Reports of Cases

OPINION OF ADVOCATE GENERAL
SAUGMANDSGAARD ØE
delivered on 14 December 2017[1]

Case C-13/17

Fédération des entreprises de la beauté
v
Ministre des Affaires sociales, de la Santé et des Droits des femmes, Ministre de l'Éducation nationale, de l'Enseignement supérieur et de la Recherche, Ministre de l'Économie et des Finances, formerly Ministre de l'Économie, de l'Industrie et du Numérique

(Request for a preliminary ruling
from the Conseil d'État (Council of State, France))

(References for a preliminary ruling — Approximation of laws — Cosmetic products — Regulation (EC) No 1223/2009 — Article 10(2) — Assessment of the safety of cosmetic products — Qualifications of the safety assessor — Recognition of equivalent training courses — Types of courses concerned — Possible reference solely to courses given in third countries — Disciplines similar to pharmacy, toxicology or medicine — Member States' discretion — Criteria for identification)

I. Introduction

1. This request for a preliminary ruling from the Conseil d'État (Council of State, France) concerns the interpretation of Article 10(2) of Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products.[2] It is the first such request.[3] Article 10(2) describes the qualifications which are required of persons entrusted with the assessment of the safety of cosmetic products,[4] which are formal qualifications awarded on completion of either 'a university course of theoretical and practical study in pharmacy, toxicology, medicine or a similar discipline' or 'a course recognised as equivalent by a Member State'.

1 Original language: French.

2 OJ 2009 L 342, p. 59. Several amendments have been made to the regulation, but the provisions that are relevant in the present case have not been altered.

3 In its judgment of 21 September 2016, *European Federation for Cosmetic Ingredients* (C-592/14, EU:C:2016:703, paragraphs 33 and 36), the Court admittedly mentioned the general thrust of Article 10, pointing out that it requires the safety of cosmetic products to be assessed before they are placed on the market, but it gave no ruling on the interpretation of Article 10(2).

4 As regards how that assessment is to be carried out in practice, see, in particular, Scientific Committee on Consumer Safety, *Notes of Guidance for the Testing of Cosmetic Ingredients and their Safety Evaluation — 9th revision*, version of 25 April 2016, available at http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_190.pdf

2. This request for a preliminary ruling has arisen in the course of an action for the annulment of the order on the professional qualifications of assessors of the safety of cosmetic products for human health adopted on 25 February 2015 by the Ministers who are the defendants in the main proceedings [5] ('the contested order'). In that order, the French legislature defined the courses which it recognised as being 'equivalent', within the meaning of Article 10(2) of Regulation No 1223/2009, mentioning only formal qualifications awarded within the European Economic Area ('EEA') and including, in particular, diplomas in veterinary medicine and ecotoxicology.

3. The referring court first of all asks the Court of Justice whether, under Article 10(2), the Member States may recognise as equivalent courses only courses that are given in countries outside the European Union. Secondly, it asks the Court whether, under that provision, the Member States may determine the disciplines that are considered to be 'similar' to pharmacy, toxicology or medicine and, if so, what criteria they must apply.

II. Legal context

A. EU law

4. As is indicated in recitals 1 and 69 of Regulation No 1223/2009, that regulation recast Directive 76/768/EEC on the approximation of the laws of the Member States relating to cosmetic products, [6] which it replaced.

5. According to recital 4 thereof, Regulation No 1223/2009 'comprehensively harmonises the rules in the Community in order to achieve an internal market for cosmetic products while ensuring a high level of protection of human health'.

6. Recital 19 of that regulation states that the information that is to be made available to the competent authorities must include, 'in particular, … a cosmetic product safety report documenting that a safety assessment has been conducted'.

7. Article 1 of the regulation, entitled 'Scope and objective', states that the 'regulation establishes rules to be complied with by any cosmetic product made available on the market, in order to ensure the functioning of the internal market and a high level of protection of human health'.

8. Article 10 of the regulation, entitled 'Safety assessment', provides:

'1. In order to demonstrate that a cosmetic product complies with Article 3, the responsible person shall, prior to placing a cosmetic product on the market, ensure that the cosmetic product has undergone a safety assessment on the basis of the relevant information and that a cosmetic product safety report is set up in accordance with Annex I.

