

Maximum Vitamin Amounts in Food Supplements: Towards Science-based and Streamlined EU Mutual Recognition and Risk Assessment Procedures?

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Food supplements – vitamins and minerals– free movement of goods – national legislation setting maximum amounts of vitamins in food supplements not to be exceeded – mutual recognition – science-based risk assessments – obligation for Member States to have a mutual recognition procedure in place – latest and most relevant international scientific opinions to be taken into account – relationship between mutual recognition and risk assessments

Articles 34 and 36 Treaty on the Functioning of the European Union

Directive 2002/46 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, [2002] OJ L183/51

I. INTRODUCTION

One of the cornerstones of EU free movement of goods law remains the acceptance of a system of mutual recognition: products manufactured legally in one's home Member State can be exported to and marketed in another – host – Member State.¹ However, EU mutual recognition has never been absolute.² The host Member State may invoke public interest reasons – such as the protection of public health – with a view to limit or even prohibit those products on its territory.³ Although this principle of mutual recognition

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¹ See Commission interpretative communication on facilitating the access of products to the markets of other Member States: the practical application of mutual recognition [2003] OJ C265/2.

² S Weatherill, “Why there is no ‘principle of mutual recognition’ in EU law (and why that matters to consumer lawyers)” in K Purnhagen and P Rott (eds), *Varieties of European Economic Law and Regulation. Liber amicorum for Hans Micklitz* (Edward Elgar 2014) 402–403.

³ See already to that extent CJEU, Case 120/78, *Rewe-Zentral AG v Bundesmonopolverwaltung für Branntwein* EU: C:1979:42, para. 8.

seems clear in theory, practice shows that it remains unclear *precisely when and how* mutual recognition procedures have to be set up under EU primary law and what role they should play in the more general context of risk assessments also mandated by EU law.⁴ The Court of Justice's First Chamber *Noria* judgment of 27 April 2017 offers two welcome clarifications on that matter, yet also leaves one crucial issue unaddressed in this respect.

II. FACTS

The maximum amounts of vitamins that can be included in food supplements have varied consistently among Member States. In an attempt to avoid that those varying maximums would impede the free movement of food supplements, Article 5 of Directive 2002/46 on the approximation of the laws of the Member States relating to food supplements mandates the European Commission to set maximum amounts of food supplements per daily portion of consumption as recommended by the manufacturer.⁵ When doing so, the Commission is to take into account the "upper safe levels of vitamins and minerals established by scientific risk assessment based on generally accepted scientific data", the "intake of vitamins and minerals from other dietary sources" and the "reference intakes of vitamins and minerals for the population".⁶

Absent political agreement on the specific amounts to be set, however, EU-wide maximums have not yet been established. As a result, Member States have continued to set their own amounts not to be exceeded. In its *Solgar* judgment, the Court of Justice of the European Union acknowledged that Member States still retained the power to do so, as long as they respected the principles underlying the free movement of goods.⁷

The *Noria* case arose against this background. Under French law, an interministerial Order of 9 May 2006 relating to nutrients which may be used in the manufacture of food supplements, determines the maximum daily doses for vitamins and minerals to be included. Per Decree No 2006-352, those amounts cannot be exceeded by products produced and marketed in France.⁸ Neither the Decree nor the Order provide explicitly for a mutual recognition procedure that would permit food supplements exceeding those vitamin thresholds to be marketed in France. Although such procedures were in place for substances with a nutritional or physiological effect or plants and preparations of plants,⁹ a similar procedure had not been foreseen in the specific context of vitamins added to food supplements. The only way to receive authorisation for products exceeding the maximum amounts set by French law is to

⁴ See A Szajkowska, *Regulating Food Law. Risk Analysis and the Precautionary Principle as General Principles of EU Food Law* (Wageningen Academic Publishers 2012) 36–59.

⁵ See N Coutrelis and C Mathias, "Maximum Nutrient Amounts: How to Cope with the European Commission's Inaction. A national challenge in light of the ECJ rulings" [2011] EFFL 218.

⁶ Art 5(1) and (2) of Directive 2002/46 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, [2002] OJ L183/51.

⁷ CJEU, Case C-446/08, *Solgar Vitamin's France and Others v Ministre de l'Économie, des Finances et de l'Emploi and Others*, EU:C:2010:233.

⁸ CJEU, Case C-672/15, *Noria Distribution SARL*, EU:C:2017:310, paras. 8 and 10 (hereafter *Noria Distribution*).

