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POSITIVE LISTS AND THE APPROVAL OF FOOD CONTACT MATERIALS

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The knowledge of regulations on packages for direct food contact is of crucial importance for packaging professionals. In general, these regulations deal with the compliance of materials intended to come into contact with food to ensure the consumer health through the control of accidental chemical contamination, occurring by the interaction between the package and the food. In addition, knowing the national and international regulations is necessary so the national industry can correctly specify its packages related to technical requirements for the domestic and foreign market.

This article addresses specifically the Positive Lists, adopted by most of the regulations for food contact materials. A positive list is a list of substances approved for use in the formulation of materials, which were previously studied and may show certain limitations for the concerned application.

First, it is important to define some concepts:

- Migration - the transfer of components from the material to food products, due to physicochemical phenomena.
- Overall or global migration - the total amount of components transferred from the material to the food products or their simulants, under usual conditions of use, production and storage or under equivalent conditions of testing. Overall migration is a measure of the food-material interaction, which leads to contamination.
- Specific migration - the amount of a particular component with toxicological interest, which is transferred from the material to the food products or to their simulants, under equivalent conditions of assay.
- Overall or global migration limit - the maximum permissible amount of components transferred from the material to a food simulant, under the assay conditions.
- Specific migration limit (SML) - the maximum permissible amount of a specific component transferred from the material to a food simulant, under assay conditions.
- Composition limit - the maximum permissible residual amount of a particular component of toxicological interest in the food contact material.
- Simulant - a product that simulates the extractive power of a group of foods having similar characteristics. For example, distilled water simulates aqueous foods; aqueous solution of acetic acid simulates acid foods; aqueous solution of ethanol simulates alcoholic drinks and isooctane and/or olive oil simulates fatty foods.

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In order to include or exclude a substance from a Positive List, it is necessary to present technical and scientific information, which indicates whether there is a risk to health, documented as a petition, that is submitted to the competent authority.

In Brazil, the National Health Surveillance Agency (ANVISA) of the Ministry of Health is responsible for the regulation about the approval for food contact materials.

In addition to administrative documents, a technical dossier should follow a petition, which may have minor differences in its content, depending on the concerned law. However, some overall aspects that must be provided are described below:

A) SUBSTANCE IDENTIFICATION

The substance to be approved must be thoroughly detailed regarding its name, composition and synthesis methods. It is necessary to describe:

- Chemical name: it must be IUPAC name or the name as per the Chemical Abstracts, their synonyms (if any) and trade name. Of note, IUPAC means International Union of Pure and Applied Chemistry, an international and non-governmental, scientific agency, acknowledged as the authority for the chemical nomenclature, terminology, standardized methods and atomic weights.
- CAS number (Chemical Abstracts Service Number).
- Molecular and structural formula. In case of polymers, provide molecular weight (Mn). If Mn could not be determined, chose between relative or intrinsic viscosity or melt flow index. Details on the methods used for determining these measures are also required.
- Complete description of the synthesis process, including purification procedures and chemical equations of all stages of the synthesis. It is also required to provide the list of reagents, solvents, catalysts, purification agents, amounts and concentrations used, respective specifications and CAS number of each component involved in the synthesis.
- Concentration of impurities and percentage of purity together with the analytical data and calculations.
- Analytical data characterizing the substance. For example: infrared (IR) spectra, ultraviolet (UV) absorption, nuclear magnetic resonance (NMR), and/or mass spectrum.

B) CHEMICAL AND PHYSICAL PROPERTIES OF THE SUBSTANCE

It is necessary to inform:

- Physical properties: boiling, melting, and decomposition temperatures (if any), density, solubility, and information related to lipophilicity. In case of polymers, vitreous transition temperature (Tg), crystallization degree and melt flow index. Chemical properties: reactivity, stability, hydrolysis, decomposition and interaction with foods.

C) SUBSTANCE APPLICATION (USE)

- To inform the possibilities of use of the substance. For example: films, molded products, coatings, additives for polymers, paper preservatives, etc.
- Technological function of the substance in the production of the final product. For example: monomer, antioxidant, antistatic agent, preservative, defoamer, sizing agents, etc.
- Maximum percentage of the substance used in the final product formulation and minimum percentage for obtaining the desired technical effect.

- Information on the final product processing.
- Information on the conditions of the contact between the food and the final product.

D) SUBSTANCE AUTHORIZATIONS

It is advisable to inform if the substance was previously approved regarding international regulations, and on which it is based. Example: approval for direct or just indirect contact, generic approval or approval just for the contact with dry foods, etc.

