INDUSTRIAL GUIDELINES ON TRACEABILITY OF MATERIALS AND ARTICLES FOR FOOD CONTACT

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I. OBJECTIVE

The objective of this paper is to provide guidelines to the industry on how to implement traceability in order to fulfil the requirements set down in Article 17 of the Framework Regulation (Regulation (EC) No 1935/2004) on materials and articles in contact with food.

"Article 17

Traceability

1. The traceability of materials and articles shall be ensured at all stages in order to facilitate control, the recall of defective products, consumer information and the attribution of responsibility.

2. With due regard to technological feasibility, business operators shall have in place systems and procedures to allow identification of the businesses from which and to which materials or articles and, where appropriate, substances or products covered by this Regulation and its implementing measures used in their manufacture are supplied. That information shall be made available to the competent authorities on demand.

3. The materials and articles which are placed on the market in the Community shall be identifiable by an appropriate system which allows their traceability by means of labelling or relevant documentation or information."

In several parts of these guidelines, traceability tools are proposed which go beyond what is the strict legal requirement of the above article 17, or which extend the application of such traceability tools in the current industrial practice. Any requirement in excess of what is required for legal compliance should be conisdered as a target.

This document is a living document and will be updated periodically (e.g. by the addition of additional sector specific guidelines)

II. SCOPE

The Framework Regulation covers any type of food contact material or article, regardless of its composition. This Code therefore aims to cover a very wide scope of materials and articles. Any material or article not explicitly covered in these guidelines should be aligned with the most appropriate material listed and treated in a similar manner.

For complex non-packaging multi-material products such as household appliances it could happen that these guidelines are too general.

II.1 Materials

The scope of this paper is determined by article 1 of the Framework Regulation (EC) No 1935/2004, and examples of food contact materials are given in Annex I of this Regulation:

- Active and intelligent materials and articles
- Adhesives
- Ceramics
- Cork
- Rubbers
- Glass
- Ion-exchange resins
- Metals and alloys
- Paper and board
- Plastics
- Printing inks
- Regenerated cellulose
- Silicones
- Textile
- Varnishes and coatings
- Waxes
- Wood

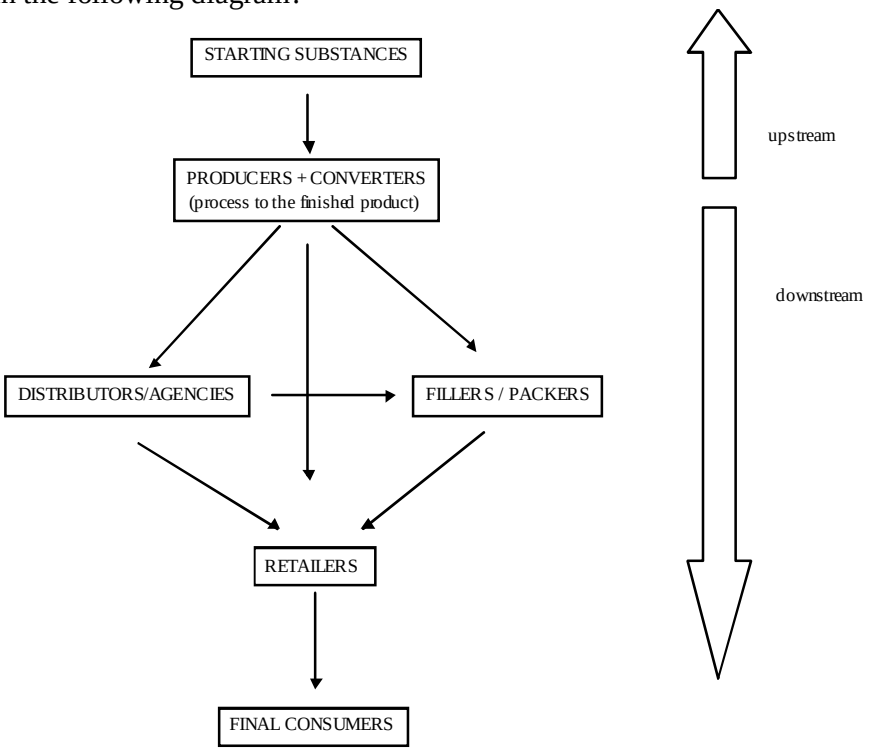
This list was used as a reference for contacting representative trade associations within the supply chain who take responsibility for each material group.
The trade associations, who have worked together on this document, are listed in Annex 1.
Industry guidelines concerning traceability of materials and articles, which served as the basis for this document, are described in Annex 2.

II.2 Applications

The scope of this document is specified as food-contact materials and articles, when first placed on the market at the retail stage, and also, where appropriate, to those starting materials used for the manufacture of the said food-contact materials and articles.

