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## **COMMISSION STAFF WORKING DOCUMENT**

**on the Understanding of certain provisions on Flexibility provided in the Hygiene Regulations and related official controls on products of animal origin**

### **Guidelines for competent authorities**

#### *Accompanying the documents*

**Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs**

**Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin**

**Commission Delegated Regulation (EU) 2019/624 of 8 February 2019 concerning specific rules for the performance of official controls on the production of meat and for production and relaying areas of live bivalve molluscs in accordance with Regulation (EU) 2017/625 of the European Parliament and of the Council**

**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,
- Commission Notice on the implementation of food safety management systems covering Good Hygiene Practices and procedures based on the HACCP principles, including the facilitation/flexibility of the implementation in certain food businesses (2022/C 355/01),
- Commission Notice providing guidance on food safety management systems for food retail activities, including food donations (2020/C 199/01),

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

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

[https://food.ec.europa.eu/safety/biological-safety/food-hygiene/guidance-platform\\_en](https://food.ec.europa.eu/safety/biological-safety/food-hygiene/guidance-platform_en)

In addition, the Commission Notice on the implementation of Regulation (EU) 2017/625 of the European Parliament and of the Council (Official Controls Regulation) (2022/C 467/02)<sup>1</sup> should be considered.

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

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<sup>1</sup> [EUR-Lex - 52022XC1208\(01\) - EN - EUR-Lex \(europa.eu\)](#)

## 1. INTRODUCTION

This document should serve as a basis for a better understanding of certain provisions for flexibility provided in the Hygiene Regulations<sup>2</sup> and lead to a better use of these provisions by Member States. It should be stressed that the flexibility of the Hygiene Regulations 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 Regulations (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 6).

As the principles and requirements of the Hygiene Regulations 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.

Flexibility provisions are also laid down in EU requirements as regards official controls on products of animal origin and clarified in this guidance.

## 2. DEROGATIONS/EXEMPTIONS FROM ANNEXES OF THE HYGIENE REGULATIONS

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

In certain cases, the Hygiene Regulations provide for the competent authority to authorise certain 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:

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<sup>2</sup> Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs (OJ L 139, 30.4.2004, p. 1) and Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin (OJ L 139, 30.4.2004, p. 55)

- 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 up to Member States to grant the derogations/exemptions at national level on a case-by-case basis. When national measures are required (e.g. second example) drafts of these national must be notified to the Commission and other Member States in accordance with Directive (EU) 2015/1535<sup>4</sup> (See Chapter 6.1) except for foods with traditional characteristics for which the simplified procedure should be used (Chapter 6.3).

Other derogations or exemptions can only be granted by the Commission and these situations are exhaustively defined in the Hygiene Regulations<sup>5</sup>. Derogations from Annexes I and II to Regulation (EC) No 852/2004 may be adopted in accordance with the regulatory procedure with scrutiny and derogations from Annexes II and III to Regulation (EC) No 853/2004 by delegated acts.

### 3. ADAPTATIONS OF ANNEXES<sup>6</sup>

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

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>7</sup> (e.g. traditional dried reindeer

<sup>3</sup> Article 7 of Commission Regulation (EC) No 2074/2005 of 5 December 2005 laying down implementing measures for certain products under Regulation (EC) No 853/2004 of the European Parliament and of the Council and for the organisation of official controls under Regulation (EC) No 854/2004 of the European Parliament and of the Council and Regulation (EC) No 882/2004 of the European Parliament and of the Council, derogating from Regulation (EC) No 852/2004 of the European Parliament and of the Council and amending Regulations (EC) No 853/2004 and (EC) No 854/2004 (OJ L 338 22.12.2005, p. 27)

<sup>4</sup> Directive (EU) 2015/1535 of the European Parliament and of the Council of 9 September 2015 laying down a procedure for the provision of information in the field of technical regulations and of rules on Information Society services (OJ L 241, 17.9.2015, p. 1)

<sup>5</sup> Paragraph 2 of Article 13 of Regulation (EC) 852/2004, and Paragraph 2 of Article 10 of Regulation (EC) No 853/2004.

