Modus Operandi for the management of new food safety incidents with a potential for extension involving a chemical substance
The Health and Consumer Protection Directorate-General of the European Commission has developed a modus operandi for the management of new food safety incidents with a potential for extension involving a chemical substance. This modus operandi has been agreed with the Standing Committee on the Food Chain and Animal Health (Section Toxicological Safety). It should be considered as a dynamic document aiming at a common approach for the management of such incidents. It may be modified on the basis of future experience.

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Modus Operandi for the management of new food safety incidents with a potential for extension involving a chemical substance

Standing Committee on the Food Chain and Animal Health (section Toxicological Safety)
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1. **SCOPE**

This document covers the management of new food safety incidents with a potential for extension, involving a chemical substance and presenting a potential risk for public health. The incident could result from an accident, a lack of precaution or a fraud. This modus operandi would apply for example in situations where a Member State having managed the initial incident identifies other products in the supply chain that also contain the substance in question. The objective is to avoid, if possible, the escalation on an incident into a crisis. It is important to note that any incident involving a chemical substance for which explicit provisions exist such as limits is not covered by this modus operandi.

2. **PROCEDURE**

The procedure proposed is summarised in the procedural flow-chart (see 2.4). This procedure includes three different aspects: information, evaluation and action.

2.1. **Information**

2.1.1. *Rapid Alert System for Food and Feed (RASFF)*

- Member States (MS) should notify the RASFF immediately and in any event no later than it is made publicly available at national level.

- RASFF should be used to circulate all follow-up information on the incident.

2.1.2. *Science/Analytical tests*

- The RASFF notification of any newly identified problem should be accompanied or followed as soon as possible by any information available, such as toxicological data, possible extent of the problem, etc. This should not delay the RASFF notification.

- The RASFF notification concerning such a problem which requires testing should contain the analytical method and sampling strategy applied, for use by the other Member States.

- Member States should not develop their own (possibly divergent) method but collaborate with the Member State having sent the initial notification. Provided it is fit for purpose, the original method should

1 More detailed elements on information exchanges in case of an incident can be found in the CODEX document: “Principles and guidelines for the exchange of information in food safety emergency situations” (Ref: CAC/GL 19-1995, Rev1-2004)
be applied pending further refinements to be developed normally under the leadership of the notifying country.

2.2. Evaluation

The evaluation of the incident is based on the best possible characterisation of the incident and the establishment of the context in which the incident occurs. This involves first the competent authorities of the Member States (including scientific opinions from national structures), and if necessary the Commission and possibly the European Food Safety Authority (EFSA).

The evaluation should facilitate the choice of the most appropriate risk management tool.

2.3. Action

This phase consists in the use of the management tools available to control the incident. Some of the tools are implemented at Member State level and some of them are implemented at the EU level. The “Food safety incident” toolbox (see 3) describes the main tools available for managing the incident.

Following the evaluation, actions on the market may have been decided, for example, in the Standing Committee on the Food Chain and Animal Health (SCOFCAH), through an agreement in writing on a harmonised approach.

If necessary, adoption of emergency measures under article 53 of Regulation (EC) No 178/2002 (“General Food Law”) could lead to binding EU measures.

A follow-up of the actions taken should be implemented.

- Collation of Member States monitoring data;
- If necessary, Commission control missions to verify that the relevant measures are taken by the Member States and/or the country of origin (e.g. import controls, implementation of HACCP, etc).
2.4. Flow-chart

Event or incident occurring in a MS involving FS and having potential effects on public health. The extension of a previous incident could be considered as an event.

National measures on batches taken by MS which trigger the RASFF notification.

Information on the event and potential measures taken by the MS should be transmitted to the COM through the RASFF system as soon as possible and in any case no later than made publicly available by the MS.

Except if this were to cause undue delay, notification on the event should contain:
- Analytical method (to avoid MS developing their own method);
- Sampling strategy;
- Elements on toxicology;
- Limits applied to take the measure if appropriate;
- Bibliography if available;

EFSA participation

Use of the « Food safety incident » toolbox attached

Meeting with MS about measures to be taken:
- Agreement on which MS takes the lead for the development of the analytical method;
- Agreement on a harmonised approach on the basis of a written document;
- Investigation on the origin of the event by the MS in order to clean up the supply chain;

If appropriate, adoption of specific binding measures (Article 53 of General Food Law).

Follow-up could include:
- Measurement of the extent of the event;
- Assessment of possible further impact on public health;
- Adjustment of toxicological risk assessment (EFSA);
- FVO inspection to verify the implementation of the measures.

Meeting with MS on the review of measures implemented:
- New developments concerning the event;
- Need to repeal, maintain, extend the measures.
3. **FOOD SAFETY INCIDENT TOOLBOX**

Elements for a "toolbox" intended to characterise and manage a new food safety incident or a food safety incident with a potential for extension involving a chemical substance and to propose subsequent actions.

The use of the available tools will be possible after establishment of the nature of the incident.

