PlasticsEurope
Association of Plastics Manufacturers

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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 paper explains, without going deeply into the details, the different scopes of the legislations on food contact[1] and on REACH[2] with regard to the presence of certain substances which figure on the REACH candidate list and which are permitted for food contact.

The REACH Candidate list is a holding list of substances pending potential decisions on a transfer of these substances to the authorisation list (REACH Annex XIV). Substance authorisation under REACH will require a risk assessment for specific uses, an analysis of the possible alternatives and often a socio-economic analysis. Candidate list substances are considered Substances of Very High Concern (SVHC) on the basis of intrinsic hazard properties for human health or the environment. Such identification is made without taking risk into consideration. If a candidate list substance is passed to the authorisation list and an authorisation applied for, a risk assessment is made as part of the authorisation procedure.

Substances approved for use in food contact plastics have already been through a risk assessment. The specific use in food contact materials and articles is not subject to a risk assessment for human health under REACH. All food contact materials are subject to the requirements of the Framework regulation on food contact materials (Regulation (EU) No.1935/2004). Plastics Food Contact Materials have additional obligations according to the European Regulation (EU) n° 10/2011 which approves monomers and additives for use in food contact plastic materials

Monomers and additives used in the manufacture of food contact materials are assessed by the European Food Safety Authority on the basis of their toxicological properties in food contact applications. Substances included in such materials are cleared subject to either being present below stated levels in plastic articles or not being transferred into food above stated levels.

Given the two contrasting assessment mechanisms – hazard and risk – it is possible for a substance to be listed on the REACH Candidate list of SVHCs because of its hazard and cleared for use in food contact materials following a risk assessment by EU authorities.

Environmental concerns

Even though food contact plastics have undergone a robust safety assessment for consumer use, consideration should be given to the fact that certain food contact materials may give rise to concern because of the use of certain substances that have been placed on the REACH candidate list because they are considered to have met the definition of Persistent, Bio accumulative and Toxic or Very Persistent and Very Bio accumulative. However if such substances are present in another substance or article below the SVHC declaration limit (see above) of 0.1% w/w they can continue to be used but if they do not meet this requirement their presence must be declared down the supply chain in accordance with the requirements of the REACH regulation.

[1] http://ec.europa.eu/food/food/chemicalsafety/foodcontact/index_en.htm
[2] http://ec.europa.eu/enterprise/sectors/chemicals/REACH/index_en.htm

Background

Plastics use in Europe is governed by several regulations; which ones apply to a given product depends upon the applications of the plastic material in question. However two of the most significant regulatory areas are the REACH regulation and regulations governing plastics in contact with food. It is important to have an understanding of the similarities of, and differences between, the two schemes since some aspects of the two regimes may at first sight appear to be contradictory.

The REACH Regulation

The REACH (Registration, Evaluation, Authorisation and Restriction of Chemicals) regulation (EU Regulation 1907/2006) has been described as the most ambitious piece of legislation the European Union has ever devised. It is truly massive in its scope, requiring the registration, with a technical dossier, of all substances manufactured or imported into the European Union in quantities above one tonne per year. As the volume increases, the data requirement in the technical dossier increases. For substances manufactured or imported in quantities above ten tonnes per year a Chemical Safety Report (CSR) is required detailing all supported uses, and risk management measures to handle them safely

Each registration dossier has a section on the hazard classification of the substance. This is based on studies of well-established endpoints such as acute and chronic toxicity, ecotoxicity, carcinogenicity, mutagenicity and reprotoxicity or physical hazards. A hazard classification indicates a given effect of a substance without direct connection to the amount of the substance, in its conditions of use. However a risk assessment will assess whether the use of the substance in each different application results in an exposure for the workers or the consumers. For example boric acid is listed as an approved monomer and additive for the manufacture of Food Contact Plastics. This chemical and its salts have been noted in seawater. It also exists in plants and especially in almost all fruits. Boric acid in high doses is poisonous and shows significant developmental toxicity. Recently it has been added to the REACH candidate list. At low levels this chemical is used in pharmaceutical applications as an antibacterial compound in an acne treatment. When used at low levels boric acid presents no risk for the consumers. The classification acts as a notice of warning for the substances as such. In food contact applications boric acid can be used as a cross-linking agent for polyvinyl alcohol (PVA) for plastics multilayers or as a stabilizer in specific polyacrylonitrile polymers.

