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Position Paper

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 regulation[1] and the regulations on food contact materials and plastic materials and articles intended to come into contact with food [2,3]. Companies manufacturing and selling products on the European market are required to submit extensive dossiers to various European authorities and 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 and related exposure routes of all chemical substances. In contrast, safety assessments for food contact substances are specifically aimed at food consumption to ensure that substances used in food contact applications are not transferred to food at levels that 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 in 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 must contain details of the uses for the substance and, in cases in which the substance is classified as

hazardous, a series of detailed exposure scenarios that describe the conditions under which the substance can be used safely. Dossiers are submitted to the European Chemicals Agency (EChA) in Helsinki, Finland.

The REACH regulation: E for Evaluation

EChA may decide to evaluate the registered 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 designated to a substance 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). Whichever reason for listing, however, it is important to stress that the designation is based on intrinsic hazard properties only and not the result of a risk assessment. Such substances are listed on the EChA website, the list being termed the **Candidate List of Substances of Very High Concern (SVHCs)**. The candidate list is published on the EChA website[4], and the sale of such substances carries a requirement for companies to communicate the fact to their immediate customers if the substance is present in another substance or mixture at level at or exceeding 0.1% w/w[5].

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. SVHCs that are approved food contact substances do not need to be assessed under REACH authorisation for human health effects since they have already been assessed for safety in food contact materials under the relevant regulations already[6].

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 food contact materials subject to harmonised European legislation, with such legislation being in place at EU level since 1990[7].

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 also 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 there is contact with food, FCM dossiers are detailed and target specific human health properties. Thus, in making a REACH registration of an already approved food contact substance, no consideration of human health aspects of FCM use is required in the REACH dossier 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 detailed 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. EU food contact legislation sets an overall migration limit (OML) as the maximum permitted total amount of non-volatile substances that can migrate into food. Next to that, EFSA may place 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 OML is currently set at 10 mg per square decimetre or at 60 mg of substances migrating into one kilogramme of food, i.e. 0.006% w/w of food can arise from substances migrated from the FCM. This is a measure of the inertness of the material rather than a specific concern on toxicity. It should give a consumer the assurance of protection from substances that show no toxicity concerns at this level. Other substances which have allocated SMLs below the 60 mg/kg overall migration level are approved subject to the SML being met. Companies must show that these levels are met and do so by measurement, calculation or targeted modelling showing that at levels used it is impossible for the SMLs to be exceeded.

It should be noted that all approved substances, whether they originate from natural sources or are specifically manufactured, have toxic properties at certain level of exposure. Based on the toxicological properties and migration data of a substance, EFSA determines whether the safety threshold of a substance is above or below the overall migration limit of 60 mg/kg in the food. If above this level, the 60 mg/kg limit applies. If below this level, a specific migration limit (SML) indicates the safety threshold.

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. Figures 1 and 2 show a schematic of the two distinct evaluation schemes.

