

Polymer dispersions as raw materials for food contact materials

Polymer dispersions are used as raw materials (binders) in many waterborne applications, for example, adhesives, varnishes and coatings, printing inks, non-wovens, paper and paperboard and textile finishing agents. Polymer dispersion technology has been used safely and successfully for more than 50 years and has contributed to a significant reduction in the release of organic solvents in the environment. Common to all dispersions and covered by this paper, is a film forming process during application.

Polymer dispersions are mixtures as defined under Article 3(2) of the REACH Regulation¹, consisting mainly of water and high molecular weight polymer droplets. Based on polymer molecular weight and chemical nature, the polymer droplets can be solid or highly viscous. The particle size of such polymer droplet can widely vary between ca. <100 nm (<0.1 µm) and 10,000 nm (10 µm)² in diameter. Polymer dispersions are not categorised as nanomaterials. For more details, please refer to the EPDLA position paper on nanomaterials³.

Polymer dispersions may be used as raw materials for manufacturing of materials and articles intended to come into contact with food. For an intended use as a raw material in materials and articles intended to come into contact with food, polymer dispersion producers may provide adequate information along the supply chain.

Regulatory framework for food contact materials in Europe

Regulation (EC) No. 1935/2004 of the European Parliament and of the Council of 27 October 2004⁴ lays down the basic requirements and criteria for any material and article intended to come into contact with food. Annex 1 to Regulation (EC) No 1935/2004 lists groups of materials and articles for which specific measures may be adopted if intended to come into contact with food, according to Article 5 of Regulation (EC) No 1935/2004. As of today, only a few of the 17 groups of materials and articles for which specific measures can be adopted are subject to specific regulations.

As an example, the consolidated Regulation (EU) No 10/2011⁵ on plastic materials and articles intended to come into contact with food sets out specific requirements such as a positive list of monomers, other starting substances, additives and polymer production aids, generic and substance-specific restrictions as well as rules to assess suitability for the use as food contact material (FCM) or article.

¹ Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC

² nm = nanometre / µm = micrometre

³ <https://specialty-chemicals.eu/epdla/> EPDLA position paper on polymer dispersions and nanotechnology (updated June 2018)

⁴ Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC: <http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1509380070000&uri=CELEX:02004R1935-20090807>

⁵ Commission Regulation (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food: <http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1509380070000&uri=CELEX:02004R1935-20090807>, and Commission Regulation (EU) 2020/1245 of 2 September 2020 on plastic materials and articles intended to come into contact with food, <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32020R1245&from=EN>.

However, there are specific groups of materials and articles that are not yet covered by a specific measure according to Regulation (EC) No 1935/2004. Said articles (manufactured using polymer dispersions as raw materials, which are intended to come into contact with food) include for example adhesives, varnishes and coatings, paper and paper board or printing inks. Therefore, other criteria to establish compliance with Regulation (EC) No 1935/2004 must be applied.

If substances in a dispersion intended to come into contact with food are covered by EU material-specific restrictions, these restrictions shall also apply to the dispersion-based product. For substances in dispersions not listed in harmonised EU Regulations, national legislation of EU Member States or non-EU countries may be applied to evaluate their suitability for the intended use. Examples of such legislations are:

- German Bedarfsgegenständeverordnung⁶,
- Dutch Warenwet⁷,
- Italian Decree of 21 March 1973 as amended⁸.
- Swiss Ordinance of 1 December 2020 on materials and objects intended to come into contact with food⁹

For substances in polymer dispersions that are listed neither in harmonised EU Regulations nor in national legislation, reference can be made to non-legally binding texts such as:

- EFSA Opinions
- German BfR Recommendations such as the BfR recommendation XIV
- Resolutions of the Council of Europe, and
- Other rules to ensure compliance with Articles 3 and 4 of Regulation (EC) No 1935/2004, such as internationally accepted scientific principles on risk assessment.

Voluntary industry guidelines are also available such as guidelines from the Food Contact Additives Association (FCA)¹⁰ or the European Association of adhesives and sealants (FEICA)¹¹.

Polymer dispersion producers might apply one or more of these Regulations, like Regulation (EU) No 10/2011. However, as polymer dispersions may not be in scope of some of these Regulations, certain elements would not be supported as a standard (e.g. information on Dual Use Additives). Some information might require a secrecy agreement and will therefore not be publicly available.

It must be emphasised that the responsibility for the full compliance of the final FCM to Article 3 of Regulation (EC) 1935/2004 lies with the manufacturers of the final article as only they have knowledge of the real or foreseeable conditions of use.

⁶ [BedGgstV](#)

⁷ [Warenwetregeling verpakkingen en gebruiksartikelen](#)

⁸ Decreto ministeriale 21 marzo 1973 - Disciplina igienica degli imballaggi, recipienti, utensili, destinati a venire in contatto con le sostanze alimentari o con sostanze d'uso personale (S.O. n. 69 alla G.U. n. 104 del 20 aprile 1973)

⁹ [Ordonnance du DFI sur les matériaux et objets destinés à entrer en contact avec les denrées alimentaires \(Ordonnance sur les matériaux et objets\) du 16 décembre 2016 / Verordnung des EDI über Materialien und Gegenstände, die dazu bestimmt sind, mit Lebensmitteln in Berührung zu kommen \(Bedarfsgegenständeverordnung\) vom 16. Dezember 2016 / Ordinanza del DFI sui materiali e gli oggetti destinati a entrare in contatto con le derrate alimentari del 16 dicembre 2016](#)

¹⁰ [FCA Guidelines on Risk Assessment of non-listed substances \(NLS\) and non-intentionally added substances \(NIAS\) under the requirements of Article 3 of the Framework Regulation \(EC\) 1935/2004 \(October 2016\)](#)

¹¹ [FEICA guidance on migration testing of adhesives intended for food contact material \(May 2016\)](#)

The party (or legal entity) placing the finished food contact article on the market must test and ensure in each case the suitability of this article for the application concerned, including their effect on the smell and taste of the food, as well as the conformity to any given limitations (for example overall migration and specific limits).

