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NON PAPER

Draft

COMMISSION REGULATION (EC) No …/..

of […]

laying down the principles of good manufacturing practice in respect of materials and articles intended to come into contact with foods

(Version updated to 28 February 2006)

(EN)

(Text with EEA relevance)

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Explanatory memorandum

- The Framework Regulation EC No 1935/2004 sets out the main principles and procedures applicable to food contact materials (FCM). It establishes in Article 3 that materials and articles should be manufactured in compliance with good manufacturing practice (GMP) so that under normal and foreseeable conditions of use, they do not transfer their constituents into food in quantities which could endanger human health, bring about unacceptable changes in the composition of the food or bring about deterioration of the organoleptic characteristics of the food. It empowers the Commission to set specific rules to ensure compliance with the rules of Article 3.

- Not all industries operate according to good manufacturing practice or have detailed GMP guidelines. Most Member States have not issued GMP guidelines. The Food and Veterinary Office report on a desk study to evaluate official controls with regard to food contact materials in the Member States (DG SANCO8004/2005) points out that few Member States stated that all industries operate or are in the way of operating in compliance with GMP.

- In September 2005 isopropylisothioxanthone (ITX) a substance originating from the printing ink applied to the outer surface of the packaging was found in certain foods. The substance had been transferred from the outer to the inner food contact surface during the storage of the unfilled packaging material through direct contact between the two surfaces.

- Substances used in printing inks are not regulated at European level. They are applied to the outer surface and not expected to be transferred into food. If the outer printed surface comes into direct contact with the inner food contact surface e.g. when the packaging is rolled up in big reels substances from the printing ink can be transferred to the inner surface. This process is called set-off. The substance can then migrate from the inner surface into the food and thus lead to a contamination of the food.

- If good manufacturing practice is applied such a transfer should be avoided/minimized.

- This text is aimed at clarifying the principles of good manufacturing practice in respect to food contact materials and articles and at introducing specific rules for printing inks.

- GMP should be applied at all stages of production of the food contact materials and articles.

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Text	***Comments*** *(for internal SANCO use)*
NON PAPER Draft **COMMISSION REGULATION (EC) No …/..** **of […]** **laying down the principles of good manufacturing practice in respect of materials and articles intended to come into contact with foods**	
THE COMMISSION OF THE EUROPEAN COMMUNITIES, Having regard to the Treaty establishing the European Community, Having regard to Regulation (EC) No 1935/2004 of the European Parliament and the Council of 27 October 2004 on materials and articles intended to come into contact with food1, and in particular Article 5(1) thereof, [After consulting the European Food Safety Authority ('The Authority')] Whereas:	*Legal basis*
(1) Framework Regulation (EC) No 1935/2004 establishes that that materials and articles should be manufactured in compliance with good manufacturing practice (GMP). It provides for the adoption of specific measures to ensure compliance with this rule by the Commission. This Regulation establishes general principles of good	*(1) The general requirement for the application of good manufacturing practice (GMP) is established in the Framework Regulation. However no specifications on GMP exist. It is necessary to specify the general principles of GMP in the sense of Article 3 of Framework Regulation 1935/2004*

[1] OJ L 338, 13.11.2004, p. 4

manufacturing practice. (2) Some industry sectors have established GMP guidelines while others do not have GMP guidelines. (3) In order to ensure conformity with the principles and guidelines of good manufacturing practice, it is necessary to lay down detailed provisions on certain obligations of the business operator. (4) It is necessary that all business operators should operate an effective quality management of their manufacturing operations. (5) The principles should apply to all sectors however sector specific guidelines should be laid down for each sector. (6) The principles and guidelines should primarily concern personnel, premises, production, documentation, quality control. (7) The requirements need to be flexible in order to avoid undue burdens for small businesses. (8) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health, HAS ADOPTED THIS REGULATION:	*(2) not all sectors have GMP guidelines* *(3) Principles and guidelines on GMP should be conform in the EU and their enforcement should be harmonised.* *(4) Quality management is part of the GMP* *(5) Separation between general principles and specific guidelines* *(6).* *(7) Provisions for small businesses are necessary as regards management structure, documentation, quality control but also to parts of the processing.*

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Article 1 Subject matter and Scope	*Article 1*
1. This Regulation lays down the principles and guidelines of good manufacturing practice in respect of materials and articles intended to come into contact with food. It is applicable to all stages of production.	*Specific measure to lay down GMP principle and guidelines applicable to all stages of production.*
2. This Regulation is an implementing measure within the meaning of Article 5(1) of Regulation (EC) No 1935/2004.	
Article 2 Definitions	*Article 2*
1 For the purposes of this Regulation, the definitions laid down in Regulation (EC) No 1935/2004, its relevant implementing measures shall apply.	*Definitions of Framework Regulation apply* *New definitions included as necessary.*
2. For the purposes of this Regulation, the following definitions shall also apply: 'good manufacturing practice' means the part of quality assurance which ensures that products are consistently produced and controlled in accordance with the quality standards appropriate to their intended use 'quality assurance' means the total sum of the organised arrangements made with the object of ensuring that food contact materials are of the quality required for their intended use;	

