Reports of Cases

OPINION OF ADVOCATE GENERAL
BOBEK
delivered on 15 December 2016[1]

Case C-672/15

Procureur de la République
v
Noria Distribution SARL

(Request for a preliminary ruling from the Tribunal de grande instance de Perpignan (Regional Court, Perpignan, France))

(Food supplements — Vitamins and minerals — Mutual recognition — Fixing of maximum daily doses)

I – Introduction

1. Noria Distribution SARL ('Noria') is being prosecuted for having sold in France food supplements containing vitamins and minerals in quantities exceeding maxima set under French law. Noria does not deny doing so. However, it argues in response that those maxima are not valid because they were set in breach of EU law. Noria adds that it produces and sells the same products lawfully in other Member States. In its view, French law is also in violation of EU law because it does not contain any simplified mutual recognition procedure that would allow Noria to import its products into France.

2. The national court hearing the case asks whether the absence of a simplified mutual recognition procedure is indeed compatible with EU law. The national court also enquires whether certain aspects of the way the maxima in question were fixed are compatible with EU law. Specifically it wishes to ascertain (a) whether, in setting those maxima, account should be taken not only of national but also international scientific research and (b) whether nutrients can be grouped and maxima expressed as multiples of recommended daily allowances.

1 — Original language: English.

II – Legal framework

A – *EU law*

1. Directive 2002/46

3. Recital 13 of Directive 2002/46/EC[2] ('the Directive') states that excessive intake of vitamins and minerals can have adverse effects on health, justifying the setting of maximum levels. Recital 14 states that:

'When maximum levels are set, therefore, account should be taken of the upper safe levels of the vitamins and minerals, as established by scientific risk assessment based on generally acceptable scientific data, and of intakes of those nutrients from the normal diet. Due account should also be taken of reference intake amounts when setting maximum levels.'

4. Article 2 of the Directive defines the following terms:

'(a) "food supplements" means foodstuffs the purpose of which is to supplement the normal diet and which are concentrated sources of nutrients or other substances with a nutritional or physiological effect, alone or in combination, marketed in dose form, namely forms such as capsules, pastilles, tablets, pills and other similar forms, sachets of powder, ampoules of liquids, drop dispensing bottles, and other similar forms of liquids and powders designed to be taken in measured small unit quantities;

(b) "nutrients" means the following substances:

(i) vitamins,

(ii) minerals.'

5. Article 3 provides that:

'Member States shall ensure that food supplements may be marketed within the Community only if they comply with the rules laid down in this Directive.'

6. Article 4 states that:

'1. Only vitamins and minerals listed in Annex I, in the forms listed in Annex II, may be used for the manufacture of food supplements, subject to paragraph 6.

…

2 — Directive of the European Parliament and of the Council of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements (OJ 2002 L 183, p. 51).

6. By way of derogation from paragraph 1 and until 31 December 2009, Member States may allow in their territory the use of vitamins and minerals not listed in Annex I, or in forms not listed in Annex II, provided that:(a) the substance in question is used in one or more food supplements marketed in the Community on the date of entry into force of this Directive,

(b) the European Food Safety Authority has not given an unfavourable opinion in respect of the use of that substance, or its use in that form, in the manufacture of food supplements, on the basis of a dossier supporting use of the substance in question to be submitted to the Commission by the Member State not later than 12 July 2005.

7. Notwithstanding paragraph 6, Member States may, in compliance with the rules of the Treaty, continue to apply existing national restrictions or bans on trade in food supplements containing vitamins and minerals not included in the list in Annex I or in the forms not listed in Annex II.'

7. Article 5 foresees that:

'1. Maximum amounts of vitamins and minerals present in food supplements per daily portion of consumption as recommended by the manufacturer shall be set, taking the following into account:

(a) upper safe levels of vitamins and minerals established by scientific risk assessment based on generally accepted scientific data, taking into account, as appropriate, the varying degrees of sensitivity of different consumer groups;

(b) intake of vitamins and minerals from other dietary sources.

2. When the maximum levels referred to in paragraph 1 are set, due account should also be taken of reference intakes of vitamins and minerals for the population.

3. To ensure that significant amounts of vitamins and minerals are present in food supplements, minimum amounts per daily portion of consumption as recommended by the manufacturer shall be set, as appropriate.

4. The maximum and minimum amounts of vitamins and minerals referred to in paragraphs 1, 2 and 3 shall be adopted by the Commission. Those measures, designed to amend non-essential elements of this Directive by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 13(3).'

8. Article 11 provides that:

'1. Without prejudice to Article 4(7), Member States shall not, for reasons related to their composition, manufacturing specifications, presentation or labelling, prohibit or restrict trade in products referred to in Article 1 which comply with this Directive and, where appropriate, with Community acts adopted in implementation of this Directive.

2. Without prejudice to the Treaty, in particular Articles 28 and 30 thereof, paragraph 1 shall not affect national provisions which are applicable in the absence of Community acts adopted under this Directive.'

B – *National law*

1. Decree

9. Décret n°2006-352 du 20 mars 2006 relatif aux compléments alimentaires (Decree No 2006-352 of 20 March 2006 on food supplements) ('the Decree') transposes the Directive into French law. According to its Article 5, vitamins and minerals can be used in the manufacture of food supplements under conditions to be laid down by ministerial order.

10. Article 6 of the Decree provides that *substances with a nutritional or physiological effect* can be used in food supplements essentially if they have been authorised by certain national procedures including by application of Article 16 of the Decree.

11. Article 7 of the Decree states that *plants and preparations of plants* can be used in food supplements essentially if they are traditionally recognised as foodstuffs, or have been authorised by certain national procedures including by application of Article 16 of the Decree.