E) SUBSTANCE MIGRATION DATA

Usually, specific migration (SM) is performed; however, in case SM is impossible to be determined due to substance properties, it is required to perform the overall migration assay. For both assays, severe conditions of temperature and time are used. Information on the substance to be analyzed, the simulant, and the analytical method used must be described in details, in compliance with the requirements of law.

F) TOXICOLOGICAL DATA

Estimated daily intake (EDI) of the substance is calculated by combining the migration assay results and the information on the final product application. EDI is used to determine the types of toxicological studies required, which will be performed under the proposed conditions of use. Information on the substance and the methods used must be described in details, according to the requirements of law.

Formulation assessment

The formulation assessment forward to Positive Lists should be performed before other tests required by the legislation, since the composition of the product must be in compliance with regard to the suitability for direct food contact.

The formulation assessment is a theoretical analysis to check all components composing the material intended to be used for food contact, based on provisions of the legislation that is relevant to the study. Only substances contained in the Positive Lists are allowed for manufacturing food contact packages and packaging materials.

In case the product complies with the requirements related to the formulation, the other analyses within the law may be conducted as a continuation of the process of approval. Otherwise, the formulation should be changed, in order to become suitable for food contact.

CETEA provides theoretical assessment of formulations, so as to prove the compliance with the Brazilian/MERCOSUR, European Union and/or FDA regulations, as one of the technical consultancy services rendered to the companies in charge manufacturing and using food packaging materials.

To perform such assessment, some procedures need to be followed:

1. Describe information on the composition of the product in a specific form supplied by CETEA. The primary information for the study comprises: Chemical Name of each substance in the product and its respective CAS number (see Chart 1), Qualitative Chemical Composition, i.e., amount of each substance present in the product analyzed and the intended application of the product in details. Documents such as Data Sheet and Assay Certifications, reports of the substances contained in the product are also necessary. All this information is considered confidential and exclusive.

Chart 1. Details on the CAS number.

CAS Number or CAS Registry Number
CAS is a division of the American Chemical Society comprised by scientists who develop and make available one of the most complete digital information for scientific research. CAS Registry (CAS Registry Number or CAS Number) is a numerical identification which corresponds to one substance only. Since 1957, the substances identified in the literature have been registered. Currently, the CAS Registry is one of the largest databases worldwide, with more than 25 million of organic and inorganic substances. CAS number may have 9 digits, separated into three parts by hyphens: the first part, from the left, may have up to six digits; the second one has two digits; and the last one have a single digit. Example: 58-08-2 is the CAS number for Caffeine 1310-73-2 is the CAS number for the Sodium hydroxide or Caustic Soda 10043-01-3 is the CAS number for the Aluminium sulfate CAS offers CAS number searching services within specific and particular online database. However, there are also free search websites at the internet. More information is available at: http://www.cas.org/

2. Confirmation of the provided information, i.e., it is checked if the CAS number matches the same Chemical Name provided. Such check may be performed in free search websites available at the internet, in online databases of the own service provided by the CAS Registry, and eventually in literatures available at the bibliographic collection of the ADI of CETEA and on the Internet.
3. Search for substances contained in the product in the Positive Lists related to the study. To accomplish such step, the assessor is required to have critical vision to interpret the law and detect potential limitations and restrictions.
4. Write a detailed report, containing all study history and, if the substances contained in the product are compliant with the concerned law, a statement is issued attesting the compliance of the product analyzed, taking into account the formulation provided actually reflects the practice.

In Brazil, the following Positive Lists are available:

- Cellulose Packages and Equipment available in the Annex I and V of Ordinance. n. 177 of March 04, 1999.
- Metallic Packages and Equipment available in the RDC Resolution n. 20, March 22, 2007.
- Synthetic Fibers of Regenerated Cellulose available in the item 4 of the Resolution n. 218, August 01, 2002.
- Films of Regenerated Cellulose available in the item 4 of the Resolution n. 217, August 01, 2002.
- Polymer and/or Resin-Based Film-Forming Preparations available in the item 3 of the Resolution n. 124, May 19, 2001.
- Elastomeric Packages and Equipment available in the Parts I, II, III and IV of Resolution n. 123, May 19, 2001.
- Wax and paraffin available in the item 3, of the Resolution n. 122, June 19, 2001.

- Plastic Packages and Equipment available in the RDC Resolution n. 17, March 17, 2008 and RDC Resolution n. 56, November 16, 2012.

All these regulaments were subject to the process of harmonization, coordinated by the GMC, the Mercosur executive body, i.e., these resolutions rules are valid in all countries of Mercosur.

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