<sup>6</sup> Paragraphs 3-5 of Article 13 of Regulation (EC) No 852/2004 and Paragraphs 3-5 of Article 10 of Regulation (EC) No 853/2004.

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>8</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>9</sup>, (e.g. special facilities for cutting of meat in food businesses with slaughterhouses of low (specified) capacity (CZ)).

Notification procedure in accordance with the Hygiene Regulations is to be used (See Chapter 6.2) except for foods with traditional characteristics for which the simplified procedure should be used (Chapter 6.3).

## 4. EXCLUSIONS

### 4.1. Activities excluded from the scope of Regulation (EC) No 178/2002<sup>10</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 Regulations<sup>11</sup>.

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).

### 4.2. Activities excluded from the scope of Regulation (EC) No 852/2004<sup>12</sup> (general food hygiene) and of Regulation (EC) No 853/2004<sup>13</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>14,15</sup> (e.g. raw milk, eggs<sup>16</sup>, honey, fruit, vegetables, wild game).

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

<sup>8</sup> Paragraph 4 (a)(ii) of Article 13 of Regulation (EC) No 852/2004 and Paragraph 4 (a)(ii) of Article 10 of Regulation (EC) No 853/2004.

<sup>9</sup> Paragraph 4 (b) of Article 13 of Regulation (EC) No 852/2004 and Paragraph 4 (b) of Article 10 of Regulation (EC) No 853/2004.

<sup>10</sup> Paragraph 3 of Article 1 of Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ L 31, 1.2.2002, p. 1)

<sup>11</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.

<sup>12</sup> Paragraph 2 (c) of Article 1 of Regulation (EC) No 852/2004.

<sup>13</sup> Paragraph 3 (c) of Article 1 of Regulation (EC) No 853/2004.

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

Member States are obliged to adopt national rules. However, general provisions of Regulation (EC) No 178/2002 and Regulation (EU) 2017/625<sup>17</sup> apply to regulate these activities.

#### **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 (EU) 2017/625 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>18,19</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>20</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. The definition of small quantities must be in line with the preamble of these regulations, which justifies this exclusion by the close relationship between the producer and the consumer. As these provisions are exceptions to the general rule, they should be strictly applied and cannot lead to take out of the scope of these Regulations a large proportion of the activity concerned.

##### **(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.

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

<sup>16</sup> Without prejudice to other EU legislation e.g provisions of Part VI to Annex VII. of Regulation (EU) No 1308/2013 of the European Parliament and of the Council of 17 December 2013 establishing a common organisation of the markets in agricultural products and repealing Council Regulations (EEC) No 922/72, (EEC) No 234/79, (EC) No 1037/2001 and (EC) No 1234/2007 (OJ L 347, 20.12.2013, p. 671)

<sup>17</sup> Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products, amending Regulations (EC) No 999/2001, (EC) No 396/2005, (EC) No 1069/2009, (EC) No 1107/2009, (EU) No 1151/2012, (EU) No 652/2014, (EU) 2016/429 and (EU) 2016/2031 of the European Parliament and of the Council, Council Regulations (EC) No 1/2005 and (EC) No 1099/2009 and Council Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC and 2008/120/EC, and repealing Regulations (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council, Council Directives 89/608/EEC, 89/662/EEC, 90/425/EEC, 91/496/EEC, 96/23/EC, 96/93/EC and 97/78/EC and Council Decision 92/438/EEC (Official Controls Regulation) (OJ L 95, 7.4.2017, p. 1)

<sup>18</sup> Paragraph 3 (d) of Article 1 of Regulation (EC) No 853/2004.

<sup>19</sup> Without prejudice to other EU legislation e.g provisions of Part V to Annex VII of Regulation (EU) No 1308/2013.

<sup>20</sup> Paragraph 3 (e) of Article 1 of Regulation (EC) No 853/2004.

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>21</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 activity is recognised as marginal, localised and restricted in accordance with national law<sup>22</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** (NB: local does not mean national),

*Marginal*: such activity is only a small/minor/insignificant part of the supplying establishment's business or 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.

Drafts of national measures related to the exclusions in this Chapter 4 must be notified to the Commission and other Member States in accordance with Directive (EU) 2015/1535 (See Chapter 6.1).