III. STAKEHOLDERS WITHIN THE FOOD CONTACT MATERIALS AND ARTICLES SUPPLY CHAIN

The stakeholders involved along the supply chain of food-contact materials and articles are represented in the following diagram:



Using the above diagram, it is possible to identify a point where the food contact material or article is manufactured, i.e. the converters and producers. At this point there is a separate identity, “upstream” and “downstream”. Converters transform materials, which have been produced by “upstream” suppliers, into finished articles or semi-finished goods. Producers manufacture articles directly from starting materials, using processes involving chemical, as well as physical change

The scheme illustrated above assumes that the whole chain is within the European Community. However, in some cases, part of the chain can be outside the Community; therefore another stakeholder must be included in the scheme, namely the Importer. Imports may take place at different levels, such as:

- Import of starting materials by the converters and producers;
- Import of empty packaging by distributors or fillers;
- Import of food contact articles by distributors or retailers;
- Import of filled food contact materials and articles by distributors or retailers.

IV. DEFINITIONS

Among the numerous definitions of traceability, the following was selected:

"The ability to trace back the history of a food contact material or article from the retail stage to the point of its manufacture, identifying all appropriate information."[1]

There are two levels of traceability, i.e.:

Level 1: within the operation of each stakeholder

This level covers the systems that each stakeholder has in place to link his products to the raw materials used to produce them.

Level 2: between different stakeholders

This level is concerned with the transmission of information along the chain. It should be possible from any point downstream, and in particular from the retailing point to go back up the chain to understand by whom the material or article has been manufactured.

This also implies that, in the opposite direction, the material or article can be traced from any point up the chain down to the retailing point.

Both levels must function to achieve full traceability.

V. TRACEABILITY BACK TO WHERE?

The traceability chain ends at the retailer and the starting point for traceability of a food contact material or article, is placed at the point at which it, or its components/ingredients are first placed on the market with the intention of being "for food contact use".

In the case of materials or articles, or their components/ingredients which have been imported from outside the European Community, traceability shall extend back to the importer responsible for placing them on the EU market for an intended food-contact application.

VI. LEVEL 1: TRACEABILITY WITHIN A STAKEHOLDER'S OPERATION

VI.1 The role of Quality Systems

Traceability has become an integral requirement of modern quality management systems. According to the ISO 9000 management standard, companies that have adopted this system are required to prepare and maintain documented procedures aimed at identifying the product, from the purchase of starting materials through the production process, and shipment. All procedures for the identification of production batches and single products must be appropriately documented (e.g. in writing or through computer archiving).

ISO 9000 is not the only system requiring industry to establish procedures for traceability; other systems, such as good manufacturing practice, in place in many industries, have the same requirements.

All these systems have the aim of ensuring a constant quality of products during manufacture.

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[1] definition based on:
*Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28/01/2002 laying down the general principles and requirements of food law, OJ L31/1
*European Commission Proposal of regulation concerning traceability and labelling of genetically modified organisms and traceability of food and feed products derived from GMOs, adopted 25/07/2001, 2001/0180(COD)
*Codex Alimentarius Commission ; 2-7/07/2001+ Comments European Commission on this matter

VI.2 The industrial practice

The business operator ensures that the incoming starting materials are supplied with information given by the relevant supplier. This information is either printed on the starting materials' containers, or reported on labels, bar codes, or in accompanying documentation.

Information must be provided which enables the identification of:

1. Name of supplier and type (grade) of starting material;
2. Location of production, date, batch number and/or shift of manufacture and/or order number;
3. When appropriate (for example in the case of plastics) documents certifying the legislation with which they are complying;
4. Documents of analysis that, depending on their nature, report the key attributes against the agreed specifications.

The downstream user often carries out further analyses in order to confirm the suitability of the starting materials for their intended use. Also, according to ISO 9000 procedures, downstream users can carry out audits to ensure that the upstream supplier's process is under control, and therefore the relevant technical attributes of the starting materials are constantly maintained.

The above considerations ensure that all measures are taken to identify defects before they can cause an effect on the finished product(s)

VI.3 Need for quality systems

Some companies involved in the food contact materials and articles distribution chain, especially small and medium size enterprises, may not have the critical mass for being accredited through a certified quality system. Nevertheless, they should establish an equivalent quality system internally. Whatever procedure is adopted, it is essential that every manufacturer of a food contact material or article maintains a documented quality system aimed at identifying and preventing the production of defective products and, in the case of delayed defects detection, allowing minimal product recall.

VI.4 Requirements for shipped materials and articles

Food contact-materials or articles, and/or their container, and/or the accompanying documentation shall always report all appropriate information, e.g. the manufacturer's name, a reference relative to the location and date of production.

The upstream producer ensures that essential production information is transferred to customers. Essential production information is:

a) Producer name and address;
b) Article number/product name;
c) Production date and identification of the product.

