

Mowi Poland S.A.

v

European Commission

Judgment of the General Court (Sixth Chamber) of 24 September 2025

(Public health – Specific hygiene rules for food of animal origin – Regulation (EC) No 853/2004 – Point 3(e) of the Annex to Delegated Regulation (EU) 2024/1141 – Action for annulment – *Locus standi* – Interest in bringing proceedings – Admissibility – Concept of ‘frozen product’ – Lack of consultation with EFSA – Article 13 of Regulation No 853/2004)

*1. Action for annulment – Natural or legal persons – Regulatory acts – Acts not entailing implementing measures and concerning the applicant directly – Concept of direct concern – Criteria – Act directly affecting the applicant’s legal situation – Commission regulation amending specific hygiene requirements for food of animal origin – Contested provision imposing obligations on the applicant – Admissibility*

*(Art. 263, fourth para., TFEU; Commission Regulation 2024/1141, annex, point 3(e))*

*(see paragraphs 21-24, 34, 40, 53-57)*

*2. Public health – Hygiene of food of animal origin – Consumer protection – Obligations of food business operators – Specific requirements – Fishery products – Stiffening and storage – Concept of ‘frozen product’*

*(Regulation of the European Parliament and of the Council No 853/2004, Annex III, Section VIII, Chapter VII, point 2; Commission Regulation 2024/1141, annex, point 3(e))*

*(see paragraphs 26, 27, 39, 43-52)*

*3. Action for annulment – Natural or legal persons – Interest in bringing proceedings – Action capable of securing a benefit for the applicant*

*(Art. 263, fourth para., TFEU)*

*(see paragraphs 58-60)*

*4. Public health – Hygiene of food of animal origin – Consumer protection – Regulation No 853/2004 – Commission’s obligation to consult the European Food Safety Authority (EFSA) – Scope – Matters that could have a significant impact on public health*

*(Regulation of the European Parliament and of the Council No 853/2004, Art. 13 and Annex III, Section VIII, Chapter VII, point 2; Commission Regulation 2024/1141, recital 13 and annex, point 3(e))*

*(see paragraphs 69, 74-77, 82-93)*

## Résumé

Hearing an action for annulment, which it upholds, the General Court rules, for the first time, on the European Commission’s obligation to consult the European Food Safety Authority (EFSA) before adopting a provision that could have a significant impact on public health under Article 13 of Regulation No 853/2004. ([1](#))

The applicant, Mowi Poland S.A., is a company which uses, to slice smoked salmon, the ‘stiffening’ technique, which consists of cutting smoked salmon fillets by lowering their initial temperature to a level between  $-7^{\circ}\text{C}$  and  $-14^{\circ}\text{C}$ .

By its action, the applicant seeks, in essence, the annulment of point 3(e) of the annex to Delegated Regulation 2024/1141, (2) adopted by the Commission (‘the contested provision’). That provision adds point 4 to Chapter VII of Section VIII of Annex III to Regulation No 853/2004, that point 4, first, providing for the possibility of using stiffening as a stage of production, whilst specifying that maintaining fishery products at the temperature required by this technique must be limited to ‘a period of time as short as possible and in any case not exceeding 96 hours’ and, secondly, providing that storage and transport at that temperature are not allowed.

## ***Findings of the Court***

In examining the admissibility of the action, the Court finds, initially, that the applicant has standing to bring proceedings. The regulation to which the contested provision belongs is a regulatory act which does not entail implementing measures and is of direct concern to the applicant, within the meaning of the third limb of the fourth paragraph of Article 263 TFEU.

