royal	
Black Star	
Black Sun	
Burbank	
Burmosa	
Calita	
Casselman	Kesselman
Catalina	
Celebration	
Centenaria	
Del Rey Sun	
Delbarazur	
Dólar	
Eclipse	
Eldorado	
Eric Sun	
Flavor King	
Formosa	
Fortune	
Friar	
Frontier	
Gavearli	
Gaviota	
Globe Sun	
Goccia d'Oro	
Golden Japan	Shiro

Variety Cultivar and/or trade name	Synonyms
Golden King	
Golden Kiss	
Golden Plum	
Goldsweet 4	
Grand Rosa	
Green Sun	
Hackman	
Harry Pickstone	
Howard Sun	
Kelsey	
Lady Red	
Lady West	
Laetitia	
Laroda	
Larry Ann	Larry Anne, Tegan Blue, Freedom
Late Red	
Late Santa Rosa	
Linda Rosa	
Mariposa	Improved Satsuma, Satsuma Improved
Methley	
Midnight Sun	
Morettini 355	Cœur de Lion
Narrabeen	
Newyorker	
Nubiana	
Obilnaja	
October Sun	
Original Sun	
Oro Miel	
Ozark Premier	Premier
Pink Delight	
Pioneer	
Queen Ann	
Queen Rosa	
Red Beaut	
Red Rosa	
Red Sweet	
Redgold	
Redroy	
Reubennel	Ruby Nel
Royal Black	
Royal Diamond	
Royal Garnet	
Royal Star	
Roysum	

Variety Cultivar and/or trade name	Synonyms
Ruby Blood	
Ruby Red	
Sangue di Drago	
Santa Rosa	
Sapphire	
Satsuma	
Simka	
Sir Prize	Akihime
Songold	
Southern Belle	
Southern Pride	
Souvenir	
Souvenir II	
Spring Beaut	
Starking Delicious	
Stirling	
Suplumeleven	
Suplumthirteen	
Suplumtwelve	
Susy	
TC Sun	
Teak Gold	
Top Black	
Tracy Sun	
Wickson	
Yakima	
Yellow Sun	
Zanzi Sun'	

II

(Acts whose publication is not obligatory)

COMMISSION

COMMISSION DECISION

of 28 February 2005

establishing guidance notes supplementing part B of Annex II to Council Directive 90/219/EEC on the contained use of genetically modified micro-organisms

(notified under document number C(2005) 413)

(Text with EEA relevance)

(2005/174/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Directive 90/219/EEC of 23 April 1990 on the contained use of genetically modified micro-organisms [1], and in particular the introductory paragraph of part B of Annex II thereto,

After consulting the European Food Safety Authority [2],

Whereas:

(1) The criteria listed in part B of Annex II to Directive 90/219/EEC must be met in order to establish the safety of a genetically modified micro-organism (GMM) for human health and the environment and its suitability for inclusion in part C of Annex II to that Directive.

(2) The application of those criteria should be facilitated through the provision of guidance notes for Member States, as an aid to ensuring that the national competent authorities carry out their preliminary assessment in an appropriate manner and provide appropriate information to users as to the content of dossiers to be submitted.

(3) The measures provided for in this Decision are in accordance with the opinion of the Committee established under Article 21 of Directive 90/219/EEC,

HAS ADOPTED THIS DECISION:

Article 1

The guidance notes set out in the Annex to this Decision shall be used to supplement part B of Annex II to Directive 90/219/EEC.

Article 2

This Decision is addressed to the Member States.

Done at Brussels, 28 February 2005.

For the Commission
Stavros DIMAS
Member of the Commission

[1] OJ L 117, 8.5.1990, p. 1. Directive as last amended by Regulation (EC) No 1882/2003 of the European Parliament and of the Council (OJ L 284, 31.10.2003, p. 1).
[2] The EFSA Journal (2003) 18, pp. 1 to 15.

ANNEXE

Notes explicatives complétant l'annexe II, partie B, de la directive 90/219/CEE

INTRODUCTION

Seuls les types de MGM qui satisfont aux critères généraux et aux critères spécifiques énoncés dans la partie B de l'annexe II sont jugés recevables pour figurer dans la partie C de l'annexe II.

Tous les MGM figurant dans la partie C de l'annexe II seront publiés au Journal officiel, accompagnés de leurs caractéristiques d'identification ou sources de référence appropriées. Pour déterminer si un type de MGM peut être inscrit à l'annexe II, partie C, il y a lieu d'examiner tous les éléments et, le cas échéant, le processus utilisé pour construire le MGM. Il convient de signaler que, même si tous les aspects doivent être pris en considération, seules les propriétés du MGM seront examinées au regard des critères énoncés à l'annexe II, partie B. Si tous les constituants du MGM ont été examinés individuellement et jugés sans danger, il est probable que le MGM satisfera aux critères d'innocuité. Cela ne doit cependant pas être considéré comme acquis et cette hypothèse doit être vérifiée avec soin.

Si des MGM intermédiaires sont produits pour obtenir un MGM définitif, ces intermédiaires doivent aussi être examinés au regard des critères de l'annexe II, partie B, pour chaque type considéré, afin d'exclure de facto l'utilisation confinée dans son ensemble. Les États membres doivent veiller à ce que les présentes lignes directrices soient appliquées par les utilisateurs, afin de faciliter le respect des critères lors de la préparation des dossiers établissant l'innocuité des types de MGM à inscrire dans la partie C de l'annexe II, ainsi que par les autorités nationales compétentes pour évaluer le respect de la réglementation.

Les dossiers doivent contenir des éléments de preuve précis et concrets pour permettre aux États membres de vérifier que les déclarations concernant l'innocuité des MGM au regard des critères susmentionnés sont justifiées. Il conviendra d'appliquer le principe de précaution en cas d'incertitude scientifique, et aucune exemption ne sera envisagée pour un MGM en l'absence de preuves convaincantes du respect de ces critères.

L'autorité nationale compétente qui reçoit un dossier à cet effet doit, après s'être assurée du respect des critères, transmettre ce dossier à la Commission qui, à son tour, consulte le comité institué par l'article 21 de la directive au sujet de l'inscription du MGM en question à l'annexe II, partie C. Les définitions des termes utilisés sont données dans l'appendice 1.

1. CRITERES GÉNÉRAUX

1.1. *Vérification/authentification de la souche*

L'identité de la souche doit être établie et authentifiée, et le vecteur ou insert bien caractérisé en ce qui concerne sa structure et sa fonction telles qu'elles apparaissent dans le MGM final. Un historique détaillé de la souche (et de ses modifications génétiques) est très utile pour évaluer l'innocuité. Il convient de connaître les liens taxinomiques avec les micro-organismes apparentés, connus et nocifs, car cela peut renseigner sur d'éventuelles caractéristiques nocives qui ne s'expriment pas en temps normal, mais qui pourraient s'exprimer du fait de la modification génétique. Les systèmes de culture de cellules et de tissus eucaryotes doivent être vérifiés afin d'en établir l'identité suivant les critères de classifications internationales (par exemple: ATCC).

