## Food contact spotlight

# EU suggests tough resin purity laws for plastics in food contact

On 13 March the European Commission released a proposal for a further amendment to its rules on plastics in food contact given in *Regulation 10/2011*. If adopted it would be the 18th amendment to this EU law.

One element of the proposals in particular, is problematic – a section that would require all substances used in the manufacture of plastic food contact materials and articles to be of a high level of purity. While food contact grades of plastics are typically already of high purity, the level of purity envisaged by the draft 18th amendment would be imposed on starting substances and would be nearly impossible to demonstrate in most instances. Even if it were, it would create highly onerous requirements for raw materials suppliers to monitor and assess.

**A proposed amendment to Regulation 10/2011 will require all starting materials for plastic manufacture to show a high level of purity**

*Source: Plastics Europe*

The text is now open for a *four-week public consultation*, which will close on 15 April. If adopted in its current format the new purity rules would apply 18 months after adoption. Non-compliant products already placed on the market could still be sold until exhaustion of existing stocks.

**Assessing high purity**

The new section on high-purity inputs and how this would function in practice were addressed in *a webinar of 21 March* by the law firm Keller and Heckman, co-hosted with the US Plastics Industry Association (PLASTICS).

The European Commission is proposing introducing the requirement that 'substances used in the manufacture of plastic materials and articles… shall be of a high degree of purity.' This will be achieved by recasting Article 8 of Regulation 10/2011, and adding a new Article 3a, which defines 'high degree of purity.' A substance would have a 'high degree of purity' if it could be demonstrated that all constituents, including contaminants and non-intentionally added substances meet one of the following conditions:

- Compliance with the Positive List of Regulation 10/2011 (Annex I, Table 1), including any specific migration limits
- Having passed a risk assessment as outlined in Article 19 of Regulation 10/2011
- Passing an individual toxicological assessment that concludes 'genotoxicity is ruled out;' and that any migration of the substance from the plastic material or article would be below 0.05mg/kg, assuming 100% of the substance migrates to food
- If the substance's identity is unknown or unassessed, showing migration into food would be no more than 0.00015mg/kg, again assuming a 100% migration scenario.

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Keller and Heckman suggested this be treated as a decision tree. So a substance would only consider the second Article 19 qualification if it does not have an entry on the positive list.

If an Article 19 assessment is not conducted and genotoxic behaviour of the substance could be discounted, manufacturers of the starting substance would only need confirm migration is less than 0.05mg/kg (0.05 parts per million).

If genotoxicity could not be ruled, or the identity of the impurity could not be confirmed, calculations would need to show migration would not exceed the much lower threshold of 0.00015mg/kg (0.15 parts per billion).

**The 18th Amendment will potentially create testing and information requirements for any company selling polymer pre-cursors into the EU's food plastics market**

*Source: Deposit Photos*

**Applicability**

The public consultation for Amendment 18 states that the high purity rules are being introduced 'for substances obtained from waste and natural materials.' The recital to the amendment says that: 'specific rules need to be laid down as regards the purity of substances of natural origin…. [and] when the natural material has only been slightly refined, it has many different constituents, some of which may be unknown, and its composition can be variable or difficult to predict.' It adds that plastics produced 'from waste are likely to contain incidental contamination,' and so should also have high purity when employed in food contact.

In fact the text of the new Article 8 would make 'any substance' used to make a food contact plastic subject to it, including virgin materials that have previously been considered perfectly safe.

Keller and Heckman's analysis of the change makes clear high purity status would be applicable not just to monomers and additives used to manufacture primary resins, but also:

- Secondary materials, such as, aids to polymerisation, catalysts, colourants
- Impurities and other non-intentionally added substances, such as degradation products.

A central challenge is that this obligation would be applicable to any starting materials and apply all the way up the supply chain. Jeff Keithline – a partner at Keller and Heckman – illustrated this with an example using dimethyl terephthalate (DMT), a monomer commonly used to make polyethylene terephthalate (PET). Refined grades offering 99.99% purity are available, which implies that the purified DMT contains impurities at a concentration less than 1000 parts per million (ppm). The draft amendment would require purity to several factors better than this, however – a level that Keithline believes would be impractical to achieve commercially.

