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REACH and Food Contact Regulations for Plastics: substances listed in the REACH candidate list can be used to manufacture Plastic Food Contact Materials and Articles

This document compares and contrasts two key regulations for European manufacturers of polymers used in the manufacture of plastics materials and articles, namely the REACH regulation¹ and the regulations on plastic materials and articles intended to come into contact with food². Both of these regulations require the submission of extensive dossiers to European authorities. In both cases, companies have to meet a number of legal obligations to demonstrate safe use before a substance is approved.

REACH applies to all chemical manufacturers and importers. The obligations apply to all potential uses of all chemical substances. In contrast the safety assessment for food contact substances is highly targeted so that they ensure that substances used in food contact applications are not transferred to food at levels which pose a risk to human health.

REACH

The REACH regulation: R for registration

The REACH regulation refers to registration (the “R” of REACH) of chemical substances manufactured and imported into the EU. Registrants must submit a technical dossier containing information on the physico-chemical, environmental (e.g. persistence/degradability in the environment), ecotoxicity and human health properties of the substance. The dossier also contains details of the uses for the substance and, in cases in which the substance is classified as hazardous, a series of detailed exposure scenarios to determine the conditions under which the substance may be used safely.

The REACH regulation: E for Evaluation

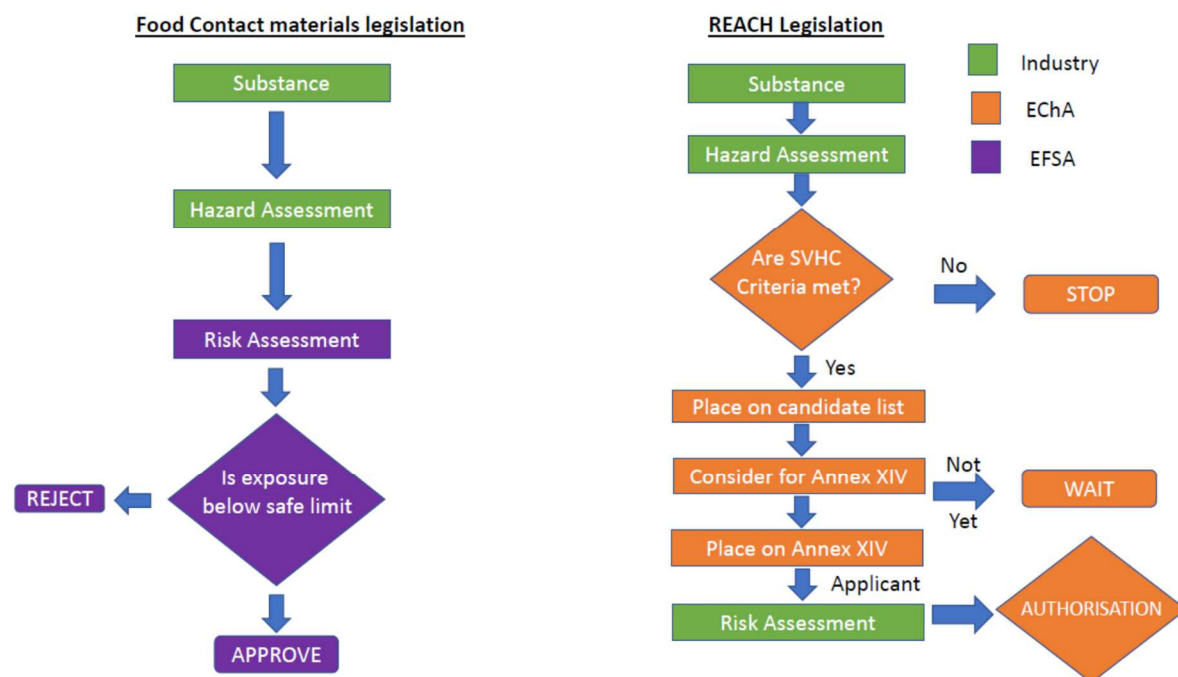
Dossiers are submitted to the European Chemicals Agency (ECHA). ECHA may then evaluate the substance (the “E” of REACH) and, in some cases, may designate substances as **Substances of Very High Concern (SVHCs)** based on their intrinsic hazard properties. The hazard properties which trigger an SVHC listing are those of “CMR”: carcinogenicity (C: the potential to cause cancer), mutagenicity (M: the potential to damage cells), reprotoxicity (R: the potential to adversely affect the reproduction system). SVHC status can also be obtained for the potential to exhibit environmental hazards such as Persistence (P), Bioaccumulation (B) and Toxicity (T) and substances regarded as Very Persistent (vP) and Very Bioaccumulative (vPvB). SVHC listing is, however, not restricted to these endpoints and ECHA may designate a substance as an SVHC on other properties and designate it a Substance of Equivalent Concern (SEC). Such substances are listed on the ECHA website, the list being termed the **Candidate List of Substances of Very High Concern (SVHCs)**.