## 5 DEROGATIONS AND ADAPTATIONS TO OFFICIAL CONTROLS ON PRODUCTS OF ANIMAL ORIGIN

Since the application of Regulation (EU) 2017/625 on official controls, adaptations under national law of official controls are no longer possible, except within the frame of pilot studies (Article 18(9)). Based on experiences gained, certain derogations (under certain conditions) have been granted directly in a Delegated Regulation (i.e. Delegated Regulation (EU) 2019/624<sup>23</sup>), directly applicable in all Member States. Further derogations (within the competences given to the Commission in Regulation (EU) 2017/625) or withdrawal of derogations might be considered in future when relevant. Current derogations include criteria and conditions under which:

<sup>21</sup> Paragraph 5 (b) of Article 1 of Regulation (EC) No 853/2004.

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

<sup>23</sup> Commission Delegated Regulation (EU) 2019/624 of 8 February 2019 concerning specific rules for the performance of official controls on the production of meat and for production and relaying areas of live bivalve molluscs in accordance with Regulation (EU) 2017/625 of the European Parliament and of the Council (OJ L 131, 17.5.2019, p. 1)

- ante-mortem inspection might be performed by the official auxiliary at the slaughterhouse or by the official veterinarian at the holding of provenance;
- post-mortem inspection might be performed while the official veterinarian is not present in the slaughterhouse (low-capacity slaughterhouses or game-handling establishments).

Other derogations concern the official control requirements (meat inspection) of reindeer and grouse, in specific parts of the EU.

Member States may adopt national measures implementing pilot projects limited in time and extent, to evaluate alternative practical arrangements for the performance of official controls on the production of meat. Such alternative arrangements will mostly be carried out in parallel with the existing requirements since compliance with the objectives of the food safety requirements must be guaranteed. Draft national measures should be notified in accordance with the procedure in Chapter 6.1.

Based on experiences gained or scientific and technological developments, the Commission may also amend Commission Implementing Regulation (EU) 2019/627<sup>24</sup>, including additional flexibility provisions, using the examination procedure.

## **6. NOTIFICATIONS OF DRAFT NATIONAL MEASURES**

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 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.

### **6.1 Notification procedure in accordance with Directive (EU) 2015/1535**

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.

In the case of a pilot project (Chapter 5), this notification procedure also applies. In addition, the results should also be communicated to the Commission (SANTE) as soon as they are available.

Notification procedure under Directive (EU) 2015/1535 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 (EU) 2015/1535 is managed by DG GROW, which has developed TRIS, a software used by the Member States and

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<sup>24</sup> Commission Implementing Regulation of 15 March 2019 laying down uniform practical arrangements for the performance of official controls on products of animal origin intended for human consumption in accordance with Regulation (EU) 2017/625 of the European Parliament and of the Council and amending Commission Regulation (EC) No 2074/2005 as regards official controls (OJ L 131, 17.5.2019, p. 51)



the Commission to transmit the draft measures. The translations are dealt with by DG GROW.

## **6.2 Notification procedure in accordance with the Hygiene Regulations<sup>25</sup> is to be used:**

Member States notifying the draft national measures (Chapter 3) 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.

NB: If a draft national measure falls under both procedures (the specific Hygiene procedure and that of Directive (EU) 2015/1535), TRIS is to be used. In that case, the Member State indicates both legal basis. It is also possible to send draft measures via TRIS while specifying that their only legal basis is the hygiene regulations (mentioning the articles). The translations would be dealt with by DG GROW.

## **6.3 Derogation from Regulation (EC) No 852/2004 for foods with traditional characteristics: Article 7 of Regulation (EC) No 2074/2005:**

A simplified notification procedure (information and certain conditions to be met) is laid down for the foods with traditional characteristics in Article 7 of Regulation (EC) No 2074/2005. The objective of this derogation was to recognise with a simplified procedure the traditional foods existing when the Hygiene Regulations were adopted. 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.

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<sup>25</sup> Paragraphs 5-7 of Article 13 of Regulation (EC) No 852/2004 and Paragraphs 5-7 of Article 10 of Regulation (EC) No 853/2004,