

Provisional text

JUDGMENT OF THE COURT (Third Chamber)

1 October 2020 (*)

(Reference for a preliminary ruling – Food safety – Novel foods and novel food ingredients – Regulation (EC) No 258/97 – Article 1(2)(e) – Concept of ‘food ingredients isolated from animals’ – Placing on the market – Whole insects intended for human consumption)

In Case C-526/19,

REQUEST for a preliminary ruling under Article 267 TFEU from the Conseil d’État (Council of State, France), made by decision of 28 June 2019, received at the Court on 9 July 2019, in the proceedings

Entoma SAS

v

Ministre de l’Économie et des Finances,

Ministre de l’Agriculture et de l’Alimentation,

THE COURT (Third Chamber),

composed of A. Prechal, President of the Chamber, L.S. Rossi, J. Malenovský, F. Biltgen and N. Wahl (Rapporteur), Judges,

Advocate General: M. Bobek,

Registrar: A. Calot Escobar,

having regard to the written procedure,

after considering the observations submitted on behalf of:

- Entoma SAS, by F. Molinié, avocat,
- the French Government, by A.-L. Desjonquères and C. Mosser, acting as Agents,
- the Italian Government, by G. Palmieri, acting as Agent, and by M. Russo and G. Damiani, avvocati dello Stato,
- the European Commission, by C. Hödlmayr and C. Valero, acting as Agents,

after hearing the Opinion of the Advocate General at the sitting on 9 July 2020,

gives the following

Judgment

- 1 This request for a preliminary ruling concerns the interpretation of Article 1(2)(e) of Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients (OJ 1997 L 43, p. 1), as amended by Regulation (EC) No 596/2009 of the

European Parliament and of the Council of 18 June 2009 (OJ 2009 L 188, p. 14) ('Regulation No 258/97').

- 2 The request has been made in proceedings between Entoma SAS, on the one hand, and the ministre de l'Économie and des Finances (Minister for the Economy and Finance, France) and the ministre de l'Agriculture et de l'Alimentation (Minister for Agriculture and Food, France), on the other hand, and concerns a prefectoral order ordering, first, the suspension of the placing on the market by Entoma of whole insects intended for human consumption and, second, the withdrawal of those insects from the market until the obtention of an authorisation to place them on the market, issued following an assessment demonstrating that they do not present any danger to the health of the consumer.

Legal context

EU law

Regulation No 258/97

- 3 Recitals 1 and 2 of Regulation No 258/97 stated:

- (1) ... differences between national laws relating to novel foods or food ingredients may hinder the free movement of foodstuffs [and] create conditions of unfair competition, thereby directly affecting the functioning of the internal market;
- (2) ... in order to protect public health, it is necessary to ensure that novel foods and novel food ingredients are subject to a single safety assessment through a [Union] procedure before they are placed on the market within the [European Union] ...'

- 4 Article 1 of that regulation provided:

1. This Regulation concerns the placing on the market within the [Union] of novel foods or novel food ingredients.

2. This Regulation shall apply to the placing on the market within the [Union] of foods and food ingredients which have not hitherto been used for human consumption to a significant degree within the [Union] and which fall under the following categories:

...

- (c) foods and food ingredients with a new or intentionally modified primary molecular structure;
- (d) foods and food ingredients consisting of or isolated from micro-organisms, fungi or algae;
- (e) foods and food ingredients consisting of or isolated from plants and food ingredients isolated from animals, except for foods and food ingredients obtained by traditional propagating or breeding practices and having a history of safe food use;
- (f) foods and food ingredients to which has been applied a production process not currently used, where that process gives rises to significant changes in the composition of structure of the foods or food ingredients which affect their nutritional value, metabolism or level of undesirable substances.

3. Where necessary, it may be determined in accordance with the procedure laid down in Article 13(2) whether a type of food or food ingredient falls within the scope of paragraph 2 of this Article.'

- 5 Article 3(1) of that regulation laid down:

'Foods and food ingredients falling within the scope of this Regulation must not:

- present a danger for the consumer,
- ...’

6 Article 12 of Regulation No 258/97 stated:

‘1. Where a Member State, as a result of new information or a reassessment of existing information, has detailed grounds for considering that the use of a food or a food ingredient complying with this Regulation endangers human health or the environment, that Member State may either temporarily restrict or suspend the trade in and use of the food or food ingredient in question in its territory. It shall immediately inform the other Member States and the [European] Commission thereof, giving the grounds for its decision.