¹ http://ec.europa.eu/enterprise/sectors/chemicals/REACH/index_en.htm

² https://ec.europa.eu/food/safety/chemical-safety/food-contact-materials_en

The REACH regulation: A for Authorisation

SVHCs are then prioritised to ascertain whether they are subject to authorisation (the “A” of REACH) or, in some cases, restrictions are placed on uses. Authorisation decisions are based on detailed risk assessments of the substance and its uses, consideration of (less hazardous) alternatives and, in some cases, a socio-economic evaluation of uses. Substances which are SVHCs and approved for food contact substances do not need to be assessed under REACH authorisation for human health effects since they have been assessed for safety in food contact materials under the relevant regulations already (see below).



Food Contact Materials

Europe has had a long-standing tradition of regulation of Food Contact Materials (FCMs), especially plastic food contact materials. Plastic food contact materials remain one of the few materials subject to harmonised European legislation, with such legislation being in place at EU level since 1990.

Substances are assessed for use in FCMs by the European Food Safety Authority (EFSA). A dedicated panel studies an extensive dossier submitted by manufacturers. Dossiers include not only toxicological data but migration data (assessing the substance’s potential to migrate from FCMs into food). EFSA approves both monomers (the chemical building blocks which form polymers which are then converted into plastic materials) and additives (substances used to produce a technical effect in the FCM). Since the packaged material is food, FCM dossiers are detailed and generally go into far more detail than a standard REACH risk assessment for a non-food application. Thus, in making a REACH registration of a food contact substance, no consideration of human health aspects of FCM use is required since it is already considered as covered by the EFSA assessment: clearly it is safe for use if listed as approved for FCMs.

Two different assessment methodologies

It is important to remark on the different status of FCM approvals: substances may be approved as monomers used to manufacture FCMs or as additives.

From the above description of the REACH process, it can be seen that the SVHC assessment of a substance arises from a conclusion on hazard properties. If it meets one or more of the CMR, PBT/vPvB or SEC criteria it can be designated as an SVHC without any assessment of uses.

Approval of a substance for FCMs however is based on extensive studies of toxicity and the ability of a substance to migrate from FCMs into food. EFSA often places restrictions on the use of such substances, either as a maximum level of the substance in the FCM (known as the Qm) or as maximum level which can migrate into food, regarded as the Specific Migration Limit (SML). Such levels include large safety factors to ensure that any migration is orders of magnitude below any level which may induce health effects.

The Qm level is currently set at 10 mg per square decimetre or at 60 mg of substance migrating in one kilogramme of food, i.e. 0.0006% w/w of food can arise from the packaging. This is a measure of the inertness of the material rather than specific concerns on toxicity, but this gives consumer protection from numerous substances which would show no toxic concerns at this level. Other substances which are allocated SMLs below 60 mg/kg are approved subject to the SML being met. Companies must show that these levels are met, either by measurement or calculation showing that at levels used it is impossible for an SML to be exceeded.

It should be noted that all approved substances, whether those arising from natural sources or specifically manufactured, have toxic properties at some level of exposure. EFSA determines whether the toxicity has relevance at the 60 mg/kg level in food.

Hence it can be seen that the hazard assessment under REACH (CMR, BPT/vPvB, SEC) may conclude that a substance is an SVHC on the basis of a hazard assessment but the same substance may be approved for use in food contact materials on the basis of an extensive risk assessment showing safe use levels.

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