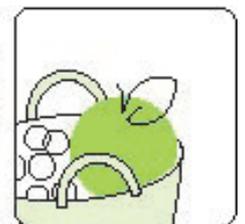
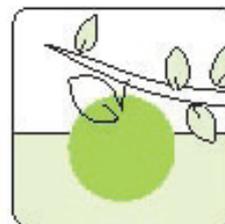
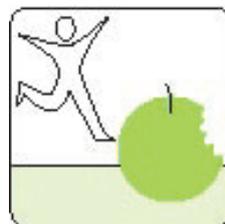


# COMMISSION STAFF WORKING DOCUMENT on the Understanding of certain provisions on flexibility provided in the Hygiene Package Frequently Asked Questions Guidelines for the competent authorities







EUROPEAN COMMISSION

Brussels, 12.8.2010  
SEC(2010) 986 final

**COMMISSION STAFF WORKING DOCUMENT**

**on the Understanding of certain provisions on Flexibility provided in the Hygiene  
Package**

**Guidelines for the competent authorities**

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### NOTE

These Guidelines should be used together with the Guidance documents for the implementation of the Hygiene Regulations:

- Guidance document on the implementation of certain provisions of Regulation (EC) No 852/2004,
- Guidance document for the implementation of certain provisions of Regulation (EC) No 853/2004,
- Guidance document on the implementation of procedures based on the HACCP principles, and on the facilitation of the implementation of the HACCP principles in certain food businesses,

where terminology and rules for the implementation of Hygiene Regulations, including flexibility provisions, are explained.

Guidance documents are published on the website of DG SANCO on the following link:

[http://ec.europa.eu/food/food/biosafety/hygienelegislation/guide\\_en.htm](http://ec.europa.eu/food/food/biosafety/hygienelegislation/guide_en.htm)

*Disclaimer: this Commission Staff Working Document does not necessarily reflect the view of the Commission.*

## 1. INTRODUCTION

This document should serve as a basis for a better understanding of certain provisions for flexibility provided in the Hygiene Regulations and lead to a better use of these provisions by Member States. It should be stressed that the flexibility of the Hygiene Package is not limited to the points mentioned in this document.

Flexibility provisions contained in the Hygiene Regulations offers the possibilities:

- to grant:
  - (i) **derogations/exemptions** from certain requirements laid down in Annexes (see Chapter 2),
  - (ii) **adaptations** of certain requirements laid down in Annexes (see Chapter 3),
- to **exclude** some activities from the scope of the Hygiene Package (see Chapter 4).

When making use of flexibility provisions, Member States have in general to adopt national measures.

The leading principles for implementing flexibility provisions are subsidiarity and transparency:

- based on the principle of subsidiarity, Member States are best placed to find solutions to local situations,
- based on the transparency principle, each draft of such national measures must be notified to the Commission and to the other Member States (see Chapter 5).

As the principles and requirements of the Hygiene Package opened the European Union market for all food business operators, all national measures must be notified to the Commission and to the other Member States at the stage of the draft in order to inform them and give them the possibility to comment on the draft legislation which after adoption becomes applicable. Different notification procedures are laid down.

### (a) **Notifications of draft national measures**<sup>1</sup>

Notification procedures also provide a certain level of "harmonisation" of rules at EU level (e.g. definition of small quantities, localised, marginal and restricted activity, establishments situated in regions that are subject to special geographical constraints etc.).

According to the case-law of the Court of Justice of the European Union, failure to fulfil the notification obligation, as a procedural defect in adoption of

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<sup>1</sup> Also referred to in letters to the Chief Veterinary officers No E2/RD/ca D(2006) 520001 of 19.1. 2006 and No SANCO/E2/ACR/ca D(2008) 520889 of 27.11.2008.

the technical regulations concerned, renders such technical regulations inapplicable and unenforceable against individuals.

National measures without notification may lead to the opening of an infringement procedure.

- (b) **A specific notification procedure** for derogations for foods with traditional characteristics after adoption at national level.

## 2. DEROGATIONS/EXEMPTIONS FROM ANNEXES<sup>2</sup>

**Derogations/Exemptions** mean that Member States are given the possibility to authorise food business operators not to apply specified requirements of the Hygiene Package in specified circumstances.

