Reports of Cases

OPINION OF ADVOCATE GENERAL
SAUGMANDSGAARD ØE
delivered on 20 May 2021 [1]

Case C-836/19

Toropet Ltd
v
Landkreis Greiz

(Request for a preliminary ruling from the Verwaltungsgericht Gera (Administrative Court, Gera, Germany))

(Reference for a preliminary ruling – Public health – Health rules applicable to animal by-products not intended for human consumption – Regulation (EC) No 1069/2009 – Article 7(1) – Classification reflecting the level of risk to public and animal health – Article 10(a) and (f) – Category 3 material – Decomposition, spoilage and presence of foreign bodies in the material – Obligation to downgrade to Category 2 material – Article 9(h) – Article 4(1) and (2) – Obligation to monitor operators from the collection to the use or disposal of animal by-products)

I. Introduction

1. This request for a preliminary ruling from the Verwaltungsgericht Gera (Administrative Court, Gera, Germany) concerns the interpretation of Regulation (EC) No 1069/2009 [2] on animal by-products, specifically the downgrading of animal by-products which no longer meet the requirements for their original category.

2. This request has been made in proceedings between Toropet Ltd and the Landkreis Greiz (administrative district of Greiz, Germany) concerning the latter's decision to downgrade a number of animal by-products from Category 3 to Category 2 and then to dispose of those by-products, on the grounds that they had been changed by mould, decay and foreign bodies.

[1] Original language: French.

[2] Regulation of the European Parliament and of the Council of 21 October 2009 laying down health rules as regards animal by-products and derived products not intended for human consumption and repealing Regulation (EC) No 1774/2002 (Animal by-products Regulation) (OJ 2009 L 300, p. 1).

3. For the reasons set out below, I am of the view that animal by-products which were originally classified in Category 3 but no longer conform to the level of risk associated with that category because they have decomposed or become spoiled or mixed with foreign bodies, must be downgraded to a lower category. [3]

II. Legal context

A. EU law

1. Regulation No 1069/2009

4. Recitals 11, 29 and 38 of Regulation No 1069/2009 read as follows:

'(11) …The chief objectives of the rules on animal by-products, namely the control of risks to public and animal health and the protection of the safety of the food and feed chain, should be clearly laid down. The provisions of this Regulation should permit the achievement of those objectives.

…

(29) Animal by-products and derived products should be classified into three categories which reflect the degree of risk that they pose to public and animal health, on the basis of risk assessments. Whilst animal by-products and derived products posing a high risk should only be used for purposes outside the feed chain, their use posing a lower risk should be permitted under safe conditions.

…

(38) Animal by-products should only be used if the risks to public and animal health are minimised in the course of their processing and the placing on the market of derived products manufactured on the basis of animal by-products. If this option is not available, the animal by-products should be disposed of under safe conditions. … In general, the options [available for use] for a higher risk category should be available for the lower risk categories as well, unless special considerations apply in view of the risk attached to certain animal by-products.'

5. Article 2(1)(a) of that regulation reads as follows:

'1. This Regulation shall apply to:

(a) animal by-products and derived products which are excluded from human consumption under Community legislation; …'

[3] The lower categories are categories 1 and 2, which include 'high-risk' material and have stricter requirements. It can be seen from the decision to refer that the material at issue in the main proceedings does not include Category 1 material, which poses the highest risks, and was therefore downgraded to Category 2.

6. Paragraphs 1 and 2 of Article 4 of that regulation, entitled 'Starting point in the manufacturing chain and obligations', provide as follows:

'1. As soon as operators generate animal by-products or derived products falling within the scope of this Regulation, they shall identify them and ensure that they are dealt with in accordance with this Regulation (starting point).

2. Operators shall ensure at all stages of collection, transport, handling, treatment, transformation, processing, storage, placing on the market, distribution, use and disposal within the businesses under their control that animal by-products and derived products satisfy the requirements of this Regulation which are relevant to their activities.'

7. Paragraph 1 of Article 7 of the same regulation, entitled 'Categorisation of animal by-products and derived products', provides as follows:

'Animal by-products shall be categorised into specific categories which reflect the level of risk to public and animal health arising from those animal by-products, in accordance with the lists laid down in Articles 8, 9 and 10.'

8. Article 9 of Regulation No 1069/2009, entitled 'Category 2 material', provides, in Article 9(d) and (h):

'Category 2 material shall comprise the following animal by-products:

…

(d) products of animal origin which have been declared unfit for human consumption due to the presence of foreign bodies in those products;

…

(h) animal by-products other than Category 1 material or Category 3 material.'

9. Article 10 of that regulation, entitled 'Category 3 material', provides, in Article 10(a) and (f):

'Category 3 material shall comprise the following animal by-products:

(a) carcases and parts of animals slaughtered or, in the case of game, bodies or parts of animals killed, and which are fit for human consumption in accordance with Community legislation, but are not intended for human consumption for commercial reasons;

…

(f) products of animal origin, or foodstuffs containing products of animal origin, which are no longer intended for human consumption for commercial reasons or due to problems of manufacturing or packaging defects or other defects from which no risk to public or animal health arise;

…'

10. Article 14 of that regulation, entitled 'Disposal and use of Category 3 material', reads as follows:

'Category 3 material shall be:

(a) disposed of as waste by incineration, with or without prior processing;

(b) recovered or disposed of by co-incineration, with or without prior processing, if the Category 3 material is waste;

(c) disposed of in an authorised landfill, following processing;

(d) processed, except in the case of Category 3 material which has changed through decomposition or spoilage so as to present an unacceptable risk to public or animal health, through that product, …

…'

11. Article 15(1) of that regulation provides:

'1. Measures for the implementation of this Section may be laid down relating to the following:

…

(k) the level of risk to public or animal health with respect to certain material which is considered as unacceptable as referred to in Article 14(d).

