

European Regulation of Plastic Materials and Articles that come into Contact with Food

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We recently received a question from a PMA member regarding the process for issuing a Declaration of Compliance ("DoC") pursuant to European regulation of plastic materials and articles that come into contact with food. The purpose of this article is to provide a brief overview of these requirements and to encourage members to consider these issues prior to being asked for a DoC and to work collaboratively with others in the supply chain to exchange necessary information.

Regulation (EC) 1935/2004 of 27 October 2004 on materials and articles intended to come into contact with food was passed to ensure that "any material or article intended to come into contact directly or indirectly with food ... be sufficiently inert to preclude substances from being transferred to food in quantities large enough to endanger human health or to bring about an unacceptable change in the composition of the food or a deterioration in its organoleptic properties."¹ The regulation applies to materials and articles which in their finished state:

- (a) are intended to be brought into contact with food; or
- (b) are already in contact with food and were intended for that purpose; or
- (c) can reasonably be expected to be brought into contact with food or to transfer their constituents to food under normal or foreseeable conditions of use.²

Materials and articles that fit this description must be manufactured in compliance with good manufacturing practice such that they do not transfer their constituents to food in quantities that could: endanger human health; bring about an unacceptable change in the composition of the food; or bring about a deterioration in the organoleptic characteristics thereof.³ Specific measures may apply to certain materials and articles.⁴ Covered materials and articles must be accompanied by a written declaration attesting to compliance with applicable rules (the DoC), and appropriate documentation must be maintained and provided to competent authorities on demand.⁵

Commission Regulation (EU) 10/2011 of 14 January 2011 further regulates plastic materials and articles intended to come into contact with food and highlights the importance of the DoC. At the marketing stages other than at the retail stage, a DoC must be available for plastic materials and articles, products from intermediate stages of their manufacturing and substances intended for the manufacturing of those materials and articles.⁶ Issued by the business operator, i.e. the natural or legal person(s) responsible for ensuring that the requirements of Regulation 1935/2004 are met within the business under their control⁷, the DoC must contain very specific information and permit easy identification of the materials, articles or products from intermediate stages of manufacture or

¹ Regulation 1935/2004, O.J. (L338)4.

² *Id.*, art. 1(2).

³ *Id.*, art. 3(a).

⁴ *Id.*, art. 5. In the absence of specific measures, and when other requirements are met, EU Member States can maintain or adopt national provisions. Regulation 1935/2004, art. 6.

⁵ Regulation 1935/2004, art. 16. (In the absence of specific measures, Member States may also adopt their own provisions for Declarations of Compliance).

⁶ Commission Regulation 10/2011, art. 15(1), 2011 O.J. (L12)1.

⁷ Regulation 1935/2004, art. 2.

substances for which it is issued.⁸ Appropriate supporting documentation must be made available by the business operator to national competent authorities on request and must contain conditions and results of testing, calculations, other analysis, and evidence on safety or reasoning demonstrating compliance.⁹

The purposes of the DoC are to confirm to customers that the product complies with relevant requirements of the Plastics and Framework Regulations and to provide the customer with relevant information necessary to establish or check the product's compliance with relevant legislation.¹⁰ A DoC can only be issued on the basis of information about the product for which it is issued, including all the compliance work that has been performed by the business operator issuing the DoC (the "Supporting Documents"). Thus, though the Supporting Documents are generated and kept by the business operator issuing the DoC and are not intended to be passed along the supply chain¹¹, collaboration and information sharing are essential components of the DoC process:

A key problem of complex manufacturing processes is that usually no single stage can perform the complete compliance work: information on chemical composition, presence of non-intentionally added substances such as impurities and degradation products, plastic processing conditions, composition of the food, storage and contact conditions, among others, are not all known at every step of the supply chain. Therefore, an optimized exchange of information is key to ensure the compliance of the final article. In other words, communication up and down in the supply chain can help to identify relevant information that allows suppliers and customers to adequately perform their own compliance work. It also helps to build trust, which is essential, as the DoC does not include all the information contained in the supplier's Supporting Documents.¹²

If you have any question about this overview, please let us know. We will continue to provide additional and more detailed information on this topic in future issues of Polytopics.

⁸ Commission Regulation 10/2011, arts. 15(2), (3). Information that must be included in the DoC includes, but is not limited to: (1) identity and address of the issuing business operator; (2) identity and address of the business operator which manufactures or imports the plastic materials or articles or products from intermediate stages of their manufacturing or the substances intended for the manufacturing of those materials and articles; (3) identity of the materials, the articles, products from intermediate stages of manufacture or the substances intended for the manufacturing of those materials and articles; (4) the DoC's date; (5) confirmation of compliance with relevant requirements in Regulations 10/2011 and 1935/2004; (6) adequate information relative to the substances used or products of degradation thereof for which restrictions and/or specifications are set out in Annexes I and II to [Regulation 10/2011] to allow the downstream business operators to ensure compliance with those restrictions; (7) adequate information relative to the substances which are subject to a restriction in food to enable the user to comply with relevant EU provisions or, in their absence, national provisions; (8) specifications on the use of the material or article; (9) confirmation that when a functional barrier is used in a multi-layer material or article, the material or article complies with the requirements of Article 13(2), (3) and (4) or Article 14(2) and (3) of Regulation 10/2011. Health & Consumers Directorate General, Union Guidance on Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food as regards information in the supply chain (Nov. 28, 2013) ("Union Guidance") (also requiring that the document be made available to national competent authorities on request).

⁹ Commission Regulation (EU) No 10/2011 Art. 16.

¹⁰ Union Guidance.

¹¹ *Id.*

¹² *Id.* at 5.