12. Article 16 of the Decree concerns food supplements containing *substances with a nutritional or physiological effect* or *plants or preparations of plants*, which have been legally marketed in other Member States and which are being placed on the market in France for the first time.[3] It foresees a certain procedure for authorisation of such substances, where they have not already been authorised under Article 6 or 7 ('Article 16 evaluation procedure').

13. Under the Article 16 evaluation procedure, the importer must provide, among others, any data in its possession that is useful for the evaluation of the relevant substance.[4] The competent national authority decides, within two months and on the basis of the dossier submitted, whether to authorise the product or refuse authorisation. Any refusal must be justified, either for reasons of incompleteness of the dossier, or for scientific reasons, in particular, due to risk for human health.

14. Articles 17 and 18 create a procedure for the revision of the maximum amounts of vitamins and minerals contained in food supplements, that have been fixed by decree adopted in application of Article 5.[5] Such requests are to be made to the competent national authority, which decides following consultation with the relevant national scientific body.

2. Order

15. Pursuant to Article 5 of the Decree, a ministerial order dated 9 May 2006 was adopted ('the Order'). Annexes I and II of that order include a list of vitamins and minerals that can be used in the manufacture of food supplements and the forms in which they can be used. Annex III sets out maximum daily doses for those vitamins and minerals that cannot be exceeded.

III – Facts, procedure and questions referred

16. Noria markets a number of food supplements in EU Member States.[6] Some of those products were exported to and marketed in France. They included supplements containing daily doses exceeding certain maxima foreseen in national law (as provided for in the Order).

3 — Confirmed by the French Government in its written submissions.

4 — The original French text refers to '… toutes les données en sa possession utiles à l'appréciation de la substance …'.

5 — Pending the fixing of maxima under the Directive.

6 — The order for reference does not give any detail in this regard. It states that the marketing of the relevant products 'has been agreed to in the other Member States'.

17. In criminal proceedings before the Tribunal de grande instance de Perpignan (Regional Court, Perpignan, France) (the referring court), Noria was prosecuted for having marketed in France food supplements with recommended daily doses exceeding those maxima.

18. According to the order for reference, Noria had previously requested from the competent national authority an authorisation to market its food supplements in France. That request was refused. Noria appealed before the national administrative courts. Its appeal was rejected at first instance in November 2009. The first instance judgment was upheld by the Cour administrative d'appel de Marseille (Administrative Court of Appeal, Marseille, France) in May 2014.

19. In parallel to the above events, proceedings were brought before the French Conseil d'État (Council of State) by various producers for the annulment of the Order. In the context of that case, a reference was made to this Court raising various questions about the compatibility of that order with EU law (the *Solgar* case [7]). In April 2011 following this Court's judgment in *Solgar*, the Conseil d'État (Council of State) judged that, as long as the Commission had not adopted maximum daily doses for vitamins and minerals in food supplements, these could, in principle, be fixed by national law. However, the Conseil d'État (Council of State) partially annulled the Order, specifically in relation to the maximum doses fixed for six vitamins, holding that they were disproportionate. [8]

20. In the proceedings before the national court leading to the present reference, Noria argues that the Order is incompatible with EU law. The referring court states in its request that it has doubts about the 'soundness of the legal element forming the basis for the prosecution'. [9]

21. In that regard, the referring court notes that the Decree, on the basis of which the Order was adopted, contains a 'simplified' mutual recognition procedure [10] in the form of the Article 16 evaluation procedure (see above points 12 and 13). That procedure does not, however, apply to food supplements containing vitamins and minerals. The national court states that the absence of a similar procedure for food supplements containing vitamins and minerals amounts to a 'derogation from the principle [of mutual recognition]', which may violate EU law.

22. The national court also doubts whether the way in which the maximum daily doses were set in the Order complies with the requirements of EU law in terms of adequacy of risk assessment and supporting scientific evidence.

23. In those circumstances, the Tribunal de grande instance de Perpignan (Regional Court, Perpignan) decided to stay the proceedings and to refer the following questions to the Court for a preliminary ruling:

'(1) Do Directive 2002/46 … and Community principles of free movement of goods and of mutual recognition preclude the laying down of national legislation such as the order of 9 May 2006 which refuses any mutual recognition procedure so far as concerns food supplements based on vitamins and minerals from another Member State by excluding the application of a [simplified] procedure in respect of products lawfully marketed in another Member State that are based on nutrients [whose values exceed the limits set] by the order of 9 May 2006?

7 — Judgment of 29 April 2010, *Solgar and Others* (C-446/08, EU:C:2010:233).

8 — Vitamins K, B1, B2, B5, B8 and B12. See, CE, 27 April 2011, *Solgar Vitamin's France et autres*, n°295235; FR:CESSR:2011:295235.20110427.

9 — The national court does not mention any potential impact on this case of the partial annulment of the Order. That aspect is not considered further here.

10 — The order for reference uses the two terms 'simplified' (simplifiée) and 'streamlined' (allégée) mutual recognition procedure' interchangeably. I will use 'simplified' in this Opinion.

(2) Does Directive 2002/46, in particular in Article 5, as well as the principles resulting from Community case-law on the provisions relating to the free movement of goods, permit the maximum daily doses of vitamins and minerals to be set in proportion to the recommended daily allowances by adopting a value equal to three times the recommended daily allowances for nutrients presenting the least risk, a value equal to the recommended daily allowances for nutrients presenting a risk of the upper safe level being exceeded and a value below the recommended daily allowances or even zero for nutrients involving the most risk?