2. The Commission shall examine the grounds referred to in paragraph 1 as soon as possible within the Standing Committee for Foodstuffs. It shall take the appropriate measures aimed at confirming, amending or repealing the national measure in accordance with the regulatory procedure laid down in Article 13(2). The Member State which took the decision referred to in paragraph 1 may maintain it until the measures have entered into force.’

Regulation (EU) 2015/2283

7 Regulation No 258/97 was repealed and replaced, as from 1 January 2018, by Regulation (EU) 2015/2283 of the European Parliament and of the Council of 25 November (OJ 2015 L 327, p. 1).

8 Recitals 6 and 8 of Regulation 2015/2283 state:

‘(6) The existing definition of novel food in Regulation [No 258/97] should be clarified and updated with a reference to the general definition of food provided for in 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)].

...

(8) The scope of this Regulation should, in principle, remain the same as the scope of Regulation [No 258/97]. However, on the basis of scientific and technological developments that have occurred since 1997, it is appropriate to review, clarify and update the categories of food which constitute novel foods. Those categories should cover whole insects and their parts. ...’

9 Article 1 of that regulation, entitled ‘Subject matter and purpose’, provides:

1. This Regulation lays down rules for the placing of novel foods on the market within the Union.
2. The purpose of this Regulation is to ensure the effective functioning of the internal market while providing a high level of protection of human health and consumers’ interests.’

10 Article 2 of the regulation, entitled ‘Scope’, provides:

- ‘1. This Regulation applies to the placing of novel foods on the market within the Union.
- ...’

11 Article 3 of that regulation, entitled ‘Definitions’, lays down in paragraph 2:

‘The following definitions shall apply:

- (a) “novel food” means any food that was not used for human consumption to a significant degree within the Union before 15 May 1997, irrespective of the dates of accession of Member States to the Union, and that falls under at least one of the following categories:

...

- (v) food consisting of, isolated from or produced from animals or their parts, except for animals obtained by traditional breeding practices which have been used for food production within the Union before 15 May 1997 and the food from those animals has a history of safe food use within the Union;

...’

- 12 Article 35 of Regulation 2015/2283, entitled ‘Transitional measures’, provides in paragraph 2:

‘Foods not falling within the scope of Regulation [No 258/97], which are lawfully placed on the market by 1 January 2018 and which fall within the scope of this Regulation may continue to be placed on the market until a decision is taken in accordance with Articles 10 to 12 or Articles 14 to 19 of this Regulation following an application for authorisation of a novel food or a notification of a traditional food from a third country submitted by the date specified in the implementing rules adopted in accordance with Article 13 or 20 of this Regulation respectively, but no later than 2 January 2020.’

French law

- 13 Article L. 218-5-4 of the code de la consommation (Consumer Code), in the version in force on 27 January 2016, provided:

‘If it is established that a product has been placed on the market without having been the subject of the authorisation, registration or declaration required by the rules applicable to that product, the préfet (Prefect) or, in Paris, the préfet de police (Prefect of Police) may order the suspension of its placing on the market and its withdrawal until compliance with the rules in force.’

The dispute in the main proceedings and the question referred for a preliminary ruling

- 14 At the time of the facts in the main proceedings, Entoma marketed products consisting of mealworms, locusts and crickets prepared and intended for human consumption in the form of whole insects.
- 15 By order of 27 January 2016, the Paris Prefect of Police suspended the placing on the market of whole insects marketed by Entoma, on the ground that, inter alia, Entoma did not have the authorisation to place on the market as required by Regulation No 258/97, and ordered the withdrawal of those insects from the market until such an authorisation was obtained, issued following an assessment seeking to demonstrate that those products did not present any danger for the consumer.
- 16 Entoma brought an action for annulment against that order before the tribunal administratif de Paris (Administrative Court, Paris, France). By judgment of 9 November 2017, that court rejected that action.
- 17 By judgment of 22 March 2018, the cour administrative d’appel de Paris (Administrative Court of Appeal, Paris, France) dismissed the appeal brought by Entoma, ruling that that order had been adopted lawfully on the basis of Article L. 218-5-4 of the Consumer Code.
- 18 Entoma then brought an appeal on a point of law against that judgment before the referring court, the Conseil d’État (Council of State, France). In support of its appeal, it claimed inter alia that the cour administrative d’appel de Paris (Administrative Court of Appeal, Paris) erred in law by finding that the products it marketed were covered by Regulation No 258/97 although, as they consisted of whole insects intended for consumption as such, they were excluded from the scope of that regulation. More specifically, it complains that the cour administrative d’appel de Paris (Administrative Court of Appeal, Paris) adopted an incorrect interpretation of Article 1(2)(e) of that regulation, in that that provision expressly referred only to ‘food ingredients isolated from animals’ and not to whole animals. In that regard, Entoma submits, relying on recital 8 of Regulation 2015/2283, that the inclusion of whole insects in the category of ‘novel foods’, resulting from Article 3(2)(a)(v) of Regulation 2015/2283, does not clarify the earlier definition, which was limited to parts of animals only, but rather modifies