Les renseignements historiques, les comptes rendus de sécurité, les détails taxinomiques et les données sur les marqueurs phénotypiques et génétiques doivent être recherchés dans la littérature pertinente (par exemple: Bergey's Manual of *Determinative Bacteriology*, articles et revues scientifiques, et informations données par les sociétés qui fournissent l'ADN). Des renseignements utiles peuvent aussi être obtenus auprès des collections de cultures et des associations de collections de cultures telles que la Fédération mondiale des collections de cultures (FMCC) qui publie le répertoire mondial des collections de cultures de micro-organismes, et l'Organisation européenne des collections de cultures (ECCO). Les grandes collections de cultures européennes qui conservent de vastes groupes de micro-organismes doivent également être prises en considération. Dans le cas d'un nouvel isolat ou d'une souche n'ayant pas été étudiée à fond, toutes les questions restées en suspens devront trouver une réponse grâce aux tests effectués pour confirmer l'identité du MGM. La question de l'identité pourrait en effet se poser lorsque la souche du MGM diffère notablement de la ou des souches parentes, par exemple, lorsque le MGM est issu d'une fusion cellulaire ou lorsqu'il résulte de multiples modifications génétiques.

Les tests qui permettent de confirmer l'identité de la souche font appel aux méthodes suivantes: morphologie, coloration, examen au microscope électronique, typage sérologique, profils nutritionnels fondés sur l'utilisation et/ou la dégradation, analyse des isoenzymes, profil protéique et des acides gras, pourcentage des bases C + G, empreintes ADN/ARN, amplification de séquences ADN/ARN spécifiques, analyse par sondes génétiques, hybridation avec des sondes à ADN spécifiques de l'ARNr, et séquençage des acides nucléiques. Les résultats de ces tests doivent être dûment étayés.

La situation idéale pour l'identification des gènes présents dans le MGM final est lorsque la séquence complète de nucléotides du vecteur ou de l'insert est connue. La fonction de chaque unité génétique peut alors être expliquée. La taille du vecteur et de l'insert doit se limiter autant que possible aux séquences génétiques nécessaires pour remplir la fonction voulue, de manière à réduire le risque d'introduction et d'expression de fonctions cryptiques ou d'acquisition de caractéristiques génétiques non souhaitées.

1.2. *Attestation de l'innocuité*

Il convient d'apporter la preuve de la sécurité d'utilisation du MGM en produisant des résultats d'essais antérieurs, des données tirées de la littérature ou des comptes rendus attestant l'innocuité de l'organisme. Il est à noter qu'une sécurité d'utilisation attestée ne prouve pas nécessairement l'innocuité du MGM, notamment lorsque celui-ci a été utilisé dans des conditions rigoureusement contrôlées pour des raisons de sécurité.

L'attestation dûment établie de l'innocuité de la souche réceptrice ou parentale est déterminante pour décider si un MGM satisfait au critère d'innocuité. Le MGM peut toutefois différer notablement de ses parents et il faut donc vérifier que ces différences n'affectent pas la sécurité. Une prudence particulière s'impose si la modification génétique visait à éliminer une caractéristique nuisible ou pathogène de la souche réceptrice ou parentale. Dans ce cas, des documents prouvant clairement la suppression effective des caractéristiques nuisibles ou potentiellement nuisibles doivent être produits pour établir l'innocuité. En l'absence de données sur la souche réceptrice ou parentale considérée, il est possible d'utiliser les données rassemblées pour l'espèce. Ces données, complétées par un examen de la littérature et une étude taxinomique de la variation de la souche au sein de l'espèce, peuvent permettre de prouver l'innocuité de la souche réceptrice ou parentale concernée.

En l'absence d'informations permettant de prouver l'innocuité, les tests appropriés devront être effectués pour établir l'innocuité du MGM.

1.3. *Stabilité génétique*

La modification génétique ne doit pas rendre le MGM plus stable que le micro-organisme de départ si cela risque d'avoir des effets nuisibles.

Lorsque la sécurité est susceptible d'être compromise par une instabilité de la modification génétique, il convient de prouver la stabilité du MGM. Cette remarque vaut en particulier lorsque le MGM a fait l'objet d'une mutation inactivante pour atténuer des propriétés nocives.

2. CRITÈRES SPÉCIFIQUES

2.1. *Absence de pathogénicité*

Le MGM ne doit pas être capable de provoquer des maladies ou des effets nuisibles chez l'homme, les végétaux ou les animaux sains, dans des conditions normales d'utilisation ou à la suite d'un incident relativement prévisible comme une blessure par piqûre d'aiguille, une ingestion accidentelle, une exposition à un aérosol et une dissémination entraînant une exposition de l'environnement. S'il existe une probabilité que des individus immunodéprimés soient exposés au MGM, par exemple lorsque le MGM est destiné à être utilisé dans un environnement clinique, il y a lieu de tenir compte des effets possibles de cette exposition pour évaluer l'innocuité générale de cet MGM.

Les recherches bibliographiques et les informations de base rassemblées pour l'examen des critères généraux devraient fournir la plupart des informations requises pour la présente évaluation. Il convient également d'étudier les données relatives aux consignes de manipulation et de sécurité prescrites pour l'espèce considérée et les souches proches. La consultation des listes d'organismes pathogènes pour l'homme, pour les animaux ou pour les plantes est également conseillée.

Les vecteurs viraux eucaryotes dont l'inscription à l'annexe II, partie C, est envisagée ne doivent pas provoquer d'effets nocifs pour l'homme et pour l'environnement. Leur origine doit être connue, de même que les mécanismes permettant de les atténuer et de stabiliser les caractères concernés. Il convient autant que possible de confirmer la présence de tels caractères dans le virus, avant et après la modification. Avec de tels vecteurs, il est préférable de ne recourir qu'à des mutations par délétion. Les constructions utilisant des vecteurs viraux à ADN ou ARN issus de cultures de cellules hôtes où aucun virus infectieux n'est utilisé ou susceptible d'être produit sont également envisageables.

On peut considérer que les souches non virulentes d'espèces pathogènes avérées, comme les vaccins vivants pour l'homme et l'animal, ne posent pas de risque sanitaire et qu'elles remplissent donc les critères de l'annexe II, partie B, pour autant que:

1) l'innocuité de la souche soit établie et l'absence d'effets néfastes pour l'homme, l'animal ou l'environnement attestée (littérature), ou que

2) la souche présente un déficit stable en facteurs génétiques de virulence ou ait subi des mutations stables dont on sait qu'elles atténuent suffisamment la virulence (tests de pathogénicité, analyse génétique, sondes génétiques, détection de phages et de plasmides, cartographie de restriction, séquençage, sondes protéiques), et que son innocuité soit suffisamment attestée. Le risque de réversion d'une délétion ou d'une mutation de gène par un nouveau transfert de gène doit être pris en considération.

Si une étude bibliographique et taxonomique ne livre pas les informations voulues, il convient de soumettre le micro-organisme aux tests de pathogénicité appropriés. Ces tests doivent être réalisés sur le MGM, mais il peut se révéler opportun, dans certains cas, d'effectuer des tests sur la souche hôte ou parentale. Lorsque le MGM diffère considérablement de l'organisme ou des organismes dont il dérive, il faut veiller à ne pas tirer de conclusions hâtives quant à son absence de pathogénicité.