…'

12. Article 25(1)(e) of Regulation No 1069/2009 provides:

'1. Operators shall ensure that establishments or plants under their control carrying out the activities referred to in Article 24(1)(a) and (h):

…

(e) have appropriate arrangements for the cleaning and the disinfection of containers and vehicles in place to avoid risks of contamination.'

13. Article 28 of that regulation, entitled 'Own checks', provides:

'Operators shall put in place, implement and maintain own checks in their establishments or plants in order to monitor compliance with this Regulation. They shall ensure that no animal by-products or derived products suspected or discovered not to comply with this Regulation leave the establishment or plant, unless destined for disposal.'

2. Regulation (EU) No 142/2011

14. Annex IV to Regulation (EU) No 142/2011 [4] provides as follows in Chapter I, Section 4, point 3:

'Processing plants processing Category 3 material shall have in place an installation to check the presence of foreign bodies, such as packaging material or metallic pieces, in the animal by-products or derived products, if they are processing materials which are destined for feeding. Such foreign bodies shall be removed before or during processing.'

3. Regulation (EC) No 178/2002

15. Article 14(5) of Regulation (EC) No 178/2002 [5] provides as follows:

'In determining whether any food is unfit for human consumption, regard shall be had to whether the food is unacceptable for human consumption according to its intended use, for reasons of contamination, whether by extraneous matter or otherwise, or through putrefaction, deterioration or decay.'

B. German law

16. The Tierische Nebenprodukte-Beseitigungsgesetz (Law on the disposal of animal by-products) of 25 January 2004 (BGBl. 2004 I, p. 82), in the version of 4 August 2016 (BGBl. 2016 I 1966) ('the TierNebG'), provides as follows in Paragraph 1, entitled 'Scope':

'This Law is intended to implement Regulation [No 1069/2009], as most recently amended by [Council] Regulation (EU) No 1385/2013 [of 17 December 2013] (OJ 2013 L 354, p. 86), and the directly applicable Community or EU legal acts adopted under or in implementation of that regulation.'

17. Paragraph 3 of the TierNebG lays down an obligation to dispose of certain animal by-products whilst Paragraph 12 concerns the monitoring by the competent authorities of compliance with national rules and EU law in the field covered by Regulation No 1069/2009.

18. The Thüringer Ausführungsgesetz zum Tierische Nebenprodukte-Beseitigungsgesetz (Thuringian law implementing the federal law on the disposal of animal by-products) of 10 June 2005 (Thür GVBl. 2005, p. 224) and the Thüringer Verordnung über die Einzugsbereiche nach dem Tierische Nebenprodukte-Beseitigungsgesetz (Thuringian regulation on catchment areas under the federal law on the disposal of animal by-products) of 11 October 2005 (Thür GVBl. 2005, p. 355) establish provisions concerning, respectively, the bodies responsible for

[4] Commission Regulation of 25 February 2011 implementing Regulation No 1069/2009 and implementing Council Directive 97/78/EC as regards certain samples and items exempt from veterinary checks at the border under that directive (OJ 2011 L 54, p. 1).

[5] Regulation 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).

disposing of animal by-products in categories 1 and 2 and the catchment areas within which those bodies must recover, collect, transport, store, treat, process or dispose of those by-products. [6]

III. The main proceedings, the questions referred and the procedure before the Court of Justice

19. Toropet processes and trades in animal by-products. Its customers include manufacturers of animal food, processers of animal fats and biogas plants. It operates an establishment in Germany that is approved under Regulation No 1069/2009 as an intermediate plant for Category 3 material. It is also registered as a carrier of animal by-products.

20. On 23 January 2018, during an inspection at that intermediate plant, the Landkreis Greiz found mould, decay and foreign bodies present in 38 crates containing Category 3 animal by-products. Because of the presence of the mould, decay and foreign bodies, the Landkreis Greiz downgraded the material to Category 2 and ordered the immediate disposal of the 38 crates, which was enforced the same day. Toropet was required to pay the costs associated with those operations, amounting to EUR 2 346.17.

21. That order was confirmed by a decision of 25 January 2018, by which the Landkreis Greiz explained that the defects consisting of mould, decay and foreign bodies meant that the material at issue could no longer be classified in Category 3 and could only be categorised as Category 2. However, neither Toropet nor its commercial partner, which was to process that material, was authorised to handle Category 2 material. Furthermore, because there was no separate chilling room, the material at issue could not have been stored on site until an amicable solution was found.

22. On 9 October 2018, Toropet brought an action before the Verwaltungsgericht Gera (Administrative Court, Gera) seeking a declaration annulling the administrative decision of 25 January 2018.

23. In its action, Toropet alleged that the Landkreis Greiz had erred in law by downgrading the material at issue to Category 2 without carrying out a scientific analysis. It disputes the assessment according to which the material at issue was defective, rotten or mouldy. Toropet submits that the criterion that the veterinarians and the Landkreis Greiz used, that is to say, whether the by-products were edible, meaning that they were fit for human consumption, went beyond the requirements of Article 10 of Regulation No 1069/2009.