the scope of that previous definition by supplementing it. It infers from that fact that the food products that it marketed had been lawfully placed on the market before 1 January 2018 and, on that ground, were covered by the transitional measures laid down in Article 35(2) of Regulation 2015/2283 which allowed the products to remain on the market provided that, before 2 January 2020, they were covered by an application for authorisation as ‘novel foods’ or by a notification as traditional foods subject to the rules defined by that regulation.

- 19 The Minister for the Economy and Finance contends that there was no health reason to exclude the placing of whole insects on the market from the scope of Regulation No 258/97 since the consumption of whole insects poses as many risks for the safety of consumers as the consumption of food ingredients isolated from animals.
- 20 The Conseil d’État (Council of State) took the view that, given the different possible interpretations of the terms of Regulation No 258/97, the question whether Article 1(2)(e) of that regulation must be interpreted as including within its scope foods consisting of whole animals intended to be consumed as such raises a serious difficulty of interpretation of EU law.
- 21 It is in those circumstances that the Conseil d’État (Council of State) decided to stay proceedings and to refer the following question to the Court of Justice for a preliminary ruling:

‘Is Article 1(2)(e) of Regulation [No 258/97] to be interpreted as including within its scope foods consisting of whole animals intended to be consumed as such or does it apply only to food ingredients isolated from insects?’

Consideration of the question referred

- 22 By its question, the referring court asks, in essence, whether Article 1(2)(e) of Regulation No 258/97 must be interpreted as meaning that whole insects intended for human consumption constitute ‘food ingredients isolated from animals’ within the meaning of that provision and, therefore, they fall within the scope of that regulation.
- 23 As a preliminary point, it should be noted that that question is relevant only as regards the application of Regulation No 258/97, which was applicable *ratione temporis* to the dispute in the main proceedings. Regulation 2015/2283, which repealed and replaced Regulation No 258/97 as from 1 January 2018, expressly provides that whole animals, including whole insects, fall within its scope (recital 8 and Article 3(2)(a)(v) of Regulation 2015/2283).
- 24 In order to answer the question of the referring court, it must be recalled, as a preliminary point, that Regulation No 258/97, in accordance with Article 1(1) thereof, concerns the placing on the market of novel foods and novel food ingredients (see, to that effect, judgment of 9 November 2016, *Davitas*, C-448/14, EU:C:2016:839, paragraph 17 and the case-law cited).
- 25 Article 1(2) of Regulation No 258/97 seeks to delimit the scope of the regulation, inter alia, by defining what is to be understood by ‘novel foods and food ingredients’. It is apparent from the wording itself of that provision that, to be categorised as ‘novel’ within the meaning of that regulation, foods or food ingredients must satisfy two cumulative conditions. First, the use for human consumption of those foods or food ingredients must not have been of ‘a significant degree’ in the European Union before 15 May 1997, the date of entry into force of that regulation and, second, they must fall within one of the categories expressly referred to in Article 1(2)(c) to (f) of that regulation (judgment of 9 November 2016, *Davitas*, C-448/14, EU:C:2016:839, paragraphs 18 to 21 and the case-law cited).
- 26 In the present case, it must be noted that the referring court does not ask the Court to consider the first condition laid down in Article 1(2) of Regulation No 258/97 in order to categorise whole insects intended for human consumption as ‘novel foods and food ingredients’, namely that insects have not been used for human consumption to ‘a significant degree’ within the European Union before 15 May 1997.