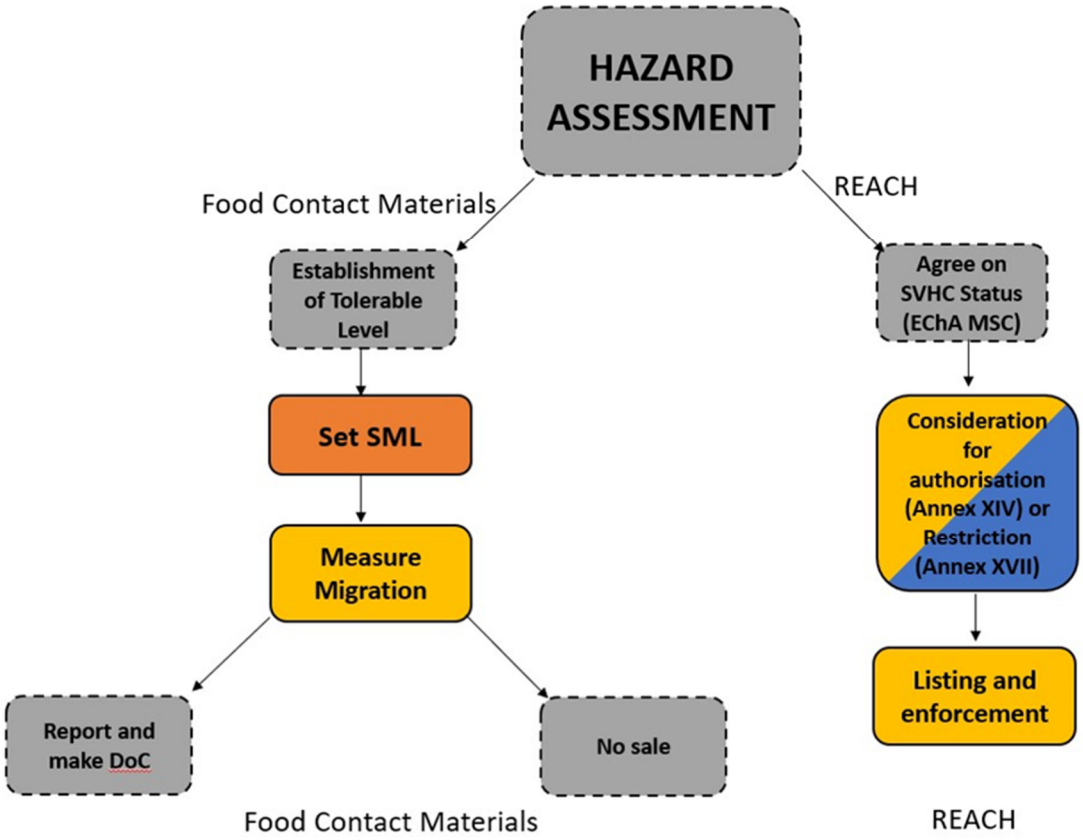

Fig 1: Flow Chart Showing the diverging routes for regulation of hazardous substances under Food Contact Material legislation (left) and REACH (right)

Monomers

Monomers are the substances used to form polymers: monomer molecules are reacted and join together to form long polymer chains which can then be used to manufacture plastic materials. In general, residual monomers are present at exceedingly low levels and do not serve any technical function in the final FCM. Whilst many regions of the world, including, notably the United States of America (under the Food and Drug Administration (FDA)) regulate food contact materials through the assessment of polymers, the EU has a long tradition of *approving monomers which can be used to manufacture polymers for food contact applications*. The level of residual monomer may be subject to regulation via the overall migration limit (OML) or via a specific migration limit (SML) that may be set if the presence of residual monomer – and its' potential for migration into food – presents a health concern. Since monomers are generally classified as hazardous substances, (their reactivity to form polymers makes use of this) there is a need to control their residual levels. Monomers with the highest hazard classification, such as vinyl chloride, are permitted with the requirement that they are not detectable in food, so concerns on the presence of such monomers in food, as a result of migration, are resolved. There are extensive requirements for the analytical methods that show that such monomers are not detectable in food* not based on reality. Moreover, any monomer which is classed as an SVHC will also be subject to SMLs. Hence the concerns which gave rise to a substance's designation as SVHC for human health are highly controlled in the case of their use as a food contact monomer.

In the food contact regulation 10/2011, monomers have the Packaging Material (PM) reference number. The Packaging Ref. No. was the previous identification system used under the Plastics Directives 2002/72/EC. The reference number is a 5-digit number and indicate if the use is as monomer or other starting substance (from 10000 to 29999) or if the substance is used as an additive or a polymer production aid (from 30000 to 99999).