(3) Does Directive 2002/46, as well as the principles resulting from Community case-law on the provisions relating to the free movement of goods, permit the doses to be set [in the light of] solely national scientific opinions even though recent international scientific opinions [conclude in favour of] higher doses in identical conditions of use?'

24. Written observations have been submitted by Noria, the French Government, the EFTA Surveillance Authority ('ESA') and the European Commission.

IV – Assessment

A – *Question 1: absence of 'simplified mutual recognition procedure'*

25. Do Articles 34 and 36 TFEU, the principle of free movement of goods and mutual recognition and/or Directive 2002/46 require Member States to foresee '(simplified) mutual recognition procedures'[11] to allow the marketing on their territory of food supplements containing vitamins and minerals that are lawfully marketed in other Member States? That is the thrust of the referring court's first question.

26. For the reasons set out below, I consider that Member States must, in principle, allow marketing on their territory of food supplements containing vitamins and minerals that are lawfully marketed in other Member States. However, such marketing may be refused if that is justified, for example, to safeguard public health. *Substantively*, any such refusals and accompanying justifications must be based on a *full risk assessment* based on up-to-date science. *Procedurally*, exactly how that is achieved is, in principle, left to the Member States.

27. Before specifically addressing the issue of 'mutual recognition procedures' (Section 2 below), I recall the general rule that Member States are free to adopt maximum amounts of vitamins and minerals in food supplements, provided this is justified on the basis of a full risk assessment (Section 1 below).

1. Adoption of maxima by Member States

28. Article 4(1) of the Directive provides that, for the manufacture of food supplements, only vitamins and minerals listed in Annex I, in the forms listed in Annex II may be used. Article 5(4) of the Directive foresees that the Commission should adopt maximum amounts of vitamins and minerals to be used in foodstuffs. However, it has not yet done so.

29. In the absence of Commission action in this regard, Member States remain competent to adopt such maxima, while respecting the Treaty rules, including those on the free movement of goods.[12]

11 — The precise meaning of this notion is discussed in detail below at points 37 to 42.

12 — Article 11(2) of the Directive; judgment of 29 April 2010, *Solgar and Others* (C-446/08, EU:C:2010:233, paragraphs 19 to 24).

30. In its judgment in *Solgar*, the Court confirmed in particular that Member States must comply with Articles 34 and 36 TFEU and 'must also be guided by the criteria laid down in Article 5(1) and (2) of [the Directive]'.[13] Those criteria are derived from the general requirement to base food law on risk assessment.[14] They require that, in fixing maxima, various factors must be taken into account, namely: (i) upper safe levels of vitamins and minerals ('upper safe level'); (ii) intakes from other dietary sources; (iii) reference intakes (together 'the Article 5 criteria').

31. It follows from the above that decisions by Member States to impose maxima on use of vitamins and minerals in food supplements must be preceded by a full risk assessment taking into account, in particular, the Article 5 criteria.

32. There appears to be rather broad agreement in all the written observations submitted to the Court on the points of law set out in the preceding paragraphs. In particular, it is not disputed that Member States have the possibility to adopt acts fixing maxima for use of vitamins and minerals in food supplements, on the basis of a full risk assessment.

2. Full risk assessment: general and product specific?

33. There is, however, a disagreement about whether a full risk assessment of the relevant vitamins and minerals was carried out before adoption of the Order. Nonetheless, that point is not raised by the referring court's first question. Whether or not a full risk assessment was carried out is for the referring court to verify. I will assume for the moment that a full risk assessment has been carried out (that is the position of the French Government), although I return to the issue in the context of the second and third questions.

34. More relevant here is the fact that there is a disagreement about whether there needs to be a procedure allowing for some form of additional (simplified) assessment on an individual basis. That is the focus of the first question.

35. In response to this, the French Government and the ESA argue in substance that, once a full risk assessment has been carried out and maxima fixed in national legislation, those maxima can be used to prevent imports. EU law does not require a specific procedure allowing for assessment of individual products which are acknowledged as exceeding the maxima.

36. By contrast, Noria and the Commission argue that, regardless of the existence of generally applicable maxima in national legislation, a procedure must exist whereby an importer can request authorisation to market its products in that Member State even if they exceed those maxima.

37. Does EU law require such a 'simplified mutual recognition procedure'?[15]

38. The Directive does not refer to or define such a requirement. Nor do I see any scope for inferring such a procedural requirement from the Directive. Can such a requirement be deduced from Articles 34 and 36 TFEU and the principle of free movement of goods and mutual recognition? Crucial to the answer is the meaning of the term '(simplified) mutual recognition procedure'.

13 — Judgment of 29 April 2010, *Solgar and Others* (C-446/08, EU:C:2010:233, paragraph 32).

14 — Article 6(1) of 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).

15 — In the *Solgar* case, it was argued that the Order was incompatible with EU law due to the absence of a mutual recognition procedure. However, that aspect was not addressed in the national court's request (see Opinion of Advocate General Jääskinen in *Solgar and Others* (C-446/08, EU:C:2009:795, points 28 and 29)) or the Court's judgment.

