Commission Regulation (EU) No 210/2013 of 11 March 2013 on the approval of establishments producing sprouts pursuant to Regulation (EC) No 852/2004 of the European Parliament and of the Council (Text with EEA relevance)

COMMISSION REGULATION (EU) No 210/2013

of 11 March 2013

on the approval of establishments producing sprouts pursuant to Regulation (EC) No 852/2004 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 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs[(1)], and in particular Article 6(3)(c) thereof,

Whereas:

(1) Regulation (EC) No 852/2004 lays down general rules for food business operators on the hygiene of foodstuffs, inter alia, for primary production and associated operations. That Regulation provides that food business operators are to ensure that establishments are approved by the competent authority, following at least one on-site visit when approval is required under national legislation, under Regulation (EC) No 853/2004 of the European Parliament and of the Council[(2)] or under a decision adopted pursuant to Regulation (EC) No 852/2004.

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

(3) On 20 October 2011, the European Food Safety Authority ('EFSA') adopted a Scientific Opinion on the risk posed by Shiga toxin-producing *Escherichia coli* (STEC) 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.

(4) In order to ensure the protection of public health in the Union and in view of that EFSA Opinion, Commission Regulation (EU) No 209/2013[(4)] amending Commission Regulation (EC) No 2073/2005 of 15 November 2005 on microbiological criteria for foodstuffs[(5)], Commission Regulation (EU) No 211/2013[(6)] and Commission Implementing Regulation (EU) No 208/2013[(7)] were adopted.

(5) In addition to the measures laid down in those acts, establishments producing sprouts should be subject to approval in accordance with Regulation (EC) No 852/2004. Such approvals, granted following at least one on-site visit, would ensure that such

Changes to legislation: *Commission Regulation (EU) No 210/2013 is up to date with all changes known to be in force on or before 28 December 2020. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes*

establishments comply with the relevant hygiene rules, thereby ensuring a high level of protection of public health. The approval of such establishments should be conditional upon their compliance with a number of requirements in order to ensure that the possibility of contamination within the facility where sprouts are produced is reduced.

(6) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee of the Food Chain and Animal Health,

HAS ADOPTED THIS REGULATION:

Article 1

For the purpose of this Regulation, the definition of 'sprouts' in Article 2 of Implementing Regulation (EU) No 208/2013 shall apply.

Article 2

Food business operators shall ensure that establishments producing sprouts are approved by the competent authority in accordance with Article 6 of Regulation (EC) No 852/2004. The competent authority shall approve those establishments only provided that they comply with the requirements set out in Annex I to Regulation (EC) No 852/2004 and in the Annex to this Regulation.

Article 3

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