Polymer dispersion producers will support these efforts by providing adequate information to their downstream users. Therefore, information on substances with given restrictions in relevant and applicable European legislation for FCM is provided upon request.

Good manufacturing practices

Commission Regulation (EC) No 2023/2006 on good manufacturing practice for materials and articles intended to come into contact with food¹² sets out general principles to ensure the suitability of the material or article for the intended end use. Article 2 of Regulation (EC) No 2023/2006 states that this Regulation “shall apply to all sectors and to all stages of manufacture, processing and distribution of materials and articles, up to but excluding the production of starting substances.”

Regulation (EC) No 2023/2006 deals mainly with the principles of quality assurance covering the manufacturing process, starting materials, operation processes, premises, equipment and quality control. EPDLA members have already established and implemented Quality Management Systems such as ISO 9001 or equivalent standards.

Non-intentionally added substances

Non-intentionally added substances (NIAS) are a specific term from Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food (Article 3.9). The term NIAS comprises all non-intentionally present substances that are defined as “impurities in the substances used or reaction intermediates formed during the production process or decomposition or reaction products”.

Until now, the term non-intentionally added substances (NIAS) has not been used in European legislation for non-plastic FCMs. However, since NIAS may also be present in non-plastic FCMs such as paper and paperboard, adhesives, varnishes and coatings, a risk assessment should be performed taking into account any existing restrictions, like SML, to proof compliance with Article 3 of Regulation (EC) No 1935/2004.

Relevant NIAS identified during product evaluation are communicated upon request to customers in order to support the risk assessment for the final FCM.

¹² [Commission Regulation \(EC\) No 2023/2006 of 22 December 2006 on good manufacturing practice for materials and articles intended to come into contact with food](#)

Dual Use additives

Dual use additives are defined as additives, which are listed in Regulation (EU) No 10/2011, and which at the same time are authorised as food additive by Regulation (EC) No 1333/2008¹³ or which are authorised flavourings by Regulation (EC) No 1334/2008¹⁴ on flavourings and certain food ingredients with flavouring properties for use in and on foods.

Dual use substances identified during product evaluation are communicated to customers upon request in order to support the risk assessment for the final FCM.

Migration testing

Following the requirements of Regulation (EC) 1935/2004, the finished FCM must be tested and/or evaluated under real use conditions or using the corresponding “food simulants”. Migration tests are defined according to Regulation (EU) No 10/2011.

For polymer dispersions, the food simulants used in Regulation (EU) 10/2011 are not applicable. The dispersion as such is not supposed to get in contact with food, as the film forming process will occur before. In addition, due to the wide range of application of dispersion-based products, no unified testing conditions can be defined for these products. The migration testing conditions developed under Regulation (EU) 10/2011 are solely meant to be applied for plastic FCMs. Applying those to other “non-plastics materials” does result in some cases to extraction / dissolution of the material in question, and therefore does not mimic the migration under real conditions.¹⁵

Template for adequate food contact information

It is recommended that any answer to inquiries on food contact status contains at least the following information:

1. Date
2. Company name
3. Product name
4. Relevant information about food contact status
 - a. Regulation (EU) 1935/2004 on materials and articles intended to come into contact with food– Traceability, Article 3 (as far as applicable)
 - b. Substances with restrictions e.g. (EU) No 10/2011 – Plastics regulation: BfR recommendations, NIAS
 - c. Others: e.g. EU member states legislation, Swiss Ordinance including restrictions
 - d. Optional: non-European legislation like FDA, Chinese GB including restrictions

¹³ Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives: <http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1509380361501&uri=CELEX:02008R1333-20170818>

¹⁴ Regulation (EC) No 1334/2008 of the European Parliament and of the Council of 16 December 2008 on flavourings and certain food ingredients with flavouring properties for use in and on foods and amending Council Regulation (EEC) No 1601/91, Regulations (EC) No 2232/96 and (EC) No 110/2008 and Directive 2000/13/EC: <http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1509380431462&uri=CELEX:02008R1334-20170713>

¹⁵ For further information: https://ec.europa.eu/food/sites/food/files/safety/docs/cs_fcm_consultation_20160909_migration-guidelines_en.pdf

Disclaimer

- The present position paper has been developed by EPDLA members in good faith, to the best of its knowledge and following the latest scientific evidence.
- The position paper is offered to all EPDLA members for further use. Each producer might add additional information in the communication towards customers, depending on the specific situation.
- EPDLA commits to update this document in view of any new relevant available information.

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About EPDLA

EPDLA (European Polymer Dispersion and Latex Association), a Cefic Sector Group founded in 1991, is dedicated to promote the safe manufacture, transportation, distribution, handling and use of waterborne polymer dispersions, in compliance with regulatory requirements and industry guidelines. EPDLA members are committed to Responsible Care® principles and have implemented risk management according to the precautionary principles.