Similarly ascorbic acid is listed as an approved substance for the manufacture of food contact plastics. As a pure acid, it must be treated with caution: some manufacturers state that when dissolved in water it has the potential to cause serious eye damage if splashes arise during use and the user is not wearing eye protection (Hazard statement code H318). This is a hazard classification that takes no account of level of exposure but refers to the properties of the pure substance. Ascorbic acid – vitamin C – not only shows no risk to consumers at lower exposure levels but is highly beneficial to human health. Hence it is the *level which sets the risk* and *no account of risk can be made without reference to level*.

The Candidate List and Authorisation of uses under REACH

One of the key parts of REACH is the authorisation process which applies to substances identified as Substances of Very High Concern (SVHC). Some of these substances, if finally placed on Annex XIV of the REACH regulation, will require an authorisation if they are to still be placed on the market. SVHCs must fulfil the requirements described in Article 57 of the REACH regulation. This means they must have hazard classifications for carcinogenicity, mutagenicity, reprotoxicity (CMR), or persistence, bioaccumulation and toxicity (PBT) or Very persistent and Very Bio accumulative (vPvB). Substances may also be added to the candidate list if there is

evidence of probable serious effects to human health or wildlife (the so-called substances of equivalent concern). The candidate list is a holding list from which substances may be selected to go through to the authorisation process after a consultation and prioritisation process. Authorisation only applies after this step.

The Candidate List is a list of substances to be considered for authorisation under REACH: It is not a list of dangerous uses of substances

There is no limit to the size of the candidate list; currently it has 138 entries. Presence of a substance on the candidate list does trigger obligations. If a candidate list substance is sold directly or is present at >0.1% by weight in another substance or product then its presence must be communicated by a supplier to its customer including information to allow safe use. This obligation carries all the way down the supply chain with the final requirement that a retailer must be able to provide such information to a consumer enquiring about the presence of SVHCs in consumer articles within 45 days (Article 33). If a substance is placed on the candidate list it does not mean that it is banned but under consideration for being placed on Annex XIV of the REACH regulation. .

Since the criteria for placing a substance on the REACH candidate list emanate from the classification and labelling section of a REACH dossier or from the PBT or vPvB assessment, it can be seen that these criteria are entirely hazard driven: they make no reference to level or conditions of use. Consideration of whether the substance can be used safely, consideration of potential alternatives and a consideration of the benefit of the use of the substance to society in general, will follow if the substance is selected for the authorisation process.

Regulations for food contact materials

Materials that are used in applications in which they come into contact with food are subject to the requirements of European Regulation 1935/2004. This covers all materials in contact with food. Some of the key requirements are set out in Article 3, which states that food contact materials must not transfer their constituents to food in quantities which could (a) endanger human health; or (b) bring about an unacceptable change in the composition of the food; or (c) bring about deterioration in the organoleptic characteristics of the food.

From the outset this can be seen as risk based. The regulation does not forbid the transfer of the constituents of the package: it merely states that if there is transfer that the constituents transferred must do no harm, change the food composition or change the taste. This means, essentially, that the food contact material must be inert to food. The regulation was a re-cast of the previous framework directive of 1989 - European Directive 89/109/EEC - which contained the same paragraph. There may have been great foresight by the authors of the original directive to write the article in this way rather than stating that there should be no transfer. The twenty four years that have passed since the original framework directive have seen tremendous developments in analytical chemistry. Minute amounts of constituents may be transferred and a food contact material that may have shown no detectable transfer in 1989 may now show signs of a minute transfer of ingredients. Such materials however are still in compliance with the framework regulation if the conditions of Article 3 are met. This is where a risk assessment of the properties of the ingredients is required. The maximum amounts of transfer to food or the authorisation of use can be reviewed by EFSA based on new information.

