

II

(Acts whose publication is not obligatory)

COMMISSION

COMMISSION RECOMMENDATION

of 25 January 2002

concerning a coordinated programme for the official control of foodstuffs for 2002

(notified under document number C(2002) 290)

(Text with EEA relevance)

(2002/66/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

HEREBY RECOMMENDS:

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 consultation of the Standing Committee for Foodstuffs,

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 the official controls by the Member States.
- (2) Such programmes place emphasis on compliance with Community legislation, the protection of public health, consumer interests and fair trade practices.
- (3) Article 3 of Council Directive 93/99/EEC of 29 October 1993 on the subject of additional measures concerning the official control of foodstuffs ⁽²⁾ requires the laboratories referred to in Article 7 of Directive 89/397/EEC to comply with the criteria in European Standard EN 45000 series, now replaced by EN ISO 17025:2000.
- (4) The results from simultaneous implementation of national programmes and coordinated programmes may provide information and experience on which to base future control activities,

1. During 2002 Member States should carry out inspections and controls including, where indicated, taking samples and analysing such samples in laboratories, with the aim of:
 - monitoring compliance with the Community rules on labelling of certain foodstuffs that may contain ingredients, which may themselves contain, consist of or may be produced from genetically modified organisms (GMOs),
 - assessing the bacteriological safety of pre-cut fresh fruits and vegetables and of sprouted seeds,
 - assessing the bacteriological safety of fruit and vegetable juices.
2. Although sampling and/or inspection rates have not been set in this recommendation, Member States should ensure that they 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 provided in the Annex to this Recommendation to help enhance the comparability of results. This information should be sent to the Commission by 1 May 2003 accompanied by an explanatory report.
4. Foodstuffs submitted for analysis under this programme should be submitted to laboratories complying with the provisions of Article 3 of Directive 93/99/EEC. However, if such laboratories do not exist in Member States for certain analysis included in this Recommendation, Member States may also nominate other laboratories providing the capacity to carry out these analyses.

⁽¹⁾ OJ L 186, 30.6.1989, p. 23.

⁽²⁾ OJ L 290, 24.11.1993, p. 14.

5. Labelling of genetically modified foodstuffs

5.1. Scope of the programme

Genetically modified foodstuffs and in particular the proper labelling of such products, are very much the subject of consumer concerns. The coordinated control of the labelling of food that may contain ingredients, which may themselves contain, consist of or may be produced from GMOs, will contribute to build up consumer confidence.

Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 on novel foods and novel food ingredients ⁽¹⁾ provides for the mandatory labelling of foods and food ingredients which contain or consist of a GMO without prejudice to the other labelling requirements of Community law.

Council Regulation (EC) No 1139/98 of 26 May 1998, concerning the compulsory indication of the labelling of certain foodstuffs produced from genetically modified organisms of particulars other than those provided for in Directive 79/112/EEC ⁽²⁾, lays down the compulsory labelling of foods and food ingredients produced from genetically modified soya (*Glycine max* L.) covered by Commission Decision 96/281/EC ⁽³⁾ and genetically modified maize (*Zea mays* L.) covered by Commission Decision 97/98/EC ⁽⁴⁾. These products were approved before the entry into force of Regulation (EC) No 258/97, according to Council Directive 90/220/EEC of 23 April 1990 on the deliberate release into the environment of genetically modified organisms ⁽⁵⁾. The labelling provisions are based on the presence of DNA or protein resulting from genetic modification.

Article 2(2) of Council Regulation (EC) No 1139/98, as amended by Commission Regulation (EC) No 49/2000 ⁽⁶⁾, introduces a 1 % *de minimis* threshold for the adventitious presence of DNA or protein resulting from the genetic modification of soya and maize in conventional foodstuffs. This provision is in force since 10 April 2000. The threshold is applied on each ingredient individually considered and not on the final product. It applies, as a combined maximum for genetically modified material from abovementioned products together with any material placed on the market pursuant to Regulation (EC) No 258/97.

In order to be able to benefit from this exemption to the mandatory labelling requirement for genetically modified foods, operators have to supply documentary evidence to satisfy the competent authorities that they have tried to avoid the use of GMOs or products thereof and that any genetically modified material (DNA or protein) in their products is due to accidental

contamination (during cultivation, harvest, transport or processing).

The aim of this element of the programme is to check the compliance with Community law ⁽⁷⁾ regarding the labelling of foods and food ingredients, which may contain or consist of or may be produced from genetically modified soya and maize.

