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Compliance work for polyolefins in food contact: Results of an official control campaign

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ABSTRACT

Passing from local converters backwards through the supply chain, nine major producers of polyolefin granulates were asked to supply the declaration of compliance (DoC) and supporting documentation (SD) underpinning the safety of the substances potentially migrating into foods, as legally required in Europe. Within half a year from the request, DoCs were delivered by the converters and the granulate producers, but no SD. Only two producers provided very limited information in addition to their DoC. Some producers refused responsibility in their DoC (general disclaimer), which implies that the customers should have done the complete compliance work – but none of them did. Virtually no data was obtained on substances used other than the specifically regulated monomers and additives, and none about reaction products (including oligomeric material) and impurities. Comprehensive two-dimensional gas chromatography (GC×GC) was used to generate semiquantitative pictures of the low molecular constituents in the granulates, visualizing the extent of compliance work expected. In conclusion, there is a broad gap between the legal requirements and reality that ought to be eliminated. It does not seem technically impossible.

1. Introduction

Article 3 of the European Regulation 1935/2004 (EC) on food contact materials (FCM) requires that the substances migrating into food do not endanger human health. “No danger” implies ruling out that the migrating substances are harmful at the level they migrate with the tools available today. Most FCM are composed of several components (e.g. a multilayer plastic with an adhesive and printing) from different manufacturers and pass through a complex chain of manufacturers. This presupposes contributions from all involved business operators and a communication enabling a systematic achievement of the task.

For FCM specifically regulated by the European Commission, such as plastics, Article 19 of European Regulation 1935/2004 requires issuing declarations of compliance (DoCs) at each stage of manufacture to inform the customer about the accomplished compliance work and delegate the work remaining to be done. The DoC must be underpinned by supporting documentation (SD) that contains data on composition, migration, toxicity and reasoning leading to the conclusion stated in the DOC. SD may remain confidential, but must be made available to the competent authorities on demand. National authorities may introduce this system also for FCM not specifically regulated by the European Commission. For the other FCMs, the European Regulation 2023/2006 (“GMP Regulation”) applies which requires that throughout the chain of manufacturers (i.e. from the starting substances and raw materials) they are to be produced according to good manufacturing practice (GMP) in the meaning of Article 3 of EC Regulation 1935/2004, i.e. with safety of food contact in mind; every substance introduced, their reaction products formed in the FCM or in the food as well as the impurities must be safe at the level they may migrate. Again supporting documentation is required, rendering compliance work traceable for competent authorities. Stating GMP according to Regulation 1935/2004 without delegating compliance work is equivalent to declaring compliance, with the effect that stating compliance with GMP is equivalent to a DoC (ALS, 2009; European Commission, 2014; Grob, Stocker, & Colwell, 2009a,b).

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