

To: Heads of Environmental Health Services in England
Directors of Trading Standards in England
Interested parties

17 October 2005

Reference: **ENF/E/05/042**

Dear Sir/Madam

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

Please find enclosed a copy of a paper developed by the European Commission which seeks to standardise the handling of food incidents, such as those involving Sudan I, across the European Union.

The Commission's proposed approach is restricted to chemicals with a potential Public Health risk and where the incident arises by accident, lack of precaution or fraud. The document is intended to cover new incidents with the 'potential for extension' by which the Commission means that the chemical might be found in products further down the supply chain. The document is not intended to prevent national action to manage the initial incident but aims to agree a consistent approach to dealing with other products that may be involved.

The Commission has requested comments from Member States by 20 October. A revised draft will be discussed by Member States in December.

Yours faithfully

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Head of Chemical Safety Division



STANDING COMMITTEE ON THE FOOD CHAIN AND ANIMAL HEALTH

WORKING DOCUMENT

Modus operandi for 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.

2. PROCEDURE

The way to ensure that concerted action is taken from the outset is to implement the following:

2.1. RASFF

- Member States should notify the RASFF immediately and in any event before making information public at national level.

2.2. Science

- 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.
- Agree with Member States that they do not develop their own (possibly divergent) method but collaborate with the Member State having sent the initial notification. The original method should be applied pending further refinements to be developed normally under the leadership of the notifying country.

2.3. Determination of the conditions for choice of the most appropriate risk management tool

- Type and level of risk;
- Determination if the incident is linked to a fraud or an unintentional event;
- Degree of proactivity/ co-operation of the operators;
- Anticipated duration for phasing out of the problem;
- Consumer information;
- Actions taken by Member States against fraudulent practices.

2.4. Action on the market

- In SCOFCAH, agreement in writing on a harmonised approach:
 - No action;
 - Withdrawal;
 - Recall;
 - Consumer information.

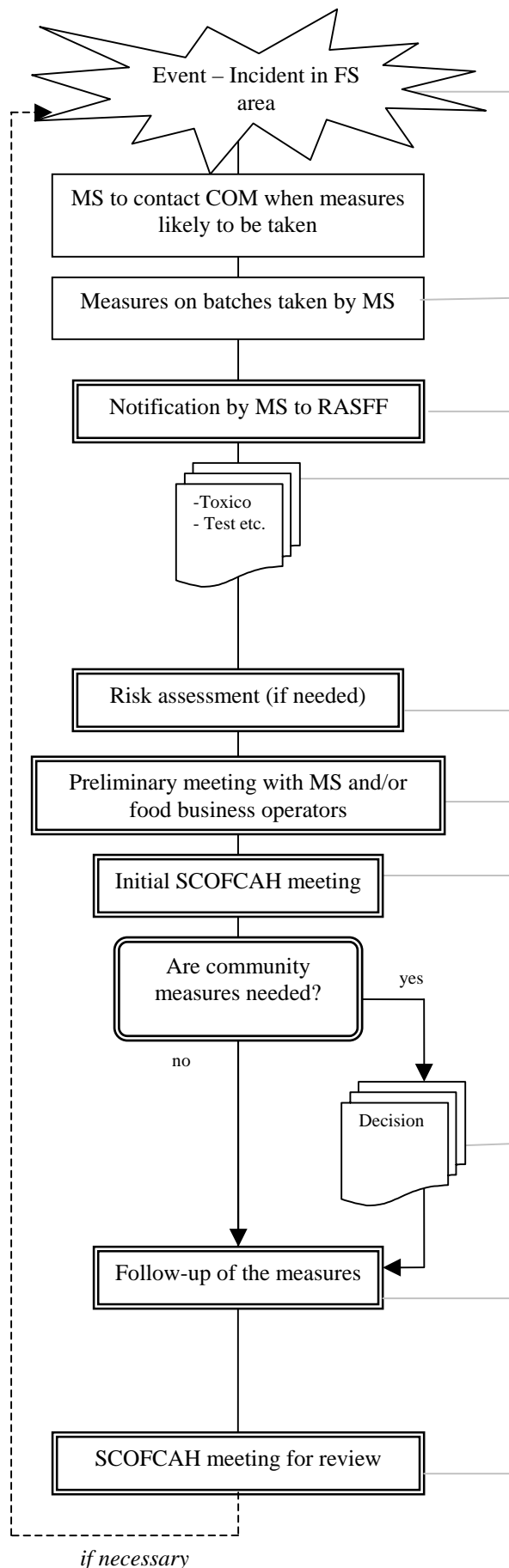
2.5. Binding EU measures

- If necessary, adoption of emergency measures under article 53 of the Food Law :
 - Special marketing conditions;
 - Special import conditions;
 - Suspension of the import of the product.

2.6. Follow-up

- 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).

PROCEDURAL 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 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;
- 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.



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.

1. CHARACTERISATION OF THE INCIDENT

1.1. The problem

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

| | |
|-----------------------|--------------------|
| Nature of the problem | Accident |
| | Lack of precaution |
| | Fraud |

1.2. Type of the chemical substance causing the problem

| | | |
|-----------------|---------------------|-------------------------------------------|
| Analytical test | Existence of a test | If necessary, improvement for routine use |
| | Absence of a test | Need for developing rapidly a test |

| | |
|-------------------------------|------------------------------------------------|
| Legal status of the substance | No status |
| | 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) |
| | Possible existence of a legal limit in another area | Action limit (MRPL) |
| | | Safety limit (MRL for VMP) |

2. TOOLS FOR MANAGING THE INCIDENT

These tools should be used by the COM, MS and/ or food business operators:

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

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

2.1. Type of measures

| | |
|------------------------|--------------------------------------------------|
| Status of the measures | Own measures by food business operators |
| | Written agreement between the MS/ COM in SCOFCAH |
| | Formal Commission Decision |

2.2. Actions on the market

2.2.1. Controls

| | |
|--------------------------|-------------------------------------------------------|
| Controls performed in MS | 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 |

2.2.2. *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.

2.2.2.1. No action

No action is taken by the competent authorities.

2.2.2.2. Withdrawal of relevant batch(es)

The withdrawal is voluntary or mandatory.

| | | 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 |
| | 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 |

2.2.2.3. Recall of relevant batch(es)

Extension of the scheme under 2.3.2.2 up to the consumer. The recall is voluntary or mandatory.

2.2.2.4. Consumer information

Consumer should be informed in particular of the withdrawal or the recall in accordance with Article 19 of Regulation 178/2002.

2.2.3. *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 |

2.3. 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 MS |
| | 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. |