The situations in which derogations can be adopted are exhaustively defined in the Hygiene Regulations and any measures providing for such derogations may only be provided via a Comitology procedure.

In certain cases, the Hygiene Regulations provide for the competent authority to authorise ascertain flexibility. These situations are usually introduced by wording, such as "if the competent authority so permits", "unless otherwise authorised by the competent authority", "with authorisation of the competent authority", etc.

Examples:

- Food chain information may accompany the animals if the competent authority so permits,
- Slaughterhouses do not need to have a separate place with appropriate facilities for the cleaning, washing and disinfection of means of transport for livestock, if official authorised places and facilities exist nearby,
- The premises where foods with traditional characteristics<sup>3</sup> are exposed to an environment necessary for the part-development of their characteristics may in particular comprise walls, ceilings and doors that are not smooth, impervious, non-absorbent or of corrosion resistant material and natural geological walls, ceilings and floors.

It is however up to Member States to grant the derogations at national level on a case-by-case basis. Drafts of national measures which will enable the use of derogations must be notified to the Commission and other Member States.

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<sup>2</sup> Paragraph 2 of Article 13 of Regulation (EC) 852/2004, Paragraph 2 of Article 10 of Regulation (EC) No 853/2004 and Paragraph 2 of Article 17 of Regulation (EC) No 854/2004.

<sup>3</sup> Article 7 of Regulation (EC) No 2074/2005.

## Notifications of draft national measures.

- Principles
  - (a) All drafts of national measures must be notified to the Commission and other Member States,
  - (b) A 3-month standstill period applies when comments may be sent to the Commission,
  - (c) All Member States and the Commission have the possibility to make comments,
  - (d) The national measures may be adopted by Member States only if consensus is reached.
- Notification procedure in accordance with Directive No 98/34/EC

All drafts national measures with the aim of laying down technical measures or specifications (e.g. all national measures adopted for the specific derogations (Chapter 2, except foods with traditional characteristics) or exclusions (Chapter 4)) are covered.

Notification procedure under Directive No 98/34/EC is managed by TRIS system. Member States notifying the draft national measures must send the draft via their national contact point to the Commission. Directive No 98/34/EC is managed by DG Enterprise, which has developed TRIS, a software used by the Member States and the Commission to transmit the draft measures. The translations are dealt with by DG Enterprise.

### Notification procedure for foods with traditional characteristics

A simplified notification procedure (simple information) is laid down for the foods with traditional characteristics (Article 7 of Regulation (EC) No 2074/2005). In this case Member States must no later than 12 months after granting individual or general derogations notify the Commission and the other Member States derogations granted with a description of the requirements adapted and the foodstuffs and establishments concerned. Neither a standstill period nor comments from other Member States and the Commission are applicable.

## 3. ADAPTATIONS OF ANNEXES<sup>4</sup>

**Adaptations** mean that Member States are given the possibility to adapt the requirements laid down in the Annexes of the Hygiene Package in specified circumstances.

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<sup>4</sup> Paragraphs 3-5 of Article 13 of Regulation (EC) No 852/2004, Paragraphs 3-5 of Article 10 of Regulation (EC) No 853/2004 and Paragraphs 3-5 of Article 17 of Regulation (EC) No 854/2004.

The responsibility for adapting the rules to specific local situations is to be left to Member States since they are better placed to judge and find appropriate solutions, provided the achievement of the Hygiene Regulations' objectives are not compromised.

Member States may adopt national measures in order to **adapt requirements laid down in Annexes**. The main purpose of those national measures is limited to the following circumstances:

- (a) To enable the continued use of traditional methods of production (any stage of production, processing or distribution of food)<sup>5</sup> (e.g. traditional dried reindeer meat (FI), raw-dried meat products from minced and non-minced meat (BG), immediate evisceration of poultry (FR)),
- (b) To accommodate the needs of food businesses situated in regions that are subject to special geographic constraints<sup>6</sup>, (e.g. washbasins with hot and cold running water on farms producing cheese in mountain areas (DE), facilities for washing foodstuffs separate from washbasins on farms producing cheese in mountain areas (DE)),
- (c) To adapt requirements on the construction, layout and equipment of establishments<sup>7</sup>, (e.g. special facilities for cutting of meat in food businesses with slaughterhouses of low (specified) capacity (CZ)).