39. The principle of mutual recognition is derived from the prohibition of quantitative restrictions on imports between Member States and measures having an equivalent effect thereto, set out in Article 34 TFEU. [16] According to that principle, if a product has been lawfully manufactured and/or marketed in one Member State, then other Member States must as a general rule accept importation of that product into their territory. [17]

40. The prohibition on restrictions on the free movement of goods is not, however, absolute. Member States can still justify refusals to allow importation of products lawfully produced or marketed in other Member States. That can be done, for example, to safeguard public health, subject to the requirements of necessity and proportionality. [18]

41. It follows that a 'mutual recognition procedure' in this context is not a procedure that would require Member States to recognise automatically and authorise import of any food supplement produced or marketed legally in other Member States. Member States must have the opportunity to verify the absence of genuine risks for public health and refuse imports, if such risks are indeed considered to exist. [19]

42. A 'mutual recognition procedure' would then be a procedure whereby a Member State basically verifies if there is a genuine risk for public health *and hence whether or not it has a valid justification for refusing importation*. If no such risk and no valid justification exist, the importation cannot be legitimately prevented. [20]

43. But what happens if the risk already appears to have been fully researched and the justification fully developed? In the present case, that is the contention. The French Government effectively argues that it has justified its requirements relating to *specific nutrients* on the basis of a *full risk assessment* complying with EU law requirements in terms of thoroughness and consideration of specific factors.

44. Given those circumstances, what precise purpose would a mutual recognition procedure practically serve? What concrete steps would it require a Member State to take?

45. Would it be to repeat the same assessment of the same nutrient(s) as has already been conducted? [21] If that is indeed what is being suggested, then the answer is, in my view, a clear no.

46. If a Member State has complied with EU law requirements in terms of a full risk assessment of a nutrient, and has adopted generally applicable maxima on that basis, neither Article 34 TFEU nor the principles of free movement or mutual recognition require it to revise that conclusion simply because an individual importer does not like the result. On the other hand, it ought to be added that the EU law principle of effective judicial protection requires that the original act imposing generally applicable maxima must of course be open to judicial review under (primarily) national procedural rules.

16 — See, for example, judgment of 5 February 2004, *Commission* v *France* (C-24/00, EU:C:2004:70, paragraphs 21 and 22).

17 — Judgment of 20 February 1979, *Rewe-Zentral* (120/78, EU:C:1979:42, paragraphs 14 and 15). See also judgments of 17 June 1981, *Commission* v *Ireland*, (C-113/80; EU:C:1981:139), and of 10 February 2009, *Commission* v *Italy*, (C-110/05; EU:C:2009:66).

18 — See, for example, in relation to restrictions on inclusion of vitamins in foodstuffs, judgments of 23 September 2003, *Commission* v *Denmark* (C-192/01, EU:C:2003:492, paragraphs 42 and 43); of 5 February 2004, *Commission* v *France* (C-24/00, EU:C:2004:70, paragraphs 49 and 50); of 5 February 2004, *Greenham and Abel* (C-95/01, EU:C:2004:71, paragraphs 37 and 38); and of 14 July 1983, *Sandoz* (174/82, EU:C:1983:213, paragraphs 16 and 17).

19 — See, in this sense in relation to processing aids, judgment of 28 January 2010, *Commission* v *France* (C-333/08, EU:C:2010:44, paragraph 109), where such a requirement is referred to as a 'mutual recognition clause'.

20 — The adjective 'simplified' (or 'streamlined') implies something not too time consuming or complex. I will focus here on the basic expression 'mutual recognition procedure'.

21 — The national court refers to the Article 16 evaluation procedure, which exists for various *other* substances in food supplements (see above points 10 to 12). In that procedure, the importer provides data for the evaluation of the relevant substance. The competent national authority must assess the dossier and may justify refusal on public health grounds. To the extent that the French authorities have already taken into account all such data in their original risk assessment, an application of the Article 16 evaluation procedure here would simply involve repeating that assessment.

47. In their submissions, both Noria and the Commission refer to the Court's case-law on prior authorisations to support the argument that Member States must foresee simplified procedures for allowing commercialisation of imported products.

48. According to that case-law, where a Member State requires prior authorisation, the authorisation procedure must respect minimum requirements. Thus, it must be 'readily accessible and can be completed within a reasonable time, and, if it leads to a refusal, the decision of refusal must be open to challenge before the courts'. A refusal can be made 'only if such substance poses a genuine risk to public health'. [22]

49. However, those cases are very different from the present one. They focused on situations where Member States required importers to obtain authorisation before marketing their product *apparently without having first conducted a full risk assessment that would justify eventual prohibition*. The Court required in such cases that importers were able to trigger a procedure that would involve proper consideration by Member States of the justifications for any restrictions. That procedure had to be effective and the decisions appealable.

50. The Court had taken a similar approach in earlier cases involving *broad prohibitions on use of additives not based on a full risk assessment*. Again in those cases, the Court has required the possibility for importers to request authorisation, and such requests can only be rejected after a full risk assessment. [23]

51. However, those situations are completely different from ones where a detailed assessment of the public health justification for a particular restriction has *already* been carried out, and complies with the requirements of EU law in terms of scientific rigour.

52. In the 'prior authorisation cases' and 'broad prohibition' cases referred to above, the fundamental issue was not whether (or not) Member States foresaw specific procedural solutions national law, but rather that they ultimately had to base their restrictions on science.

53. Once a scientific risk assessment has been carried out, EU law does not require Member States to invent procedures providing for a repetition of that assessment, on the basis of the same evidence.

3. New evidence and fresh assessments

54. The above analysis assumes that the 'mutual recognition procedure' involves the Member State basically being asked to reread the same file to see if it comes to a different result. I do not consider that such an exercise is required by EU law.

55. The answer could, of course, be different if the Member State *were indeed being asked to do something different*. Whether such differences existed in the present case is a question of fact, to be ascertained by the national court. However, one specific possibility is worth highlighting here.

56. In my view, importers must certainly be able to present *new scientific evidence* that could lead to a reconsideration of the original restrictions. By 'new scientific evidence' I understand evidence post-dating the restrictions or otherwise not taken into account in the original assessment. Member States must give that evidence due consideration.