Voici quelques exemples de souches réceptrices ou parentales permettant d'obtenir des MGM susceptibles de satisfaire aux critères requis pour pouvoir figurer dans la partie C de l'annexe II:

— dérivés de souches bactériennes suffisamment inactivées, comme *Escherichia coli* K12 et *Staphylococcus aureus* 83254, dont la croissance et la survie dépendent de l'apport de nutriments absents chez l'homme ou dans l'environnement en dehors du milieu de culture (par exemple: besoins en acide diaminopimélique et en thymine),

— les cultures de cellules et de tissus eucaryotes (végétaux ou animaux, y compris de mammifères) peuvent également être considérées comme des hôtes suffisamment inactivés. Les MGM dérivés de ces cellules doivent remplir les autres critères mentionnés dans le présent document (absence d'agents adventices nuisibles et vecteurs non mobilisables),

— souches d'hôtes de types sauvages non pathogènes occupant des niches écologiques extrêmement spécialisées, de sorte qu'une dissémination accidentelle aurait un impact minime sur l'environnement, ou bien très répandues mais inoffensives, de sorte qu'une dissémination accidentelle aurait des conséquences minimes pour l'homme, l'animal et les plantes. Il s'agit par exemple d'hôtes tels que les bactéries lactiques, les rhizobactéries, les thermophiles extrêmes, les bactéries ou champignons produisant des antibiotiques. Il doit s'agir de micro-organismes dont les caractéristiques génétiques et moléculaires ont été bien étudiées.

Le vecteur ou l'insert tels qu'ils apparaissent dans le MGM final ne doivent pas contenir de gènes exprimant une protéine active ou un transcrit (facteurs de virulence, toxines, etc.) à des concentrations et sous une forme conférant au MGM un phénotype susceptible de provoquer une maladie chez l'homme, l'animal ou les plantes, ou d'entraîner des effets néfastes pour l'environnement.

Il convient d'éviter d'utiliser un vecteur ou un insert contenant des séquences qui codent pour des caractères nocifs chez certains micro-organismes, même s'ils ne confèrent pas au MGM un phénotype susceptible de provoquer une maladie chez l'homme, l'animal ou les plantes, ou d'entraîner des effets néfastes pour l'environnement. Il faut également veiller à ce que le matériel génétique inséré ne code pas pour un déterminant de pathogénicité capable de se substituer à une mutation inactivante présente dans l'organisme parental.

Le phénotype résultant d'un vecteur peut dépendre de l'organisme récepteur ou parental. Ce qui est vrai pour un hôte n'est pas automatiquement applicable lorsque la construction est transférée à un hôte différent. Par exemple, un rétrovirus inactivé utilisé comme vecteur dans des bactéries ou dans la plupart des lignées cellulaires serait incapable de produire des particules virales infectieuses. En revanche, ce même vecteur utilisé dans une lignée cellulaire d'encapsidation produirait des particules virales infectieuses et, selon la nature de la désactivation et des séquences insérées, pourrait conférer au MGM un phénotype susceptible de provoquer une maladie.

2.1.1. Absence de génotoxicité

Le MGM ne doit pas produire de toxines non voulues ni présenter une génotoxicité accrue du fait de la modification génétique. Les exotoxines, les endotoxines et les mycotoxines figurent parmi les toxines bactériennes. L'examen de la souche réceptrice ou parentale peut donner d'utiles informations sur ce point.

Lorsque la souche réceptrice ou parentale est exempte de toxines, il faut prendre garde à ce que le vecteur ou l'insert n'introduise pas de toxines et à ce qu'il ne stimule ou ne déréprime pas la production de toxines. La recherche de toxines doit être effectuée avec soin, bien que la présence de ces substances ne signifie pas nécessairement qu'il faille exclure le MGM de l'annexe II, partie C.

2.1.2. Absence d'allergénicité

Alors que tous les micro-organismes sont potentiellement allergisants, certaines espèces sont des allergènes reconnus dont on peut trouver la liste dans les directives 93/88/CEE du Conseil et 95/30/CE de la Commission [1] et 95/30/CE de la Commission [2] et dans leurs versions modifiées. Il convient d'examiner si le MGM considéré appartient à ce groupe. Les constituants allergisants des micro-organismes comprennent les parois cellulaires, les spores, les métabolites naturels (par exemple: enzymes protéolytiques) et certains antibiotiques. Si le vecteur et l'insert sont exprimés dans le MGM final, le produit génique ne doit pas avoir d'activité biologique susceptible de produire des allergènes notables. Il est à noter que ce critère ne peut pas être appliqué de manière absolue.

2.2. *Absence d'agents pathogènes nuisibles*

Le MGM ne doit pas contenir d'agents adventices connus tels que mycoplasmes, virus, bactéries, champignons ou autres cellules végétales ou animales, symbiotes, susceptibles d'entraîner des effets néfastes. L'utilisation d'une souche réceptrice ou parentale notoirement exempte d'agents adventices nuisibles permet d'éviter ce risque, mais il ne faut pas partir du principe qu'un MGM est nécessairement exempt d'agents adventices parce que le ou les organismes parentaux l'étaient. Il se peut en effet que de nouveaux agents aient été introduits pendant la construction du MGM.

Il convient en particulier de vérifier avec soin que les cultures de cellules animales ne contiennent pas d'agents adventices potentiellement nocifs comme le virus de la chorio-méningite lymphocytaire ou des mycoplasmes tels que *Mycoplasma pneumoniae*. Les agents adventices sont parfois difficiles à détecter. Tous les éléments tendant à réduire l'efficacité du dépistage doivent être pris en considération.

2.3. *Transfert de matériel génétique*

Le matériel génétique inséré dans le MGM ne doit pas être transférable ni mobilisable si cela risque de conférer un phénotype nocif au micro-organisme récepteur.

Le vecteur et l'insert ne doivent transférer aucun marqueur de résistance au MGM si la résistance risque de compromettre le traitement thérapeutique. La présence de tels marqueurs n'implique pas a priori que le MGM ne pourra pas être inscrit à l'annexe II, partie C, mais elle fait ressortir la nécessité de veiller à ce que de tels gènes ne soient pas mobilisables.

Si le vecteur est un virus, un cosmide ou tout type de vecteur dérivé d'un virus, il doit aussi être rendu non lysogène lorsqu'il est utilisé comme vecteur de clonage (absence du répresseur cI-lambda). L'insert ne doit pas être mobilisable du fait de la présence, par exemple, de séquences de provirus transférables ou d'autres séquences de transposition fonctionnelles.

Certains vecteurs qui sont intégrés dans le chromosome de l'hôte peuvent aussi être considérés comme non mobilisables, mais l'analyse doit être effectuée cas par cas, notamment en ce qui concerne les mécanismes susceptibles de faciliter la mobilité des chromosomes (par exemple, présence d'un facteur sexuel chromosomique) ou la transposition à d'autres réplicons pouvant être présents chez l'hôte.

2.4. *Innocuité pour l'environnement en cas de dissémination involontaire*

Des dommages pour l'environnement ne peuvent survenir qu'à la condition que le MGM puisse survivre et qu'il présente des caractéristiques dangereuses. Lors de l'évaluation des dommages pour l'environnement, il y a lieu de tenir compte des diverses conditions environnementales existant dans les États membres et, si nécessaire, d'envisager des scénarios extrêmes. Le cas échéant, les modalités des précédentes disséminations (volontaires ou non) seront précisées, ainsi que tout effet associé sur l'environnement.