5.2. Sampling and method of analysis

Controls may have to be applied to both final products and raw materials through inspections at the appropriate stages of placing on the market of ingredients or products. Compliance with the 1 % threshold for labelling, in case of adventitious presence of modified DNA or protein resulting from the genetic modification, shall be established by checking documents provided by the operators and taking samples for analysis. Laboratories should use PCR or ELISA based methods for qualitative and quantitative analysis in foodstuffs of DNA or protein resulting from genetic modification. Specific recommendations concerning methods of analysis are included in Annex I.

The results of the controls should be recorded on the record sheet model provided in Annex II to this recommendation.

6. Bacteriological safety of pre-cut fresh fruits and vegetables and of sprouted seeds

6.1. Scope of the programme

There is no Community legislation fixing specific microbiological criteria for fresh fruits and vegetables. Experience shows that there is potential for a wide range of these products to become contaminated with micro-organisms, including human pathogens. Most of the reported outbreaks have been associated with bacterial contamination, particularly members of *Enterobacteriaceae* (*Salmonella* spp., *Escherichia coli* O157:H7).

There are certain factors which contribute to the microbiological contamination with pathogens, particularly when fruits and vegetables are eaten raw. These pathogens can derive from agricultural practices or from other processes along the production chain. Another aspect contributing to the microbial risk for consumers is the increasing consumption of new products (e.g. sprouted seeds) or fruits and edible plants imported as a part of the globalisation of the trade in these commodities. Additionally, the application of technologies such as cutting, slicing, skinning and shredding, remove the natural protective barriers of the intact plant and open the possibility for providing a suitable medium for the growth of contaminants.

⁽¹⁾ OJ L 43, 14.2.1997, p. 1.

⁽²⁾ OJ L 159, 3.6.1998, p. 4.

⁽³⁾ OJ L 107, 30.4.1996, p. 10.

⁽⁴⁾ OJ L 31, 1.2.1997, p. 69.

⁽⁵⁾ OJ L 117, 8.5.1990, p. 15.

⁽⁶⁾ OJ L 6, 11.1.2000, p. 13.

⁽⁷⁾ This recommendation is without prejudice to the Commission proposals of 'food-feed/traceability' and their consequences for labelling and testing.

Good agricultural practices and good manufacturing practices can help control microbial hazards associated with all stages of the production of fresh fruits and vegetables from primary production to packing and trade. The effective implementation of the HACCP (Hazard analysis and critical control points) principles, where applicable, according to Council Directive 93/43/EEC on the hygiene of foodstuffs⁽¹⁾, is another important element to ensure safety of fruits and vegetables.

The aim of this element of the programme is to assess the microbiological safety of pre-cut fresh fruits and vegetables and of sprouted seeds to monitor possible risks for human health. In view of this it is recommended to verify the application of the HACCP principles by food operators and test for some pathogens such as *Salmonella* spp, toxigenic *E. coli* (in particular *E. coli* O157:H7) and *Listeria monocytogenes*.

6.2. Sampling and method of analysis

The verifications should concern ready to eat fresh fruits and vegetables that have been peeled, cut or otherwise physically altered from their original form intended to be consumed raw, and sprouted seeds.

The competent authorities of the Member States should carry out controls at the level of establishments of production and/or at retail level in order to verify the application of the HACCP principles including, where indicated, taking samples of products for analysis. These samples shall be of one hundred grams minimum each and the product shall be kept in its original packaging. Samples should be placed in refrigerated containers and sent immediately to the laboratory for analysis.

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

Laboratories are allowed to use a method of their choice provided that its level of performance matches the aims to be achieved. However, the most recent version of standard ISO 6579 is recommended for the detection of *Salmonella*, the most recent version of standard EN/ISO 16654 is recommended for the detection of toxigenic *E. coli* and the most recent versions of standards EN/ISO 11290-1 and EN/ISO 11290-2 are recommended for detection and enumeration of *Listeria monocytogenes*. Additional equivalent methods recognised by competent authorities may also be used.

The results of the controls should be recorded on the record sheet model provided in Annex III to this recommendation.