⁹ *Noria Distribution*, para. 9.

request a revision of the thresholds applicable in France, which would require generally applicable regulations to be modified.¹⁰

Noria Distribution markets food supplements across the EU. Confronted with the absence, in French law, of a mutual recognition procedure for vitamins, it could not ask for an authorisation to market products which were produced lawfully in another Member State, yet exceeded the daily doses maxima set by the 2006 Order in France. Proceeding to market those products without authorisation in France and in violation of the maximum amounts in place there, Noria was criminally prosecuted.¹¹ In the course of the criminal proceedings, Noria invoked the incompatibility of the absence of a mutual recognition procedure with EU free movement law. The Tribunal de grande instance of Perpignan was receptive to those arguments and raised three questions to the Court of Justice.

Firstly, the French court asked whether Directive 2002/46 and the EU free movement of goods principles allow for a national legal regime which does not offer a mutual recognition procedure in the context of food supplements for vitamins and minerals exceeding the French daily doses maxima limits, although lawfully produced or marketed in another Member State.¹²

Secondly and related to this first question, the Perpignan court asked whether the criteria applied under French law to set maximum daily doses could be permitted still as a matter of EU free movement law. Under French law, maximum values have been set as equal to three times the recommended daily allowances for nutrients presenting the least risk. In practice, the envisaged calculation could result to setting the maximum value at zero.¹³

Thirdly, the court asked whether the setting of maximum amounts could only be based on national scientific opinions on the matter, even though recent international scientific opinion seems to allow for higher doses to be consumed in identical conditions of use.¹⁴

III. JUDGMENT

In response to the first question, the Court of Justice reiterated its attachment to the free movement of goods. Confirming its holding in *Solgar* that Member States remained competent to set maximum daily doses in the absence of harmonised rules on the matter, the Court additionally also re-established that those Member States are nevertheless required to comply with Articles 34 and 36 TFEU in doing so.¹⁵ From the point of view of Article 34 TFEU, any national measure setting limits on maximum daily doses of vitamins constitutes a *prima facie* prohibited measure having an equivalent to a quantitative restriction, “since a food supplement whose nutrient content exceeds the maximum limits set by that legislation cannot be marketed in France, even if that food

¹⁰ Opinion of AG Bobek in Case C-672/15, *Noria Distribution SARL*, EU:C:2017:310, para. 14 (hereafter AG’s Opinion).

¹¹ *Noria Distribution*, para. 12.

¹² *Noria Distribution*, para. 14.

¹³ *Noria Distribution*, para. 14.

¹⁴ *Noria Distribution*, para. 14.

¹⁵ *Noria Distribution*, para. 16.

supplement is lawfully manufactured or marketed in another Member State”¹⁶. A measure restricting or prohibiting the marketing of foodstuffs produced in another Member State can be justified on the basis of Article 36 TFEU if the Member State concerned can demonstrate a genuine risk to public health.¹⁷ In addition, the rules in place “must make provision for a procedure enabling economic operators to obtain the authorisation to market food supplements including nutrients in doses exceeding those authorised. The procedure must be one which is 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”.¹⁸ Given that such a procedure did not exist for food supplements in French law¹⁹, the French legal framework was considered incompatible with Article 36 TFEU.²⁰

As far as the second question was concerned, the Court repeated its previous case law that when setting maximum daily doses, Member States were to be guided by the criteria laid down in Article 5(1) and (2) of Directive 2002/46²¹, taking into account the upper safe levels of vitamins and minerals established by scientific risk assessment based on generally accepted and relevant scientific data and not on purely hypothetical considerations.²² According to the Court, setting upper safe limits in the absence of a proven risk to human health and without such a scientific assessment does not satisfy those criteria.²³ Although Member States can determine the maximum amounts at a level below those upper safe limits and even at zero, they would have to assess, on a case-by-case basis, whether maximum amounts should be set below that level.²⁴ Nutritional needs of the population may play a role in that regard, but the absence of such needs cannot as such justify a total prohibition on the marketing of food supplements.²⁵ Therefore, a method which consists in setting those amounts without taking into account all of those elements, on the sole basis of the nutritional needs of the population concerned, or without that setting being carried out on a case-by-case basis, is not compatible with Article 5 of Directive 2002/46 or with the provisions of the TFEU relating to the free movement of goods.²⁶ The Court leaves it to the national court to make that assessment in the specific case at hand.²⁷

On the third question, the Court interpreted the notion of generally accepted scientific data in Article 5 of Directive 2002/46. It held that in the absence of reliable international scientific data, such an assessment can be carried out merely on the basis of more reliable national scientific opinions.²⁸ That *modus operandi* cannot, by contrast, be relied on

¹⁶ *Noria Distribution*, para. 19.

¹⁷ *Noria Distribution*, paras. 21 and 23.

¹⁸ *Noria Distribution*, para. 22.

¹⁹ *Noria Distribution*, para. 25.

²⁰ *Noria Distribution*, paras. 26 and 27.

²¹ *Noria Distribution*, paras. 16 (also reiterating that point already in the first question), 31 and 39.