2.4.1. Survie des organismes

Pour déterminer si un MGM est susceptible d'avoir des effets néfastes pour l'environnement ou de provoquer des maladies chez les animaux et les végétaux, il faut chercher à savoir si ses caractéristiques biologiques vont renforcer, maintenir ou affaiblir sa capacité de survie dans l'environnement. Si le MGM est rendu biologiquement incapable de survivre dans l'environnement, il ne survivra pas longtemps en dehors du confinement, de sorte que le risque d'interaction avec l'environnement est limité.

L'étude des éventuels effets néfastes pour l'environnement doit aussi tenir compte du devenir possible des MGM disséminés involontairement dans le réseau trophique.

[1] JO L 268 du 29.10.1993, p. 71.
[2] JO L 155, 6.7.1995, p. 41.

2.4.2. Dispersion

Pour pouvoir s'implanter dans l'environnement, un MGM doit survivre à la dispersion, trouver une niche et s'y installer. La méthode de dispersion et la probabilité de survie pendant la dispersion doivent être prises en considération. De nombreux micro-organismes survivent lorsqu'ils sont dispersés dans des aérosols et des gouttelettes ou via des insectes et des vers, par exemple.

2.4.3. Implantation des organismes dans l'environnement

L'implantation dans un environnement particulier dépend de la nature de l'environnement dans lequel le MGM est disséminé et de sa capacité à survivre au transfert dans ce nouvel environnement. Le potentiel d'implantation dans une niche appropriée varie en fonction de la taille de la population viable, de la taille de la niche et de la fréquence des niches adaptées à l'espèce. Ce potentiel est différent pour chaque espèce. La résistance ou la sensibilité aux facteurs de stress biotique et abiotique joue également un rôle important dans l'implantation d'un MGM dans l'environnement. La persistance d'un MGM dans l'environnement pendant une période assez longue est liée à sa capacité à survivre et à s'adapter aux conditions environnementales ou à développer un taux de croissance compétitif. Ces facteurs peuvent être influencés par la modification génétique et le site de l'intégration. Dans certains cas, la modification génétique est peu susceptible de produire cet effet, notamment lorsque:

— le produit génique contribuant à la formation d'un métabolite secondaire, formé à la fin de la croissance, est incapable d'initier la croissance.

2.4.4. Transfert de matériel génétique

On dispose aujourd'hui de davantage d'informations sur le transfert de matériel génétique entre micro-organismes. Même si le MGM a une capacité de survie très limitée, il importe de déterminer la capacité du matériel génétique introduit à persister dans l'environnement ou à être transféré à d'autres organismes et à créer des nuisances. Il a été démontré que le transfert de matériel génétique intervenait, en conditions expérimentales, par exemple, dans le sol (y compris dans la rhizosphère), dans l'appareil digestif des animaux et dans l'eau, par conjugaison, transduction ou transformation.

Le risque de transfert de matériel génétique à partir d'un MGM qui a une faible probabilité de croissance et des chances de survie limitées est très faible. Un transfert actif est quasiment exclu si le MGM ne contient pas de plasmides autotransférables ou de phages transducteurs. Le risque est très faible si le vecteur/insert n'est pas autotransférable et s'il est peu mobilisable.

APPENDIX 1

Definitions of terms used in this document

Adventitious agents — other micro-organisms, active or latent, existing alongside/inside the required micro-organism.

Antigen — any molecule which induces B cells to produce a specific antibody. A molecule which can be specifically recognised by the adaptive elements of the immune system, that is by B cells or T cells or both.

Allergen — an antigen which can sensitise individuals such that a hypersensitivity reaction is provoked in individuals on subsequent exposure to this allergen.

Allergy — immediate hypersensitivity reactions, occurs when an IgE response is directed against an innocuous antigen such as a non-pathogenic, non-viable bacteria cell. The resulting release of pharmacological mediators by IgE sensitised mast cells produces an acute inflammatory reaction with symptoms such as asthma, eczema, or rhinitis.

Conjugation — the active transfer of DNA from one host to another.

Cosmid — type of cloning vector comprising a plasmid in which the *cos* sequences of a lambda phage have been inserted.

Disease — any disturbance of structure or function in an immunocompetent human, animal or plant of such a degree as to produce detectable illness or disorder.

Expression — the process of producing RNA transcripts, proteins and polypeptides using the information contained in the genes, of the GMM. In this guidance expression is also a measure of the anticipated or known level of expression of the inserted genetic material.

Mobilisation — the passive transfer from one host to another.

Mobilisation defective — vectors defective in one or more transfer functions and which are unlikely to be mobilised by other elements which supply the missing functions.

Pathogenicity — the ability of the micro-organism to cause disease which can be by infection, toxicity or allergenicity. Pathogenicity is a taxonomically significant attribute and is the property of a species.

Plasmid — an extrachromosomal self-replicating piece of DNA, found in many micro-organisms, that generally confer some evolutionary advantage to the host cell.

Recipient or parental micro-organism — the micro-organism(s) to which the genetic modification occurred.

Rhizobacteria — bacteria which inhabit the rhizosphere, i.e. the soil adhering to plant roots, eventually entering the roots either intracellularly or intercellularly. Rhizobacteria are often used as microbial/seed inoculants in agriculture.

Transduction — the incorporation of bacterial DNA in bacteriophage particles and their transfer to recipient bacteria.

Transformation — the uptake of naked DNA by a cell.

Vector — a carrier DNA or RNA molecule, e.g. plasmid, bacteriophage into which a genetic material sequence can be inserted for introduction into a new host cell where it will be replicated *and* in some cases expressed.

Virulence — the capacity to cause harm. Individual strains of a micro-organism can vary widely in their ability to harm the host species.

COMMISSION RECOMMENDATION

of 1 March 2005

concerning a coordinated programme for the official control of foodstuffs for 2005

(Text with EEA relevance)

(2005/175/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Directive 89/397/EEC of 14 June 1989 on the official control of foodstuffs [1], and in particular Article 14(3) thereof,

After consulting the Standing Committee on the Food Chain and Animal Health,

Whereas:

(1) It is necessary, with a view to the sound operation of the internal market, to arrange for coordinated food inspection programmes at Community level designed to improve the harmonised implementation of official controls of foodstuffs by the Member States.

(2) Such programmes should place emphasis on compliance with Community legislation on foodstuffs, which is particularly designed to protect public health and consumer interests, and to ensure fair trade practices.

(3) Directive 89/397/EEC lays down the general principles for the performance of official control of foodstuffs, including the inspections to be carried out by the competent authorities of the Member States. It also provides for the Commission to transmit annually a recommendation concerning a coordinated programme of inspections for the following year.

(4) Commission Recommendation of 19 December 2003 concerning a coordinated programme for the official control of foodstuffs for 2004 [2], sets out certain recommendations for a coordinated programme of official controls, including the assessment of the bacteriological safety of cheeses made from raw or thermised milk. This investigation should be extended to other categories of cheeses made from pasteurised milk in order to be able to draw meaningful conclusions on the safety of these products.

(5) Council Directive 93/99/EEC of 29 October 1993 on the subject of additional measures concerning the official control of foodstuffs [3] supplements the rules laid down in Directive 89/397/EEC. It provides that the official laboratories in Member States, as referred to in Article 7 of Directive 89/397/EEC, are to comply with the criteria set out in European Standard EN 45000 series, now replaced by EN ISO 17025:2000.