…

The Commission, in close cooperation with all stakeholders, shall adopt appropriate guidelines to enable undertakings, in particular small and medium-sized enterprises, to comply with the requirements laid down in Annex I. Those guidelines shall be adopted in accordance with the regulatory procedure referred to in Article 32(2).

5 *JORF* (Official Journal of the French Republic) No 64 of 17 March 2015, p. 4941, document No 18.

6 Council Directive of 27 July 1976 (OJ 1976 L 262, p. 169), amended on several occasions, and most recently by Commission Directive 2009/36/EC of 16 April 2009 (OJ 2009 L 98, p. 31).

2. The cosmetic product safety assessment, as set out in Part B of Annex I shall be carried out by a person in possession of a diploma or other evidence of formal qualifications awarded on completion of a university course of theoretical and practical study in pharmacy, toxicology, medicine or a similar discipline, or a course recognised as equivalent by a Member State.

…'

9. Annex I to Regulation No 1223/2009 concerns the 'Cosmetic product safety report'. Part B of that annex, which is entitled 'Cosmetic product safety assessment', states, in paragraph 4 thereof, that the report must contain, inter alia, 'proof of [the] qualification of [the] safety assessor'.

10. The regulation was integrated into the EEA Agreement by Decision of the EEA Joint Committee No 49/2013 of 5 April 2013 amending Annex II (Technical regulations, standards, testing and certification) to that agreement.[7]

11. The annex to Commission Implementing Decision 2013/674/EU of 25 November 2013 on Guidelines on Annex I to Regulation No 1223/2009[8] states, in section 4.4. thereof, entitled 'Assessor's credentials and approval of Part B', the following:

'The safety assessor is to be a professional with the necessary knowledge and expertise to draw up an accurate safety assessment, as indicated by the qualification requirements in Article 10(2) of Regulation (EC) No 1223/2009. That section of the cosmetic product safety report aims at ensuring that this requirement is met and that the necessary evidence is provided.

…

A person who has obtained qualifications in a third country may act as a safety assessor if they have completed "a course recognised as equivalent [to a university course of theoretical and practical study in pharmacy, toxicology, medicine or a similar discipline] by a Member State".

Proof is to be provided of the safety assessor's qualification (i.e. copy of the diploma and, where needed, proof of equivalence) [as referred to] in Article 10 of Regulation (EC) No 1223/2009.'

B. French law

12. The third paragraph of Article L. 5131-2 of the Code de la santé publique (Code on Public Health)[9] provides that 'the qualified persons responsible for the safety assessment must have completed a university course as described in Article 10 of Regulation (EC) No 1223/2009, or an equivalent course included in a list set out by order of the Ministers responsible for health, industry and higher education, or a course recognised as equivalent by a Member State of the European Union'.

7 OJ 2013 L 231, p. 23.

8 OJ 2013 L 315, p. 82.

9 As amended by Article 3 of Loi nº 2014-201 du 24 février 2014 portant diverses dispositions d'adaptation au droit de l'Union européenne dans le domaine de la santé (Law No 2014-201 of 24 February 2014 containing various provisions implementing EU law in the field of health) (*JORF* No 47 of 25 February 2014, p. 3250, document No 4).

13. The aim of the contested order[10] is, according to its preamble, to define 'the courses recognised as being equivalent to the diplomas in medicine, pharmacy or toxicology that are required of assessors of the safety of cosmetic products for human health'. Article 1 of the contested order provides that 'the list of courses that are recognised as equivalent to the university courses referred to in Article 10 of Regulation (EC) No 1223/2009 and Article L. 5131-2 of the Code on Public Health is set out in the annex', which reads as follows:

'1. The French State diploma for the profession of veterinary surgeon, the State veterinary diploma or one of the diplomas, certificates or other documents evidencing formal qualifications in veterinary medicine issued by the other Member States of the European Union, the States party to the [EEA Agreement] or the Swiss Confederation.

2. The French doctoral degree, or one of the diplomas, certificates or other documents evidencing qualification at the same level as the French doctoral degree issued by the other Member States of the European Union, the States party to the [EEA Agreement] or the Swiss Confederation, awarded on completion of research in the field of toxicology or ecotoxicology.

3. The French masters degree or one of the diplomas, certificates or other documents evidencing qualification issued by the other Member States of the European Union, the States party to the [EEA Agreement] or the Swiss Confederation recognised, by the issuing State, as being at masters level (conferring 120 European credits (ECTS) after a first diploma conferring 180 ECTS credits). The diploma, certificate or other evidence of qualification must confer at least 60 ECTS European credits in the field of toxicology or ecotoxicology and in the field of risk assessment.