22 — See judgment of 5 February 2004, *Commission* v *France* (C-24/00, EU:C:2004:70, paragraphs 26, 27 and 36). See also judgments of 16 July 1992, *Commission* v *France* (C-344/90, EU:C:1992:328, paragraphs 9 and 10); of 23 September 2003, *Commission* v *Denmark* (C-192/01, EU:C:2003:492, paragraph 46); and of 5 February 2004, *Greenham and Abel* (C-95/01, EU:C:2004:71, paragraphs 35 and 36).

23 — See, for example, judgments of 6 May 1986, *Muller and Others* (304/84, EU:C:1986:194, in particular paragraphs 24 and 26); and of 12 March 1987, *Commission* v *Greece* (176/84, EU:C:1987:125, paragraph 39).

57. I would not describe that as a 'mutual recognition procedure'. It appears to me rather more akin to a standard form of a new, fresh administrative review, commonly present in the national systems of administrative procedure: new facts came to light, which made the previously adopted administrative decision difficult to maintain for the future. Nonetheless, whatever such a procedure is called, a possibility must exist for importers to submit new evidence. [24]

58. The existence of such a requirement is confirmed by several factors. Food law must be based on a full scientific risk analysis. [25] That requirement, in itself, clearly implies up-to-date science. I do not think that that expression could be read as meaning a full albeit outdated scientific risk assessment. That conclusion is, moreover, supported by references in the case-law to assessments on the basis of 'the most recent results' of scientific research. [26] Systemically, it is also confirmed by the existence in the Directive (as well as many other EU law acts) of mechanisms and procedures designed to ensure new scientific research is taken into consideration. [27]

59. Procedurally speaking, exactly how the requirement to consider new scientific evidence is fulfilled is a matter for Member States. However, in doing so, Member States must ensure that those procedures are effective. In that regard, the minimum conditions already well established by the Court in relation to prior authorisation systems for nutrients in food supplements and referred to above can, in my view, be applied *mutatis mutandis*. Thus, Member States must ensure that the procedure for assessing new scientific evidence is readily accessible, can be completed within a reasonable time, [28] and if it leads to refusal must be open to challenge before the courts. [29]

60. It is up to the national court to determine whether, in this case, Noria was in a position to present such new evidence but was unable to do so effectively in the way outlined above.

4. Conclusion on the first question

61. In the light of the above, I propose to reply to the national court's first question as follows:

Article 34 TFEU and the principle of mutual recognition preclude a national rule, which prohibits importation of food supplements lawfully produced or marketed in another Member State, on the basis that those food supplements contain a nutrient in quantities exceeding a given maximum, where such maximum has been fixed without a prior scientific risk assessment guided by the criteria laid down in Article 5(1) and (2) of Directive 2002/46. Article 34 TFEU and the principle of mutual recognition require Member States to ensure that importers may seek revision of that prior risk assessment on the basis of scientific evidence not previously taken into account by the Member State. Procedures for reviewing such new scientific evidence must be readily accessible, completed within a reasonable time and the resulting decisions must be open to challenge before national courts.

24 — This can be contrasted, for example, with a broad prohibition accompanied by a prior authorisation system where it is rather clear that a full review of existing evidence has not been conducted. See, in this sense, judgment of 16 July 1992, *Commission* v *France* (C-344/90, EU:C:1992:328) at paragraph 7: this confirms a positive scientific assessment of the relevant substance but goes on to accept the national prohibition, subject to efficient authorisation procedures. See also paragraphs 13 to 15 of that judgment.

25 — Article 6(1) of Regulation No 178/2002.

26 — See, for example, judgment of 29 April 2010, *Solgar and Others* (C-446/08, EU:C:2010:233, paragraph 69).

27 — Article 12 of the Directive; Article 22 of Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (OJ 2006 L 396, p. 1).

28 — That does not imply any specific time frame. If there is indeed new evidence, Member States are expected to act with celerity but they must also have sufficient time to give due consideration to that evidence.

29 — See above points 48 and 49.

5. Post scriptum on Regulation No 764/2008

62. Neither the national court nor any of the parties have referred to Regulation (EC) No 764/2008,[30] also known as the 'mutual recognition regulation' ('the Regulation'). For that reason, I assume it is not an issue in the main proceedings and will not consider it in detail.

63. Nonetheless, the Regulation does at least present some interest from a systemic point of view as the Commission has in the past stated that it applies to decisions based on national rules fixing maximum amounts of nutrients in food supplements.[31] Seen from this perspective, the Regulation confirms the general approach to the first question presented in this section.

64. Under the Regulation, one of the actions that must be taken by a Member State intending to adopt a decision prohibiting importation of products lawfully manufactured or sold in other Member States is to inform the operator concerned of the (public health) justifications for refusal, setting out supporting scientific evidence and allowing the operator to comment (see Article 6).

65. Thus, EU secondary law, in codifying what could be described as a 'mutual recognition procedure', aspires to impose rather limited procedural requirements on Member States. Effectively, if a decision to refuse importation is made, it must be reasoned and the operator must have had a chance to submit comments. The Regulation does not require a rerun of already executed risk assessments. It does not explicitly impose any time limit for the final decision. There is no obligation to foresee a specific provision in national law setting out the procedure.

66. To that extent, I consider that the Regulation provides further support that primary EU free movement law and the general principle of mutual recognition cannot in themselves impose detailed procedural requirements on Member States, in terms of adoption of specific mutual recognition provisions or procedures for 'repeat reviews' of scientific evidence. National law must, however, comply with the general requirements set out above in relation to the original assessment and allow for updating of that assessment on the basis of new scientific evidence (see point 56).