(6) The implementation of coordinated programmes is without prejudice of all other official controls carried out by Member States in the framework of their national control programmes.

(7) The results from the simultaneous implementation of national programmes and coordinated programmes may provide information and experience on which to base future control activities and legislation,

HEREBY RECOMMENDS:

1. During 2005 Member States should carry out inspections and controls including, where indicated, taking samples and analysing such samples in laboratories, with the aim of:

   (a) assessing the bacteriological safety of cheeses made from pasteurised milk (continuation of the coordinated programme started in 2004 following the Recommendation of 19 December 2003 concerning a coordinated programme for the official control of foodstuffs for 2004);

   (b) assessing the bacteriological safety of mixed salads as regards *Listeria monocytogenes*;

[1] OJ L 186, 30.6.1989, p. 23.
[2] OJ L 6, 10.1.2004, p. 29.
[3] OJ L 290, 24.11.1993, p. 14. Directive as last amended by Regulation (EC) No 1882/2003 of the European Parlament and of the Council (OJ L 284, 31.10.2003, p. 1).

(c) assessing safety, quality and labelling of poultry meat as regards the use of water retention agents;

(d) assessing the safety of certain foods for infants and young children as regards the levels for nitrate and patulin.

2. Although sampling and/or inspection rates are not set out in this Recommendation, Member States should ensure that those rates are sufficient to provide an overview of the subject under consideration in each Member State.

3. Member States should provide information as requested following the format of the record sheets set out in Annexes I to IV to help enhance the comparability of results. That information should be sent to the Commission, at the latest by 1 May 2006, accompanied by an explanatory report which should include comments on the results and on the enforcement measures taken.

4. Foodstuffs to be analysed under the coordinated programme for 2005 should be submitted to official laboratories complying with Article 3 of Directive 93/99/EEC. However, if such laboratories do not exist in Member States for certain analyses covered by this Recommendation, Member States may nominate other laboratories providing the capacity to carry out these analyses.

5. Bacteriological safety of cheeses made from pasteurised milk

5.1. Scope of the coordinated programme for 2005

The aim of this element of the programme is to continue the microbiological investigation started in 2004 under the coordinated programme for 2004, which only focused on cheeses made from raw or thermised milk, in order to cover other cheeses made from milk submitted to a higher heat treatment than thermisation (i.e. pasteurisation). This extension of the coordinated programme is recommended in order to be able to draw meaningful conclusions on the safety of cheeses. The results of this investigation will be analysed and provided together with the results of the 2004 survey in order to have a general overview in this sector.

5.2. Sampling and method of analysis

The investigations should concern fresh, soft and semi-hard cheeses made from milk which has been submitted to a pasteurisation process. The competent authorities of the Member States should take representative samples of these products, both at production and retail levels, including imported products, with a view to testing for the presence of *Salmonella* and *Listeria monocytogenes* and enumeration of *Staphylococcus aureus* and *Escherichia coli*. If *Listeria monocytogenes* is detected, the number of these bacteria should be enumerated. When samples are taken at retail level, tests may be limited to the presence of *Salmonella* and enumeration of *Listeria monocytogenes*. The samples, of 100 grams minimum each or of one cheese if less than 100 grams, should be handled hygienically, placed in refrigerated containers and sent immediately to the laboratory for analysis.

Laboratories should be allowed to use a method of their choice provided that its level of performance matches the aim to be achieved. However, the most recent version of standard ISO 6785 or EN/ISO 6579 is recommended for the detection of *Salmonella*, the most recent versions of standards EN/ISO 11290-1 and 2 are recommended for detection of *Listeria monocytogenes*, the most recent version of EN/ISO 6888-1 or 2 is recommended for the enumeration of *Staphylococcus aureus* and the most recent version of standard ISO 11866-2,3 or ISO 16649-1,2 is recommended for the enumeration of *Escherichia coli*. Additional equivalent methods recognised by competent authorities may also be used.

The overall level of sampling should be left to the judgement of the competent authorities of Member States.

The results of the controls should be recorded on the model record sheet set out in Annex I.

6. Bacteriological safety of mixed salads as regards *Listeria monocytogenes*

6.1. Scope of the coordinated programme for 2005

During recent years there has been an increase in the consumption of ready-to-eat food, such as mixed salads containing raw vegetables and other ingredients such as meat or seafood. That kind of product may pose a potential risk to public health due to the presence of pathogenic bacteria, such as *Listeria monocytogenes*. The implementation of specific hygiene measures, including appropriate shelf life and temperature control, are essential to avoid growth of pathogenic bacteria eventually present in the products and protect public health.

The aim of this element of the programme is to assess the microbiological safety of pre-mixed salads containing raw vegetables and other ingredients such as meat or seafood, as regards *Listeria monocytogenes* in order to promote a high level of consumer protection and to collect information on the prevalence of these bacteria in such products.

6.2. Sampling and method of analysis

The investigations should concern pre-packaged mixed raw vegetable salads containing meat or seafood or other ingredients which:

(a) are not heat treated in the final package;

(b) need cold storage;

(c) are intended to be eaten without heat treatment or can be eaten without heat treatment before consumption.

The competent authorities of the Member States should take samples of those products at retail level, preferably in supermarkets, with a view to testing for the presence and enumeration of *Listeria monocytogenes* at the same time. One sample consists of one sample unit (one unopened package). The samples, possibly taken in proximity to the expiry date, should be placed in refrigerated containers and sent immediately to the laboratory for analysis. The temperature of storage and the shelf-life of the products should be recorded at the time of sampling and the information included in the explanatory report accompanying the results of the investigation.

At the laboratory, the sample should be treated in order to ensure that all ingredients are thoroughly mixed.

The most recent versions of standard EN/ISO 11290-1 and 2 are recommended for detection and enumeration of *Listeria monocytogenes*. However, laboratories should be allowed to use a method of their choice provided that its level of performance matches the aim to be achieved.

The overall level of sampling should be left to the judgement of the competent authorities of Member States.

The results of these controls should be recorded on the model record sheet set out in Annex II.

7. Safety, quality and labelling of poultrymeat as regards the use of water retention agents

7.1. Scope of the coordinated programme for 2005

Recent sampling in certain Member States has shown a significant number of products placed on the market with excessive added water and hydrolysed proteins used as water retention agents in poultry meat and poultry meat preparations.

Article 5(1) of Council Directive 71/118/EEC of 15 February 1971 on health problems affecting the production and placing on the market of fresh poultrymeat [1] prohibits the placing on the market of fresh poultrymeat where agents that specifically promote water retention have been used.

A recent Commission Staff Working Document (SEC(2004) 1130) has also drawn to the attention of Member States that although water retention agents may be used in poultry preparations and products, their use must be according to codes of good practice approved by Member States or to good manufacturing practices and with due regard to the rules applicable to consumer protection including food labelling legislation, as provided in Directive 2000/13/EC of the European Parliament and of the Council of 20 March 2000 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs [2].

The aim of this element of the programme is to verify at Community level the correct implementation of Directive 71/118/EEC as regards the use of water retention agents in chilled and frozen poultrymeat (chicken breast) and their use in frozen poultry (chicken breast) preparations in order to promote consumer protection and to check for correct labelling.

