Corrigendum to Commission Decision 2004/478/EC of 29 April 2004 concerning the adoption of a general plan for food/feed crisis management

(Official Journal of the European Union L 160 of 30 April 2004)

Decision 2004/478/EC should read as follows:

COMMISSION DECISION

of 29 April 2004

concerning the adoption of a general plan for food/feed crisis management

(2004/478/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety [1], and in particular Article 55 thereof,

Whereas:

(1) Article 55 of Regulation (EC) No 178/2002 provides that the Commission shall draw up, in close cooperation with the European Food Safety Authority, hereinafter referred to as 'the Authority', and the Member States, a general plan for crisis management in the field of the safety of food and feed.

(2) The draft general plan has been the subject of consultations with the Authority and has been discussed in detail with the Member States through the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS DECISION:

Article 1

The general plan for food/feed crisis management, provided for in Article 55 of Regulation (EC) No 178/2002 and set out in the Annex, is hereby established.

Article 2

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

Done at Brussels, 29 April 2004.

For the Commission

David BYRNE

Member of the Commission

[1] OJ L 31, 1.2.2002, p. 1. Regulation as last amended by Council Regulation (EC) No 1642/2003 (OJ L 245, 29.9.2003, p. 4).

ANNEX

GENERAL PLAN FOR FOOD/FEED CRISIS MANAGEMENT

1. **Scope of the general plan for food/feed crisis management**

Section 3 of Chapter IV of Regulation (EC) No 178/2002 envisages new methods of risk management in the field of food and feed: the setting-up by the Commission of a crisis unit in which the Authority participates and the adoption of a general plan for food/feed crisis management specifying, in particular, the practical procedures necessary to manage a crisis. The general plan for food/feed crisis management is hereinafter referred to as the 'general plan'.

The three articles of section 3 are interconnected:

Article 55 provides for the drawing up by the Commission, in close cooperation with the Authority and the Member States, of a general plan for food/feed crisis management which specifies the crisis situations and the practical procedures necessary for managing a crisis, including the principles of transparency to be applied and a communication strategy.

Article 56 provides for the constitution of a crisis unit by the Commission.

Article 57 specifies the tasks of the crisis unit.

In particular, according to Article 55, the general plan shall specify the types of situation involving direct or indirect risks to human health deriving from food and feed which are unlikely to be prevented, eliminated or reduced to an acceptable level by provisions in place or by way of the application of Articles 53 and 54.

In addition, Article 56 provides that the Commission shall set up a crisis unit 'when it identifies a situation involving a serious direct or indirect risk to human health deriving from food or feed and the risk cannot be prevented, eliminated or reduced by existing provisions or cannot be managed adequately solely by way of application of Articles 53 and 54'.

Therefore, the general plan specifies:

— the crisis situations,

— the procedure leading to the application of the general plan,

— the establishment of a network of crisis coordinators,

— the practical procedures for managing a crisis,

— the role of the crisis unit,

— the practical functioning of the crisis unit (composition, means of operation, actions),

— the link between the crisis unit and the decision-making process,

— the resolution of the crisis,

— the management procedures in the event of a potentially serious risk,

— the communication strategy,

— the principles for transparency.

The management procedures established by the general plan will constitute guidelines applicable to the Member States, the Authority and the Commission.

2. **Crisis situations**

2.1. **Crisis situations involving a serious direct or indirect risk to human health**

The crisis situations are those where critical factors are involved at such a level that the Commission considers that the management of the risk in question deriving from food or feed will be of such complexity that it cannot be managed adequately by existing provisions or solely by way of application of Articles 53 and 54.

Experience has shown that situations involving risks are normally managed appropriately using existing procedures. This means that the situations which should be considered to be crisis situations will be very few in number, not to say exceptional.

These critical factors are, in particular, the following:

the situation involves a serious direct or indirect risk to human health and/or is perceived or publicised as such or can be perceived and/or publicised as such

and

the risk is spread or could be spread by a large part of the food chain

and

it is highly likely that the risk will spread to several Member States and/or non-Community countries.

The general plan implies the setting up of a crisis unit where the direct or indirect risk involved is considered to be serious. The general plan will therefore include in almost all cases the setting up of a crisis unit.