4. The diploma of advanced studies (Diplôme d'études approfondies (DEA)) in toxicology or ecotoxicology.

5. The diploma of higher studies (Diplôme d'études supérieures (DESS)) in toxicology or ecotoxicology.'

III. The dispute in the main proceedings, the questions referred and the procedure before the Court

14. It is apparent from the documents before the Court that the Fédération des entreprises de la beauté ('FEBEA') is a professional organisation which has as its members more than 300 undertakings active in the cosmetics sector in France.

15. On 4 September 2015, that organisation brought an action before the Conseil d'État (Council of State) seeking the annulment of the contested order, for misuse of powers, and of the ministerial decision of 10 July 2015 dismissing its administrative appeal against that order.

16. In support of its application, FEBEA argues, amongst other things, that the order at issue infringes Article 10(2) of Regulation No 1223/2009, *first*, in that, in determining which disciplines are considered to be 'similar' to pharmacy, toxicology or medicine, it includes ecotoxicology, whereas the regulation confers no power on the Member States to do that, and, *secondly*, in that it recognises the equivalence of courses given within the European Union, the EEA and the Swiss Confederation, whereas the recognition of equivalence to which that provision refers relates only to courses given in third countries.

10 Mentioned in point 2 of this Opinion.

17. According to the referring court, Article 10(2) of Regulation No 1223/2009 leaves it to the Member States to recognise which courses are equivalent to the diplomas or other evidence of formal qualifications awarded on completion of a university course of theoretical and practical study in pharmacy, toxicology, medicine or a similar discipline of which any person entrusted with a cosmetic product safety assessment must be in possession.

18. Even if the words 'course recognised as equivalent' which appear in that provision refer only to courses given in countries to which the regulation does not apply, as FEBEA maintains, it might be considered that, in order for that provision to be fully implemented, it is necessary, for the purposes of recognising the equivalence of such courses, to specify in advance both the content of the concept of 'similar disciplines' and the level of qualifications called for by the regulation.

19. In that context, by decision of 16 December 2016, received at the Court of Justice on 12 January 2017, the Conseil d'État (Council of State) decided to stay the proceedings and refer the following questions to the Court for a preliminary ruling:

'(1) Does the recognition of the equivalence of courses by Member States under Article 10(2) of Regulation [No 1223/2009] solely relate to courses given in countries outside the European Union?

(2) Do the provisions of Article 10(2) of that regulation authorise Member States to determine the disciplines that may be considered to be "similar" to medicine, pharmacy or toxicology, within the meaning of the regulation, and the levels of qualification that satisfy the requirements of the regulation?

(3) If the second question is answered in the affirmative, according to what criteria may disciplines be considered to be "similar" to medicine, pharmacy or toxicology?'

20. Written observations have been lodged by FEBEA, the French Government and the European Commission. At the hearing on 19 October 2017, all of those parties presented oral argument.

IV. Analysis

21. The referring court has submitted three questions to the Court for a preliminary ruling. The first concerns the concept of 'courses recognised as equivalent by a Member State' used in Article 10(2) of Regulation No 1223/2009, while the second and third concern what is meant by a 'similar discipline' to pharmacy, toxicology or medicine, for the purposes of that same provision. Given the similar scope of the last two questions, it seems, in my view, appropriate to address them together.

A. The scope of the concept of a 'course recognised as equivalent by a Member State' within the meaning of Article 10(2) of Regulation No 1223/2009 (the first question)

22. By its first question the referring court asks the Court of Justice, in essence, whether the concept of a 'course recognised as equivalent by a Member State' used in Article 10(2) of Regulation No 1223/2009 is to be interpreted as referring exclusively to courses given in countries outside the European Union.

23. It is apparent from the national case file that, in the dispute in the main proceedings, FEBEA alleges that the contested order is unlawful in that it recognises the equivalence of diplomas obtained, inter alia,[11] within the European Union, whereas recognition of equivalence as between Member States is absolutely unnecessary.[12] FEBEA made a similar argument before the Court, maintaining that action at national level was necessary only in so far as concerned persons holding diplomas issued in third countries, who could act as assessors of the safety of cosmetic products within the European Union only if one of the Member States recognised the equivalence of their diplomas.