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Additional difficulty would arise because a raw material supplier will often not know if a monomer is destined for food contact applications or not, and might be purchased in bulk for both food and non-food packaging.

Furthermore a lack of transparency means the manufacturer would be unable to calculate whether volatile impurities, like solvents, would be removed during processing as it would be very unlikely to have this level of knowledge so far down its supply chain.

**Purity in context**

The draft amendment proposes to require the same level of additional data be included in future declarations of compliance (DoCs). Currently Regulation 10/2011 requires these to include 'adequate information relative to the substances used or products of degradation thereof.' The amendment would change this section of Annex IV to require 'adequate information relative to the substances used, including impurities in the substances used, reaction intermediates formed during the production process, decomposition or reaction products, in particular.'

**The changes to Regulation 10/2011 are not likely to be adopted formally until after June's European Parliamentary elections**

*Source: European Parliament*

Keithline highlights that the draft amendment's emphasis on starting materials runs directly counter to a recently stated goal of EU food contact law. The commission's recent review of *Regulation 1935/2004*, specifically called for a shift away from primary materials to guaranteeing the safety of finished materials and articles (see *Food Contact World* 10.19, 14 October 2022)

In conclusion, Keithline says that if enacted in its current form the new Article 8 would be 'very difficult to meet and likely would be commercially infeasible - as most material producers do not identify all impurities down to 0.1ppm (or potentially even lower as may be required for some starting substances based on the structure of the requirements of the new amendment). The extra work is not proportional to the risk. Especially as no such similar requirements are being set for non-plastic food contact materials.'

**Other changes**

Several other changes in the 18th amendment proposal are potentially significant, if less controversial than the purity requirements. The soon to be adopted *Packaging and Packaging Waste Regulation (PPWR)* will set mandatory re-use rules for certain food contact formats. Others – including member states governments and some retailers – are keen to introduce more re-use plastic containers on sustainability grounds.

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The 18th amendment says, 'repeated use may lead to unacceptable deterioration of the plastic material or article, leading to an increase of constituents into food that may endanger human health.' To counter this it proposes a new obligation on the manufacturer, or entity placing a re-useable plastic container on the market, to provide users with information on how to identify such deterioration and alleviate it. Additional data on the 'maximum lifespan of the material or article' would also be required in future DoCs.

Hazel O'Keeffe, also a partner at Keller and Heckman, explained that the amendment will remove the reference to the Provisional List of Additives in Article 7 of Regulation 10/2011 (this list silver-based surface biocides and triclosan). The amendment will make surface biocides only subject to the EU's *Biocidal Products Regulation 528/2012* (i.e., they will not be required to be listed on the Plastics Regulation and the Provisional List will be removed). Editorial changes to explain this are part of the amendment.

The amendment will introduce rules for discarded 'off-cuts and scraps' from production plants (which meet the definition of a by-product in the Waste Framework Directive 2008/98) – with Regulation 1616/2022 confined to post-consumer recycled (PCR) materials manufactured from waste or originating therefrom. This is achieved by rewriting Article 10 of the original regulation. There will be additions to the Annex of the Good Manufacturing Practices Regulation to ensure that such material is collected and handled appropriately. This will avoid it becoming contaminated with substances that could present a risk once they are converted into a final food contact article.

The wording of Article 9 is being changed. In the text 'substances used in the manufacture of plastic layers in plastic materials and articles shall be subject to the following restrictions and specifications,' the words 'plastics layers' are proposed for deletion.

Migration testing requirements for small packs – those holding under 500ml or 500g of food – are being reformed via the amendment. These will no longer be allowed to use the default migration test surface area to volume ratio of 6dm$^2$ per kg of food. The commission notes that for these smaller packs this level 'often leads to an underestimation of the real migration of substances into food.'

There are also minor changes to test protocols in Annex III for the simulants to be used for natural and processed cheese, specifically.



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ISSN 2040-2856

Published by
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