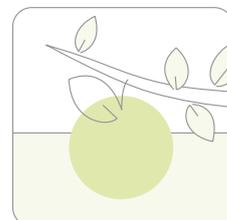
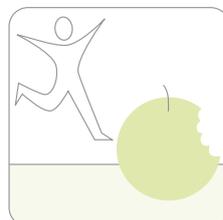
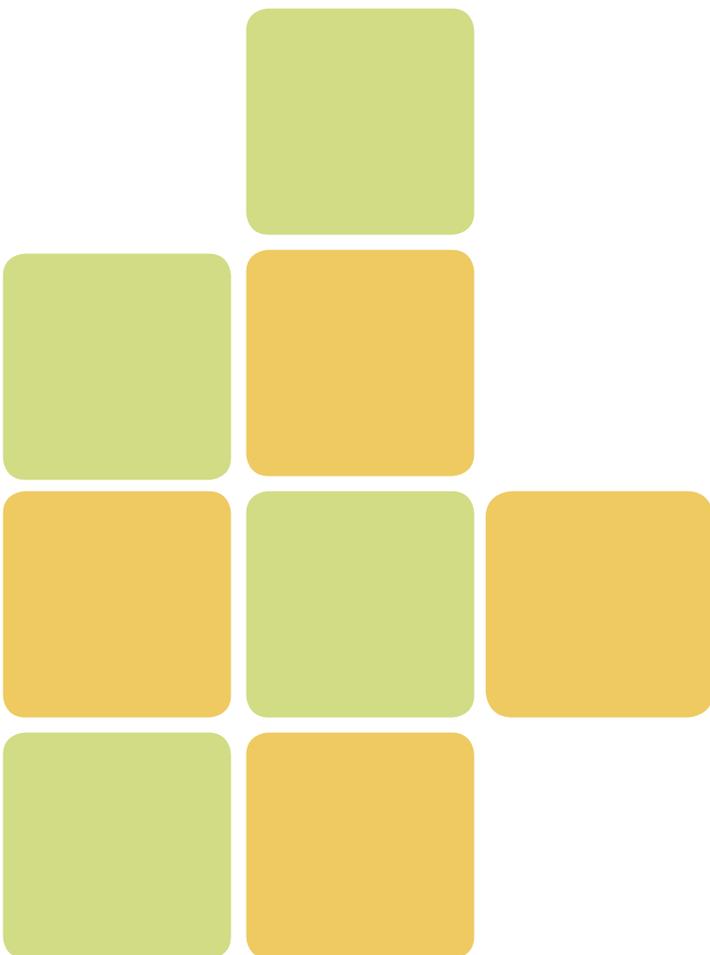


Modus Operandi for the management of new food safety incidents with a potential for extension involving a chemical substance



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

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. Information¹

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.