7.2. Sampling and method of analysis

For sampling, analysis and calculation of results, the competent authorities of the Member States should follow the analytical protocol described in Annex V.

It is recommended to focus the sampling on wholesale supplies of frozen chicken breast as well as retail sales of chilled and frozen chicken breast. The overall level of sampling should be left to the judgement of the competent authorities of Member States.

The results of the following controls should be recorded on the model sheet set out in Annex III.

[1] OJ L 55, 8.3.1971, p. 23. Directive as last amended by Regulation (EC) No 807/2003 (OJ L 122, 16.5.2003, p. 36).

[2] OJ L 109, 6.5.2000, p. 29. Directive as last amended by Directive 2003/89/EC (OJ L 308, 25.11.2003, p. 15).

8. Safety of certain foods for infants and young children as regards the levels for nitrate and patulin

8.1. Scope of the coordinated programme for 2005

Foodstuffs containing contaminants exceeding the levels which are toxicologically acceptable may pose a potential risk to public health, especially for sensitive groups of the population such as infants and young children. The presence of contaminants can be reduced by means of good manufacturing or agricultural practices.

In order to protect public health, specific maximum levels of nitrate and patulin in food intended for infants and young children have been set in Commission Regulation (EC) No 466/2001 of 8 March 2001 setting the maximum levels for certain contaminants in foodstuffs [1] and Commission Regulation (EC) No 655/2004 of 7 April 2004 amending Regulation (EC) No 466/2001 as regards nitrate in foods for infants and young children [2].

The aim of this element of the programme is to verify that foods intended for infants and young children placed on the market do not exceed the maximum levels of nitrate and patulin established in Community legislation in order to ensure a high level of consumer protection.

8.2. Sampling and method of analysis

The competent authorities of the Member States should take representative samples of foods for infants and young children, in particular the foods containing carrots, potatoes, leafy vegetables and apple products at, in particular, the retail level, without ignoring the production and import (if relevant), with a view to testing for nitrate (foods containing carrots, potatoes and leafy vegetables) and patulin (foods containing apple products other than processed cereal-based foods).

Sampling and analysis methods set out in the following Community legislation are recommended for the official control of the levels of nitrate and patulin:

— Commission Directive 2002/63/EC of 11 July 2002 establishing Community methods of sampling oofor the official control of pesticide residues in and on products of plant and animal origin and repealing Directive 79/700/EEC [3], as regards nitrate,

— Commission Directive 2003/78/EC of 11 August 2003 laying down the sampling methods and the methods of analysis for the official control of the levels of patulin in foodstuffs [4], as regards patulin.

The overall level of sampling should be left to the judgement of the competent authorities of Member States.

The results of the following controls should be recorded on the model sheet set out in Annex IV.

Done at Brussels, 1 March 2005.

For the Commission
Markos KYPRIANOU
Member of the Commission

[1] OJ L 77, 16.3.2001, p. 1. Regulation as last amended by Regulation (EC) No 208/2005 (OJ L 34, 8.2.2005, p. 3).
[2] OJ L 104, 8.4.2004, p. 48.
[3] OJ L 187, 16.7.2002, p. 30.
[4] OJ L 203, 12.8.2003, p. 40.

ANNEX I

BACTERIOLOGICAL SAFETY OF CHEESES MADE FROM PASTEURISED MILK

Member State: _____

Bacterial groups/ criteria [1]	Sampling stage	Product identification	Number of samples	Analysis results [2]			Measures taken (number and kind) [3]
				S	A	U	
Salmonella spp. n=5 c=0 Absent in 25 g	Production	unripened soft (fresh) cheese					
		ripened soft cheese					
		semi-hard cheese					
	Retail	unripened soft (fresh) cheese					
		ripened soft cheese					
		semi-hard cheese					
Staphylococcus aureus n=5 c=2 m=100 cfu/g M=1 000 cfu/g	Production	unripened soft (fresh) cheese					
		ripened soft cheese					
		semi-hard cheese					
	Retail	unripened soft (fresh) cheese					
		ripened soft cheese					
		semi-hard cheese					
Escherichia coli n=5 c=2 m=100 cfu/g M=1 000 cfu/g	Production	unripened soft (fresh) cheese					
		ripened soft cheese					
		semi-hard cheese					
	Retail	unripened soft (fresh) cheese					
		ripened soft cheese					
		semi-hard cheese					

Bacterial groups/ criteria (1)	Sampling stage	Product identification	Number of samples	Analysis results (2)				Measures taken (number and kind) (3)
				S		A	U	
				A	P	≤ 100 cfu/g	> 100 cfu/g	
Listeria monocytogenes n=5 c=0 Absent in 25 g	Production	unripened soft (fresh) cheese						
		ripened soft cheese						
		semi-hard cheese						
	Retail	unripened soft (fresh) cheese						
		ripened soft cheese						
		semi-hard cheese						

(1) The number of sample units (n) to be taken may be reduced when sampling at retail level. When a reduced sampling is made this should be indicated in the report.

(2) S=Satisfactory, A=Acceptable, U=Unsatisfactory; in the case of *Listeria monocytogenes* A=Absence, P=Presence. As regards *Staphylococcus aureus* and *Escherichia coli*, the result is satisfactory if all the values observed are < m, acceptable if maximum of c values are between m and M, and unsatisfactory if one or more values are > M or more than c values are between m and M.

(3) For reporting enforcement measures it is recommended to use the following categories: verbal warning, written warning, improved in-house control required, recall of product required, administrative penalty, court action, other.

ANNEX II

MICROBIOLOGICAL SAFETY OF MIXED SALADS

(as regards *Listeria monocytogenes*)

Member State: _____

Bacterial pathogens	Product identification (1)	Number of samples	Analysis results						Measures taken (number and kind) (2)
			Detection in 25 g		Enumeration cfu/g				
			Absence	Presence	<10	10-99	100-999	≥1 000	
Listeria monocytogenes									

(1) The product should be identified based on its main ingredients.
(2) For reporting enforcement measures it is recommended to use the following categories: verbal warning, written warning, improved in-house control required, recall of product required, administrative penalty, court action, other.

ANNEX III

SAFETY, QUALITY AND LABELLING OF POULTRY MEAT AS REGARDS THE USE OF WATER RETENTION AGENTS

Member State: _____

Sample code	Name of product and label description	Packer/ processor and health mark	Ingredient list	Label: chicken declaration	% moisture	% fat	% nitrogen	% protein	% ASH	Hydroxy-proline g/100g	Excess hydroxy proline g/100g	% Carbo hydrate	Calculated chicken content Using 3.85 factor	Corrected chicken content Where hydrxi-proline greater than 0,08	Measures taken (number and kind) (1)

(1) For reporting enforcement measures it is recommended to use the following categories: verbal warning, written warning, improved in-house control required, recall of product required, administrative penalty, court action, other.

ANNEX IV

SAFETY OF CERTAIN FOODS FOR INFANT AND YOUNG CHILDREN AS REGARDS THE LEVELS FOR NITRATE AND PATULIN

Member State: _____

1. NITRATE

Sampling stage	Product identification	Number of samples	Analysis results (mg/kg)				Measures taken (number and kind) [1]
			<100	100-150	151-200	>200	
Retail							
Production							
Import (if any)							

2. PATULIN

Sampling stage	Product identification	Number of samples	Analysis results (µg/kg)			Measures taken (number and kind) [1]
			<10	10-25	>25	
Retail						
Production						
Import (if any)						

[1] For reporting enforcement measures it is recommended to use the following categories: verbal warning, written warning, improved in-house control required, recall of product required, administrative penalty, court action, other.