2.2. **Crisis situations where there is a potentially serious risk**

It is important to provide in the plan for cases where the risk is potential but could evolve into a serious risk which is unlikely to be prevented, eliminated or reduced by existing provisions or solely by way of application of Articles 53 and 54. In this case, a crisis unit will not be set up but adequate provisions should be made to ensure effective management of this type of situation.

3. **Procedure leading to the application of the general plan**

Information possibly leading to the application of the general plan for food/feed crisis management and, where necessary, to the setting up of a crisis unit may originate from:

— rapid alert notifications (rapid alert system for food and feed),

— information from Member States (other types of notifications, information given in the Standing Committee on the Food Chain and Animal Health, etc.),

— information from the Authority,

— reports from the Food and Veterinary Office (FVO),

— information from the EU epidemiological network,

— information from non-Community countries or international bodies,

— any other source (consumer groups, industry, other stakeholders, media, etc.).

When, on analysing the information concerning risks, the Commission takes the view that the conditions established in sections 2.1 or 2.2 might be met, it shall make preliminary contact with the Member State(s) concerned to examine the situation and with the Authority to request information on the risk involved.

On the basis of the assessment of all relevant information available, the Commission shall determine whether the conditions set out in section 2.1 or section 2.2 have been met.

4. **Establishment of a network of crisis coordinators**

Each Member State, the Authority and the Commission shall designate one crisis coordinator and his/her alternate at the appropriate level. The names and contact details of the designated coordinators and alternates shall be notified to the Commission.

Meetings of the coordinators shall be organised by the Commission shortly after their designation. At the first meeting, the Commission shall distribute a handbook providing a complete list of the coordinators and alternates and their contact details. The handbook shall also include a list of the Community Reference Laboratories. Practical operating procedures will be discussed in order, for instance, to ensure that each coordinator can be contacted at short notice in the event of a crisis or that effective cooperation is ensured on the risk communication strategy (see section 7). Stakeholders shall be consulted about the results of these meetings which are of interest to them.

The practical procedures should ensure that action is taken quickly. Where necessary, they will be annexed to the general plan.

5. Practical procedures for the management of a crisis involving a serious direct or indirect risk to human health

5.1. Establishment of the crisis unit

When, on analysing the information concerning risks, the Commission takes the view that the conditions listed in section 2.1 might be met and, in particular, that the risk is likely to be serious, it shall make preliminary contact with the Member State(s) concerned to examine the situation and with the Authority to request information on the risk involved.

On the basis of the assessment of all relevant information available, the Commission shall set up a crisis unit if the conditions mentioned in section 2.1 are considered to be met.

The Commission shall immediately inform the Member States and the Authority that a crisis unit has been set up.

The decision to set up a crisis unit will mean that sections 5, 7 and 8 of the general plan apply to all the parties concerned (Commission, Authority, Member States).

5.2. Role of the crisis unit

The crisis unit shall be responsible for gathering and evaluating all the relevant data and identifying the options available for managing the crisis.

It shall also have the role of informing the public about the risks in question and the measures taken in this regard.

The crisis unit is an additional tool for ensuring that crises are managed effectively by ensuring better coordination and by taking action quickly. Consequently, all members of the crisis unit shall have to cooperate in order to collect and share all available relevant information; they shall also work together on the evaluation of the data collected and identify appropriate risk management options. The members of the crisis unit shall also cooperate on communication and identify the best ways of informing the public in a transparent way.

However, the crisis unit is not responsible for adopting decisions on the management of risk or for implementing legislation (control aspects).

Its operational methods will not replace the procedures used in the framework of the Commission's or the Member States' or the Authority's own competence.

As a consequence, crisis management decisions shall be adopted according to specific procedures already in place (in particular, comitology procedures).

Each Member State shall continue to be responsible for the management of official controls on its territory. The specific procedures they have put in place to coordinate the necessary urgent controls in situations of crisis will remain. The Health and Consumer Protection Directorate-General shall be responsible for sending urgent missions from the FVO, if necessary.