24. Toropet asserts that it is clear from Article 14(d) of that regulation that the decomposition and spoilage of animal by-products do not justify downgrading those by-products, because they can be recovered in accordance with Article 14(b) of that regulation and because disposal is not always necessary. Moreover, that company is of the view that the animal by-products at issue could fall within Article 10(f) of that regulation because that article only excludes products that pose significant risks caused by animal diseases. According to Toropet, meat changed by mould or decay does not represent such a risk.

[6] Toropet claims that the Landkreis Greiz did not have competence to dispose of the material at issue in the main proceedings. It should be noted in that respect that the questions referred concern only the reclassification of the material at issue and do not concern its removal by the Landkreis Greiz, as laid down in German law.

25. That company asserts, in particular, that, because the Category 3 material was not intended for use as human food,[7] it was irrelevant whether or not the matter at issue was fit for human consumption. The presence of foreign bodies in the material concerned, it argues, cannot lead to reclassification as long as simple mechanical separation is possible.

26. The referring court states that the animal by-products at issue concerned primarily material initially classified in Category 3, either under Article 10(a) of Regulation No 1069/2009, which includes carcases and parts of slaughtered animals which are *fit for human consumption* but are not intended for human consumption, or under Article 10(f), covering products of animal origin or foodstuffs containing products of animal origin, which are *no longer intended for human consumption* for commercial reasons or other reasons *from which no risk to public or animal health arises*. The animal by-products under Article 10(a) included abomasums and ears. Those under Article 10(f) concerned, in particular, sausage meat and beef pizzle.

27. That court notes that decomposition and spoilage of Category 3 material, in principle, make it unfit for human consumption and cause a risk to public and animal health. It therefore enquires whether those changes must lead to the material being reclassified in a different category.

28. The referring court observes that, as clear from recital 11 and Article 1 of Regulation No 1069/2009, its chief objectives are to control risks to public and animal health and to protect the safety of the food and feed chain. Any danger is therefore not limited to public health. Article 14(d) of Regulation No 1069/2009, it suggests, also emphasises that decomposition and spoilage cause risks to public and animal health.

29. However, the referring court is also of the view that Article 14(d) of Regulation No 1069/2009 militates against the original classification being amended subsequently because the material concerned has decomposed or become spoiled. In its view, it can in fact be concluded from that provision that decomposition and spoilage do not in principle affect the *classification* of the Category 3 material but merely its *use*. According to that court, although under Article 14(d) of that regulation material cannot be used to manufacture feed, it appears that it can, in contrast, be used for other purposes, for example when it is recovered by co-incineration in accordance with Article 14(b).

30. The referring court is also uncertain as to the interpretation of Article 9(d) of Regulation No 1069/2009. Under that article, material which has been declared unfit for human consumption due to the presence of foreign bodies must indeed be classified in Category 2. However, it would appear from Chapter I, Section 4, point 3 of Annex IV to Regulation No 142/2011 that the presence of foreign bodies is insufficient to give rise to classification in Category 2, provided they can be removed using installations able to check for them, in accordance with the rules applicable to processing plants processing Category 3 material. The referring court is also uncertain whether preventing the risk of the presence of foreign bodies is relevant where the Category 3 material is not intended to be processed into feed but instead to be incinerated or used in the production of biodiesel.

[7] In that connection Toropet draws attention to the Category 3 material under Article 10(h) (including blood, placenta, wool and feathers) and (p) (including catering waste) of Regulation No 1069/2009 which, in its view, could present health risks but would nevertheless remain in Category 3.

31. Under those circumstances, the Verwaltungsgericht Gera (Administrative Court, Gera) stayed the proceedings and referred the following questions to the Court of Justice for a preliminary ruling:

'(1) Is Article 10(a) of Regulation No 1069/2009 to be interpreted as meaning that the original classification as Category 3 material is lost if fitness for human consumption no longer applies due to decomposition and spoilage?

(2) Is Article 10(f) of Regulation No 1069/2009 to be interpreted as meaning that the original classification as Category 3 material for products of animal origin, or foodstuffs containing products of animal origin, is lost if a risk to public or animal health arises from the material as a result of later decomposition or spoilage processes?

(3) Is the provision of Article 9(d) of Regulation No 1069/2009 to be interpreted restrictively as meaning that material mixed with foreign bodies such as sawdust is only to be categorised as Category 2 material when the material is to be processed and is destined for feeding purposes?'

32. The request for a preliminary ruling, of 14 November 2019, was registered at the Registry of the Court of Justice on 18 November 2019.

33. The Landkreis Greiz and the European Commission filed written observations. Those parties and Toropet also submitted written answers to the Court's questions of 2 December 2020.

IV. Analysis

34. By the three questions it has referred, which can appropriately be addressed together, the referring court enquires in essence whether material originally classified as Category 3 material within the meaning of Article 10(a) and (f) of Regulation No 1069/2009 loses that classification as a result of decomposition or spoilage (first and second questions) or of becoming mixed with foreign bodies (third question) with the effect that it must be downgraded.

35. It should be noted that the original classification, that is to say, the classification of the animal by-products at issue in the main proceedings, from the time of collection, in Category 3, is not disputed. In contrast, there is doubt as to whether such animal by-products must be reclassified where they present defects such as mould, decay or foreign bodies *subsequently in their life cycle*.[8]

36. Whilst Toropet considers that animal by-products falling under Article 10(a) and (f) of Regulation No 1069/2009 which have such defects must remain in Category 3, the Landkreis Greiz and the Commission take the opposite view that those by-products must be reclassified in Category 2.