²² *Noria Distribution*, para. 33.

²³ *Noria Distribution*, para. 34.

²⁴ *Noria Distribution*, paras. 35 and 37.

²⁵ *Noria Distribution*, para. 38.

²⁶ *Noria Distribution*, para. 40.

²⁷ *Noria Distribution*, para. 41.

²⁸ *Noria Distribution*, para. 46.

where such international data are also available.²⁹ Setting upper limits on the basis of national scientific opinions only, even though recent international scientific opinions concluding in favour of the possibility of setting higher limits are also available, is a practice precluded by Directive 2002/46 and the TFEU provisions relating to the free movement of goods.³⁰

IV. COMMENT

The *Noria* judgment offers Member States clear guidance on two points. On the one hand, when conducting risk assessments on the basis of relevant scientific data, Member States also have to include relevant studies that do not necessarily focus on their own territories or population (1). On the other hand, Member States also have to have in place tailored mutual recognition procedures (2). Simultaneously, however, the judgment remains ambivalent on how the envisaged mutual recognition procedures are to interact with food supplement risk assessment frameworks set up at Member State level (3).

1. Relevant scientific data do not necessarily concern the specific Member State's territory

Noria explicitly confirms that relevant scientific data sufficiently establishing the public health risk on the basis of the latest scientific research have to inform Member States' risk assessments accompanying the setting of maximum vitamin amounts.³¹ The Court confirms its previous case law,³² adding to it that relevant international scientific data also have to be taken into consideration in that regard.³³

It is nevertheless important to nuance the reliance on international studies in this judgment. The Court did not say that international scientific data have always to be used in studies regarding the maximum amounts of vitamins in food supplements. However, when such studies are available and when their results are relevant for decisions to be taken in the context of an EU Member State, that Member State needs to take those studies into account as well. At the same time, however, when no international scientific data are available or when those data are not or no longer relevant, the judgment can be understood as still allowing Member States to continue to rely only on national data for the purposes of assessing risks in the specific food supplement context. If both relevant national and international data are available, Member States will seemingly have to include both in their risk assessment.

The Court in that regard above all clarifies that the relevance of scientific studies is not to be determined on the basis of territory- or population-linked criteria only. The mere fact that the underlying data of a scientific study do not concern the territory or

²⁹ *Noria Distribution*, para. 47.

³⁰ *Noria Distribution*, para. 50.

³¹ *Noria Distribution*, para. 49.

³² CJEU, Case C-95/01, *Greenham and Abel*, EU:C:2004:71, para. 47; CJEU, Case C-192/01, *Commission v Denmark*, EU:C:2003:492, para. 48; CJEU, Case C-24/00, *Commission v France*, C-24/00, EU:C:2004:70, para. 55; Case C-41/02, *Commission v Netherlands*, EU:C:2004:762, para. 49; CJEU, Case C-333/08, *Commission v France*, EU:C:2010:44, para. 89.

³³ *Noria Distribution*, paras. 50–51.

population of the Member State can no longer suffice to exclude them as irrelevant from a Member State risk assessment point of view. The Court's judgment could thus be understood as requiring national authorities even more actively than before to look for other relevant studies not conducted on their territories or focusing on their population in order to be able to take them into consideration in their risk assessment. It will fall upon national authorities to justify the studies they have chosen and to explain to those concerned why those studies are indeed relevant.

2. An obligation to set up mutual recognition procedures

In addition to clarifying the notion of relevant scientific data, the Court also clearly obliges Member States to have in place "a procedure for the placing on the market of that Member State of food supplements whose content in nutrients exceeds the maximum daily doses set by that legislation and which are lawfully manufactured or marketed in another Member State".³⁴ Building on earlier case law stressing the importance of such a procedure,³⁵ the Court now makes unequivocally clear that it always has to be provided as a matter directly of Article 36 TFEU.

In line with previous case law, the Court does not impose overly-specific criteria on Member States on how to organise those mutual recognition procedures. It only repeats that procedures in place have to be readily accessible and reasonably timed in order to ensure that products manufactured lawfully in another Member State can be marketed as fast as possible in another Member State.³⁶ Other procedural conditions are left to the Member States' discretion, as long as they effectively allow for mutual recognition requests to be made by producers or importers of a food supplement legally manufactured in another Member State.

3. Mutual recognition procedures and risk assessment frameworks: (where) do they interact?

The fact that a mutual recognition procedure has to be in place, does not imply that the Member State concerned is to automatically authorise the marketing of that product on its territory. To the extent that the producer or importer asks for authorisation to market his food supplement lawfully produced in another Member State, the host Member State may always refuse on the basis of public health risks that have been identified when conducting its risk assessment preceding the setting of maximum amounts. Under EU secondary legislation enabling mutual recognition procedures, a reference to a previously carried out risk assessment would be sufficient in order to justify a decision refusing a marketing authorisation when no new evidence has been brought forward.³⁷ It would seem that the Court had this framework in mind when interpreting Article 36 TFEU as requiring a similar mutual recognition procedure to be in place.