**Regulation 10/2011 states "Where it is specified that no migration of a particular substance is permitted, compliance shall be established using appropriate migration test methods selected in accordance with Article 11 of Regulation (EC) No 882/2004 that can confirm the absence of migration above a specified limit of detection. For the purposes of the first sub-paragraph, unless specific detection limits have been set for particular substances or groups of substances, a detection limit of 0,01 mg/kg shall apply."*

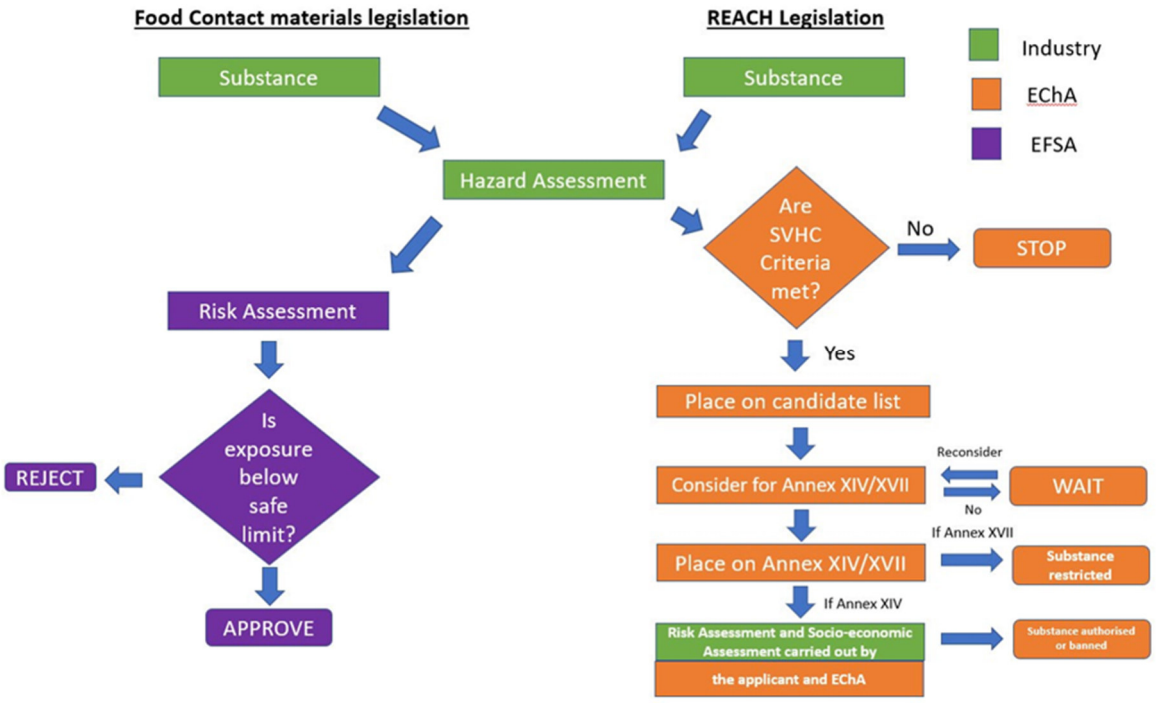

Fig 2: Overall schemes of approval and rejection for substance regulated under food contact regulations (left) and REACH (right)

Additives

As detailed above, if a polymer additive is classified as sufficiently hazardous in order to be regarded as an SVHC for human health under REACH and if it is also approved for use in food contact materials a detailed safety assessment has been conducted and a specific migration limit set. The rules and requirements that apply to monomers equally apply to additives. Contrary to monomers, however, additives are intended to be in the final FCM because they perform a technical function in the FCM.

As of the last amendment to the plastics implementation measure, there are 1077 substances approved as monomers and additives for use in plastic food contact materials in Europe, 301 of which have limitations below the overall migration limit of 10 mg/dm^2.