Similarly, the Authority shall continue to be responsible for managing the procedures for providing a scientific opinion in the event of a request for an urgent scientific opinion from the Scientific Committee or one of its scientific panels.

5.3. **Practical operation of the crisis unit**

Composition

The crisis unit shall be composed of the crisis coordinators (or their alternates) from the Commission and the Authority, the crisis coordinator(s) of the Member States directly concerned and other representatives of the Commission, the Authority and the Member State(s) directly concerned. The Authority shall provide the necessary scientific and technical assistance.

The purpose of the crisis unit will be to facilitate rapid and efficient action. Its members will be involved in regular and emergency meetings of the crisis unit and will need to demonstrate a high degree of expertise and commitment. They will have to be able to take on a number of responsibilities, which means that it is necessary to designate people with a high level of responsibility in the food/feed sector.

The crisis unit may consider that the expertise of other public or private persons is necessary for the management of the crisis and may request the permanent or *ad hoc* assistance of these persons. For example, experts from the Community or national reference laboratories may be requested to take part in the crisis unit when their expertise as regards laboratory analyses is needed.

The persons responsible in the Commission and in the Authority for communication on food and feed safety shall be associated with the work of the crisis unit.

Practical procedures for the operation of the crisis unit

The Commission's crisis coordinator (or his/her alternate) shall chair the crisis unit. The Chair shall, in particular, ensure the link between the work of the crisis unit and the decision-making process. He/she shall be assisted by the appropriate technical expert(s) of the competent Unit(s) concerned in the Commission.

The Chair shall ensure the smooth operation of the crisis unit and the distribution of tasks amongst members, taking into account their competence.

As soon as possible after it has been decided to set up a crisis unit, the Chair shall invite the Authority's coordinator and the coordinators of the Member States directly affected by the crisis to a first meeting of the crisis unit. Coordinators may be accompanied by a limited number of persons. The Chair may specify a limit for the maximum number of accompanying persons.

The Authority's coordinator and the Member States' coordinators involved in the crisis unit must ensure adequate participation in the meetings of the crisis unit in terms of availability, expertise and level of responsibility. In concrete terms it will mean that the crisis coordinator or his/her alternate will attend all meetings and will be accompanied by the relevant persons.

The Authority shall be responsible for providing scientific and technical assistance if necessary, in particular regarding the state of scientific knowledge (collection and evaluation of all relevant scientific information in relation to the risk in question).

The crisis unit shall be responsible for maintaining close contact with the stakeholders concerned, in particular when information has to be shared.

Means of operation

The Commission shall staff the secretariat for the meetings of the crisis unit (minutes etc.) and place at the disposal of the crisis unit all the human and material resources necessary for its smooth operation (in particular, meeting rooms, means of communication, etc.).

The crisis unit will use the technical arrangements in place for the RASFF network to communicate or disseminate information, particularly requests for information to the Member State(s) and the information submitted by them.

Action taken by the crisis unit

In accordance with Article 57 referred to above, the crisis unit shall take the following action:

— Action in relation to the collection of relevant scientific data and all scientific information making it possible to manage the risk in question as effectively as possible. In particular:

  — sharing of the scientific information available to the different members of the crisis unit,

  — where necessary, members will be required to collect more scientific information,

  — where necessary, coordination of the action taken to make up for scientific shortcomings,

  — where necessary, members will be required to contact international organisations, the stakeholders concerned and non-Community countries to ensure that all relevant information is made available and shared,

  — where necessary, the crisis unit may call upon the assistance of the Community Reference Laboratories.

The allocation of tasks on the collection of scientific data shall take into account the specific expertise of the Authority and the mechanisms for sharing scientific data already set up by the Authority on these issues (Authority's networks).

The allocation of tasks on the collection of scientific data may also include, where necessary, the assistance of other networks managed by the Commission, such as the Rapid Alert and Response System (EWRS) in the field of human illnesses or the ADNS in the field of animal health or the networks operating in the area of research and managed by DG Research.

— Action relating to the collection of other relevant data (data other than the scientific data referred to above). In particular:

  — sharing of all other relevant data available (results of official controls, results of analyses performed by official control laboratories, data obtained from non-Community countries, etc.),

  — where necessary, tasks shall be allocated to members with a view to collecting more data,

  — where necessary, tasks shall be allocated to members with a view to contacting international organisations, the stakeholders concerned and non-Community countries to ensure that all relevant information is made available and shared.