Substances approved for use in food contact plastics have already been through a safety assessment

In the case of plastics used as food contact materials, a further regulation – regulation (EU) No 10/2011– must be complied with. This sets out approved monomers and additives that can be used subject to either maximum levels (known as QM) or maximum amounts of transfer to food – known as Specific Migration Limits (SMLs). It also states that the total level of migration of all migrating species cannot exceed 60 mg of migrants per kilogram of food. This measure of inertness refers to the three conditions of the framework regulation discussed earlier. These QM and SML values are set by the European Commission (DG Health & Consumer Protection) based on a detailed safety assessment by the European Food Safety Authority (EFSA) including review of appropriate toxicological data related to oral route.
This may include the assessment of substances classified as hazardous and consequently, in extreme cases, may include substances that are described as SVHCs in the REACH process. What the EFSA does is ensure that no risk arises from the use of these substances in packaging or in articles by declaring a maximum level that may be present in food. This level, derived from the risk assessment, gives the limit at which the requirements of the Framework Regulation are met and takes into account a significant margin of safety.

It should be stated that in numerous cases, the SML of a substance used in packaging/articles is extremely low. No individual substance can have a migration exceeding 60 milligrams per kilogram of food and many substances are approved for use subject to SMLs below 60 milligrams. This level is far below the SVHC declaration level.

It is also important to note that two types of substances are approved under Regulation (EU) No 10/2011: monomers and additives. Monomers are the molecular building blocks of high molecular weight polymers. Monomers form chemical bonds with each other, gradually building up the polymer chain until it is of sufficiently high molecular weight to have the properties that are useful for the end application: strength, flexibility or rigidity, clarity or opacity. Since the monomers have reacted they are not present in the final product except in low residual quantities being tolerable following a risk assessment as described above. By their nature monomers are reactive and potentially hazardous and some of them may therefore appear on the REACH candidate list. In such cases the concerns which led to the substance being placed on the candidate list do not apply to the final articles since these are made of the polymers and not the monomers. Additives, which are intentionally added to plastics to achieve a physical or chemical effect during processing of the plastic or in the final material or article, will however be present in the final article. Those which are approved by Regulation (EU) No 10/2011 are listed in Annex 1 of that regulation.

Moreover the use of a number of ‘non-listed’ substances is also permitted provided industry complies with both the Framework Regulation and the provisions of Article 19 and Article 6 4.b. of Regulation (EU) No 10/2011. The safety of these substances needs to be demonstrated using internationally recognised scientific principles on risk assessment according to the terms of these regulations and details of such assessments need to be made available to authorities upon request.

Where a REACH dossier can refer to substance approvals under Food Contact legislation

Registered uses

A REACH registration dossier must include details of the applications of a substance and must show that these uses do not pose a risk to humans or the environment. In the case of substances that have been reviewed by EFSA for use in food contact materials, REACH states

that within a registration dossier such a risk assessment does not need to be made for human health again (Article 14). This is because to be listed as an approved monomer or additive in food contact materials and articles a substance must have undergone assessment by EFSA: there is not only a risk assessment showing the use to be safe but it is a risk assessment carried out by EFSA. Hence the use section of a REACH registration dossier for such a substance will reference its approval by EFSA under the regulation (EU) No 10/2011. The REACH dossier will, however, need to give an assessment of the environmental risk, if applicable, since such an assessment is not part of the EFSA process.

Use of SVHCs in food contact materials and articles

This will include substances that are considered as SVHCs. As was mentioned in the REACH section, the assignment of the SVHC designation to a substance is one that comes about from a study of the hazard status of a substance. This is in contrast to the assessment of a substance as a component of food contact materials which will set a migration limit below which the transfer is considered safe and renders the food contact material to be inert.

In the case of monomers or additives listed as SVHCs, it is important to note that if such substances are approved in food contact regulations a maximum permitted level in the final article will have been set. So SVHC substances that are authorized by the regulation (EU) n° 10/2011 can continue to be used to prepare Food Contact Materials only if the final materials meet the requirements of this regulation and other legislations applicable to them (e.g. regulation on waste).

Environmental concerns

Even though food contact plastics have a robust safety assessment for consumer use, consideration should be given to the fact that certain food contact materials may give rise to concern because of the use of certain substances that have been placed on the REACH candidate list because of their PBT and vPvB properties. If such substances are below the SVHC declaration limit (see above) of 0.1% w/w in the plastic they can continue to be used but if they do not meet this requirement their presence must be declared down the supply chain in accordance with the requirements of the REACH regulation.

Contact: michel.cassart@plasticseurope.org