³⁴ *Noria Distribution*, para. 28.

³⁵ CJEU, Case C-24/00, *Commission v France*, EU:C:2004:70, para 26; CJEU, Case C-95/01, *Greenham and Abel*, EU:C:2004:71, para. 35; CJEU, Case C-333/08, *Commission v France*, EU:C:2010:44, para. 81.

³⁶ *Noria Distribution*, para. 22.

³⁷ See Art 6 of Regulation 764/2008 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, [2008] OJ L218/21 and AG's Opinion, para. 64.

It therefore follows from the judgment that, under Article 36 TFEU, Member States can still refuse an authorisation by referring to a previous risk assessment when a request for authorisation of a legally produced product in another Member State is not accompanied by new data or facts showing that the maximum amounts set previously at Member State level no longer correspond to the latest scientific findings. In that understanding, the mutual recognition procedure envisaged would then serve as a tool to inform the producer or importer concerned about the risk assessment made at Member State level and the resulting maximum amount decisions based on public health considerations.

The Court's judgment is less clear on the extent to which a subsequent mutual recognition request and the accompanying procedure should be conceived as instruments also to challenge previously-made risk assessments. In the hypothesis where the importer or producer of a food supplement lawfully manufactured in another Member State offers new facts or new data, showing that the maximum amounts set at Member State level no longer correspond to the latest scientific findings, the mutual recognition procedure may constitute an instrument to challenge the findings of a previously conducted risk assessment. A Member State could then use the requests for mutual recognition to review its risk assessment and, as a result, modify its upper limits when determining maximum vitamin amounts.

Advocate General Bobek seemed favourable to that interpretation. According to his Opinion, the purpose of EU-imposed mutual recognition procedures should lie in allowing new circumstances or new scientific data leading to another conclusion than the ones having informed the earlier adoption of maximum daily doses to be voiced.³⁸ Those new facts, and the challenge they offer to the rules in force in a specific Member State, and not the actual request mutually to recognise a product manufactured legally in another Member State, would, in the Advocate General's Opinion, have to constitute the key objective of any procedure allowing a business to ask for authorisation of a legally manufactured product from another Member State.³⁹ According to the Advocate General, the principle of mutual recognition in EU internal market law would therefore specifically and only 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.⁴⁰

The Court did not follow the Advocate General on this point, obliging the Member States only to provide for mutual recognition procedures and for a judicial review procedure against decisions refusing to authorise products. In so holding, it left the Member States in control to decide whether a mutual recognition procedure is to become of itself an instrument to challenge previously executed and implemented risk assessments. On the one hand, Member States could allow for a fresh risk assessment to be carried out within the mutual recognition procedure context, in accordance with the arrangements set under national law. On the other hand, Member States could demand or request a new risk assessment to be carried out, not within the framework of the mutual

³⁸ AG's Opinion, paras. 50 and 51.

³⁹ AG's Opinion, para. 55.

⁴⁰ AG's Opinion, para. 61.

recognition procedure, but every time the relevance of scientific data would be contested in the context of a mutual recognition request. In *Noria*, the Court does not want to impose either modus operandi on Member States, leaving it to each Member State to decide whether to take such action. From that point of view, Member States could also decide not to provide for any interaction between mutual recognition and risk assessment procedures, all without violating EU law.

Although *Noria* would have been the perfect opportunity to shed some light on the interaction between both procedures as a matter of EU law, the Court clearly chose not to do so. Whilst understandable from a national procedural autonomy point of view, it is submitted that the Court's current reasoning in this respect above all opens the door to the emergence of a variety of mutual recognition procedures with different consequences in terms of risk assessments across the EU Member States. Given that the rest of the judgment clearly is in favour of a more streamlined science-based approach to food supplement risk assessments, the Court's lack of a more explicit dictum on how to integrate mutual recognition procedures within that approach is remarkable to say the least.

V. CONCLUSION

The *Noria* judgment confirms the Court's previously established case law on Member States' maximum daily vitamin dosage regulations. In the absence of EU harmonisation, Member States remain at liberty to prohibit the marketing of certain food supplements, so long as their decision is based on relevant, reliable and – if available – international scientific data and as long as some kind of mutual recognition procedure is available. *Noria* does not, however, fully clarify how mutual recognition procedures are to differ from or relate to risk assessment procedures and frameworks in place as a matter of EU law. As a result, diversified national risk assessment and mutual recognition procedures are likely to remain in place for now.