37. In this Opinion I will now, first, make a number of observations on the specific case where animal by-products are mixed with foreign bodies (section A), and will then set out why, in my view, material such as that at issue in the main proceedings must be downgraded to Article 2

[8] I would add that, besides the changes at issue in the main proceedings, the referring court states that part of the Category 3 material inspected contained Category 2 material within the meaning of Article 9(a) of Regulation No 1069/2009. Under Article 9(g) of that regulation, a mixture of that kind (Category 2 material with Category 3 material) is expressly covered by the rules associated with the stricter category, that is to say, Category 2.

where it no longer corresponds to the level of risk associated with its original classification (section B), relying on an analysis of the following provisions of Regulation No 1069/2009: Article 7 in conjunction with Article 10, Article 9(h), Article 10(a) and (f), Article 4(2) and Article 14(d).

A. Preliminary considerations: application of Regulation No 1069/2009 to mixtures of animal by-products and foreign bodies

38. As a preliminary remark, I believe it is useful to summarise the guidance contained in the recent judgment in *P.F. Kamstra Recycling and Others*[9] before determining what it means as regards the nature of the foreign bodies and how they affect classification of the animal by-products with which they are mixed.

39. In summary, the cases that gave rise to that judgment concerned mixtures of animal by-products in Category 3 within the meaning of Article 10 of Regulation No 1069/2009 with non-hazardous waste within the meaning of Regulation No 1013/2006.[10] They turned on whether shipments of those mixtures were subject to Regulation No 1069/2009 or to Regulation No 1013/2006.

40. After analysing the preparatory legislative documentation relating to Regulation No 1069/2009 and its purpose and scheme, the Court of Justice held that mixtures of that nature and, accordingly, their shipment, fell within its scope of application.[11]

41. I emphasise that whilst the Court held that Regulation No 1069/2009 covers mixtures of animal by-products with non-hazardous waste, it did not rule on the types of *non-hazardous* waste that could be mixed with animal by-products or on the category of material to which the mixtures in question might belong.

42. In the present case, it is common ground that the mixture at issue in the main proceedings contained foreign bodies which, given their nature,[12] were regarded as non-hazardous waste within the meaning of Regulation No 1013/2006.

43. In the light of the judgment in *Kamstra Recycling*, therefore, that mixture is, in principle,[13] subject to application of Regulation No 1069/2009.

44. I would nevertheless draw attention to two aspects.

9 Judgment of 3 September 2020 (C-21/19 to C-23/19, EU:C:2020:636; 'the judgment in *Kamstra Recycling*').

10 Regulation of the European Parliament and of the Council of 14 June 2006 on shipments of waste (OJ 2006 L 190, p. 1).

11 See the judgment in *Kamstra Recycling*, paragraphs 52, 53 and 55.

12 According to information provided by the Landkreis Greiz to the referring court, those foreign bodies comprised plaster or wall residue, crushed plastic components and wood waste. It emerges from Toropet's answers to the Court's questions that, as well as plaster residue, those foreign bodies consisted in part of ground animal bone which was already included in the material from the start.

13 The only exception identified relates to animal by-products mixed or contaminated with hazardous waste (see the judgment in *Kamstra Recycling*, paragraph 50).

45. First, the fundamental premiss should be that the non-hazardous waste at issue in the main proceedings, especially the plaster pieces, does not consist of easily removable foreign bodies, such as plastic packaging or metallic pieces within the meaning of Chapter I, Section 4, point 3 of Annex IV to Regulation No 142/2011. [14]

46. Second, I emphasise that, although any mixture of Category 3 animal by-products with non-hazardous waste falls within the scope of Regulation No 1069/2009, it remains to be determined whether such a mixture must be downgraded, at least in certain cases, in the light of the provisions of that regulation. That issue, which is not addressed in the judgment in *Kamstra Recycling*, [15] is crucial to this case.

B. The obligation to downgrade Category 3 material where it is 'contaminated' with mould, decay or foreign bodies

47. As a preliminary remark, it should be noted that Regulation No 1069/2009 contains no express provision concerning the 'downgrading' of material that was originally classified in Category 3.

48. As I will demonstrate below, the obligation to downgrade that I am proposing is required by the inherent rationale of the classification of Category 3 material, which is based on the risk to public and animal health presented by foreign bodies and changes to the animal by-products concerned as the result of mould and decay. I will also show that this risk can be assessed at any time in the life of an animal by-product.

1. Classification of material into categories according to its level of risk (Articles 7 to 10 of Regulation No 1069/2009)

49. Section 4 of Chapter I of Title I of Regulation No 1069/2009, which includes Articles 7 to 10, relates to the classification of animal by-products and derived products.

50. According to Article 7(1) of that regulation which governs the classification of animal by-products, those products are categorised into specific categories according to the level of risk they present to public and animal health.

51. That article therefore establishes two relevant factors that are interconnected for the purposes of classification: the specific categories and the level of risk.

[14] Annex IV to Regulation No 142/2011 applies to processing plants processing Category 3 material which, in principle, remains in the same category after foreign bodies such as nose rings and ear tags are removed. In that situation therefore, the question of an obligation to reclassify does not arise.

