Commission Regulation (EU) No 209/2013 of 11 March 2013 amending Regulation (EC) No 2073/2005 as regards microbiological criteria for sprouts and the sampling rules for poultry carcases and fresh poultry meat (Text with EEA relevance)

COMMISSION REGULATION (EU) No 209/2013

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(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 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs[(1)], and in particular Article 4(4) thereof,

Whereas:

(1) Regulation (EC) No 852/2004 lays down general rules for food business operators on the hygiene of foodstuffs, taking particular account of procedures based on the application of hazard analysis and critical control point (HACCP) principles. Article 4 of that Regulation provides that food business operators are to adopt specific hygiene measures concerning, inter alia, compliance with microbiological criteria for foodstuffs and sampling and analysis requirements.

(2) Commission Regulation (EC) No 2073/2005 of 15 November 2005 on microbiological criteria for foodstuffs[(2)] lays down microbiological criteria for certain micro-organisms and the implementing rules to be complied with by food business operators when implementing the general and specific hygiene measures referred to in Article 4 of Regulation (EC) No 852/2004.

(3) Chapter 1 of Annex I to Regulation (EC) No 2073/2005 sets out the food safety criteria to be complied with by certain food categories, including sampling plans, analytical reference methods and limits for micro-organisms or their toxins and metabolites. That Chapter lists the food safety criteria for sprouted seeds, as regards Salmonella.

(4) Following the outbreak of Shiga toxin-producing *E. coli* (STEC) in May 2011 in the Union, consumption of sprouts was identified as the most likely origin of the outbreaks.

(5) On 20 October 2011 the European Food Safety Authority ('EFSA') adopted a Scientific Opinion on the risk posed by Shiga toxin-producing *Escherichia coli* and other pathogenic bacteria in seeds and sprouted seeds[(3)]. In its Opinion, EFSA concludes that the contamination of dry seeds with bacterial pathogens is the most likely initial source of the sprout-associated outbreaks. In addition, the Opinion states that, due to the high humidity and the favourable temperature during sprouting, bacterial pathogens present on dry seeds can multiply during sprouting and result in a public health risk.

Changes to legislation: *There are currently no known outstanding effects for the Commission Regulation (EU) No 209/2013. (See end of Document for details)*

(6) In its Opinion, EFSA recommends, inter alia, that microbiological criteria should be strengthened as one of the components of a food safety management system for the sprouted seeds production chain. That recommendation concerns the existing microbiological criteria on *Salmonella* for sprouted seeds and the consideration of microbiological criteria on other pathogens. EFSA also states that available data indicates a higher risk for sprouts in comparison with other sprouted seeds.

(7) In its Opinion, EFSA considers different options for microbiological criteria for pathogenic *E. coli* for seeds: before the start of the production process, during sprouting and in the final product. In that context, EFSA states that the detection and mitigation of a contamination problem earlier in the sprouted seed production chain may have advantages as it avoids contamination being amplified during the full sprouting process. It also acknowledges that testing seeds alone does not allow for the detection of contamination which may come at a later stage in the production process. EFSA therefore concludes that microbiological criteria could be useful during the sprouting process and/or for the final product. When considering a microbiological criterion for the final sprouted seeds, EFSA notes that the time required for the detection methods for pathogenic bacteria combined with the short shelf-life may not allow withdrawing the product in the event of non-compliance. In its opinion EFSA considers that it is currently not possible to evaluate the extent of public health protection provided by specific microbiological criteria for seeds and sprouted seeds. This highlights the need for data collection to conduct quantitative risk assessment. Therefore this criterion should be reviewed taking into account progress in science, technology and methodology, emerging pathogenic micro-organisms in foodstuffs and information from risk assessment.

(8) In order to ensure the protection of public health in the Union and in view of that EFSA Opinion, Commission Regulation (EU) No 211/2013 of 11 March 2013 on certification requirements for imports into the Union of sprouts and seeds intended for the production of sprouts[(4)] and Commission Implementing Regulation (EU) No 208/2013 of 11 March 2013 on traceability requirements for sprouts and seeds intended for the production of sprouts[(5)] were adopted.