B – *Question 2*

67. By its second question, the national court asks whether maximum daily doses of vitamins and minerals can be set in proportion to recommended daily allowances, basically as multiples of reference intakes.[32] The national court also asks whether vitamins and minerals can be grouped for that purpose depending on level of risk they present, for example, for all low-risk nutrients, the maximum is set at three times the reference intake.

1. However results are presented, a full risk assessment is required

68. It is useful to distinguish at the outset between presentation and substance.

69. As set out above at point 29, Member States are free to set maximum amounts of vitamins and minerals in food supplements, until the Commission does so.

30 — Regulation of the European Parliament and of the Council of 9 July 2008 laying down procedures relating to the application of certain national technical rules to products lawfully marketed in another Member State and repealing Decision No 3052/95/EC (OJ 2008 L 218, p. 21).

31 — European Commission Enterprise and Industry Directorate-General Guidance document, 'The application of the Mutual Recognition Regulation to food supplements', Brussels, 1.2.2010, at point 4.2.

32 — As referred to in Article 5 of the Directive.

70. The real question of *substance* is whether a full risk assessment has been conducted on a case-by-case basis and taking into account, in particular, the Article 5 criteria.[33] As long as that has been done, EU law does not contain specific rules on the way in which those maxima must be *presented*.

71. There is no requirement that maxima be presented nutrient by nutrient. There is no requirement that maxima be presented as absolute amounts (for example, in mg) as opposed to multiples of recommended daily allowances.

72. In replying to this question, Noria and the ESA basically argue that a full scientific assessment has not been carried out, and the way the maxima are presented proves (or at least confirms) that point.

73. Whether or not such a full scientific assessment has been carried out and how that is proven are questions of fact and evidentiary rules for the national court to resolve. However, I do not consider that the choice of a particular method of presentation can *in itself* constitute irrefutable proof that a full assessment was or was not carried out.

74. This conclusion is, moreover, clearly supported by the Court's judgment in *Commission* v *Germany*.[34] In that judgment the Commission contested a German rule which automatically classified products that contained three times the recommended daily dose of vitamins (the rule applied to a range of vitamins) as medicinal products. The Court condemned what it referred to as the 'triple amount rule', because it was not preceded by a pharmacological evaluation of each vitamin or group of vitamins. In doing so, the Court acknowledged that the evaluation 'may correctly lead to the same result'. However, the reality was that such a case-by-case analysis had not been conducted.[35]

2. Observations on the adequacy of the risk assessment

75. I would add the following observations concerning the adequacy of the risk assessment.

76. First, as mentioned above, the risk assessment must, in principle, be carried out on a nutrient-by-nutrient basis. Some form of common assessment cannot be completely excluded, but would have to be duly justified.[36] In their observations, the French Government confirmed that the maxima were fixed on the basis of scientific opinions of the relevant French body, and annexed copies of those. I note that those opinions appear to cover some but not all nutrients for which maxima have been fixed and which appear in the Noria products (on the basis of the product descriptions contained in Noria's observations).

77. Second, the risk assessment must be based on data of a certain quality. For example, Article 5 of the Directive refers to 'generally accepted scientific data'. What this implies, in particular whether there is a need to refer to international scientific research, is further discussed under question 3.

78. Third, Noria, the Commission and the ESA's observations on these questions refer to one of the Article 5 criteria in particular, namely the upper safe level. It is unclear whether upper safe levels were ever fixed for all the nutrients concerned.

33 — 'Case-by-case' should, in principle, be read as 'nutrient-by-nutrient' since restrictions must be based on real risk. However, it cannot be excluded that there is some justification for grouping nutrients for the purposes of scientific evaluation. See, on that point, judgment of 29 April 2004, *Commission* v *Germany* (C-387/99, EU:C:2004:235, paragraphs 79 and 82), which envisages the grouping of substances in this way. See also my Opinion in *Queisser Pharma* (C-282/15, EU:C:2016:589) at point 83.

34 — Judgment of 29 April 2004, C-387/99, EU:C:2004:235.

35 — Judgment of 29 April 2004, *Commission* v *Germany* (C-387/99, EU:C:2004:235, paragraphs 81 and 82).

36 — See above, footnote 32.

79. Whether those levels have actually been fixed is a question of fact for the national court. It is the case that those levels constitute one of the Article 5 criteria and as such must, in principle, be taken into account in the fixing of maxima. [37]

80. That said, even where upper safe levels have *not* been established, it may still be possible for Member States to invoke the precautionary principle to justify protective measures. Thus, as confirmed by the Court in *Solgar*, if 'scientific uncertainty persists as regards the existence or extent of real risks to human health … Member State may, in accordance with the precautionary principle, take protective measures without having to wait until the reality and seriousness of those risks are fully demonstrated. However, the risk assessment cannot be based on purely hypothetical considerations'. [38]

3. Conclusion

81. In the light of the above, I propose to reply to the national court's second question as follows:

Article 34 TFEU and the principle of mutual recognition preclude a national rule, which prohibits importation of food supplements lawfully produced or marketed in another Member State, on the basis that those food supplements contain a nutrient in quantities exceeding a given maximum, where such maximum has been fixed without a prior scientific risk assessment guided by the criteria laid down in Article 5(1) and (2) of Directive 2002/46. Where such a prior risk assessment has been conducted, the aforementioned principles and provisions of EU law do not prevent presentation of resulting maxima either (a) by group of two or more nutrients or (b) as multiples of reference intakes.