[15] That issue was the subject of some discussion at the hearing in that case. However, since the central question concerned the interaction between Regulation No 1069/2009 and Regulation No 1013/2006, the Court stated in paragraph 44 of the judgment in *Kamstra Recycling* that 'for the purposes of interpreting Article 1(3)(d) of Regulation No 1013/2006 and, consequently, of the applicability of Regulation No 1069/2009, whether the material concerned belongs to Category 1, Category 2 or Category 3 is irrelevant'.

52. As regards classification, the animal by-products covered by Regulation No 1069/2009 are classified into one of the three categories laid down in Articles 8, 9 and 10 of that regulation, [16] which contain the lists of Category 1, Category 2 and Category 3 material respectively. There are no derogations from that classification, with the effect that animal by-products must fall within one of those three categories. [17]

53. The level of risk is the only criterion which differentiates the three categories, in so far as Category 3 material is material considered to be low risk [18] whereas Category 1 and Category 2 material is material that poses a high risk to public and animal health, with Category 1 material being that which poses the highest risk. [19] The legislature drew up a detailed list of the material in each category on the basis of an assessment of those risks.

54. It should be noted that the level of risk which determines classification in Category 1, 2 or 3 is also the relevant criterion for the end use of animal by-products. In Articles 12, 13 and 14, read in the light of recital 38, Regulation No 1069/2009 in fact establishes lists of *possible uses and methods of removal for each category* of material and the rules applicable to each use and each removal method in order to minimise that risk.

55. Admittedly, the options for use and removal applicable to a high-risk category are also available for low-risk material. [20] However, those uses and removal methods are governed by different rules which are sometimes even more restrictive depending on the category into which the material is classified. [21]

56. That categorisation according to risk is also supported by recital 29 of Regulation No 1069/2009, which states that animal by-products considered to pose a high risk should not be used within the feed chain, whereas the use of material posing a lower risk should be permitted under certain conditions.

57. I note in that respect that the lists of Category 1 material and Category 3 material are exhaustive. [22] They must therefore be interpreted strictly as meaning, first, that they include only the material to which they refer expressly and, second, that, as I set out above, that material must correspond to the level of risk associated with the category concerned. The fact that the lists are exhaustive can be inferred from the presence of the subcategory in Article 9(h) of Regulation No 1069/2009 which encompasses, within Category 2, matter that falls within neither Category 1 nor Category 3.

16 That categorisation is one of the obligations on operators that collect and identify animal by-products 'under conditions which prevent risks arising to public and animal health' in accordance with Article 21(1) of Regulation No 1069/2009.

17 See also the last sentence of point 57 of this Opinion.

18 See, to that effect, judgment of 23 May 2019, *ReFood* (C-634/17, EU:C:2019:443, paragraph 50), which describes Category 3 material as 'being less hazardous'.

19 See footnote 3 of this Opinion. I would add that recitals 8 and 29 of Regulation No 1069/2009 refer to classification according to the 'degree of risk'.

20 See, to that effect, the last sentence of recital 38 of Regulation No 1069/2009. Conversely, that means, in my view, that uses specifically laid down for the low-risk category, that is to say, Category 3, such as those in Article 14(d) of Regulation No 1069/2009, are not available to the high-risk categories, that is to say, Categories 1 and 2.

21 See, for example, the transformation of animal by-products into compost or biogas, which is an option for use available to both Category 2 and Category 3 material. The rules for such use in Category 2 are however more restrictive than in Category 3 in so far as the material must undergo pressure sterilisation before processing for that use.

22 It should also be pointed out that under Article 7(3) of Regulation No 1069/2009 the lists of material in Categories 1, 2 and 3 may be amended as a result of a risk assessment taking into account scientific progress.

58. However, there are situations in which defects such as those associated with the presence of mould, decay or foreign bodies [23] can change the level of risk of the material affected by them. [24] Where that occurs, a *change in the level of risk*, in my view, leads to a *change in classification*.

59. In a matter such as that in the main proceedings, it is therefore necessary to ascertain whether mould and decay or foreign bodies such as pieces of plaster or sawdust are capable of changing the level of risk of material that was originally classified as Category 3 material within the meaning of Article 10(a) and (f) of Regulation No 1069/2009. [25]

60. If that material can no longer be classified in Category 3 as it was originally, because it presents a higher risk and because the requirements to be complied with for that category are not met, it will be necessary in that case to find a category to cover that 'contaminated' material. As I will set out in the following subsection, that category is in fact Category 2 primarily by virtue of the residual subcategory under Article 9(h) of Regulation No 1069/2009.

2. Existence of a default subcategory (Article 9(h) of Regulation No 1069/2009)

61. As I stated in point 57 of this Opinion, in contrast to Articles 8 and 10 of Regulation No 1069/2009 which establish a closed list of the material in Category 1 and Category 3 respectively, Article 9(h) of that regulation establishes a non-exhaustive list of Category 2 material. In accordance with its wording, that default subcategory encompasses animal by-products other than Category 1 material or Category 3 material.

62. Furthermore, as apparent from the last sentence of recital 35 of Regulation No 1069/2009, out of precaution, that default classification should be applied to 'any other animal by-products which are not listed under one of the three categories'. In the light of that phrase, Article 9(h) of Regulation No 1069/2009 must be interpreted broadly as meaning that it covers any animal by-product that has not been categorised specifically. [26]

63. To my mind, therefore, the existence of that default subcategory reflects the legislature's intention to ensure that no animal by-product falls into a legal vacuum in terms of its classification, so that material originally classified in Category 3 and which does not contain any Category 1 material but cannot or can no longer be classified as Category 3 material due to the level of risk it poses is, *by default*, automatically classified as Category 2 material within the meaning of Article 9(h) of Regulation No 1069/2009.