7. Bacteriological safety of fruit and vegetable juices

7.1. Scope of the programme

As for fresh fruits and vegetables, there are no specific microbiological standards for juices in Community legislation. Council Directive 93/43/EEC on the

hygiene of foodstuffs requires juice to be manufactured in a hygienic way and requests food operators to apply the HACCP principles for ensuring the safety and wholesomeness of their products. Food operators are also encouraged to develop and implement on a voluntary basis a code of practice outlining ways to minimise the contamination of fruit while it is being grown, harvested, stored and processed to make juice and to minimise the contamination of fruit juice concentrate while it is being stored, transported or restored into juice for consumption.

The experience in this sector shows that all juices (fruit and vegetable) have the potential to be contaminated with microbiological hazards, in particular juice that has not undergone any form of heat treatment. While it is recognised that there is a low probability for juice being contaminated with dangerous pathogens, the consequences, if it is, can be severe for at-risk groups. Most of the reported outbreaks have been associated with pathogens such as *Salmonella* spp., *Escherichia coli* O157: H7.

The aim of this element of the programme is to assess the bacteriological safety of fruit and vegetable juices and to monitor possible risks for human health. In view of this it is recommended to verify the application of the HACCP principles by food operators and to test for some pathogens such as *Salmonella* spp., toxigenic *E. coli* (in particular *E. coli* O157:H7) and *Listeria monocytogenes*.

7.2. Sampling and method of analysis

The verifications should concern fruit and vegetable juices, in particular apple and citrus juices, that have not been pasteurised.

The competent authorities of the Member States should carry out controls at the level of establishments of production and/or at retail level in order to verify the application of the HACCP principles including, where indicated, taking samples of products for analysis. For the sampling and methods of analysis it is recommended to apply the same criteria as indicated in point 6.2 for fresh fruits and vegetables.

The results of the following controls should be recorded on the record sheet model provided in Annex IV to this recommendation.

Done at Brussels, 25 January 2002.

For the Commission

David BYRNE

Member of the Commission

⁽¹⁾ OJ L 175, 19.7.1993, p. 1.

ANNEX I

RECOMMENDATIONS CONCERNING ANALYSIS OF FOODSTUFFS FOR COMPLIANCE WITH LABELLING OF GMO

This annex is to provide a list of methods that have been submitted to ring trial evaluation and that could be used for the scope of this programme. These studies have been performed according to harmonised international protocols (e.g. IUPAC, AOAC, ISO), and cover a wide range of laboratories, usually no fewer than eight. An essential criterion for consideration is the performance of the method and the quality of the data presented in the final report. The testing method should produce acceptably accurate, precise, and reproducible results for the given analyte. At least seven methods meet these criteria and could be considered as possible references for regulatory compliance.

These methods are listed below, grouped per type of method and type of organism (soybean, maize). The categories are:

- Qualitative PCR methods for screening of foodstuffs containing soybean
- Qualitative PCR methods for screening of foodstuffs containing maize
- Qualitative PCR methods for screening of foodstuffs containing maize and soybean
- Real-time PCR method for the quantification of GM-soybean
- Real-time PCR method for the quantification of GM-maize
- Immunoassay for detection and semi-quantification of GM-soybean

The methods listed are at present being used world-wide in a large number of proficiency tests and either have been annexed to the CEN standards on GMO testing that are under development (elaborated by CEN/TC275/WG11) or will be submitted before long. Therefore, they can be considered as consistent with the highest international performance criteria.

Recommended validated methods

Table 1: Qualitative PCR methods for screening of foodstuffs containing soybean

Matrix	Authorised GMO that can be detected in the assay	GMO concentrations analysed	Target	Coordinator (Reference)
Soy flour Soybeans	GTS 40-3-2 (Roundup Ready soybean)	0 %, 0,1 %, 0,5 %, 2 %	35S promoter nos terminator	JRC, (Lipp <i>et al.</i> , 1999) (1) BgVV (2)
Soy meal	GTS 40-3-2 (Roundup Ready soybean)	0 %, 0,1 %, 0,5 %, 2 %	Herbicide tolerance gene epsps	DMIF-GEN, 1999 (3)
Processed foods: Acidified soybeans	GTS 40-3-2 (Roundup Ready soybean)	0 %, 2 %, 100 %	35S promoter nos terminator	JRC, (Lipp <i>et al.</i> , 2001) (4)