C – *Question 3*

82. By its third question the national court asked whether maximum doses for nutrients in food supplements can be set on the basis of national scientific opinion alone. The national court is specifically concerned with situations where international scientific opinion foresees safe maxima that are higher than those proposed by national scientific opinion.

83. For the reasons developed below, I consider that maximum doses for nutrients in food supplements must be set taking into account the most *relevant* and *recent* scientific evidence, whether that is national or international only or includes both. Member States are not required to automatically align maxima set under national law with those referred to in international opinion, simply because the latter are higher than those referred to in national opinion. If relevant and in particular contradictory international scientific evidence exists, however, it cannot be ignored: Member States are obliged to take it into account when making their own assessment and explain why they decided to adopt a different approach.

84. No applicable EU law act specifies clearly whether sources of scientific evidence used when setting maximum amounts of vitamins and minerals present in food supplements can be national only or must imperatively include international opinion.

37 — Judgment of 29 April 2010, *Solgar and Others* (C-446/08, EU:C:2010:233, paragraph 66).

38 — Judgment of 29 April 2010, *Solgar and Others* (C-446/08, EU:C:2010:233, paragraph 67).

85. The only potentially relevant reference in the Directive appears in Article 5 and recital 14,[39] which requires upper safe levels to be established by 'scientific risk assessment based on *generally accepted scientific data*'.[40] It does not state whether the 'generally accepted scientific data' must be national or international.

86. Regulation No 178/2002 (the General Food Regulation) does not explicitly require risk assessments to be based on international scientific data either. Article 6(2) and recital 18 of the General Food Regulation provide that 'risk assessment shall be based on the *available scientific evidence* and undertaken in an independent, objective and transparent manner'.[41]

87. The case-law of the Court requires that, when setting maximum amounts of vitamins and minerals, Member States must undertake a scientific assessment of the risks to human health which is based on the relevant scientific data and not on purely hypothetical considerations.[42] It also refers to 'comprehensive assessment of the risk for health based on the most reliable scientific data available and the most recent results of international research'.[43] The Court's case-law does, therefore, arguably constitute a basis for saying that maxima must be based on *international* scientific opinion.

88. However, I do not consider that this should be read as an absolute requirement, amounting to a *de facto* obligation of quoting international scientific opinion. This follows partly from the fact that no such requirement appears in detailed secondary legislation (in particular the General Food Regulation) and the fact that case-law descriptions of the data, references and/or evidence that must be taken into account are not consistent in this regard.[44] More importantly, it is rather clear from a broader reading of the case-law that the fundamental concern is not about the details of bibliographies. It is rather that restrictions are justified on the basis of solid science demonstrating real risk or at least the inability to exclude risk, which results from a lack of science. That approach stands in contrast to restrictions based on outdated or partial assessments, or hypothetical risks.[45]

89. In other words, what the case-law seems to me to be primarily concerned with is the *quality* of the data relied on (in terms of its credibility, accuracy, and relevance), not necessarily the *origin* of the data (national or international). Whether or not full risk assessments in practice rely on sources from 1, 2 or 10 countries appears rather irrelevant in itself. What is relevant is whether the data relied on is convincing and not contradicted by other significant stream of research.

39 — As explained above at points 30 and 31 of this Opinion, according to existing case-law, in setting maxima Member States must be 'guided' by the criteria laid down in Article 5 of the Directive.

40 — Case-law requires Member States to be 'guided' by the Article 5 criteria when setting the maximum levels of nutrients in food supplements (see above, point 30). The Directive does not, strictly speaking, apply directly in such cases. Nonetheless, it must clearly be central to any systemic understanding of the evidence Member States should take into account when setting such maxima.

41 — Emphasis added.

42 — See, for example, judgment of 29 April 2010, *Solgar and Others* (C-446/08, EU:C:2010:233, paragraph 65).

43 — Judgments of 29 April 2010, *Solgar and Others* (C-446/08, EU:C:2010:233, paragraph 69); of 23 September 2003, *Commission* v *Denmark* (C-192/01, EU:C:2003:492, paragraph 51); of 5 February 2004, *Commission* v *France* (C-24/00, EU:C:2004:70, paragraph 53).

44 — See, for example, judgment of 5 February 2004, *Greenham and Abel* (C-95/01, EU:C:2004:71, paragraph 42) referring to 'the results of international scientific research' (paragraph 40); 'the most reliable scientific data available and the most recent results of international research' (paragraph 47); or simply to the 'latest scientific data' (paragraph 42). In earlier cases the Court has been more specific, referring to international research and citing the work of various clearly identified bodies (judgment of 12 March 1987, *Commission* v *Greece* (C-176/84, EU:C:1987:125, paragraphs 38 and 45); see also judgment of 6 May 1986, *Muller and Others* (304/84, EU:C:1986:194, paragraph 24). Such specifications have not been repeated in such detail in later judgments.

45 — See judgment of 5 February 2004, *Commission* v *France* (C-24/00, EU:C:2004:70, paragraph 71) for an example of a case where the Commission's claim that no health risk had been demonstrated was considered as not established on the basis of an opinion from a French national scientific committee. It is, however, unclear whether that opinion itself referred to international research (see footnote 46 below on the notion of 'international opinion').