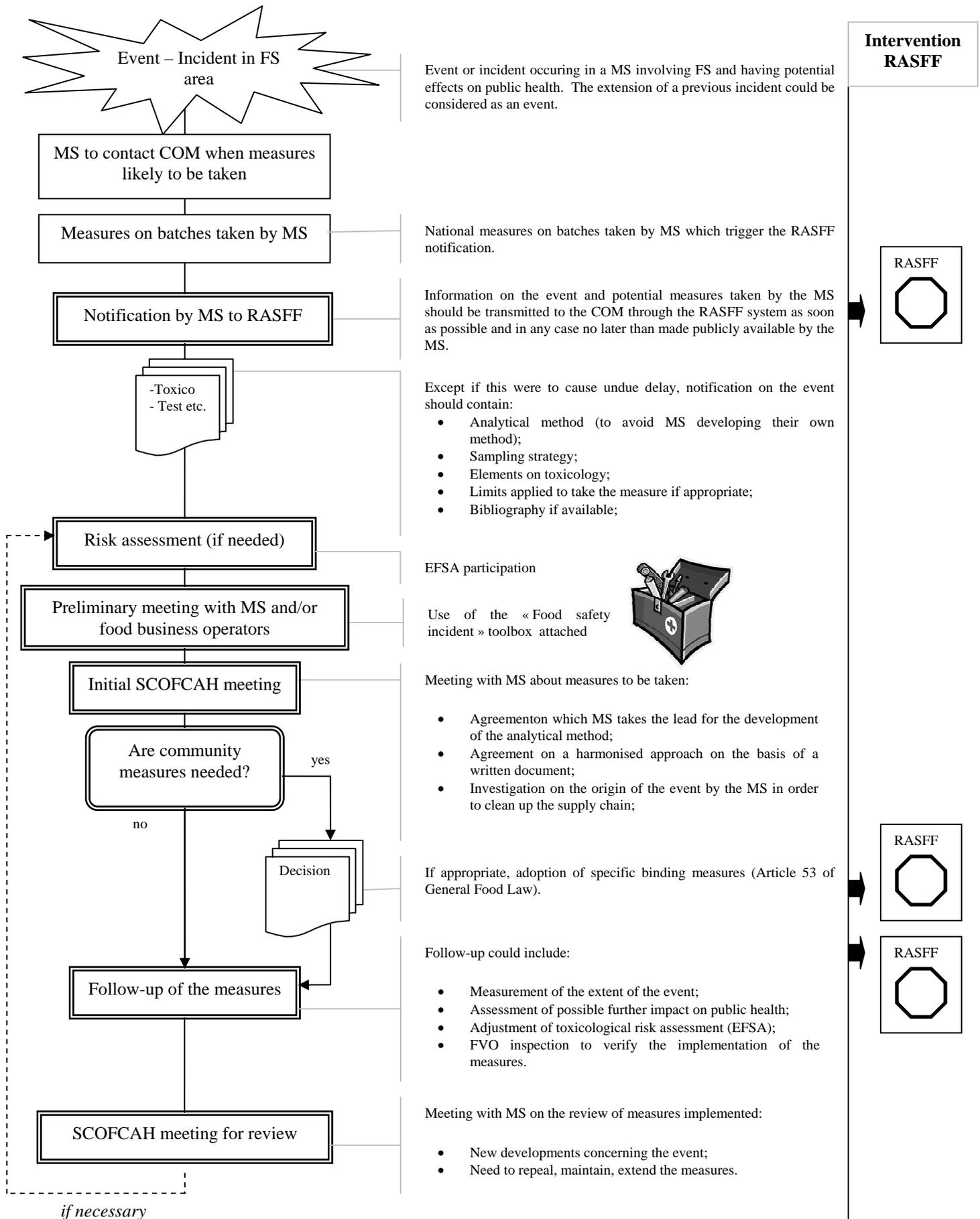
Following the evaluation, actions on the market may have been decided, for example, in the Standing Committee on the Food Chain and Animal Health (SCOFCAH), through an agreement in writing on a harmonised approach.

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





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

Nature of the problem	Accident
	Lack of precaution
	Fraud

Severity of the problem	Acute incident with high level of severity
	Repetition of incidents

Complexity of the problem (size and scale)	Problem still at local level
	Problem with national extension
	Problem with European or international extension

3.1.2. Type of the chemical substance causing the problem

Analytical test	Existence of a (validated) test	If necessary, revised the method, so it is suitable for routine use
	Absence of a test	Need for developing (+ validating) rapidly a test

Legal status of the substance	Not covered by specific legislation
	Not authorised (not listed on a positive list)
	Prohibited

Limit for the substance causing the problem	Absence of legal limit for this substance	Possible use of the limit of detection of the analytical test
		Possible establishment of an action limit (for management) agreed by SCOFCAH and taking into account if possible the available toxicological data about the substance
	Possible existence of a legal limit in another area	Action limit (MRPL)
		Safety limit (MRL for veterinary medicinal products)

3.1.3. *The consumers vis-à-vis the incident*

Consumers at risk	Specific groups at risk
	No specific groups at risk

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

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

Awareness of the operators in the sector in which the incident occurred	Pro-activity of the operators largely involved in the management of such incident.
	Weak reaction of the operators not accustomed to this type of incident.

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*

Status of the measures	Own measures by food business operators
	Written agreement between the Member States/Commission in the Standing Committee
	Formal Commission Decision

3.2.3. *Actions on the market*

3.2.3.1. Controls

Controls performed in Member States	Own checks carried out by food business operators
	Random check on the market and/ or at the import
	Systematic checks on the market and/ or at the import

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.

Food production and distribution chain		
Withdrawal based on the results of analytical tests	Raw material	Analytical test → if presence of the chemical = withdrawal
	Processed product	Analytical test → if presence of the chemical = withdrawal
Withdrawal based on analytical tests on raw material and traceability for processed products	Raw material	Analytical test → if presence of the chemical = withdrawal (+ traceability of sub-lots if necessary)
	Processed products	1. Traceability strictly implemented all along the food chain = withdrawal
		2. Traceability on the basis of a management limit and the % of incorporation of the ingredient in the food product = withdrawal
		3. Traceability after 1 transformation = withdrawal

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

Action carried out on food containing the chemical substance	Destruction
	Re-processing
	Cleaning of the supply chain + Food kept on the market

3.2.4. *Binding measures on EU markets and/ or imports*

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

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.