24. The French Government, on the other hand, maintains that the Member States' recognition of the equivalence of courses pursuant to Article 10(2) of Regulation No 1223/2009 relates to courses given within the European Union, without prejudice to the freedom of every Member State to recognise, on a case-by-case basis, the equivalence of courses taken in third countries by persons wishing to act as assessors of the safety of cosmetic products.

25. In similar spirit, the Commission considers, essentially, that this last type of recognition does not fall within the scope of Article 10(2), because the expression 'course recognised as equivalent' used in that provision refers to courses other than university courses, rather than to courses taken in third countries, which may be recognised by the Member States on a case-by-case basis in accordance with Directive 2005/36/EC,[13] without such recognition being binding on the other Member States.

26. That is also my belief, for the following reasons.

27. The Court has consistently held that it follows from the need for a uniform application of EU law that, where an EU act makes no express reference to the laws of the Member States for the purpose of defining a particular concept, that concept must be given an independent interpretation, which the Court of Justice will arrive at after taking into account not only the wording of the provision in question but also its context and the objectives pursued by the rules of which it is part.[14]

28. *First of all*, as regards the *wording* of Article 10(2) of Regulation No 1223/2009, I would emphasise that that provision makes a clear distinction, in my eyes, between two categories of qualifications, evidenced by a diploma or other document, which enable individuals to take on the task of assessing the safety of a cosmetic product, as described in Part B of Annex I to that regulation. They are, *first*, the qualifications expressly mentioned by the EU legislature — using the words 'formal qualifications awarded on completion of a university course of theoretical and practical study in pharmacy, toxicology, medicine or a similar discipline' — and, *secondly*, qualifications not expressly described, but nevertheless accepted as valid, which require action on the part of the Member States in the form of a recognition of equivalence — in accordance with the words 'formal qualifications awarded on completion of … a course recognised as equivalent by a Member State'.

29. The question asked by the referring court arises from its doubt as to whether the second of those categories relates only to courses given outside the European Union, as FEBEA maintains.

11 I would reiterate that the contested order refers not only to diplomas issued in the other Member States of the European Union, but also to those issued in States party to the EEA and in the Swiss Confederation.

12 The description in the order for reference of the pleas put forward by the applicant in the main proceedings is brief, but additional information is given in the opinion of the rapporteur public of the Conseil d'État (Council of State), Mr Lessi, which is included in the case file sent to the Court (see, in particular, page 3 of that document).

13 Directive of the European Parliament and of the Council of 7 September 2005 on the recognition of professional qualifications (OJ 2005 L 255, p. 22).

14 See, inter alia, judgments of 9 March 2017, *Pula Parking* (C-551/15, EU:C:2017:193, paragraph 42), and of 27 September 2017, *Nintendo* (C-24/16 and C-25/16, EU:C:2017:724, paragraph 70).

30. In this connection, I find nothing in Regulation No 1223/2009 — or, more specifically, in Article 10(2) thereof — to suggest that the words 'a course recognised as equivalent' refer solely to courses taken in third countries. Indeed, the provisions in question make no express distinction by reference to the country in which the person entrusted with the assessment of the safety of a cosmetic product has studied. Yet, if the EU legislature had meant to address the specific issue of interaction with arrangements in third countries in this field it would probably have done so, in much clearer terms. [15]

31. Like the French Government and the Commission, I am of the opinion that it is clear from the very wording of Article 10(2), and from the logic which underlies that provision, that the words appearing at the end of that provision must be understood as referring to qualifications that are recognised as the equivalent of the first of the two abovementioned categories, that is to say, equivalent to qualifications awarded on completion of *a university course* of theoretical and practical study in pharmacy, toxicology, medicine or a similar discipline. [16] The Commission gives as an example, and a good one to my mind, the situation where a Member State might recognise the equivalence of a course followed not at a university, but in the context of technical training or higher medical education. The open-ended wording of that provision allows account to be taken both of the great diversity of the appropriate training that already exists in the European Union and of the way in which that training may yet develop.

32. *Secondly*, the interpretation which I propose is not contradicted, and is even corroborated, in my opinion, by aspects of the *history* of the provision in question.