— Action relating to the evaluation of the information available. In particular:

  — sharing of the evaluations already performed by the members, in particular the Authority, or evaluations otherwise available,

  — organisation of the risk assessment, taking into account the specific role of the Authority in providing scientific and technical support to the crisis unit, without prejudice to the possibility of requesting a formal scientific opinion from the Authority,

  — where necessary, use of the technical support of the Community Reference Laboratories on analytical aspects.

— Action relating to the identification of the options available for preventing, eliminating or reducing to an acceptable level the risk to human health and updating of these options on the basis of the new information available and the development of the situation. In particular:

  — the members of the crisis unit shall work together to identify the options available,

  — they shall produce a common paper on the options available; this paper should include, for each option, a justification for the identification of the option, in particular the main results of the evaluation of the data available.

— Action relating to the organisation of the communication to the public on the risks involved and the measures taken.

This matter is explored in more detail in section 7.

For all kinds of action taken, the crisis unit may request the permanent or ad hoc assistance of specific persons when their expertise is considered necessary.

5.4. **Link between the crisis unit and the decision-making process**

Action relating to crisis management

The action relating to crisis management includes all action necessary for preventing, reducing and eliminating the risk involved: the crisis unit will be responsible for certain types of action, and the Commission and/or the Member States for others. The action taken will be without prejudice to the possibility set out in Article 53(2) for the Commission to adopt provisional measures in the event of emergencies, after consulting the Member States concerned and informing the other Member States.

Step 1

— The Commission shall convene the crisis unit as soon as possible after its creation.

— The crisis unit shall take action as provided for in sections 5, 7 and 8.

Step 2

— The options identified by the crisis unit shall be transmitted to the Commission, which will forward them immediately to the Member States.

— The Commission shall prepare the measures to be taken where necessary. It may also request the Authority to provide an urgent scientific opinion, if a formal scientific opinion from the Authority is deemed necessary.

Step 3

— Meeting of the Standing Committee on the Food Chain and Animal Health to examine and give an opinion on the measures proposed, where necessary.

— Where necessary, adoption of emergency measures, in particular, on the basis of the procedures provided for in Articles 53 and 54 of Regulation (EC) No 178/2002.

— In the event of a request for an urgent scientific opinion, the Authority shall take the necessary measures to ensure that the opinion is delivered as soon as possible.

Permanent action to be taken throughout the crisis

— Throughout the crisis, the crisis unit shall continuously collect and evaluate the relevant data and re-evaluate the options available. The updated options shall be transmitted to the Commission and the Member States. The Commission may prepare amended measures and submit them for consideration to the Standing Committee on the Food Chain and Animal Health.

— Throughout the crisis, the Standing Committee on the Food Chain and Animal Health shall hold regular and emergency meetings to ensure that all relevant information is shared, in particular on the adoption of all necessary measures and on the follow-up of the implementation of the crisis management measures (reports from the Member States concerned, submitted and discussed in the Standing Committee on the Food Chain and Animal Health).

— On the basis of the communication strategy indicated in section 7 and in accordance with the principles of transparency in section 8, the crisis unit shall keep the public and the stakeholders informed throughout the crisis.

Link between the crisis unit and the decision-making process

— Practical mechanisms will ensure that the work of the crisis unit and the decision-making process are adequately connected. In particular, the Standing Committee shall be regularly updated on the work of the crisis unit and the Authority shall be invited to the meetings of the Standing Committee. The crisis unit shall be kept continuously informed about the measures taken as part of the decision-making process in order to coordinate the information on this issue.

5.5. **Resolution of the crisis**

The above procedures will remain in place until the crisis unit is dissolved. When the Commission considers, after consulting the crisis unit and in close collaboration with the Member States through the Standing Committee on the Food Chain and Animal Health, that the work of the crisis unit is completed because the risk has been brought under control, it may dissolve the crisis unit.