Several tools such as alpha-numeric descriptions, bar codes, labels, the documentation that accompanies shipped goods, or even electronic tags that are capable of carrying the above information can be used, the use of these tools is dependant on the further use of the material and their cost. Some examples are reported below:

a) Usual means of identification for food and beverage metal cans are labelling, bar-coding and sometimes inkjet coding. These are applied either to individual cans or to batches and are dependant on feasibility and the needs of the product;
b) A label can be used as an appropriate information conveying tool for transport packaging containing rigid packaging such as plastic trays, glass containers, PET pre-forms etc. The same result can be achieved by reporting the information on freight documentation.

c) In the case of articles sold to the consumer without being in contact with food, such as plastic cutlery, glass jars or paper baking forms, the information can be printed or labelled on the article itself or its sales packaging, or reported in freight documents.
d) In the case of reels of films or paper that will be further processed before being used, the information can be printed on to a label fixed to the wrapping or fixed to the core, printed on the conveying tool, or printed on the freight documentation.

It must be pointed out that it is not important how the information is conveyed to the next organisation in the distribution chain, but it is of fundamental importance that the information is complete, unambiguous and is maintained along the chain.

Individual industry guidelines are outlined in detail in annex 2.

VII. LEVEL 2 - TRACEABILITY ALONG THE SUPPLY CHAIN

Traceability is achieved only if each single part of the chain complies with the rules of identification enabling it to go back to its upstream supplier(s). In other words, the information that accompanies materials and articles when they leave the manufacturing company must be maintained by each downstream user in the supply chain.

In the ideal supply chain, e.g. a chain composed entirely by ISO 9000 certified companies, traceability will be always guaranteed, as every single step of the chain will have been documented, In practice different identification rules may apply for upstream and downstream users .

Not all distribution chains are composed entirely of certified companies, and one basic concept must be introduced that forms a fundamental part of a traceability system. Upstream suppliers supplying a company operating under a certified quality system shall strictly guarantee traceability of their products. It is essential that companies operating under a certified quality system control their suppliers and ensure that the supplied products are appropriately identified.

The food contact materials and articles chain consists of three applications which must be treated differently when discussing traceability. These are, firstly, materials and articles already in contact with food; the second category is materials and articles manufactured for food use intended to be brought into contact with food. Finally, a third category is composed of material & articles that can reasonably be expected to be brought in contact with food or to transfer their constituents to food under foreseeable conditions of use.

VII.1 Materials & articles already in contact with food

Materials and articles already in contact with food are commonly called “packaging”. For ease of reading, this term will be used in the section below.
Filling represents the boundary to the downstream end of traceability of packaging materials.
When the packaging is filled with food, its information overlaps the information required of the food itself, which is guaranteed through the following:

- “Best-before” date (mandatory for all foodstuffs);
- Date of packaging and/or lot number.

It is required that fillers maintain records of specific information for the packaging material that has been used for each foodstuff, and that the link between the two information flows is not interrupted.

The objective of establishing a mandatory system for traceability primarily focuses on obligatory record-keeping of the packaging information for each lot of food packed and sold.

It is not important how the link between food and the material used for its packaging is maintained by each body in the chain, whether it consists of, for instance, document filing or electronic archiving, as long as an unequivocal and unambiguous link is demonstrated. For example, companies may choose to archive the material's shipment documentation with its reference lot number, or to store in a spreadsheet the material's reference codes versus time, if the process is continuous.

Thus, the traceability of food packaging materials will be ensured and additional marking of the material or article itself will be not be required.

VII.2. Materials & Articles intended to be brought into contact with food

These are materials and articles in a stage of their production and marketing prior to the stage at which they are brought into contact with food. Alternatively they are materials and articles sold in the retail stage with the intention of being brought into contact with food. For this reason their identification system can not overlap with the food identification system. In these cases, it is necessary that the information (e.g. manufacturer's name, date and place of production, code, etc…) be maintained down to the retail stage.
The tools employed for the identification of food contact materials can be used for food contact articles, i.e., alpha numeric descriptions or bar codes, reported on labels, directly printed or provided in appropriate documentation.

VII.3. Material & Articles that can reasonably be expected to be brought in contact with food or to transfer their constituents to food under foreseeable conditions of use

In relation to traceability information and its flow in the supply chain this section is not a separate category of food contact materials and articles. The point at which the material or article is identified as coming into contact with food, or the fact that this contact can be indirect indicates that the starting points of the traceability chain can be different. However the end point is still the retailer. At this point the material is either in contact with food or not. Thus dependant on the case either of the previous two paragraphs apply.

VIII. STRUCTURE OF THESE INDUSTRY GUIDELINES

The guidelines are divided in material groups as defined in annex I of the Framework Regulation and are available in appendix II to this document.

Each material specific guideline has the following structure:

1) Scope
2) General information
3) Traceability information and "propagation"
4) Recall
5) Others

IX. CONCLUSIONS

As a general principle, the food market does not accept food contact materials and articles of uncertain origin. The quality of food contact materials and articles is not only a legal requirement, but is increasingly becoming a competitive advantage. It is in the industry's own interest to maintain a high level of control over its production and this can be achieved only through a suitable traceability system.