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Article 3 Conformity with good manufacturing practice 1. The business operator shall ensure that manufacturing operations are carried out in accordance with good manufacturing practice as set out in the Articles and material specific rules set out in the Annex. This provision shall also apply to food contact materials intended only for export. 2. For food contact materials and articles imported from third countries, the importer shall ensure that the products have been manufactured in accordance with standards which are at least equivalent to the good manufacturing practice standards laid down by the Community.	*Article 3* *In manufacturing of FCM GMP shall be applied.*
Article 4 Quality assurance system The business operator shall establish and implement an effective quality assurance system, involving the active participation of the management and personnel.	*Article 4* *Implementation of a quality assurance system* *Needs to be flexible for small business*
Article 5 Personnel 1. At each manufacturing site, the business operator shall have a sufficient number of competent and appropriately qualified personnel	*Article 5* *Obligation of personnel and internal structure proportionate to the size of the business. It should cover small to big businesses and the*

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at his disposal to achieve the quality assurance objective. 2. The personnel shall receive initial and ongoing training, the effectiveness of which shall be verified, covering in particular the theory and application of the concept of quality assurance and good manufacturing practice. Article 6 Premises 1. Premises shall be located, designed, constructed, adapted and maintained to suit the intended operations. 2. Premises shall be laid out, designed and operated in such a way as to minimise the risk of error and to permit effective cleaning and maintenance in order to avoid contamination, cross contamination and, in general, any adverse effect on the quality of the product. Article 7 Documentation 1. The business operator shall establish and maintain a documentation system with respect to specifications, manufacturing formulae, processing and records covering the various manufacturing operations performed. Article 8 Production 1. Raw materials shall comply with pre-established specifications	*interpretation of a sufficient number of personnel depends on the size of production.* *Article 6* *General requirements for premises* *The manufacturing of FCM is not covered by the hygiene regulation therefore it is necessary to cover some principle hygiene rules.* *Article 7* *General requirements on Documentation* *Documentation will be a burden for small enterprises. Therefore I introduced the recital on flexibility for small business. Keep in mind that it covers production of all Food contact materials also artisanal ceramics etc.* *FCM GMP guidelines sometimes refer to batch related documentation. Also this is only manageable for big producers.* *Article 8*

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and be suitable for the use in food contact materials. 2. The different production operations shall be carried out in accordance with pre-established instructions and procedures 3. Appropriate technical or organisational measures shall be taken to avoid cross contamination and mix-ups. Article 9 Quality control 1. The business operator shall establish and maintain a quality control system with access to, one or more quality control laboratories appropriately staffed and equipped to carry out the necessary examination and testing of the starting materials and the testing of intermediate and finished products. 2. This quality control shall include monitoring the implementation and respect of good manufacturing practice and propose any necessary corrective measures. Article 10 Entry into force This Regulation shall enter into force on the 20th day following that of its publication in the Official Journal of the European Union. It shall apply from 1 August 2008.	*General requirement on production* *In view of Article 3 of 1935/2004 the manufacturer should be able to answer the following questions* • *What substances/raw materials are used?* • *What substances/reaction products are generated in the manufacturing process?* • *With which food will the final material be in contact?* • *What substances could be transferred into food?* • *What is the possible way of transfer into food?* • *In what concentrations could the substances be transferred into food?* • *What concentration of a substance does not pose a risk to health (toxicology of substance)?* • *What concentration of a substance does not change the organoleptic properties of food?* • *What concentration of a substance does not unacceptably change the composition of food?* *Article 9* *General requirements on quality control* *To be flexible laboratory facilities can be in-house but can also be subcontracted.* *Article 10*

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This Regulation shall be binding in its entirety and directly applicable in all Member States. Done at Brussels, […] For the Commission […] Member of the Commission	*We need a transitional time period to implement the Regulation. At least 2 years.*

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ANNEX

Text	***Comments*** *(for internal SANCO use)*
1. Printing inks Production Printing inks applied to the outer side of food contact materials and articles shall be formulated and/or applied such that : - they have no transfer to the inner, food contact surface side that may lead to a contamination of the food - they will both minimise potential migration through the substrate or the set-off from the printed outer side the food contact surface in the stack or the reel, avoiding possible contamination of the food Printed materials and articles shall be handled and stored in its finished and semi-finished states such that: - substances from the printed surface are not transferred to the inner, food contact surface side through the substrate or through set-off in the stack or reel avoiding possible contamination of the food. The printed surfaces shall not come into direct contact with food.	*Specific requirements for printing inks formulation and application* *Requirements are in part taken from the EUPIA guidelines. Major changes are* *They only talk about visible set-off that shall be avoided.* *They set a time frame for respecting migration limits of 50ppb in 5 years and 10ppb in 10 years for substances not having sufficient toxicological data in accordance with EFSA guidelines.* *They have a list of substances that can be used (dyes and pigments) and do not allow the use of CRM category 1 and 2. In my opinion this would be covered by implementing legislation and not GMP.*

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