ANNEX V

ANALYTICAL PROTOCOL

Procedure to determine chicken or added water content and collagen-based proteins in chicken breast products

FRESH CHICKEN BREAST (CHILLED OR FROZEN)

If the chicken breast does not contain any added proteins, stabilisers, or other ingredients then the method to calculate added water uses the official EC method for extraneous water (Commission Regulation (EEC) No 1538/91 ([1])). The minimum sample for the official method is five boneless skinless chicken breasts. The added water can be determined from a plot of water/protein ratio against extraneous water in boneless skinless chicken breast (Figure 1). The water protein ratio for boneless skinless chicken breast with no added water is 3,28 and for 2 % extraneous water (the limit for boneless skinless chicken breast) the water/protein ratio is 3,40.

FROZEN CHICKEN BREAST PREPARATIONS

1. *Sample receipt and storage*

   1.1. For wholesale, each sample normally consists of one 10 kg box of frozen boneless skinless chicken breast product. For retail, a minimum of five boneless skinless chicken breasts, with the same durability date or lot marking, should be taken.

   1.2. On receipt samples should be checked to ensure that any packaging has not been damaged and that the sample is in good frozen condition (if frozen).

   1.3. On receipt the samples should be stored frozen (– 18 °C ± 4 °C) prior to analysis.

2. *Object and scope*

   2.1. This method determines the chicken content (and added water by difference) and collagen-based proteins in skinless, boneless chicken breast products. It involves determination of protein nitrogen, moisture, ash, fat and hydroxyproline.

3. *Principle*

   3.1. The (apparent) fat-free chicken content is calculated using the protein nitrogen content and a nitrogen factor for boneless skinless chicken breast (Section 9). If collagen based proteins have been added to the chicken breast, then the contribution of these proteins must first be subtracted from the total protein nitrogen. The total chicken content is calculated by adding the fat content to the fat-free chicken content. A measure of the added water can be calculated by subtracting all the chicken components (chicken content, ash, and carbohydrate) from 100.

4. *Health and safety*

   4.1. The method uses a number of potentially hazardous pieces of equipment such as a heavy duty mincer and a homogeniser, and the appropriate safety precautions should be taken.

5. *Pre-training requirements*

   5.1. Training in the use of industrially sized butchery equipment is required.

6. *Apparatus*

   6.1. Scales capable of weighing with accuracy better than ± 0,1 g.

   6.2. Heavy-duty mincing machine and/or blender capable of homogenising frozen chicken breasts.

   Note: No make of mincer is recommended, however, the mincer used should have sufficient power to mince frozen or quick-frozen chicken to produce a homogeneous mixture corresponding to that obtained from a mincer fitted with a 4 mm hole disc.

([1]) OJ L 143, 7.6.1991, p. 11. Regulation as last amended by Regulation (EC) No 814/2004 (OJ L 153, 30.4.2004, p. 1).

6.3. Apparatus as specified in ISO 1442:1997 (BS 4401 — 3:1997), for the determination of water content.

6.4. Apparatus as specified in ISO 937:1978 (BS 4401 — 2:1980), for the determination of protein content or equivalent.

6.5. Apparatus as specified in ISO 936:1998 1998 (BS 4401 — 1:1998) for the determination of total ash.

6.6. Apparatus as specified in BS 4401 — 4:1970 for the determination of total fat.

6.7. Apparatus as specified in ISO 3496:1994 (BS 4401 — 11:1995) for the determination of hydroxyproline.

7. *Procedure*

Note: The sample must be kept frozen until analysed in accordance with paragraphs 7.1 to 7.10 (below) begins.

7.1. Remove the sample from the packaging and place in a large pre-cleaned plastic tray covered with foil to prevent moisture loss.

7.2. Mince or homogenise portions of the sample and return to the plastic tray. Continue this process until the entire sample has been minced/homogenised.

7.3. Using a clean large plastic spoon mix all the minced sample together taking care to ensure that all 'drip' is re-incorporated.

7.4. In the case of a wholesale sample, take a 2 kg aliquot of the sample or, in the case of the retail, take all of it if less than 2 kg, and **finely homogenise** in a blender or food processor.

Note: The remaining 8 kg of the wholesale sample can be disposed of.

7.5. Take two 50 g aliquots (for DNA if required) from the 2 kg and transfer to a suitably sized container. Place the remainder in a clean, labelled plastic bag or for convenience divide into 200 g sub-samples. Any sample that is not taken immediately for analysis should be stored frozen.

7.6. Take a sample of the homogenised material and determine the moisture content in accordance with ISO 1442.

7.7. Take a sample of the homogenised material and determine the nitrogen content in accordance with ISO 937 (or equivalent).

7.8. Take a sample of the homogenised material and determine the ash content in accordance with ISO 936.

7.9. Take a sample of the homogenised material and determine the fat content in accordance with BS 4401 — 4.

7.10. Take a sample of the homogenised material and determine the hydroxyproline content in accordance with ISO 3496.

8. *Analytical quality control*

8.1. All laboratories should analyse in every batch a suitable reference material with assigned levels of nitrogen, moisture, fat, ash and hydroxyproline in duplicate, as a quality control check. **Acceptable batches must have a measurement within two standard deviations of the assigned value. The duplicate analyses must be within the repeatability characteristics of the method.**

9. *Calculation of results*

The calculation of results has been taken from the Agency Food Surveillance Information Sheet 20/01 of December 2001, which can be found on the Agency's website at the following address.

http://www.food.gov.uk/science/surveillance/fsis-2001/20chick

9.1. Chicken content using the nitrogen factor

Based on Stubbs and More (The Analyst 1919, 44, 125) involves the analysis of the sample for nitrogen, moisture, fat and ash.

The data derived from the analysis is first used to calculate the apparent fat-free meat content as follows:

Apparent Fat-Free Meat Content = Total Nitrogen/NF × 100

NF = nitrogen factor associated with the product analysed

(3,85 for lean chicken breast meat, as recommended by AMC (The Analyst, 2000, 125, 1359-1366)). Note this factor has been found to apply to third country chicken.

The measured fat content is then added to this figure to give the apparent total chicken content.

Apparent Total Chicken Content = Apparent Fat-Free Chicken Content + fat

9.2. Added collagen protein

Hydrolysed protein from collagen can be considered to be present in a sample if the determined hydroxyproline is higher than that naturally associated with lean chicken breast (AMC data 0,08 g/100 g — The Analyst, 2000, 125, 1359-1366)

The calculation for the apparent total chicken content as used above assumes that all of the determined nitrogen is derived from the chicken muscle. If excess hydroxyproline is present, a correction is necessary.

The percent nitrogen contributed by any collagen in a sample is calculated from the hydroxyproline as follows:

COLLAGEN NITROGEN = EXCESS HYDROXYPROLINE × 1,28

The percent collagen nitrogen is then subtracted from the percent total nitrogen and the apparent total chicken content calculated as above.