- 27 Conversely, the referring court has reservations regarding the application of the second condition laid down in Article 1(2) of Regulation No 258/97. More specifically, it seeks to ascertain whether it can be considered that that condition is satisfied because whole insects may be categorised as ‘novel foods or food ingredients’, in that they fall in one of the categories set out in Article 1(2)(c) to (f) of that regulation, and more precisely of that set out in point (e) of that provision, which refers to ‘food ingredients isolated from animals’.
- 28 In that regard, it must first of all be noted that the terms ‘food ingredients isolated from animals’ are not defined in Regulation No 258/97.
- 29 According to settled case-law, the meaning and scope of terms for which EU law provides no definition must be determined by reference to their usual meaning in everyday language, while account is also taken of the context in which they occur and the purposes of the rules of which they form part (judgments of 9 November 2016, *Davitas*, C-448/14, EU:C:2016:839, paragraph 26, and of 26 October 2017, *The English Bridge Union*, C-90/16, EU:C:2017:814, paragraph 18).
- 30 In the first place, as regards the usual meaning of the expression ‘food ingredients isolated from animals’ in everyday language, it must be noted that, while it is true that the term ‘animal’ should be understood as including insects, the use of the terms ‘food ingredients’, combined with the expression ‘isolated from animals’, leads to the conclusion that the usual meaning to be attributed to that expression in everyday language is that only food ingredients consisting of parts of animals, excluding whole animals (and accordingly insects), were covered by Article 1(2)(e) of Regulation No 258/97.
- 31 First, as regards the terms ‘food ingredients’, it must be noted that Regulation No 258/97 does not define the term ‘ingredient’. However, that term, whichever official language is used, refers in general to a component of a larger, composite end product, in essence, a ‘foodstuff’ (or a ‘food’). Consequently, an ingredient is not, in principle, a product intended to be consumed in and by itself, but rather a substance or a product to be added to other substances to create a food.
- 32 Therefore, as the Advocate General observed in point 36 of his Opinion, it does not appear that whole animals can be categorised as an ‘ingredient’, as they are ‘foods’, not a ‘food ingredient’. That interpretation is supported, implicitly but necessarily, by the wording of Article 1(2)(e) of Regulation No 258/97 which draws a clear distinction between ‘foods’ and ‘food ingredients’, while using only the terms ‘food ingredients’ when it refers to animals.
- 33 Furthermore, that interpretation also corresponds, in substance, to the definition of the term ‘ingredient’ adopted in other EU legal provisions relating to food, such as those laid down in Article 2(2)(f) of Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers, amending Regulations (EC) No 1924/2006 and (EC) No 1925/2006 of the European Parliament and of the Council, and repealing Commission Directive 87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament and of the Council, Commission Directives 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No 608/2004 (OJ 2011 L 304, p. 18).
- 34 Second, as regards the expression ‘isolated from’ animals, as the Advocate General observed in points 37 and 38 of his Opinion, it refers to a process of extraction from the animal. Therefore, interpretation of that expression may not result in a reference to a whole animal, unless one were to create a tautology, in which whole animals are ‘isolated from’ whole animals.
- 35 Furthermore, that expression is clearly distinguishable, in all language versions, from the term ‘consisting of’ – the meaning of which is broader – which appears in Article 1(2)(d) and (e) of Regulation No 258/97, where the categories of foods concerned are ‘plants’, ‘micro-organisms’, ‘fungi’ or ‘algae’, and which allows the inclusion of foods composed of a single part (for example a whole ‘plant’). In that regard, Regulation 2015/2283 includes whole animals in its scope when it refers to ‘food consisting of ... animals or their parts’.
- 36 It is apparent from the above considerations that the expression ‘food ingredients isolated from animals’ has a clear and precise meaning. The wording of Article 1(2)(e) of Regulation No 258/97

does not cover ‘whole animals’ and, accordingly, does not cover whole insects.