(9) In addition to the measures laid down in those acts and considering the potential major health risk posed by the possible presence of pathogens in sprouts, provisions on additional microbiological criteria should be laid down following the EFSA recommendations, in particular on STEC serogroups which are considered of most important public health concern.

(10) Microbiological criteria are one of several control options in food safety and should be used by food business operators as a means to verify implementation of an effective food safety management system. However, due to the low prevalence and the heterogeneous distribution of some pathogens in seeds and sprouted seeds, the statistical limitations of sampling plans, and the lack of information about the application of good agricultural practices in the production of seeds, it is necessary to test all batches of seeds for the presence of the pathogens in cases where food business operators have not put in place food safety management systems including steps that reduce the microbiological risk.

If food management systems are in place and if their effectiveness is confirmed by historical data, a reduction of sampling frequency may be considered. Such frequency should, however, never be less than once per month.

(11) When laying down microbiological criteria for sprouts, flexibility should be provided with regard to the stages of sampling and the type of samples which are to be taken, in order to take into account the diversity of production systems, while maintaining equivalent food safety standards. In particular, it is appropriate to provide for alternatives to the sampling of sprouts in cases where the sampling is technically difficult. The testing of spent irrigation water for pathogenic bacteria has been proposed as an alternative strategy, as it seems to be a good indicator of the types of micro-organisms in the sprouts themselves. Due to the uncertainties regarding the sensitivity of this strategy, it is needed that food businesses operators using this alternative establish a sampling plan, including sampling procedures and sampling points of the spent irrigation water.

(12) Certain STEC serogroups (namely O157, O26, O103, O111, O145 and O104:H4) are recognised to be those causing the most of the Haemolytic Uremic Syndrome (HUS) cases occurring in the EU. Furthermore serotype O104:H4 caused the outbreak in May 2011 in the Union. Therefore microbiological criteria should be considered for these six serogroups. It cannot be excluded that other STEC serogroups may be pathogenic to humans as well. In fact, such STEC may cause less severe forms of disease such as diarrhoea and or bloody diarrhoea or may also cause HUS and therefore represent a hazard for the consumer's health.

(13) Sprouts should be considered to be ready-to-eat food, as they can be consumed without the need for cooking or other processing, which would otherwise be effective in eliminating or reducing to an acceptable level pathogenic micro-organisms. Food business operators producing sprouts should therefore comply with the food safety criteria for ready-to-eat food laid down in Union legislation, including the sampling of processing areas and equipment as part of their sampling scheme.

(14) Regulation (EC) No 2160/2003 of the European Parliament and of the Council of 17 November 2003 on the control of *Salmonella* and other specified food-borne zoonotic agents[(6)] aims at ensuring that proper and effective measures are taken to detect and control *Salmonella* and other zoonotic agents at all relevant stages of production, processing and distribution in order to reduce their prevalence and the risk they pose to public health.

(15) Regulation (EC) No 2160/2003, as amended by Commission Regulation (EU) No 1086/2011[(7)], lays down detailed rules on a *Salmonella* food safety criterion for fresh poultry meat. As a consequence of the amendments made to Regulation (EC) No 2160/2003, Regulation (EC) No 2073/2005 was also amended by Regulation (EU) No 1086/2011. However, by that amendment, certain terminological ambiguities were introduced in the text of Regulation (EC) No 2073/2005. Those ambiguities should, in the interest of clarity and consistency of Union legislation, be clarified.

(16) Regulation (EC) No 2073/2005 should therefore be amended accordingly.

(17) The measures provided for in this Regulation are in accordance with the opinion of the of the Standing Committee on the Food Chain and Animal Health and neither the European Parliament nor the Council has opposed them,

HAS ADOPTED THIS REGULATION:

Article 1

Regulation (EC) No 2073/2005 is amended as follows:

(1) In Article 2, the following point (m) is added:

(m) the definition of "sprouts" in Article 2(a) of Commission Implementing Regulation (EU) No 208/2013 of 11 March 2013 on traceability requirements for sprouts and seeds intended for the production of sprouts[8];;

(2) Annex I is amended in accordance with the Annex to this Regulation.

Article 2

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

It shall apply from 1 July 2013.

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

Done at Brussels, 11 March 2013.

For the Commission

The President

José Manuel BARROSO