9.3. Added water

An estimate of the amount of added water can be made by subtracting the chicken content and all the added ingredients from 100 using the following equation:

Added water % = 100 – (Apparent Total Chicken Content + Ash + Carbohydrate + Other Ingredients)

Carbohydrate = 100 – (protein + fat + ash + moisture)

Where total protein = total nitrogen × conversion factor **(6,25)**

From the above, the added water can be estimated as follows:

Added water % = 100 – (Apparent Total Chicken Content + Ash + Carbohydrate)

9.4. Measurement uncertainty

The average measurement uncertainty for the determination of chicken content is estimated at just less than 3 % chicken content at the 95 % confidence limit. Therefore samples can be considered to be misdescribed if the determined meat content is 5 % less than that declared.

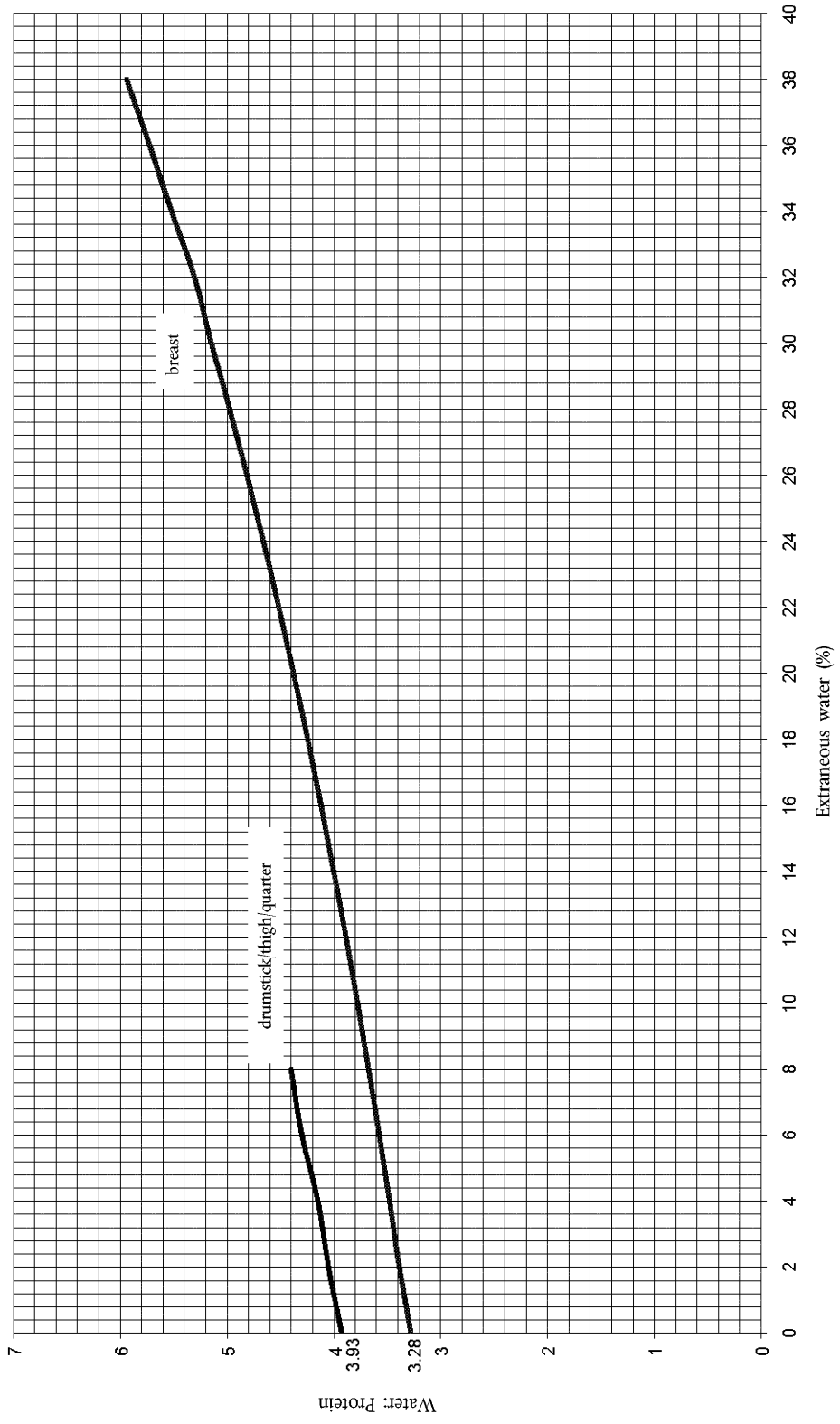

Figure 1 — Extraneous water (%) in relation to limit values for water: protein

COMMISSION DECISION

of 1 March 2005

laying down the codified form and the codes for the notification of animal diseases pursuant to Council Directive 82/894/EEC

(notified under document number C(2004) 993)

(Text with EEA relevance)

(2005/176/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to the Treaty of Accession of the Czech Republic, Estonia, Cyprus, Latvia, Lithuania, Hungary, Malta, Poland, Slovenia and Slovakia, and in particular Article 2(3) thereof,

Having regard to the Act of Accession of the Czech Republic, Estonia, Cyprus, Latvia, Lithuania, Hungary, Malta, Poland, Slovenia and Slovakia, and in particular Article 57 thereof,

Having regard to Council Directive 82/894/EEC of 21 December 1982 on the notification of animal diseases within the Community [1] and in particular Article 5 thereof,

Whereas:

(1) Directive 82/894/EEC lists the animal diseases, the occurrence of which is to be notified to the Commission and other Member States.

(2) Commission Decision 2000/807/EC [2] laid down the codified form and the codes for the notification of animal diseases pursuant to Directive 82/894/EEC.

(3) The countries that will shortly accede to the European Union have been using the Animal Disease Notification System (ADNS system) informally, but their participation should now be formalised.

(4) Several Member States have adjusted a number of the codes that refer to their regions and corresponding adjustments should now be made to the relevant Community provisions.

(5) Maps for the different countries should be included in the relevant Community provisions, in order to clarify the information sent to the Commission and the countries participating in the ADNS system.

(6) Certain equine diseases and diseases of bees have recently been added to Annex I of Directive 82/894/EEC. Accordingly those diseases should be added to the list of diseases in the provisions on the codified form and the codes for notification of animal diseases.

(7) In the interest of clarity and rationality Decision 2000/807/EC should be repealed and replaced.

(8) In order to protect confidentiality of the transmitted information, the Annexes to the present Decision should not be published.

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

HAS ADOPTED THIS DECISION:

Article 1

For the purpose of animal disease notification procedures, information on outbreaks of diseases in accordance with Directive 82/894/EEC shall be transmitted using the codified forms laid down in Annexes I, II and III to this Decision.

Article 2

For the purpose of animal disease notification procedures, information on outbreaks of diseases in accordance with Directive 82/894/EEC shall be transmitted using the codes laid down in Annexes IV to X to this Decision.

Article 3

Decision 2000/807/EC is repealed.

[1] OJ L 378, 31.12.1982, p. 58. Directive as last amended by Commission Decision 2004/216/EC (OJ L 67, 5.3.2004, p. 27).

[2] OJ L 326, 22.12.2000, p. 80. Decision as last amended by Decision 2004/67/EC (OJ L 13, 20.1.2004, p. 43).

Article 4

This Decision is addressed to the Member States.

Done at Brussels, 1 March 2005.

For the Commission
Markos KYPRIANOU
Member of the Commission