

EU legislation for oligomers in plastic food contact materials

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Oligomers in polymers are an intrinsic part of the molecular weight distribution of polymers and more specifically represent the lowest molecular weight fraction. They are formed during the production or storage of the polymer. In general, they are not removed after polymerisation.

Any polymer either homopolymer or copolymer, contains oligomers. The specific composition of this oligomeric fraction is depending on the monomer and comonomer(s) used, but also on the polymerisation process and conditions.

For the petitioning of (new) monomers to the European Food Safety Authority (EFSA), the Note for Guidance requires the inclusion in the dossier of information on the average molecular weight and molecular weight distribution, percentage of molecular weight species below 1000 Da, identification and quantification of migrating oligomers. The same requirement exists for a polymeric additive dossier. Therefore, when a new monomer or a new polymeric additive is approved, the oligomers present are addressed in the respective risk assessment.

The EU polymer approval scheme is built on a positive list of the respective monomers. Thus, if monomers are listed, any combination of monomers to build up a polymer can be used. The Regulation (EU) 10/2011 covers both the Union list for the EU market of monomers and the additives approved to be used with the specifications and limitations. Currently, there are very few specifications or limitations for the listed monomers.

The Regulation (EU) 10/2011 does not include a requirement to list oligomeric by-products in the Union List. According to article 19 of Regulation 10/2011, compliance with article 3 of the Framework Regulation (EU) 1935/2004 can be demonstrated through a risk assessment. Both articles represent the key element of risk assessment required for plastics materials and articles in the EU for oligomers. A variety of risk assessment tools exist for such assessments. These tools can be used to demonstrate the safety of these oligomers.

In conclusion, there are basically two scenarios in the EU legislation which cover the safety assessment of oligomers as part of polymers. Either the respective monomer is listed in Regulation (EU) 10/2011 with its "typical" oligomeric spectrum addressed or (as default) the risk assessment stays with the respective manufacturer or user. The risk assessment is part of the respective supporting documentation file.

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