3.1. **Characterisation of the incident**

3.1.1. *The problem*

<table>
<thead>
<tr>
<th>Nature of the problem</th>
<th>Accident</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Lack of precaution</td>
</tr>
<tr>
<td></td>
<td>Fraud</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Severity of the problem</th>
<th>Acute incident with high level of severity</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Repetition of incidents</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Complexity of the problem (size and scale)</th>
<th>Problem still at local level</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Problem with national extension</td>
</tr>
<tr>
<td></td>
<td>Problem with European or international extension</td>
</tr>
</tbody>
</table>

3.1.2. *Type of the chemical substance causing the problem*

<table>
<thead>
<tr>
<th>Analytical test</th>
<th>Existence of a (validated) test</th>
<th>If necessary, revised the method, so it is suitable for routine use</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Absence of a test</td>
<td>Need for developing (+ validating) rapidly a test</td>
</tr>
</tbody>
</table>
### 3.1.3. The consumers vis-à-vis the incident

<table>
<thead>
<tr>
<th>Consumers at risk</th>
<th>Specific groups at risk</th>
</tr>
</thead>
<tbody>
<tr>
<td>No specific groups at risk</td>
<td></td>
</tr>
</tbody>
</table>

This includes also the consumer perception, awareness and attitude towards the incident.

### 3.1.4. The operators vis-à-vis the incident

<table>
<thead>
<tr>
<th>Awareness of the operators in the sector in which the incident occurred</th>
<th>Pro-activity of the operators largely involved in the management of such incident.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Weak reaction of the operators not accustomed to this type of incident.</td>
<td></td>
</tr>
</tbody>
</table>

The larger is the involvement of the operators and their awareness of the occurrence of the problem, the easier the management of the incident will be.
3.2. Tools for managing the incident

These tools should be used by the Commission, Member States and/ or food business operators:

- according to the risk;
- in consistency with previous actions taken on comparable problems.

The incident may be managed by using a combination of the options below.

3.2.1. Timescale for action

The severity and the complexity of the incident (see 1.1) will determine the timescale in which the action should take place. In case of very severe and extended problem, risk management measures should be agreed within 24-48 hours.

3.2.2. Type of measures

<table>
<thead>
<tr>
<th>Status of the measures</th>
<th>Own measures by food business operators</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Written agreement between the Member States/Commission in the Standing Committee</td>
</tr>
<tr>
<td></td>
<td>Formal Commission Decision</td>
</tr>
</tbody>
</table>

3.2.3. Actions on the market

3.2.3.1. Controls

<table>
<thead>
<tr>
<th>Controls performed in Member States</th>
<th>Own checks carried out by food business operators</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Random check on the market and/ or at the import</td>
</tr>
<tr>
<td></td>
<td>Systematic checks on the market and/ or at the import</td>
</tr>
</tbody>
</table>

3.2.3.2. Actions

The tables describe the actions which can be carried out by the competent authorities. These actions range by increasing level of stringency from "no action" to recall, according to the level of risk.

a) No action

No action is taken by the competent authorities.
b) Withdrawal of relevant batch(es)

The withdrawal is voluntary or mandatory. The notion of “presence” of a chemical should be clarified in each case.

<table>
<thead>
<tr>
<th>Food production and distribution chain</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Withdrawal based on the results of analytical tests</strong></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td><strong>Withdrawal based on analytical tests on raw material and traceability for processed products</strong></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
</tbody>
</table>

c) Recall of relevant batch(es)

Extension of the scheme under 2.2.2.2 up to the consumer. The recall is voluntary or mandatory.

d) Consumer information

Consumer should be informed in particular of the withdrawal or the recall in accordance with Article 19 of Regulation (EC) No 178/2002.

3.2.3.3. Food containing the chemical substance

<table>
<thead>
<tr>
<th>Action carried out on food containing the chemical substance</th>
<th>Destruction</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Re-processing</td>
</tr>
<tr>
<td></td>
<td>Cleaning of the supply chain + Food kept on the market</td>
</tr>
</tbody>
</table>
### 3.2.4. Binding measures on EU markets and/ or imports

<table>
<thead>
<tr>
<th>Commission Decision</th>
<th>Special import conditions</th>
<th>Special marketing conditions</th>
<th>Compulsory controls on the market</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Special import conditions</td>
<td>Special marketing conditions</td>
<td>Compulsory controls on the market</td>
</tr>
<tr>
<td></td>
<td>Establishment of a list of obligatory point of entry in the EU</td>
<td>Listing of the exporters authorised to export on a positive list</td>
<td>Requirement of additional guarantees (sampling and analysis by the competent authorities before export)</td>
</tr>
<tr>
<td></td>
<td>Listing of the third countries authorised to export on a positive list</td>
<td>Prohibition of the import of the product coming from certain countries.</td>
<td>Official certificate with the analytical report</td>
</tr>
<tr>
<td></td>
<td>Suspension</td>
<td>Suspension on the placing on the market.</td>
<td>Analytical report attesting the absence of undue substance (exporters responsible)</td>
</tr>
</tbody>
</table>

**3.2.5. Communication on the incident**

Communication on the incident has to be considered together with the risk assessment and the actions taken. Communication at Member State and EU level should be clear, consistent and comprehensible. The elements described above could be used for communication.