[23] I would emphasise that it is for the referring court to verify whether the animal by-products concerned were in fact affected by the presence of mould, decay and foreign bodies such as pieces of plaster or sawdust.

[24] I would emphasise that the presence of mould does not necessarily cause such a change. The mould must also cause an 'unacceptable' risk to public and animal health as I will explain more fully in point 70 of this Opinion.

[25] The requirements associated with the level of risk may vary within a single category. I will refer to the methods for assessing risk and the requirements associated with Category 3 material, including the material under Article 10(a) and (f) of Regulation No 1069/2009, which are the subject matter of the dispute in the main proceedings, in subsection 3 of this Opinion.

[26] See, to that effect, Section 6(ii) of the explanatory memorandum of the Proposal for a Regulation of the European Parliament and of the Council laying down health rules as regards animal by-products not intended for human consumption, presented on 10 June 2008 (COM(2008) 345 final) ('the proposal for Regulation No 1069/2009').

64. Article 9(h) must therefore apply to Category 3 animal by-products that have been changed by mould, decay or foreign bodies and which, whilst they do not contain any Category 1 material, pose too high a level of risk to satisfy the requirements to be Category 3 material. [27]

65. What then are the requirements for the Category 3 material under Article 10(a) and (f) of Regulation No 1069/2009 whose non-compliance should lead to it being downgraded by default to Category 2?

3. The relevant level of risk in the light of the health requirements under Article 10(a) and (f) of Regulation No 1069/2009

66. Article 10 of Regulation No 1069/2009 establishes an exhaustive list of the material in Category 3. [28] It can be seen from that list that the material in that category includes only animal by-products from healthy animals found to be fit for slaughter following an ante mortem inspection or, at the very least, animal by-products that are not vectors of any disease communicable to humans or animals. [29] Only that material can be processed to manufacture animal feed. [30]

67. Under Article 10(a) of that regulation, that category includes carcases and parts of animals slaughtered and which are fit for human consumption but are not intended for human consumption for commercial reasons. The relevant level of risk of that material therefore depends on the requirement that it must be *fit for human consumption*. [31]

68. Article 10(f) of that regulation relates to products of animal origin which are no longer intended for human consumption for commercial reasons or due to defects *from which no risk to public or animal health arise*. [32]

69. Regulation No 178/2002 provides a number of indications for determining whether food is 'fit for human consumption'. Under Article 14(5), food unfit for human consumption is 'unacceptable' for human consumption for reasons of contamination, whether by extraneous matter or otherwise, or through putrefaction, deterioration or decay.

[27] I believe it is helpful here to note that point 64 of this Opinion qualifies the observations I made in point 97 of my Opinion in *P.F. Kamstra Recycling and Others* (C-21/19 to C-23/19, EU:C:2020:226), in particular in the last sentence, to the effect that when a change in the by-products concerned increases their level of risk, Category 2, or even Category 1, should be applied. In my view and in contrast to what the Commission appears to be suggesting, that does not mean that any mixture of Category 3 animal by-products with non-hazardous waste must automatically be classified in Category 2. It remains necessary to analyse the level of risk created by mixing the by-products with the non-hazardous waste. Regulation No 1069/2009 does not in my view mean that certain mixtures arising, for example, from supermarket surpluses not due to health reasons and that contain Category 3 animal by-products such as meat trays or yoghurt pots mixed with fruit or vegetables may remain in Category 3, if they do not pose a risk to public and animal health.

[28] See point 57 of this Opinion.

[29] The 16 subcategories in Article 10(a) to (p) of Regulation No 1069/2009 include references to animals that are 'fit for human consumption' and products and by-products that do not show 'any signs of disease communicable to humans or animals' and which present 'no risk to public or animal health'.

[30] By derogation, Article 18(1) of Regulation No 1069/2009 provides that Category 2 material can be used to feed certain animals, under conditions which ensure the control of risks to public and animal health.

[31] That being so, Toropet's argument referred to in point 24 of this Opinion is irrelevant. Indeed, according to the definition of 'animal by-products' referred to in Article 3(1) of Regulation No 1069/2009, all animal by-products are ultimately not intended for human consumption. Conversely, the 'fit for human consumption' criterion is relevant for the classification of animal by-products in Category 3 under Article 10(a) of that regulation.

[32] Unlike the by-products under Article 10(a) of Regulation No 1069/2009, the by-products under Article 10(f) were originally intended for human consumption. They include what was formerly food, that is to say, products of animal origin *fit for human consumption* but which have been withdrawn from distribution because there was no commercial outlet for them (for example, as the result of a 'use by' date considered to be too close or a labelling or packaging defect or because they are incorrectly presented).

70. The term 'unacceptable' used in Article 14(d) of Regulation No 1069/2009 to describe the level of risk to public and human health of Category 3 material intended to be used in the manufacture of animal feed or organic fertilisers or soil improvers and which has changed through decomposition or spoilage, must be understood with the same meaning.[33] A change in that material resulting from mould or decay, with the effect that it is no longer fit for human consumption and/or is not free of any risk to public or animal health must therefore give rise to those animal by-products that were originally classified in Category 3 under Article 10(a) and (f) of Regulation No 1069/2009 being reclassified in Category 2, within the meaning of Article 9(h) of that regulation, provided the material concerned does not contain Category 1 material.

