REGULATION (EC) No 1935/2004, Article 16 – Declaration of compliance for materials and articles intended to come into contact with food

This position paper is intended only as a guide and offers only an overview of the declaration of compliance in accordance with Regulation (EC) No 1935/2004 of 27 October 2004. It does not claim to be complete or an exact interpretation of the existing laws. It must not replace study of the relevant directives, laws and regulations. The characteristics specific to the relevant products and the different ways in which they may be used must also be taken into account.

This position paper has been updated and takes into account Regulation (EC) No 2023/2006, which has applied since 1 August 2008, relating to good manufacturing practice for materials and articles intended to come into contact with food (see Annex 2). It thus replaces the version dated 19 June 2008.

This English edition is an authorised translation of the German edition of this position paper originally released in October 2008.

Introduction

This position paper has been produced following enquiries from plant operators to mechanical and plant engineering companies in which a declaration of "compliance in accordance with Regulation (EC) No 1935/2004" is requested for materials and articles used, usually in connection with internal or external audits.

The Regulation itself does not require a declaration of compliance to be issued. Rather, it refers to specific measures that can be adopted, in which the enclosure of a written declaration is prescribed. This written declaration is currently\(^1\) prescribed as a specific measure only for certain materials and articles listed in Annex I of the Regulation. The Regulation also includes general requirements of materials and articles (in contact with food), without requiring a declaration of compliance for these. The above aspects form the subject matter of this position paper.

This position paper does not deal with labelling or traceability. For this, the VDMA Position Paper of the Association for Traceability in accordance with Regulation (EC) No 1935/2004 and the Explanations for VDMA Member Companies are available separately.

\(^1\) At the time of publication of this position paper, specific measures requiring a written declaration of compliance for the groups of materials and articles listed in Annex I of the Regulation as defined by Article 5 of Regulation (EC) No 1935/2004 apply to:

- Ceramics, Regenerated Cellulose, Plastics and Epoxy Derivatives. The rule on epoxy derivatives, Regulation (EC) No 1895/2005, applies to materials and articles of all types of plastic, articles with a surface coating and adhesives and includes the substances "BFDGE", "NOGE" and "BADGE".
Position

In accordance with Article 16, the specific measures listed in Article 5 must stipulate that the materials and articles covered by the relevant specific measures require a written declaration (declaration of compliance) stating that they conform to the regulations that apply to them.

For materials and articles for which no specific measures have been adopted in accordance with Article 5 Regulation (EC) No 1935/2004, a written declaration of compliance within the meaning of the Regulation does not need to be submitted.

A written declaration of compliance in relation to Regulation (EC) No 1935/2004 needs to be submitted only if a specific measure applies in accordance with Article 5 of the Regulation and requires this.

The compliance of materials and articles (in contact with food) in a machine or components with the general requirements\(^2\) in accordance with Article 3(1) of the Regulation can be certified on agreement if required. For the relevant certification, national regulations, standards or internationally recognised sector standards\(^3\) can be consulted if they contain statements regarding materials or test criteria that are relevant to the case.

The reason:

Article 16 of Regulation (EC 1935/2004) refers under the headword "Declaration of compliance" to Article 5, which in turn refers to Annex I. This lists groups of materials and articles for which specific measures can be adopted. If specific measures are adopted, these must stipulate in accordance with Article 16 that materials and articles covered by the relevant specific measures must include a declaration stating that they comply with the provisions that apply to them.

The declaration of compliance is therefore issued if applicable with reference to and in accordance with the requirements of the specific measure. For materials and articles to which no specific measures apply, a declaration of compliance in accordance with Article 16 Regulation (EC) No 1935/2004 is therefore not prescribed.

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\(^2\) Regulation (EC) No 1935/2004 Article 3 General requirements paragraph (1)

Materials and articles, including active and intelligent materials and articles, shall be manufactured in compliance with good manufacturing practice so that, under normal or foreseeable conditions of use, they do not transfer their constituents to food in quantities which could:

(a) endanger human health; or

(b) bring about an unacceptable change in the composition of the food; or

(c) bring about a deterioration in the organoleptic characteristics thereof.

\(^3\) Examples of national regulations, standards and internationally recognised sector standards: Examples of national regulations are the Consumer Goods Ordinance (BedGgstV), the Food, Consumer Goods and Animal Feed Code (LFGB) and the positive list in the recommendation on plastics XXI of the Federal Institute for Risk Assessment (BfR) (all from the Federal Republic of Germany). Examples of internationally recognised sector standards are the guidelines of the US Food and Drug Administration (FDA) in the 'Code of Federal Regulations (CFR) Title 21 - Food and Drugs' for the food, cosmetics and pharmaceuticals sectors.
Annex

Notes

   List of groups of materials and articles which may be covered by specific measures.
   1. Active and intelligent materials and articles
   2. Adhesives
   3. Ceramics
   4. Cork
   5. Rubbers
   6. Glass
   7. Ion-exchange resins
   8. Metals and alloys
   9. Paper and board
   10. Plastics
   11. Printing inks
   12. Regenerated cellulose
   13. Silicones
   14. Textiles
   15. Varnishes and coatings
   16. Waxes
   17. Wood

2. GMP Regulation
   Since 1 August 2008, Regulation (EC) No 2023/2006 has applied regarding good manufacturing practice for materials and articles intended to come into contact with food.
   **The GMP Regulation does not require a written declaration of compliance.**
   The GMP Regulation applies to the groups of materials and articles listed in Annex I of Regulation (EC) No 1935/2004 (see above), to combinations of these and to materials and articles recycled from these. The GMP Regulation requires compliance with good manufacturing practice, a quality assurance and control system and appropriate documentation, which must be made accessible to the authorities on request.

3. Stainless steel
   At the time of publication of this position paper, metals are not covered by specific measures requiring a written declaration of compliance in accordance with Article 5 Regulation (EC) No 1935/2004. Metals that are commonly used in the industry include stainless steel in particular (as defined by the usual designation for the industry). In the opinion of the association, stainless steel can be regarded as uncritical in this context and as meeting the latest technological standards provided that it fulfils the current specifications with regard to composition etc. and is not contaminated by unwanted components etc.

4. Elastomers
   At the time of publication of this position paper, elastomers are not covered by specific measures requiring a written declaration of compliance in accordance with Article 5 Regulation (EC) No 1935/2004.
   If, as part of the certification of compliance with the General Requirements in accordance with Article 3, material certificates for elastomers are requested (agreed), the recommendation on plastics XXI (consumer goods based on natural and synthetic rubber) from the Federal Institute for Risk Assessment (BfR) may be of relevance. The recommendations were drawn up within the framework of the Food and Consumer Goods Act (LMBG), which has been replaced by the Food, Consumer Goods and Animal Feed Code (LFGB). If applicable, the guidelines of the FDA (see Footnote 2) could also be consulted.