

IMI notification No 429943 by Sweden (24/8/2022)

Request for clarifications by the Commission services

Within the framework of the notification procedure laid down under Article 15(7) and Article 39(5) of the Directive 2006/123/EC relating to the provision of information in the field of the freedom of establishment as well as the freedom to provide services, the Swedish authorities notified via the IMI system the *'The National Food Agency's regulations and general advice on the frequency of controls for risk-based official controls'*. The Commission would like to thank the Swedish authorities for this IMI notification with the notification number No 429943.

In order to allow the Commission services to complete their analysis under the relevant provisions of EU law, the Swedish authorities are kindly invited to reply to the following request for clarifications:

Official controls

Pursuant to Article 288 of the Treaty on the Functioning of the European Union, "[a] regulation shall have general application. It shall be binding in its entirety and directly applicable in all Member States". Thus, Member States may not lay down, in an area governed by directly applicable EU legislation, national rules which interfere with the correct and complete application of EU law.

The IMI Report accompanying the notification refers to Article 9 of Regulation (EU) 2017/625 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. Indeed, paragraph 1 of Article 9 of Regulation (EU) 2017/625 provides that competent authorities shall perform official controls on all operators regularly, on a risk basis and with appropriate frequency, taking account of the factors listed in points (a) to (e) of that paragraph.

The Commission services would remind the Swedish authorities that Regulation (EU) 2017/625, including its Article 9(1), is directly applicable in the Member states and, in accordance with settled case law, in principle precludes the adoption or maintenance of parallel national provisions (see judgment of the Court of Justice of 15 November 2012, Stichting Al-Aqsa, C-539/10P and C-550/10P, EU:C:2012:711, paragraph 87).

The Commission services consider that the draft National Food Agency's regulations and general guidelines on frequency of controls for risk-based official controls notified by Sweden (hereinafter "the draft Regulations") include a number of provisions which may create legal uncertainty over the full and correct application of the provisions of Article 9(1) of Regulation (EU) 2017/625 in Sweden. In particular:

- Section 5 of the draft Regulations provides that the control authority shall determine the frequency of checks on the basis of the need for control in each activity, taking into account risks associated with the business and expected compliance with food law.
- Risks associated with the business are defined in Sections 7 to 9 of the draft Regulations by references, in particular, to consumers' access to fair information, the protection of human life and health, the scope of the activity and whether food information is manufactured, imported or formulated in the establishment for food which is subject to special authorisation or notification obligations under food law. These factors overlap with some of the aspects laid down in Article 9(1)(a) and (b) of Regulation (EU) 2017/625 but do not completely take them into account.
- Expected compliance with food law is defined in Sections 10 and 11 of the draft Regulations by references to the operator's previous compliance with the relevant requirements and whether the activity is certified by a certification body accredited for the task in accordance with Regulation (EC)

No 765/2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products. These factors overlap with some of the aspects laid down in Article 9(1)(c) to (e) of Regulation (EU) 2017/625 but do not completely take them into account. In addition, Article 9(1)(d) refers to "the reliability and results of own controls that have been performed by the operators, or by a third party at their request, including, where appropriate, private quality assurance schemes". Section 11 of the draft Regulations, which in this regard refers only to certain certification schemes where the activity is certified by a certification body accredited for the task in accordance with Regulation (EC) No 765/2008, has a scope narrower than Article 9(1)(d) of Regulation (EU) 2017/625 and is therefore not in line with that provision.

Taking account of the foregoing considerations, the Commission services would invite the Swedish authorities to clarify the draft Regulations so that they do not interfere with the direct applicability of Article 9(1) of Regulation (EU) 2017/625 or create legal uncertainty over the full and correct application of that provision.

In addition the Commission services note that the following is stated in the IMI Report as regards the scope of the draft Regulations:

"The provisions are included in a regulation that governs the planning and determination of the frequency of regular risk-based official controls to be carried out in accordance with the Food Law (2006:804) and the Law (2009:1424) on controls of protected designations of agricultural products from the undertakings that are covered by Section 23, paragraph 1, indents 1-8 and 11 of the Food Ordinance (2006:813). The undertakings concerned are thus food establishments at the stages after primary production, facilities for the production of snuff and chewing tobacco and facilities for the supply of drinking water."

In the light of the objective of Regulation (EU) 2017/625 to ensure a harmonised approach with regard to official controls and other official activities performed in view of ensuring the application of Union agri-food chain legislation (recitals 20 and 99 of Regulation (EU) 2017/625), the Commission services would invite the Swedish authorities to clarify how they intend to ensure that the inclusion of facilities for the production of snuff and chewing tobacco in the scope of the draft Regulations does not interfere with correct application of the Union agri-food chain legislation or the high level of protection of human health and consumers' interest which that legislation aims to achieve, including by any perceptions which may arise from such inclusion.

The Commission would like to highlight that this request for clarifications aims only to clarify the scope, objective and aim of the notified measure and does not constitute a formal position.

The Commission would like to thank in advance the Swedish authorities for their co-operation.