INEOS
Olefins & Polymers Europe

Explanations on the content of the INEOS O&P Europe PP or PE Regulatory Compliance Certificate (RCC)

Objectives of the RCC

The RCC provides in a concise way with all regulatory information legally needed to allow the use of the related product in the most current fields of application. Although naturally dealing in first instance with the European legislation, it also covers the most important non-European legislations as well.
The RCC is always product specific, and thus takes into account all the characteristics related to every single product, like its composition, its production sites and its general characteristics.

1. FOOD CONTACT

1.1. Food Contact EU

The European Plastics Food Contact (EUPFC) legislation is based on the **Directive 2002/72/EC** which lists the monomers and additives that can be used.. This list is regularly amended when new additives have been petitioned by their producers and approved for FC use by the EFSA (European Food Safety Agency). Directive 2002/72 has been amended several times by other EU Directives and all have been transposed in the member states national legislations. It is foreseen that the next important update will in fact be a Regulation, which will become automatically applicable in all the member states, thus repealing the current national legislations.
Another important legislation is the **Regulation (EC) 1935/2004**, the so called Packaging Framework Regulation which covers all food packaging materials. Its Art 3 stipulates that they cannot:

- endanger human health,
- bring about unacceptable changes to the composition of the food
- bring about a deterioration of the organoleptic characteristics of the food.

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Practically, the basic principles of the EUPFC legislation are that:

- Only admitted monomers and additives can be used; this positive list of admitted monomers and additives is regularly updated when new monomers or additives have been petitioned by their producers and approved for FC use by the EFSA (European Food Safety Agency) then the Commission and the European Parliament.
- Global Migration in standard food simulants must remain below the limit of 60 mg/kg food or 10 mg/dm² of article

- Specific Migration Limits (SML), expressed in mg/kg food or mg/dm² of article, are applicable to some additives and monomers, ensuring that their accumulation in the food by migration is limited to a level low enough to not endanger the human health when the food is consumed.
- Furthermore, dual additives (i.e. that can be used in the food itself and in the plastic) must also be declared by the plastic producer
- The testing must be done on the final article as used in FC application. However, in order to help our customers, our RCC generally gives some information obtained by modelling (calculation using recognized software) or by comparison with similar grades.

Specific items related to European FC: BSE / GMO

BSE: Bovine Spongiform Encephalopathy)
GMO: Genetically Modified Organisms
These 2 items are closely related to the stearates used either as acid scavenger or as demoulding / antistatic agent. The stearic acid can come from animal or vegetal origin but in either case, it brings with it deep rooted fears that we try to demystify with sound scientific arguments and facts.
Animal origin also means not compatible with kosher or halal status.

1.2. Food Contact US

The US Food Contact (USFC) legislation is radically different from the European one. Indeed, based on the composition of the plastic (monomers and additives) and on some extraction data's, the producer can list the detailed conditions under which the product can be used to respect the FDA Code of Federal Regulations (CFR).

2. LEGISLATION APPLICABLE TO CERTAIN SPECIFIC USES

Certain uses are covered by very specific pieces of legislation. The most obvious being the articles intended to come into **contact with foodstuff**. This topic has been treated in the previous chapters.
Other examples are the **toys** to which a European Standard (EN71) applies and restricts the migration of certain hazardous substances. Their phthalate content is also restricted by an EU Directive (2005/84/EC) and the compliance with the food contact legislation a must.

Cosmetics are another segment regulated by a specific EU Directive (76/768/EC) which among others restricts the use of a vast number of chemicals in the cosmetics themselves. These prohibited substances are not used neither as raw materials for the production of INEOS PE or PP grades.

3. ABSENCE OF SUBSTANCES SUBMITTED TO REGULATIONS INTENDED FOR THE PROTECTION OF THE ENVIRONMENT

Many EU and non-EU regulations control the incorporation in the raw materials of substances or hazardous substances. Their nature varies according to the sector in which they are used. Among the most important regulations governing the composition of plastics, the following can be cited.

3.1. HEAVY METALS

End of life vehicles.
The Directive 2000/53/EC and its amendments aims at reducing the amount of waste produced from end of life of vehicles (ELVs) and promote the recycling of the recovered products. It also sets limits for hazardous or heavy metals (hexavalent Chromium, Cadmium, Lead and Mercury) in the products used in the automotive industry: 0.1%, except for Cadmium, 0.01%.

RoHS (Restriction of Hazardous Substances) and **WEEE** (Waste Electrical and Electronic Equipment)
The Directive 2002/95/EC and its amendments RoHS restricts the use of six hazardous materials in the manufacture of various types of electronic and electrical equipment: Lead, Mercury, Cadmium, hexavalent Chromium, polybrominated diphelylethers (PBDEs) and polybrominated biphelyls (PBBs).
It is closely linked with the Directive 2002/96/EC and its amendments (WEEE) which sets collection, recycling and recovery targets for electrical goods and is part of a legislative initiative to solve the problem of toxic e-waste. It restricts the use of various hazardous substances like lead, mercury, cadmium, asbestos, polychlorinated biphenyls, (PCBs), hydrofluorocarbons (HFCs), hydrochlorofluorocarbons (HCFCs), brominated flame retardants, etc.

