

**[Note Bene – This document reflects the text proposed by the United Kingdom to replace the text in the European Commission non- paper]**

**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 food<sup>1</sup>, and in particular Article 5(1) thereof, [After consulting the European Food Safety Authority ('The Authority')]

Whereas:

(1) Framework Regulation (EC) No 1935/2004 establishes 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 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 of good manufacturing practice, it is necessary to lay down those principles in detail as legal provisions placing obligations on 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.
- (6) The principles should address the primary issues necessary to establish good manufacturing practice .
- (7) The principles should be applied proportionately to avoid undue burdens for small businesses.
- (8) The principles established in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS REGULATION:

#### Article 1

##### Subject matter and Scope

1. This Regulation lays down the principles of good manufacturing practice necessary to achieve conformity with Article 3 of Regulation (EC) No. 1935/2004 in respect of materials and articles intended to come into contact with food. It is 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

1 For the purposes of this Regulation, the definitions laid down in Regulation (EC) No 1935/2004, its relevant implementing measures shall apply.

2. For the purposes of this Regulation, the following definitions shall also apply:

‘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 to ensure conformity with the rules applicable to them and the quality standards necessary for their intended use;

‘good manufacturing practice’ means those aspects of quality assurance which ensures that products are consistently produced and controlled to ensure conformity with the rules

applicable to them and in accordance with the quality standards appropriate to their intended use or, where this is not known, their reasonably anticipated worst case use;

‘quality control systems’ means the systematic application of measures established within the quality assurance arrangements that ensure compliance of starting materials and intermediate and finished products with the specification determined in the quality assurance.

### 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 4

#### Quality assurance system

The business operator shall establish and implement and ensure adherence to an effective, documented quality assurance system. That system will take account of the adequacy of personnel, their knowledge and skills, and the organisation of the premises such as is necessary to ensure that finished products comply with the rules applicable to them. It will be applied taking into account the size of the business run by the operator so as not to be an excessive burden on the business.

### Article 7

#### Documentation

1. The business operator shall establish and maintain appropriate documentation with respect to specifications, manufacturing formulae, processing and records covering the various manufacturing operations performed relative to the end product.

### Article 8

#### Production

1. Raw materials shall comply with pre-established specifications that will ensure compliance of the product with the rules applicable to it.

#### Article 9

##### Quality control systems

1. The business operator shall establish and maintain an effective quality control system..
2. It shall include monitoring the implementation and achievement of good manufacturing practice and identify measures to correct any failure to achieve it.
3. Such corrective measures shall be implemented without delay.

#### 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.

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