33. Admittedly, FEBEA asserts that Regulation No 1223/2009 did not alter the rules which applied before it entered into force, which arose from Directive 76/768, such that Article 10(2) of the regulation, like the previously applicable law, again refers to diplomas obtained in one of the Member States as being the qualification required of persons entrusted with the assessment of the safety of cosmetic products. [17] It adds that there is no reason for any Member State to recognise the equivalence of qualifications obtained in the other Member States.

34. However, I consider that the content of the earlier rules tends instead to support the opposite argument, namely that Article 10(2) of Regulation No 1223/2009 does indeed cover courses given in the Member States, inasmuch as those earlier rules related exclusively to qualifications 'awarded by a competent authority in a Member State'. [18] In addition, it seems to me that, contrary to FEBEA's claim, when it recast Directive 76/768 with Regulation No 1223/2009, the legislature intended not to retain the provisions which had till then governed the assessment of the safety of cosmetic products, but instead to make substantial changes to them, precisely in order to fill the lacunae in the directive in this regard. [19]

15 As is the case with the provisions of the regulation relating to testing on animals (see recital 45, Article 11(2) and point 3 of Article 35).

16 The Commission emphasises that the EU legislature thus set out the requirements regarding both the level and the nature of the qualifications to which the first category relates.

17 FEBEA states that, in accordance with Article 7a(1)(e) of Directive 76/768, which refers to Article 1 of Council Directive 89/48/EEC of 21 December 1988 on a general system for the recognition of higher-education diplomas awarded on completion of professional education and training of at least three years' duration (OJ 1989 L 19, p. 16), it was necessary for relevant persons to possess either a diploma obtained in one of the Member States and attesting to education and training received mainly in the European Union or to have three years' professional experience certified by the Member State which has recognised a third-country diploma.

18 In accordance with the first and second indents of Article 1(a) of Directive 89/48, to which Article 7a(1)(e) of Directive 76/768 refers.

19 See the paragraphs of the explanatory memorandum for the proposal for a directive to which I refer in footnote 42 to this Opinion, as well as Ciarlo, G., 'Le règlement de l'Union européenne sur les "cosmétiques": 35 ans d'évolution vers une législation européenne plus claire et des produits plus sûrs', *Revue du droit de l'Union européenne*, 2013, No 4, pp. 713 to 717, and Reinhart, A., *KosmetikVO — Verordnung (EG) Nr. 1223/2009 über kosmetische Mittel — Kommentar*, C. H. Beck, Munich, 2014, p. 226 et seq., especially paragraphs 3, 9 and 13.

35. Furthermore, the French Government alleges, and with reason in my opinion, that it is clear from the legislative work which led to the adoption of Article 10(2) that the aim of that provision was to define the harmonised criteria governing the minimum qualifications by reference to which each Member State might determine what training must be completed in order to carry out, on its own territory, the assessment of the safety of cosmetic products, subject to the proviso of not laying down training requirements that could constitute discrimination between nationals of the Member States.

36. Indeed, I would point out that the Commission's proposal [20] stated, first, that the safety assessor must possess a formal qualification awarded on completion of a *university course of study* or of *a course recognised as equivalent* by the Member State concerned and, secondly, that that course must have lasted for a least three years and must have included both theoretical and practical study in at least one of the disciplines mentioned. The original formulation of those criteria, which is preserved, in substance, [21] in the final version of the provision in question, seems to me to support the interpretation that the recognition of equivalence referred to in Article 10(2) of Regulation No 1223/2009 relates to courses other than university courses, rather than specifically to courses given in third countries.

37. *Thirdly*, in so far as concerns the regulatory *context* of Article 10(2) of Regulation No 1223/2009, FEBEA argues, first, that the mutual recognition of diplomas obtained within the European Union has been harmonised, separately, by Article 53 TFEU and that only the recognition of diplomas obtained outside the European Union remains within the competence of the Member States and may therefore be left to the discretion of each of them. Nevertheless, I would emphasise that the objective of Regulation No 1223/2009 is, according to Article 1 thereof, not to govern the recognition of diplomas, so as to promote the free movement of persons, but to '[establish] rules to be complied with by any cosmetic product made available on the market', which is in the interests of the free movement of goods.