Table 2: Qualitative PCR methods for screening of foodstuffs containing maize

Matrix	Authorised GMO that can be detected in the assay	GMO concentrations analysed	Target	Coordinator (Reference)
Maize flour	Bt-176	0 %, 0,1 %, 0,5 %, 2 %	35S promoter	JRC, (Lipp <i>et al.</i> , 1999) (1)
Maize flour	Bt-176 (construct-specific)	0 %, 0,1 %, 0,5 %, 2 %	Overlap between insect resistance gene cryIAb and CDPK promoter	DMIF-GEN, 1999 (3)
Maize flour	Bt-176 (construct-specific)	0 %, 100 %	Overlap between insect resistance gene cryIAb and CDPK promoter	BgVV (2)

Matrix	Authorised GMO that can be detected in the assay	GMO concentrations analysed	Target	Coordinator (Reference)
Maize flour	Bt-11 (construct-specific)	0 %, 100 %	Junction region of adh 1S-Intron2 (IVS2) and pat gene	BgVV (2)
Maize flour	T25 (construct-specific)	0,1 %, 1 %, 100 %	CaMV 35S terminator and the pat gene	BgVV (2)
Maize flour	MON810 (event-specific)	0,1 %, 1 %, 100 %	Edge fragment covering genomic maize DNA to CaMV promoter	BgVV (2)
Processed foods: polenta	Bt-176	0 %, 2 %, 100 %	35S-promoter	JRC, (Lipp <i>et al.</i> , 2001) (4) BgVV (2)

Table 3: Qualitative PCR methods for screening of foodstuffs containing maize and soybean

Matrix	Authorised GMO that can be detected in the assay	GMO concentrations analysed	Target	Coordinator (Reference)
Processed foods: Baby food; Biscuits	Bt-176 GTS 40-3-2 (Roundup Ready soybean)	0 %, 2 %, 100 %	35S promotor nos terminator (for soybean only)	JRC, (Lipp <i>et al.</i> , 2001) (4)

Table 4: Real-time PCR method for the quantification of GM-soybean

Matrix	Authorised GMO that can be detected in the assay	GMO concentrations analysed	Target	Coordinator (Reference)
Soybean meals and texturised vegetable protein	GTS 40-3-2 (Roundup Ready soybean)	0,1 %, 0,5 %, 1 %, 2 %, 5 %	Herbicide tolerance gene (Roundup Ready)	BgVV (EU Tender Report, 2000) (5)

Table 5: Real-time PCR method for the quantification of GM-maize

Matrix	Authorised GMO that can be detected in the assay	GMO concentrations analysed	Target	Coordinator (Reference)
Maize flour	Bt-176 (construct-specific)	0,1 %, 0,5 %, 1 %, 2 %	Overlap between insect resistance gene cryIAb and CDPK promoter	BgVV, (Broll <i>et al.</i> , in preparation) (6)

Table 6: Immunoassay for detection and semi-quantification of GM-soybean

Matrix	Authorised GMO that can be detected in the assay	GMO concentrations analysed	Antibody	Target GMO	Coordinator (Reference) Date
Dried soybean powder	GTS 40-3-2 (Roundup Ready soybean)	0 %, 0,5 %, 1 %, 2 %	Ab against CP4EPSPS	Herbicide tolerance protein (Roundup Ready)	JRC, (Lipp <i>et al.</i> , 2000) (6)

Recommendations

- It is recommended to follow precisely the protocols referred to above. Changes (for example in primer sequences) to the protocol may adversely affect the quality of results.
- It is recommended to use the appropriate protocols for the range of GMO percentages for which the method has been validated.
- It is recommended to use the appropriate protocols in conjunction with the matrices listed. It is further recommended to pick from the lists above the best method of choice if no validated method is available for a particular matrix to be analysed, or for a threshold which is being applied. For example the method provided by producers of analytical instruments that deliver probes to quantify cry1AB (present in Bt-11, MON-810, MON-809 and Bt-176), the 35S promoter (present in all five authorized maizes) and for the nos terminator (present in Bt-11, MON-809 and T25) have not yet been internationally validated but they can be considered as having a high degree of method performance.
- Following these recommendations it should be possible to utilise reliable methods that should allow the detection and/or quantification of Roundup Ready soybean GTS 40-3-2 as well as all five authorised GM maize varieties Bt-11, MON-810, MON-809, Bt-176 and T25 in the following food matrices:
 - Foodstuffs derived from soy:* soy bean, soy flower (all types), soy meal, tofu, soy bean bakery products
 - Foodstuffs derived from maize:* maize, maize flour (all types), maize snacks, maize chips, maize bakery products, polenta
 - Foodstuffs derived from soy and maize:* baby food, raw material for food supplements, biscuits.
- For further information, it is advised to consult the compendium of validated methods that do not meet the criteria as stipulated above but that nonetheless may provide good analytical guidance. This compendium, compiled by the European Commission Joint Research Centre can be downloaded from <http://biotech.jrc.it/documents>.