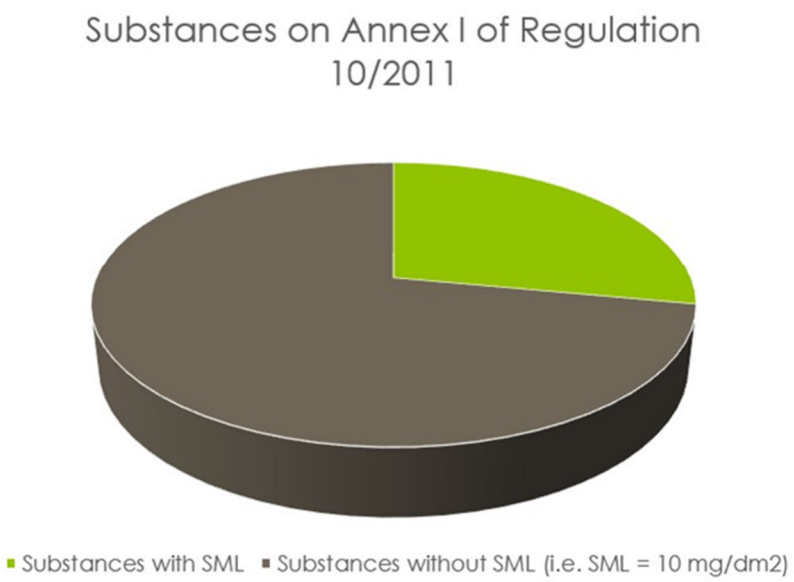

Figure 3: Division between approved substances with a Specific Migration Limit (SML) in EU Regulation 10/2011 and those without (for which the global migration limit of 10 mg/dm^2 applies)

This shows that EFSA felt the need to apply more strict requirements for these substances since the 10 mg/dm^2 limit was considered not to be sufficient as a safety threshold. Given the fact that EFSA's assessment method is based on risk rather than hazard only, it is possible that substances with specific hazards that render them as SVHCs under the REACH regulation may also be approved for food contact uses when risk is taken into account.

Candidate List Substances with Environmental Hazards

More recently, some substances have been included in the SVHC candidate list because of their environmental properties. If they are approved for use in food contact materials, such substances have been assessed for human health in the same way that holds for other substances. This assessment as such will not exempt the user from the responsibilities to assess the use of the substance from an environmental perspective and to follow any specific actions required as a result of the REACH evaluation process. If the substance is placed on Annex XIV (Authorisation List") or Annex XVII ("Restriction List") of the REACH regulation, the user must apply for authorisation (or be aware that the supplier has been granted an authorisation) or the user must use the substance in accordance with any specific restriction(s) as detailed in Annex XVII.

Summary

Whilst REACH and the food contact regulations have similarities in that they both assess the safety of chemicals, there are understandable differences in emphasis. REACH applies to all substances for any application whereas the food contact regulations only assess the safety to human health of the substances concerned.

The European Union has produced several regulations in the field of food contact materials that give a very high standard of protection, with substances only approved for use after submission of extensive toxicity and migration data and approval by independent authorities. These EU regulations are widely respected globally and frequently amended and copied in other global jurisdictions.

The responsibilities of the European Chemicals Agency for REACH and the European Food Safety Authority for food contact materials differ in parts. Although, the status of substances under the two regulatory processes may appear to be different (where part of the REACH processes identifies the hazard of substances and food contact regulations determine a safe level of exposure), only substances which have been assessed in detail by EFSA are approved for use in FCM. Human health assessments that have been performed under the food contact regulations do not need to be repeated under REACH for food contact use. For substances with an environmental hazard, food contact users must follow the REACH process and take any regulatory action in the same way as nonfood contact users.

References

1. REACH regulation: European regulation 1907/2006 of 18th December 2006
2. Food Contact materials “framework” regulation: European regulation 1935/2004 as amended
3. The “Plastics implementation Measure” for food contact materials: European regulation 10/2011 as amended
4. The REACH Candidate List of Substances of Very High Concern: All news - ECHA (europa.eu)
5. REACH Regulation (see reference 1): Article 33
6. REACH Regulation (see reference 1): Article 14(5)
7. Commission Directive 90/128/EEC of 23 February 1990 relating to plastic materials and articles intended to come into contact with foodstuffs (Official Journal L 075 , 21/03/1990 P. 0019 – 0040)

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