As regards direct concern, the Court finds that the two criteria provided for by the case-law are met. First, the implementation of the contested provision is purely automatic and results from the relevant regulation alone without requiring the application of intermediate rules. Secondly, the contested provision imposes obligations on the applicant. In this regard, the Court notes that, before the adoption of the contested provision, there was no legally binding obligation governing the use of stiffening as a stage of production. As regards the requirements relating to storage, it was not clear from the provisions in force before the adoption of the contested provision that it was prohibited to keep smoked salmon at stiffening-required temperature for a period exceeding 96 hours. In the first place, since those provisions do not define the concept of ‘storage’, they do not specify from what point a fishery product should be considered to be stored. In the second place, smoked salmon, as a processed fishery product, did not fall within the scope of Chapter VII, point 1, of Section VIII of Annex III to Regulation No 853/2004. With regard to point 2, neither Regulation No 853/2004 nor Regulations No 178/2002 (3) and No 852/2004 (4) define the concept of ‘frozen product’. However, the Court observes that, in various provisions of Regulation No 853/2004, the concept of ‘frozen product’ is associated with a temperature not exceeding  $-18^{\circ}\text{C}$ . Thus, it was not apparent from the provisions in force before the adoption of the contested provision that smoked salmon, placed at a temperature used for stiffening, which varies, as far as the applicant’s practice is concerned, between  $-7^{\circ}\text{C}$  and  $-14^{\circ}\text{C}$ , had be considered to be a ‘frozen product’ within the meaning of Chapter VII, point 2, of Section VIII of Annex III to Regulation No 853/2004. It follows that, before the adoption of the contested provision, operators of ‘stiffened’ smoked salmon were subject to the requirements laid down in Chapter IX, point 5, of Annex II to Regulation No 852/2004 which refers to the possibility of removing products from the temperatures necessary for ‘limited periods’, without indicating a time limit, and providing that no health risk results therefrom.

Next, the Court finds that the applicant has an interest in bringing proceedings, because that the possible annulment of the contested provision is likely to procure an advantage to the applicant, namely that of not having to comply with the requirements imposed by that provision under Article 3(1) of Regulation No 853/2004. Thus, the Court finds that the action is admissible.

As regards the merits of the case, the Court examines the fourth plea in law, according to which, by failing to consult EFSA in the procedure for drafting the contested provision, the Commission infringed Article 13 of Regulation No 853/2004. The latter provides that the Commission is to consult EFSA on any matter falling within the scope of that regulation that could have a significant impact on public health.

In the present case, it is common ground between the parties that the Commission did not consult EFSA prior to the adoption of the contested provision. First, the issue to which the contested provision relates falls within the scope of Regulation No 853/2004. Secondly, as regards the assessment of the significant impact on public health, it can be inferred from the *travaux préparatoires* for Delegated Regulation 2024/1141 and the Commission’s arguments put forward in the context of the present action that the reason which led to the adoption of the contested provision is linked to the fact that there were ‘ambiguities’ in the previous legal framework regarding stiffening and the prohibition on storing and transporting fishery products at the temperature required by that technique, while maintaining smoked

salmon at that temperature for a long period would be likely to lead to health risks. Such an issue must be categorised as a matter that could have a significant impact on public health. It is apparent from the Commission's own arguments that maintaining smoked salmon at stiffening-required temperature for a long period could have an impact on the health of consumers and, therefore, have an impact on public health. Furthermore, such an impact on public health appears to be significant since, according to the Commission, accepting the interpretation adopted by the applicant with regard to Chapter VII, point 2, of Section VIII of Annex III to Regulation No 853/2004 would lead to a situation that is 'manifestly dangerous for the health of consumers'. Accordingly, the Commission was required to consult EFSA under Article 13 of Regulation No 853/2004 before adopting the contested provision.

That finding is borne out by the fact that it is apparent from recital 27 of Regulation No 853/2004 that scientific advice should underpin EU legislation on food hygiene. The scientific basis taken into account by the Commission for the purposes of drafting the contested provision is not apparent from Delegated Regulation 2024/1141 or from its explanatory memorandum. Admittedly, the President of the European Parliament requested EFSA, by letter of 14 May 2024, to issue a scientific opinion on the impact of the stiffening and thawing procedures on the survival and development of biological hazards, to which the Executive Director of EFSA replied by letter of 12 June 2024. However, that exchange is subsequent to the date of adoption of Delegated Regulation 2024/1141, namely 14 December 2023, and, therefore, it is, in any event, without impact on the legality of this regulation.

Accordingly, the Court upholds the fourth plea in law and annuls the contested provision.

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( [1](#) ) 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 2004 L 139, p. 55](#)).

( [2](#) ) Commission Delegated Regulation (EU) 2024/1141 of 14 December 2023 amending Annexes II and III to Regulation (EC) No 853/2004 of the European Parliament and of the Council as regards specific hygiene requirements for certain meat, fishery products, dairy products and eggs ([OJ L, 2024/1141](#)).

( [3](#) ) 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 2002 L 31, p. 1](#)).

( [4](#) ) Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs ([OJ 2004 L 139, p. 1](#)).