38. FEBEA also refers to the guidelines for the application of Annex I to Regulation No 1223/2009 set out in Commission Implementing Decision 2013/674, and argues that those guidelines specifically indicate that the recognition of equivalence mentioned in Article 10(2) of the regulation should apply solely to 'qualifications [obtained] in a third country'. [22]

39. On this point I would immediately state that, even assuming that that passage of the guidelines is to be understood in the way that FEBEA proposes, which the Commission disputed at the hearing, the fact remains that the Court's interpretation of Article 10(2), in the light of the wording, context and aims of that provision, will alone be binding. [23]

40. Moreover, the Commission has argued in its pleading that the passage in question does not contradict its contention in the present case that the recognition of courses given in third countries is not governed by Article 10(2) of Regulation No 1223/2009. It has stated that it is necessary, in this regard, to take into consideration the provisions of Directive 2005/36 on the recognition of professional qualifications, [24] which the French Government too has argued.

20 Article 7(2) of the proposal for a regulation dated 5 February 2008 (COM(2008) 49 final, p. 27) was worded as follows: 'the cosmetic product safety assessment, as set out in Part B of Annex I shall be carried out by a person in possession of a diploma, certificate or other evidence of formal qualifications awarded on completion of a university course of study, or a course recognised as equivalent by a Member State, extending over a period of at least three years of theoretical and practical study in pharmacy, toxicology, medicine or a similar discipline.'

21 As regards the elimination of the proposed requirement concerning the duration of the course, see point 61 of this Opinion.

22 See the second paragraph of the extract set out in point 11 of this Opinion.

23 See, by analogy, judgment of 6 September 2012, *Chemische Fabrik Kreussler* (C-308/11, EU:C:2012:548, paragraph 22 et seq.).

24 Directive of the European Parliament and of the Council of 7 September 2005 (OJ 2005 L 255, p. 22), which repealed Directive 89/48, cited in footnote 17 to this Opinion. The arrangements laid down by Directive 2005/36, which apply as between the Member States of the European Union, have been extended to the other countries of the EEA and to the Swiss Confederation.

41. I note that, under Article 21 of Directive 2005/36, the evidence of certain formal qualifications issued by the competent bodies of a Member State enjoys automatic recognition in the other Member States, provided that the qualifications in question satisfy the minimum training conditions laid down in a harmonised manner by that directive.[25] Included among those professional qualifications are the qualifications of doctors and pharmacists, which are also mentioned in Article 10(2) of Regulation No 1223/2009 within the first category of qualifications required of persons entrusted with the assessment of the safety of cosmetic products.[26]

42. In so far as concerns evidence of qualifications issued in third countries, it is clear from recital 10[27] and Article 2(2)[28] of Directive 2005/36 that that directive leaves it to each Member State to recognise, in accordance with its own national rules, professional qualifications obtained outside the European Union by third-country nationals or by nationals of another Member State, subject to compliance with the minimum training requirements for certain professions. As the Commission emphasises, that is merely an option, not an obligation, and any such recognition is not binding on the other Member States.[29] The French Government therefore argues, rightly in my view, that Directive 2005/36 is not meant to regulate the recognition of qualifications obtained in third countries, which is a matter that falls within the competence of the Member States, subject to the observance of certain minimum requirements, and that that logic should be applied, by analogy, to the qualifications within the second of the categories referred to in Article 10(2) of Regulation No 1223/2009.[30]

43. *Fourthly*, as regards the general *objectives* of Regulation No 1223/2009, I would point out that they are to ensure the functioning of the internal market and a high level of protection of human health,[31] in particular, by clarifying the requirements relating to the assessment of the safety of cosmetic products.[32] In this regard, the Court of Justice has already highlighted the fact that 'it is clear from Articles 3, 10 and 11 of that regulation that [a cosmetic] product is to be safe for human health, that its safety must be assessed on the basis of the relevant information and that the safety report must be drafted and included in the [relevant] cosmetic product information file'.[33]

44. As regards the specific objectives of Article 10(2) of the regulation, it seems to me that that provision is aimed at ensuring that the person entrusted with the assessment of the safety of a cosmetic product is appropriately and adequately qualified to carry out that task under the best possible conditions, so as to protect human health fully.[34]

25 Article 21 of Directive 2005/36 refers to the list of qualifications set out in Annex V to the directive.

26 See the two categories mentioned in point 28 of this Opinion.

27 According to recital 10 thereof, Directive 2005/36 'does not create an obstacle to the possibility of Member States recognising, in accordance with their rules, the *professional qualifications acquired outside the territory of the European Union* by *third country nationals*. All recognition should respect in any case minimum training conditions for certain professions' (my emphasis).