90. Whether or not an individual national administrative decision meets such requirements is a factual issue, to be addressed by the national courts when evaluating scientific evidence put before them. It is fair to acknowledge, however, that in practical terms, is difficult to conceive that in a highly specialised field of research as is the impact on human health of vitamins and minerals, all the most up-to-date and relevant research would be contained within a single Member State and could therefore all be described as 'national opinion'. It certainly begs the question what, in today's increasingly interconnected world of research, such a notion would entail. [46]

91. However, such a possibility cannot be completely excluded. If it does exist, I consider it would be simply wrong to argue solely on that basis that the Member State has not conducted a full risk assessment. Conversely, the simple fact that a risk assessment *does* refer to non-national scientific opinion should obviously not be taken as meaning that the assessment is comprehensive. Again, this is in practice a factual assessment of the quality and comprehensiveness of individual research, which may or may not coincide with national boundaries.

92. In the light of the above, I do not consider that EU law contains an absolute requirement for risk assessments always to be based on international opinion.

93. Finally, the fact that international research indicates that higher amounts of nutrients are acceptable in food supplements without any risk for human health is not decisive to the extent that the risk assessment is comprehensive and takes into account the most relevant and recent evidence, whether national or international. [47]

94. EU law requires Member States to ensure that, before adopting restrictions, a full risk assessment is conducted. Any restrictions based on that assessment must be necessary and proportionate. However, EU law does not require Member States to come to the same conclusions in its assessment or to apply the same restrictions. *A fortiori,* nor does it require Member States to align their conclusions and restrictions with those of the most 'permissive' Member State. Were it otherwise, the discretion retained by Member States in that regard would be negated. [48] Mutual recognition would effectively be transformed from a fundamental principle into an absolute obligation for Member States.

95. In the light of the above, I propose to reply to the national court's third question as follows:

Article 34 TFEU and Directive 2002/46 do not preclude, as a matter of principle, national legislation which set maximum amounts for vitamins and minerals allowed in food supplements on the sole basis of national scientific opinions. Article 34 TFEU and Directive 2002/46 do not require Member States to align such maximum amounts with recent international scientific opinions for the sole reason that those opinions foresee safe maxima that are higher than those foreseen in national scientific opinions in (under) the same condition of use. It is for the national court to decide whether, on the facts of the case, the national measure at issue is based on a full risk assessment based on the most recent and relevant scientific data available, be it national or international.

46 — Is 'national' scientific opinion defined *institutionally* (because it was generated and adopted by a national body) or *substantively* (because a decision relies, at least formally, only on science of 'national' origin)? As an entirely hypothetical example, is it still a 'national' scientific opinion, if it was signed off by its director-general of Belgian origin? What if the scientific committee included a Canadian national? What if the opinion draws on research by labs in France, employing researchers from across the globe? What if the seemingly 'national' studies quoted in a 'national' opinion of an administrative authority themselves actually rely on and incorporate into their own substantive argument international studies? In an increasingly intertwined and interconnected world, certainly in some areas of (exact) sciences, it is unclear what would qualify strictly speaking as 'national scientific opinion', and, above all, what would be the practical utility of such a distinction. Fortunately, replying to the national court's third question does not require a detailed exploration of that thorny issue.

47 — It may be that international research points to lower acceptable maxima than national research and that would not be a reason for ignoring it either.

48 — Judgments of 23 September 2003, *Commission* v *Denmark* (C-192/01, EU:C:2003:492, paragraphs 42 and 43); of 5 February 2004, *Commission* v *France* (C-24/00, EU:C:2004:70, paragraphs 49 and 50); of 5 February 2004, *Greenham and Abel* (C-95/01, EU:C:2004:71, paragraphs 37 and 38); and of 14 July 1983, *Sandoz* (174/82, EU:C:1983:213, paragraphs 16 and 17).

V – Conclusion

96. In the light of the above, I propose to reply to the questions posed by the Tribunal de grande instance de Perpignan (Regional Court, Perpignan) as follows:

Question 1 Article 34 TFEU and the principle of mutual recognition, read in the light of Directive 2002/46/EC of the European Parliament and of the Council of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements, preclude a national rule, which prohibits importation of food supplements lawfully produced or marketed in another Member State, on the basis that those food supplements contain a nutrient in quantities exceeding a given maximum, where such maximum has been fixed without a prior scientific risk assessment guided in particular by the criteria laid down in Article 5(1) and (2) of that directive. Where such a prior risk assessment has been conducted, Article 34 TFEU and the principle of mutual recognition, read in the light of Directive 2002/46, require Member States to allow importers to seek revision of that prior risk assessment on the basis of scientific evidence not previously taken into account by the Member State. Procedures for reviewing such new scientific evidence must be readily accessible, completed within a reasonable time and the resulting decisions must be open to challenge before national courts.

Question 2 Article 34 TFEU and the principle of mutual recognition, read in the light of Directive 2002/46, preclude a national rule, which prohibits importation of food supplements lawfully produced or marketed in another Member State, on the basis that those food supplements contain a nutrient in quantities exceeding a given maximum, where such maximum has been fixed without a prior scientific risk assessment guided in particular by the criteria laid down in Article 5(1) and (2) of that directive. Where such a prior risk assessment has been conducted, those principles and provisions of EU law do not prevent presentation of resulting maxima either (a) by group of two or more nutrients or (b) as multiples of recommended daily allowances.

Question 3 Article 34 TFEU and Directive 2002/46 do not preclude, as a matter of principle, national legislation which set maximum amounts for vitamins and minerals allowed in food supplements on the sole basis of national scientific opinions. Article 34 TFEU and Directive 2002/46 do not require Member States to align such maximum amounts with recent international scientific opinions for the sole reason that those opinions foresee safe maxima that are higher than those foreseen in national scientific opinions in (under) the same condition of use. It is for the national court to decide whether, on the facts of the case, the national measure at issue is based on a full risk assessment based on the most recent and relevant scientific data available, be it national or international.