- 37 In the second place, it should be noted that a literal interpretation of that provision is consistent both with its context and with the objectives pursued by Regulation No 258/97.
- 38 In that regard, it must first of all be observed that, as the Commission states in its observations, it does not appear that, by using the term ‘animals’, the EU legislature intended to refer specifically to insects or that it had in mind the risks posed by their consumption. It appears that, by adopting Regulation No 258/97, it decided to regulate only those products which it anticipated, in 1997, would be placed on the market. As the Advocate General noted in points 45 to 48 of his Opinion, the use of insects in the agri-food industry is a relatively new phenomenon and, as is apparent from recital 8 of Regulation 2015/2283, it is precisely in the light of ‘scientific and technological developments that have occurred since 1997’ that that legislature decided in 2015, by adopting Regulation 2015/2283, ‘to review, clarify and update the categories of food which constitute novel foods’ and to explicitly include ‘whole insects and their parts’.
- 39 Next, it should be recalled that, according to settled case-law, Regulation No 258/97 has a twofold objective consisting in ensuring the functioning of the internal market in novel foods and protecting public health against the risks to which they may give rise (judgment of 9 November 2016, *Davitas*, C-448/14, EU:C:2016:839, paragraph 31 and the case-law cited).
- 40 As regards the objective of ensuring a high level of protection of human health, as the French and Italian Governments submit in their observations, it may indeed appear illogical, from a health point of view, to seek to subject food ingredients isolated from insects to the rules, while excluding whole insects, since a whole insect is composed of all its parts and the whole insect, like its parts, is intended to be ingested by the consumer, which may therefore pose the same risks from the point of view of public health.
- 41 However, such a line of argument, based on one of the two objectives of Regulation No 258/97, does not suffice to justify a broad interpretation of the unambiguous terms ‘isolated from animals’ which has the effect of including ‘whole animals’ within the scope of that regulation.
- 42 First, as is apparent from paragraphs 30 to 36 of the present judgment, the usual meaning in everyday language of the terms ‘isolated from animals’, in Article 1(2)(e) of Regulation No 258/97, which is moreover the same in all language versions, leads to a finding that those terms clearly exclude whole animals from the scope of that provision. As the Advocate General notes in essence in point 61 of his Opinion, the clear wording of that provision cannot in principle be called into question by a teleological interpretation of that provision, which would amount to expanding the scope of that regulation and which is for the EU legislature alone to decide.
- 43 As the Advocate General also noted, in essence, in points 72 and 73 of his Opinion, such an interpretation cannot be *contra legem*. Such a limit, which undoubtedly meets the need for legal certainty and foreseeability of the law, has also been recognised in the context of the Court’s case-law on the principle that national law must be interpreted in conformity with EU law (judgments of 15 April 2008, *Impact*, C-268/06, EU:C:2008:223, paragraph 100, and of 24 January 2012, *Dominguez*, C-282/10, EU:C:2012:33, paragraph 25 and the case-law cited).
- 44 Second, and in any event, an interpretation which leads to the exclusion of whole animals, such as insects, from the scope of Regulation No 258/97 does not in itself prejudice the objective of protecting human health. As follows from the foregoing considerations, the fact that whole insects do not fall within the scope of that regulation implies only a lack of harmonisation of the conditions for placing them on the market at EU level and, therefore, that no notification or authorisation is necessary under that regulation. According to settled case-law, it is for the Member States, in the absence of harmonisation and to the extent that uncertainties continue to exist, to decide on their intended level of protection of human health and life and on whether to require prior authorisation for the placing on the market of foods, taking into account the requirements of the free movement of goods within the European Union (see, to that effect, judgment of 29 April 2010, *Solgar Vitamin’s France and Others*, C-446/08, EU:C:2010:233, paragraph 35 and the case-law cited). Therefore, the fact that whole insects are exempted from the safety assessment provided for by Regulation No 258/97 does not exclude the

possibility for Member States to provide for such an assessment in their national legislation of the possible danger which whole insects may present for public health.

- 45 In the light of all the foregoing considerations, the answer to the question referred is that Article 1(2) (e) of Regulation No 258/97 must be interpreted as meaning that foods consisting of whole animals intended to be consumed as such, including whole insects, do not fall within the scope of that regulation.

Costs

- 46 Since these proceedings are, for the parties to the main proceedings, a step in the action pending before the national court, the decision on costs is a matter for that court. Costs incurred in submitting observations to the Court, other than the costs of those parties, are not recoverable.

On those grounds, the Court (Third Chamber) hereby rules:

Article 1(2)(e) of Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients, as amended by Regulation (EC) No 596/2009 of the European Parliament and of the Council of 18 June 2009, must be interpreted as meaning that foods consisting of whole animals intended to be consumed as such, including whole insects, do not fall within the scope of that regulation.

[Signatures]

* Language of the case: French.