5.6. **Post-crisis assessment**

An overall post-crisis assessment, involving the stakeholders, shall be undertaken. A meeting of the crisis coordinators shall be held after the conclusion of a crisis in order to improve the operational procedures for the different tools used in crisis management, in light of the post-crisis assessment and on the basis of the experience gained.

6. **Management procedures in the event of a potentially serious risk**

When, on analysing the information concerning risks, the Commission takes the view that the conditions listed in section 2,2 might be met, it shall make preliminary contact with the Member State(s) concerned to examine the situation and with the Authority to request information on the risk involved.

On the basis of the assessment of all relevant information available and if the Commission considers that the conditions established in section 2,2 have been met, the Commission shall immediately inform the Member States and the Authority that sections 6, 7 and 8 of the general plan are applicable.

As soon as possible after it has been decided to apply this section of the general plan, the Commission shall take the following action:

— establish appropriate contact with the Member State(s) directly concerned and the Authority to request activation of their internal system for crisis management. Where necessary, the mechanisms for sharing scientific data developed by the Authority in the event of emergencies (Authority's networks) should be activated,

— where necessary, request activation of the competent laboratories and sharing of their analytical results,

— establish appropriate contact or hold meetings with the Member State(s) directly concerned and the Authority in order to ensure that all relevant information is shared (scientific data, control data, etc.),

— take action as regards communication (see section 7). The principles of transparency mentioned in section 8 shall apply.

This action will continue to be taken until the risk has been assessed more fully. If the risk is considered to be serious and if the Commission considers that the conditions set out in section 2.1 have been met, a crisis unit shall be set up and the procedures provided for in sections 5, 7 and 8 shall apply.

If the risk is not considered to be serious, the existing normal provisions for the management of risk shall apply.

7. **Communication strategy**

The crisis unit shall develop its communication strategy in line with the case in hand in order to keep the public informed about the risk and the measures taken.

This communication strategy shall cover the content of the message and the timing of the communication on the problems in question, including appropriate arrangements for its release.

The strategy shall take account of the specific competence and responsibilities of each of the unit's members when it comes to communicating with the public in a coordinated, consistent and transparent way. To this end, provision is made for the following procedures:

— the person responsible in the Commission for communication on food and feed safety and the person responsible in the Authority for communication shall be associated with the work of the crisis unit,

— the Member States directly concerned by the crisis, and hence members of the crisis unit, shall do all that they can to ensure that their communication policy is consistent with the communication strategy coordinated by the crisis unit,

— in the same way, the Member States which are not members of the crisis unit shall be associated with the strategy coordinated by the crisis unit through their crisis management coordinators in order to ensure consistency as regards risk communication.

The strategy adopted by the crisis unit shall involve making use of whichever channels of communication are appropriate for the cases which arise with the European Parliament and with the non-Community countries and parties concerned.

The communication strategy developed by the crisis unit shall include making appropriate preliminary contact with stakeholders where necessary and, in particular, when information is released in relation to a specific commercial brand or name.

The communication strategy shall take account of the specific role played by the organisations representing stakeholders at European level in relaying information.

The communication strategy will include establishing appropriate coordinated contacts with the non-Community countries concerned in order to provide them with clear, precise and coherent information. The communication strategy shall also include transmitting appropriate information to non-Community countries to warn them that the crisis has been resolved.

The communication strategy shall ensure that the communication process is transparent, in accordance with the principles set out in section 8.

When information is communicated as defined in section 6 of the general plan, the necessary coherence of the communication needs also to be ensured. The contacts and meetings provided for in this section shall cover, where necessary, a communication strategy to be developed in line with section 7.

8. **Principles of transparency**

When the crisis unit issues a communication, it shall take great care to ensure transparency in accordance with the principles for public information provided for in Article 10 of Regulation (EC) No 178/2002.

The general confidentiality rules will continue to apply. Furthermore, the specific confidentiality rules provided for in Article 52 of Regulation (EC) No 178/2002 will apply to the exchange of information carried out under the RASFF.

When the crisis unit communicates the results of work carried out by the Authority on its behalf, the principles of transparency and confidentiality provided for in Articles 38 and 39 of Regulation (EC) No 178/2002 with regard to the results of the Authority's work will apply.