Packaging Waste
Directive 94/62/EC and its amendments limit the content of heavy metals (hexavalent chromium, lead, mercury and cadmium) to max 0.1% (total).

CONEG Regulation USA
Coalition of North Eastern Governors model law limits the content of heavy metals (hexavalent chromium, lead, mercury and cadmium) to max 0.01% (total).

3.2. OTHER ENVIRONMENTAL HAZARDOUS SUBSTANCES

Ozone layer depleting agents

Regulation 2037/2000/EC prohibits the marketing and use of ozone depleting agents like chlorofluorocarbons, fully halogenated chlorofluorocarbons, carbon tetrachloride and other fluorocarbons.

US Clean Act Title VI, Classes 1 and 2 substances are similar to those prohibited by the 2037/2000/EC.

'N' substances

Substances "dangerous for the environment" are classified 'N' by the Directive 67/548/EEC or its multiple ATP (Adaption to Technical Progress). This old Directive has now been replaced by the CLP (Classification, Labelling and Packaging) Regulation (EC) 1272/2008 whose Annex 1 lists the classified substances, including those 'N'.

Phthalates

Phthalates are used in large amount as plasticisers of PVC. In such a case, their content can be as high as 50% w/w of the final compound. Some phthalates have recently been classified as oestrogen disruptors and classified as toxic for the reproduction (Reprotoxic Cat 2).

In PO, some phthalates are also used as a minor component of the catalytic system to produce PP (as 'technical agents' following Directive 2007/19/EC). They are not used in PE. Their final theoretical concentration in PP would be far below 10 ppm if they remained intact after the polymerisation. We have however analytical evidence that the phthalate present in the catalytic system does not survive this step and that it cannot be seen any more at detectable level (<< 1 ppm) in the final polypropylene.

Recently, several phthalates have reached a considerable level of attention from the authorities and the NGO's because of their introduction in the Candidate Lists for Authorisation under REACH, which aims to bring their use to an end in the next 5 to 10 years.

4. ABSENCE OF SUBSTANCES SUBMITTED TO VARIOUS RESTRICTIONS

We take every possible measure during the manufacture of our products, to avoid any contamination of the stream of raw materials (monomers and additives) that could result in the presence of undesired substances in the finished product.

It is however scientifically impossible to guarantee the total absence of hundreds of particular substances in a product, and we cannot analyse them in that respect neither. We therefore confirm that the substances in question are not used as monomers or additives for the production of a grade, which also means that they are not intentionally added to the process or incorporated in the product. We however do not perform any

specific test to verify the absence of these substances in the final product and cannot guarantee that there is no trace amount of them, as impurity or otherwise.

We have listed (by alphabetical order) the most current substances or families of chemicals whose absence is frequently requested by our customers. We are conscious that this list is getting every year longer, but it only reflects the growing concerns for product safety and willingness to control the risks at best.

- Some are very closely related to the world of plastics (like the absence of recycled products or of brominated flame retardants)
- Others are only listed because frequently asked for (melamine, PVC etc)
- When nicknames or acronyms are used, we have also mentioned them
- When a legislation text is associated, we have mentioned its references.
  Here is their list:
  - Directive 2000/13/EC (Allergens)
  - Directive 2002/16/EC, 2004/13/EC repealed by Regulation (EC) 1895/2005 (Epoxy Derivatives)
  - Directive 2006/122/EC (Perfluoro Compounds)
  - Regulation (EC) 282/2008 (Recycled Products)
  - US EPA Method 610 (Poly Aromatic Hydrocarbons)
  - California Proposition 65 (Chemicals causing cancer or being reproductive toxicants)
  - Japan SPEED 98 (Endocrine Disruptors)

5. COMPLIANCE WITH OTHER NEW EU LEGISLATIONS

GMP for Food Contact

GMP (Good Manufacturing Practice) is covered by Regulation (EC) 2023/2006 which requires the assessment of the following points:

- Full traceability from the starting materials to the end product, as delivered to the customer
- Risk analysis (according to a HACCP type methodology) in order to identify critical steps and to define the appropriate actions
- Personnel information and training
- Alignment of subcontractors on Good Manufacturing Practice for food-contact
- Process and procedures auditing, on field, including actions taken to prevent contamination and emergency response, among others.

REACH

Plastics are considered as mixtures by REACH: polymers (long polymeric chains) and additives. Polymers are exempt of registration if their monomers (at > 2% w/w) are registered and additives must all have been registered by their manufacturers / importers. There is thus formally no further registration obligation for the PP and PE under REACH.

Furthermore, as they are not classified as 'hazardous' nor PBT / vPvB, there is no obligation to identify their uses or produce Exposure Scenarios.
REACH also sets the obligation to declare the presence of SVHC (Substances of very High Concern) if present at concentrations above 0.1%.

As a conclusion

The RCC is largely influenced by the complexity of the legislation governing the world where plastics are used. We have tried to convey a simple and coherent message but are conscious that this aim is not always reached, and that the many different ways to see a question (substance name, chemical composition, acronym, nicknames, legislation, etc) do not help to find the answer at the first sight.
We however hope that with the help of this document, you will have a better understanding of the various pieces of legislation governing the use of plastics in the XXIst century and get the conviction that they are well covered to remain materials of choice for many applications respecting our resources, the human health and the environment.