71. I will make the following remarks as regards whether, as the referring court enquires in its third question, notwithstanding the presence of foreign bodies as a result of which the material is 'unfit for human consumption' within the meaning of Article 9(d) of Regulation No 1069/2009, the material concerned may nevertheless remain classified in Category 3, either because those foreign bodies can easily be removed or because the material can be used for purposes other than feed, by incinerating it or processing it into biogas.

72. First, as I stated in point 45 of this Opinion, I am relying on the premiss that the foreign bodies at issue cannot easily be removed.

73. Second, in the light of the information provided by the referring court, I note that neither the Landkreis Greiz nor Toropet appears to have invoked Article 9(d) of Regulation No 1069/2009 before that court. That article, which was expressly referred to in the third question referred, is, in my view, relevant nevertheless.

74. Indeed, if foreign bodies such as pieces of plaster or sawdust have changed Category 3 animal by-products, here, material under Article 10(a) and (f) of Regulation No 1069/2009, so far as to make them *unfit for human consumption*, it would seem inconceivable that the mixture in question should remain in Category 3, when it has the same characteristics and the same level of risk as the Category 2 material referred to in Article 9(d) of that regulation. It should, therefore, be classified in Category 2, either under Article 9(d) in the case of products of animal origin within the meaning of that provision, or under the default provision in Article 9(h) of that regulation, in the case of other animal by-products.

75. I would emphasise that there is no reason to treat material whose level of risk has changed to that of Category 2 set out in Regulation No 1069/2009 differently from material originally classified in that category.[34] The same reasoning applies to material that was originally classified in Category 2 under Article 9(h) of that regulation and has subsequently decomposed or become spoiled.

76. I would add, third, that the fact that an operator plans to change the original use of the material by disposing of it or processing it into biogas instead of into animal feed does not mean that material which must be classified in Category 2 in view of the risk it poses to public and animal health can remain in Category 3.

[33] I would clarify in that respect that implementing measures may be laid down under Article 15(1)(k) of Regulation No 1069/2009 in relation to the level of risk of certain material to public or animal health where that level is considered unacceptable as referred to in Article 14(d) of that regulation.

[34] Furthermore, a situation in which material that is ultimately identical in terms of the risk it poses but is monitored at different points in the animal by-product chain could be classified differently and accordingly be subject to more favourable or stricter rules would in practice give rise to unequal treatment between economic operators in the animal by-products sector.

77. To find otherwise would be contrary both to the inherent rationale of the classification established by the legislature in Articles 8 to 10 of Regulation No 1069/2009, in which the sole relevant criterion is the level of risk, and to one of the principal objectives of that regulation, that is to say, to control risks to public and animal health, set out in recital 11 of that regulation.

78. Article 4(2) of Regulation No 1069/2009 supports the interpretation I propose.

4. The obligation on operators to ensure that the original classification is maintained at all times (Article 4(2) of Regulation No 1069/2009)

79. Under Article 4(2) of Regulation No 1069/2009, all operators [35] have a clear obligation to ensure that animal by-products satisfy the requirements of that regulation 'at all stages of collection, transport, handling, treatment, transformation, processing, storage, placing on the market, distribution, use and disposal' of those animal by-products.

80. The classification of an animal by-product in a category applies, in principle, for all the operations that the by-product undergoes, from collection to use or disposal. As I have already stated in point 99 of my Opinion in *P.F. Kamstra Recycling and Others*, [36] Regulation No 1069/2009 does not envisage differential classification depending on the operations which the material concerned undergoes. Accordingly, the classification does not change merely because the animal by-products concerned are at the collection or transport stage or are intended to be disposed of or recovered. In contrast, the classification can change if the risk to public or animal health increases as a result of certain changes.

81. I note in that respect, in the first place, as I also stated in point 99 of that Opinion, that the only matter which is relevant to the classification of animal by-products is the level of risk. Recital 29 and Article 7 of Regulation No 1069/2009 corroborate that finding. [37]

82. As regards the classification of material, it therefore flows from the context of Article 4(2) of that regulation that the operator must ensure that the classification is maintained, from the collection of the animal by-products at the abattoir up to their final destination, such as the recovery or disposal of those by-products. [38] That obligation must be understood as meaning that maintaining classification in a category depends on keeping the level of risk associated with that category.

83. In the second place, that conclusion safeguards the effectiveness of Article 7(1) and Articles 8 to 10 of Regulation No 1069/2009 which establish the lists of material for the purposes of its classification, read in the light of the objective pursued by that regulation.

84. That regulation seeks, first, to lay down a coherent and comprehensive framework of health rules and, second, to ensure that those rules are proportionate to the health risks which those by-products pose when they are dealt with by operators at different stages of the chain. Those aims are clearly apparent from recitals 5 and 6 of that regulation and, in my view, underscore the fact that the degree of risk is relevant at all times.

[35] Regulation No 1069/2009 defines 'operators' in Article 3(11) as 'the natural or legal persons having an animal by-product or derived product under their actual control, including carriers, traders and users'.

[36] C-21/19 to C-23/19, EU:C:2020:226.

[37] See also points 50 and 56 of this Opinion.

[38] Thereby meaning that, in principle, where the life of an animal by-product starts with a classification in Category 3, it must, if all the requirements of Regulation No 1069/2009, including those relating to risk, have been satisfied, end in that category.