In relation to the organisation of the official controls on products of animal origin, the national measures may also **adapt requirements on official controls** in order:

- (a) To enable the continued use of traditional methods of production,<sup>8</sup>
- (b) To accommodate the needs of food businesses with a low throughput or situated in regions that are subject to special geographic constraints,<sup>9</sup>
- (c) To permit pilot projects in order to try out new approaches to hygiene controls on meat. So far only one notification (FR) was received which is under assessment.<sup>10</sup>

Member States must explain the reasons for the adaptation, the nature of the adaptation sought and, where relevant, provide a summary of the hazard analysis carried out. Products benefiting from such adaptations may, therefore, be placed on the EU market.

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<sup>5</sup> Paragraph 4 (a)(i) of Article 13 of Regulation (EC) No 852/2004, Paragraph 4 (a)(i) of Article 10 of Regulation (EC) No 853/2004, Paragraph 4 (a)(i) of Article 17 of Regulation (EC) No 854/2004.

<sup>6</sup> Paragraph 4 (a)(ii) of Article 13 of Regulation (EC) No 852/2004, Paragraph 4 (a)(ii) of Article 10 of Regulation (EC) No 853/2004, Paragraph 4 (a)(ii) of Article 17 of Regulation (EC) No 854/2004.

<sup>7</sup> Paragraph 4 (b) of Article 13 of Regulation (EC) No 852/2004, Paragraph 4 (b) of Article 10 of Regulation (EC) No 853/2004.

<sup>8</sup> Paragraph 4(a) (i) of Article 17 of Regulation (EC) No 854/2004.

<sup>9</sup> Paragraph 4 (a) (ii) of Article 17 of Regulation (EC) No 854/2004.

<sup>10</sup> Paragraph 4 (a) (iii) of Article 17 of Regulation (EC) No 854/2004.

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  - (d) The national measures may be adopted by Member States only if consensus is reached.

- Notification procedure in accordance with the Hygiene Package<sup>11</sup> is to be used:

Member States notifying the draft national measures must send the draft to the Commission and other Member States (e.g. all national measures adopted for the adaptations of the Annexes set out at Chapter 3). The translations are dealt with by the Member States notifying the draft,

If needed, comments from Member States received by the Commission may be discussed at the Standing Committee of the Food chain.

In the case of notifications of **national measures in order to permit pilot projects** the above mentioned principles and rules for notification procedure apply. The results of a pilot project must be communicated to the Commission as soon as they are available.

## 4. EXCLUSIONS

### 4.1. Activities excluded from the scope of Regulation (EC) No 178/2002<sup>12</sup>

This includes:

- (a) Primary production for private domestic use,
- (b) The domestic preparation, handling or storage of food for private domestic consumption.

"Private domestic consumption" is excluded from the scope of the EU General Food Law and, therefore, also from the scope of the Hygiene Package<sup>13</sup>.

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<sup>11</sup> Paragraphs 5-7 of Article 13 of Regulation (EC) No 852/2004, Paragraphs 5-7 of Article 10 of Regulation (EC) No 853/2004, Paragraphs 5-8 of Article 17 of Regulation (EC) No 854/2004.

<sup>12</sup> Paragraph 3 of Article 1 of Regulation (EC) No 178/2002.

<sup>13</sup> Paragraph 2 (a) and (b) of Article 1 of Regulation (EC) No 852/2004, Paragraph 3 (a) and (b) of Article 1 of Regulation (EC) No 853/2004.

In these cases, Member States may adopt more stringent national rules if they consider it necessary (e.g. *Trichinella* testing of pigs slaughtered for private domestic consumption or *Trichinella* testing of wild boar killed for the private domestic consumption by the hunter).