References

1. Lipp M, Brodmann P, Pietsch K, Pauwels J, Anklam E (1999) IUPAC Collaborative Trial Study of a Method To Detect Genetically Modified Soy Beans and Maize in Dried Powder. *J AOAC Int* 82:923-928.
2. Collection of official methods under article 35 of the German Federal Foods Act; Methods of sampling and analysis of foods, tobacco products, cosmetics and commodity goods/Federal Health Office, Loose leaf edition as of November 1999, Berlin, Köln, Beuth Verlag GmbH, No L 00.00-31.
3. DMIF-GEN Final Project (1999), DMIF-GEN-Project: Development of Methods to Identify Foods Produced by Means of Genetic Engineering. EU-Project SMT4-CT96-2072, Final Report 12/1999.
4. Lipp, M., Bluth, A., Eyquem, F., Kruse, L., Schimmel, H., Van den Eede, G., and Anklam, E. (2001) Validation of a method based on polymerase chain reaction for the detection of genetically modified organisms in various processed foodstuffs. *Eur Food Res Technol* 212:497-504.
5. EU Tender Report (2000). Development of qualitative as well as quantitative detection methods to identify a genetic modification in soybean and maize products. Report of the EU tender No. XXIV/98/A3/001.
6. Broll et al., in preparation.
7. Lipp M., Anklam E. and Stave J: 'Validation of an immunoassay for the detection and quantification of Roundup-Ready soy beans in food and food fractions', *J. AOAC* 83, 919 (2000).

ANNEX II

LABELLING OF GENETICALLY MODIFIED FOODSTUFFS

Member State: _____

Product identification	Number of product inspections	Check of documents	Method code	Analysis			Measures taken (number)							
	— Lot (size and identification) — Sample (units)	(¹)		Samples > 1 %	Samples < 1 %	(²)	None	Verbal warning	Written warning	Improved in house control required	Recall of product required	Administrative penalty	Court action	Other

(¹) Documentary evidence for adventitious presence.
 (²) Samples where no DNA and/or protein from GMO have been detected.

BACTERIOLOGICAL SAFETY OF PRE-CUT FRESH FRUITS AND VEGETABLES AND OF SPROUTED SEEDS

Member State: _____

 Establishments of productionPre-cut products RetailSprouted seeds

Bacterial pathogens	Product identification	Number of samples	Analysis results		Measures taken (Number)								
			Negative	Positive	None	Verbal warning	Written warning	Improved in house control required	Sales prohibition	Administrative penalty	Court action	Other	
<i>Salmonella</i> spp.													
Toxigene <i>E. coli</i>													
<i>Listeria monocytogenes</i> ⁽¹⁾													

⁽¹⁾ Indicate the value obtained where enumeration was performed

HACCP

 Establishments of production Retail

What was the total number of food businesses visited during the operation of this programme?

How many complied with Directive 93/43/EEC on the application of the principles of HACCP?

In those complying with Directive 93/43/EEC were documents relating to the hazards analysis or the monitoring of Critical Control Points present?

How many of the food businesses had an approved voluntary guide to good hygiene practices?

BACTERIOLOGICAL SAFETY OF FRUIT AND VEGETABLES JUICES (Unpasteurised juices)

Member State: _____

 Establishments of production Retail

Bacterial pathogens	Product identification	Number of samples	Analysis results		Measures taken (number)								
			Negative	Positive	None	Verbal warning	Written warning	Improved in house control required	Sales prohibition	Administrative penalty	Court action	Other	
<i>Salmonella</i> spp.													
Toxigene <i>E. coli</i>													
<i>Listeria monocytogenes</i> ⁽¹⁾													

⁽¹⁾ Indicate the value obtained where enumeration was performed.

HACCP

 Establishments of production Retail

What was the total number of food businesses visited during the operation of this programme?

How many complied with Directive 93/43/EEC on the application of the principles of HACCP?

In those complying with Directive 93/43/EEC were documents relating to the hazards analysis or the monitoring of Critical Control Points present?

How many of the food businesses had an approved voluntary guide to good hygiene practices?