85. Furthermore, it should be noted that Regulation No 1069/2009 imposes a series of obligations on operators, linked to the obligation under Article 4(2). Operators must, inter alia, ensure that the plants or establishments under their control comply with strict general hygiene requirements in order to avoid any risk of contamination. [39] Likewise, both the Member States, by means of official controls, [40] and the operators themselves, by implementing own checks in their establishments, [41] have an obligation of supervision along the entire chain of operations.

86. Those preventive provisions largely explain why changes such as those at issue in the main proceedings are likely to be exceptional. In addition, where such changes do occur, Article 4(2) of Regulation No 1069/2009 must play a major part in giving rise to a reclassification. Indeed, although bearing in mind that the legislature did not formally provide that material should be reclassified, [42] what purpose would that article serve if it could not be taken into account where operators encounter changes of that nature which mean that the material does not adhere to the classification scheme laid down by the legislature?

87. In the third place, whereas there was no similar provision in Regulation (EC) No 1774/2002 [43] which preceded the current regulation, in its proposal for Regulation No 1069/2009, in order to create a more risk-based method, the legislature wished to reinforce the primary responsibility of operators in respect of the requirements laid down by that regulation in relation to food and feed hygiene. [44]

88. The original classification of material in a specific category must therefore be monitored at all times and, where necessary, adjusted in line with any health risk the material may pose including any due either to the presence of foreign bodies or to decomposition or spoilage, or even both.

89. The arguments advanced by Toropet and reiterated by the referring court concerning the end use of the animal by-products as Category 3 material do not undermine that conclusion.

5. The use of the material is irrelevant for the purpose of classification (Article 14(d) of Regulation No 1069/2009)

90. Both for material mixed with foreign bodies and material that has become decomposed or spoiled, the referring court mentions the argument that the material could keep the original classification in Category 3 in view of its end use in Category 3 (recovery or disposal) including for purposes other than the manufacture of feed. [45] Therefore, according to that argument, the restriction under Article 14(d) of Regulation No 1069/2009 relating to the absence of decomposition or spoilage applies only in relation to the use of the material.

[39] Operators must, in that respect, have in place appropriate arrangements for the cleaning and the disinfection of their containers and vehicles and keep their installations in good condition (see, among other requirements, Article 25(1)(d) and (e) of Regulation No 1069/2009.

[40] See Article 4(3) and Article 45 of Regulation No 1069/2009 as well as Article 32 of Regulation No 142/2011.

[41] See Article 28 of Regulation No 1069/2009.

[42] See point 47 of this Opinion.

[43] Regulation of the European Parliament and of the Council of 3 October 2002 laying down health rules as regards animal by-products and derived products not intended for human consumption (OJ 2002 L 273, p. 1).

[44] See proposal for Regulation No 1069/2009, Section 6(ii) of the explanatory memorandum.

[45] See point 29 of this Opinion.

91. I acknowledge that, on a first analysis, that interpretation is not completely without merit. However, I share the Commission's view that such an interpretation conflicts with both the objective and the structure of Regulation No 1069/2009.

92. The restriction laid down in Article 14(d) of Regulation No 1069/2009 does not in fact mean that material such as that at issue in the main proceedings must remain in Category 3. Articles 12, 13 and 14 of that regulation are silent on the requirements to be satisfied for the purposes of material being classified into categories,[46] which are defined only in Articles 8 to 10 of that regulation.

93. Moreover, taking the end use of material into account would be tantamount to adding a further requirement for the purposes of classifying the material, which the legislature neither established nor intended.[47] The end use of an animal by-product depends on its classification, not vice versa.

94. The additional restriction in Article 14(d) of Regulation No 1069/2009 to the effect that Category 3 material must not have been changed by decomposition or spoilage if it is to be processed and used, in particular to manufacture feed, is merely a reminder that such material must not pose an unacceptable risk to public and animal health.

95. Article 14 of Regulation No 1069/2019 therefore does not undermine the inherent rationale of the classification laid down by the legislature in Articles 7 to 10 of that regulation and explained throughout this Opinion.

V. Conclusion

96. Having regard to the foregoing analysis, I propose that the Court of Justice should reply as follows to the questions referred by the Verwaltungsgericht Gera (Administrative Court, Gera, Germany):

Article 7(1), Article 9(h), and Article 10(a) and (f) of Regulation (EC) No 1069/2009 of the European Parliament and of the Council of 21 October 2009 laying down health rules as regards animal by-products and derived products not intended for human consumption and repealing Regulation (EC) No 1774/2002, read in the light of Article 4(2) of Regulation No 1069/2009, must be interpreted as meaning that animal by-products originally classified as Category 3 material within the meaning of Article 10(a) and (f) of that regulation, that have been changed by decomposition or spoilage, such as mould or decay, or mixed with foreign bodies, such as pieces of plaster or sawdust, with the effect that the material in question is no longer fit for human consumption and/or is not free of any risk to public or animal health, do not correspond to the level of risk associated with that classification and must, therefore, be downgraded.

[46] As I noted in points 54 and 55 of this Opinion, Articles 12, 13 and 14 of Regulation No 1069/2009 merely establish lists of possible uses for the material in Categories 1 to 3 set out in Articles 8, 9 and 10 respectively of that regulation, although still in line with the degree of risk posed by the various categories.

[47] Doing so would in fact produce contradictory situations in which mouldy material or material mixed with foreign bodies would have to be downgraded to Category 2 because it is intended for feed, but would remain in Category 3 because it can be used for other purposes.