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#### 4.2. Activities excluded from the scope of Regulation (EC) No 852/2004<sup>14</sup> (general food hygiene) and of Regulation (EC) No 853/2004<sup>15</sup> (hygiene of products of animal origin)

This includes the direct supply, by the primary producer, of small quantities of primary products to the final consumer and to the local retail establishment directly supplying the final consumer<sup>16,17</sup> (e.g. raw milk, eggs<sup>18</sup>, honey, fruit, vegetables, wild game).

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<sup>14</sup> Paragraph 2 (c) of Article 1 of Regulation (EC) No 852/2004.

<sup>15</sup> Paragraph 3 (c) of Article 1 of Regulation (EC) No 853/2004.

<sup>16</sup> Paragraph 2 (c) of Article 1 of Regulation (EC) No 852/2004.

<sup>17</sup> Paragraph 3 (c) of Article 1 of Regulation (EC) No 853/2004.

<sup>18</sup> Without prejudice to other EU legislation e.g provisions of Annex XIV.A.2 of Regulation (EC) No 1234/2007 establishing a common organisation of agricultural markets.

Member States are obliged to adopt national rules. However, general provisions of Regulation (EC) No 178/2002 and Regulation (EC) No 882/2004 apply to regulate these activities.

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#### **4.3. Activities excluded only from the scope of Regulation (EC) No 853/2004 (hygiene of products of animal origin)**

For all the cases mentioned under this point, Regulations (EC) No 178/2002, Regulation (EC) No 852/2004 and Regulation (EC) No 882/2004 apply and Member States are obliged to adopt national rules.

**(a) Small quantities of products other than primary products**

This includes:

- (i) Direct supply, by the farmer, of small quantities of meat from poultry and lagomorphs slaughtered on the farm to the final consumer or to local retail establishments directly supplying such meat to the final consumer<sup>19,20</sup>,
- (ii) Hunters who supply small quantities of wild game meat directly to the final consumer or to local retail establishments directly supplying the final consumer<sup>21</sup>.

The leading principle concerning "small quantities" is subsidiarity as it is up to Member States to further refine this notion depending on the local situation, and to lay down under national law the rules necessary to ensure that the safety of the food is guaranteed. Further work is ongoing to examine the extent of a possible harmonisation.

**(b) Retail**

- (i) Regulation (EC) No 853/2004 does not apply to retail establishments directly supplying food of animal origin to the final consumer (e.g. butcher shops, supermarkets, production of cheese on the farm etc). Therefore, retail establishments need not to be approved. However, Member States may adopt national rules to apply Regulation (EC) No 853/2004 (e.g. approval) to retail,
- (ii) Regulation (EC) No 853/2004 applies to retail when operations are carried out with a view to supplying another retail establishment<sup>22</sup> (e.g. a butcher shop delivering meat to a restaurant or to a school canteen). In this case, retail establishments need to be approved,
- (iii) However, Regulation (EC) No 853/2004 does not apply to retail establishments supplying another retail establishment if this later activity is recognised as marginal, localised and restricted in accordance with national law<sup>23</sup>. Establishments benefiting from this provision need not to be approved.

*Localised:* food destined for local market only, the supplied establishment should be in the immediate vicinity,

*Marginal:* such activity is only a small part of the supplying establishment's business or such activity is the main trade activity of the

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<sup>19</sup> Paragraph 3 (c) of Article 1 of Regulation (EC) No 853/2004.

<sup>20</sup> Without prejudice to other EU legislation e.g Annex IVX B.3. of Regulation (EC) No 1234/2007, establishing a common organisation of agricultural markets.

<sup>21</sup> Paragraph 3 (d) of Article 1 of Regulation (EC) No 853/2004.

<sup>22</sup> Paragraph 5 (b) of Article 1 of Regulation (EC) No 853/2004.

<sup>23</sup> Paragraph 5 (b) (ii) of Article 1 of Regulation (EC) No 853/2004.

establishment's business but represents a small amount of food in absolute terms,

*Restricted:* the supply concerns only certain types of products or establishments.

The principles on how to implement this derogation were agreed in 2005 with the Member States and laid down in the Guidance document for implementation of Regulation (EC) No 853/2004.

The intention of these provisions was, for instance, to allow a butcher to supply meat to school canteens or restaurants locally. It was never the intention to give such possibilities, for instance, to supermarkets.

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