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Delegations will find attached document D045714/03.

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EUROPEAN COMMISSION

> Brussels, XXX SANTE/10851/2016 Rev. 2 (POOL/G4/2016/10851/10851R2-EN.doc) D045714/03 [...](2016) XXX draft

COMMISSION REGULATION (EU) .../...

of XXX

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(Text with EEA relevance)

COMMISSION REGULATION (EU) .../...

of XXX

laying down transitional measures for the application of certain provisions of Regulations (EC) No 853/2004 and (EC) No 854/2004 of the European Parliament and of the Council

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to 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 origin¹, and in particular the first paragraph of Article 9 thereof,

Having regard to Regulation (EC) No 854/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption², and in particular the first paragraph of Article 16 thereof,

Whereas:

- (1) Regulations (EC) No 853/2004 and (EC) No 854/2004 provide for significant changes to the rules and procedures to be complied with by food business operators and the competent authorities of the Member States. Since the application of a number of those rules and procedures with immediate effect would have presented practical difficulties in certain cases, it was necessary to adopt transitional measures.
- (2) The Report of 28 July 2009 from the Commission to the European Parliament and the Council on the experience gained from the application of the hygiene Regulations (EC) No 852/2004, (EC) No 853/2004 and (EC) No 854/2004 of the European Parliament and of the Council of 29 April 2004³ ("the report") presents a fact-based outline of the experience gained, including the difficulties encountered, in 2006, 2007 and 2008 by all parties involved in the implementation of those Regulations.
- (3) The report includes feedback on the experiences of the transitional measures laid down in Commission Regulation (EC) No 2076/2005⁴. The report also refers to difficulties

¹ OJ L 139, 30.4.2004, p. 55.

² OJ L 139, 30.4.2004, p. 206.

 $^{^{3}}$ COM(2009) 403 final.

⁴ Commission Regulation (EC) No 2076/2005 of 5 December 2005 laying down transitional arrangements for the implementation of Regulations (EC) No 853/2004, (EC) No 854/2004 and (EC)

noted in relation to the local supply of small quantities of certain food, and mentions that further clarification of import conditions is necessary where national import rules apply in the absence of rules laid down at Union level and that crises due to imported food containing both products of plant origin and processed products of animal origin (composite products) have confirmed the need for a greater control of such products.

- (4) Commission Regulation (EC) No 1079/2013⁵ laid down transitional measures for a transitional period ending on 31 December 2016, in order to permit a smooth transition to the full implementation of the new rules and procedures. The duration of the transitional period was fixed taking into account the review of the regulatory framework on hygiene provided for in Regulations (EC) No 853/2004 and (EC) No 854/2004.
- (5) In addition, based on the information gathered during recent audits carried out by inspectors of the Health and Food Safety Directorate General of the Commission, from the competent authorities in the Member States and from the relevant food business sectors in the Union, it is necessary that certain transitional measures laid down in Regulation (EU) No 1079/2013 are maintained pending the introduction of permanent requirements indicated in the preamble of this Regulation.
- (6) Regulation (EC) No 853/2004 excludes from its scope of application the direct supply, by the producer, of small quantities of meat from poultry and lagomorphs slaughtered on the farm to the final consumer or to local retail establishments supplying directly the final consumer as fresh meat. Limiting that provision to fresh meat would impose an additional burden on small producers. Accordingly, Regulation (EU) No 1079/2013 provides for a derogation from the application of Regulation (EC) No 853/2004 for the direct supply of such commodities under certain conditions, without limiting it to fresh meat. That exclusion should be maintained during a further transitional period provided for in this Regulation, while the possibility for a permanent derogation is considered.
- (7) Regulations (EC) No 853/2004 and (EC) No 854/2004 lay down certain rules for importation of products of animal origin and composite products into the Union. Regulation (EU) No 1079/2013 provides for transitional measures derogating from a number of those rules for certain composite products for which the public health requirements for importing into the Union have not yet been laid down at Union level e.g. for composite products other than those referred to in Article 3(1) and (3) of Commission Regulation (EU) No 28/2012⁶.
- (8) A Commission proposal for a Regulation on official controls in the agri-food chain is currently being close to adoption in ordinary legislative procedure. Once adopted and applicable, that Regulation is going to provide for a legal basis for a risk-adapted approach to control composite products at importation. It is necessary to provide for

No 882/2004 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. 83)

⁵ Commission Regulation (EU) No 1079/2013 of 31 October 2013 laying down transitional measures for the application of Regulation (EC) No 853/2004 and (EC) No 854/2004 of the European Parliament and of the Council (OJ L 292, 1.11.2013, p. 10).

⁶ Commission Regulation (EU) No 28/2012 of 11 January 2012 laying down requirements for the certification for imports and transit through the Union of certain composite products and amending Decision 2007/275/EC and Regulation (EC) No 1162/2009 (OJ L 12, 14.1.2012, p. 1).

derogations during a further transitional period of four years until the new Regulation is expected to become applicable.

- (9) Regulations (EC) No 853/2004 and (EC) No 854/2004 allow the import of food of animal origin from establishments handling products of animal origin for which Annex III to Regulation (EC) No 853/2004 does not set out any specific requirements unless a harmonised list of authorised non-EU member countries has been established and a common model import certificate laid down. More time is needed for consultation of stakeholders and competent authorities of Member States and non-EU countries, taking into account the possible impact on the import of such food by establishing such list and laying down the model import certificate.
- (10) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

Article 1

Subject matter

This Regulation lays down transitional measures for the application of certain provisions of Regulations (EC) No 853/2004 and (EC) No 854/2004 for a transitional period from 1 January 2017 to 31 December 2020.

Article 2

Derogation concerning the direct supply of small quantities of meat from poultry and lagomorphs

By way of derogation from Article 1(3)(d) of Regulation (EC) No 853/2004, the provisions laid down in that Regulation shall not apply to the direct supply, by the producer, of small quantities of meat from poultry and lagomorphs slaughtered on the farm to the final consumer or to local retail establishments directly supplying to the final consumer.

Article 3

Derogation concerning public health requirements for imports of products of animal origin and food containing both products of plant origin and processed products of animal origin

1. Article 6(1) of Regulation (EC) No 853/2004 shall not apply to imports of products of animal origin for which no harmonised public health import requirements have been established.

Imports of such products shall comply with the public health import requirements of the Member State of import.

By way of derogation from Article 6(4) of Regulation (EC) No 853/2004, food business operators importing food containing both products of plant origin and processed products of animal origin, others than those referred to in Article 3(1) and (3) of Commission Regulation (EU) No 28/2012 shall be exempt from the requirements referred to in Article 6(4) of Regulation (EC) No 853/2004.

Imports of such products shall comply with the public health import requirements of the Member State of import.

Article 4

Derogation concerning public health procedures concerning imports of products of animal origin

Chapter III of Regulation (EC) No 854/2004 shall not apply to imports of products of animal origin for which no harmonised public health import requirements have been established.

Imports of such products shall comply with the public health import requirements of the Member State of import.

Article 5

Entry into force and application

This Regulation shall enter into force on the third day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall apply from 1 January 2017 to 31 December 2020.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels,

For the Commission The President Jean-Claude JUNCKER