28 In accordance with Article 2(2) of Directive 2005/36, 'each Member State may permit *Member State nationals* in possession of evidence of *professional qualifications not obtained in a Member State* to pursue a regulated profession within the meaning of Article 3(1)(a) on its territory in accordance with its rules. In the case of professions covered by Title III, Chapter III [in which Article 21 appears], this initial recognition shall respect the minimum training conditions laid down in that Chapter' (my emphasis).

29 In its written and oral observations, the Commission has made particular reference to the judgment of 9 February 1994, *Haim* (C-319/92, EU:C:1994:47, paragraph 21), and to the Opinion of Advocate General Darmon in that case (C-319/92, EU:C:1993:895, points 16 to 18 and 32).

30 At the hearing the Commission stated that, if a Member State recognises that a person is sufficiently well qualified, as a result of the training which he has received in a third country, to assess the safety of cosmetic products, the other Member States remain free to authorise him to do that task also on their own territory, or not so to authorise him. The Commission added that a product whose safety has been assessed by such a person in one of the Member States may nevertheless be sold in the rest of the European Union. I do not share FEBEA's view that distinction, which the Commission acknowledges, is incoherent. Indeed, it follows from the difference between the respective competences of the European Union in the fields of professional qualifications and of the free movement of goods.

31 See Article 1 and recitals 3, 4 and 71 of Regulation No 1223/2009.

32 See also point 34 of this Opinion.

33 Judgment of 21 September 2016, *European Federation for Cosmetic Ingredients* (C-592/14, EU:C:2016:703, paragraph 33).

34 Indeed, the main objective of the EU legislature in adopting Regulation No 1223/2009 was to improve the safety of cosmetic products, principally by tightening the requirements relating to their assessment (see Ciarlo, G., op. cit. footnote 19 of this Opinion, and the first sentence in the extract from the guidelines set out in point 11 of this Opinion).

45. I am of the opinion that those objectives preclude the interpretation proposed by FEBEA. Indeed, as the French Government submits, given the objective of creating an internal market for cosmetic products which Regulation No 1223/2009 pursues,[35] it is unlikely that any of its provisions relates specifically to the recognition of courses given in third countries without that being expressly stated. It is also true that the definition by a Member State, in precise and exhaustive terms, of the courses which it recognises as equivalent to those cited in Article 10(2) will assist in the creation of an internal market for cosmetic products, since it will facilitate the taking up of the activity of assessing the safety of cosmetic products by nationals of the other Member States who have one of the qualifications recognised as equivalent.[36]

46. Furthermore, I agree with the French Government's view that, in order to ensure a high level of protection of human health, safety assessment must be carried out only by persons who can show that they have the competence necessary to guarantee that both the final product and the substances used in are harmless, and it is for the Member States to verify that competence before allowing individuals to carry out that activity on their territory. That, to my mind, is the reason why Article 10(2) permits every Member State to determine the courses which it regards as equivalent to the university courses that are expressly mentioned by the EU legislature in that provision and which lead to automatic recognition as an adequate qualification.

47. Consequently, I propose that the answer to the first question referred for a preliminary ruling should be that Article 10(2) of Regulation No 1223/2009 is to be interpreted in the sense that the concept of a 'course recognised as equivalent' used in that provision relates to the recognition of courses other than university courses, and not specifically of courses given in third countries.

B. Whether the Member States may determine the disciplines that are 'similar' within the meaning of Article 10(2) of Regulation No 1223/2009 (the second and third questions)

48. By its second and third questions, which, in my view, it is appropriate to consider together, the referring court asks the Court of Justice whether the Member States are competent to determine the disciplines that are considered to be 'similar' to pharmacy, toxicology or medicine, within the meaning of Article 10(2) of Regulation No 1223/2009 and, if they are, according to what criteria may the competent authorities of Member States identify such similar disciplines.

49. According to FEBEA, Article 10(2) confers no competence on the Member States exhaustively to define the disciplines that may be considered to be similar to pharmacy, toxicology or medicine.[37] It maintains that the contested order creates confusion that is contrary to EU law, inasmuch as it is clear from the wording of Article 10(2) that the power to recognise equivalence which is expressly conferred on the Member States relates solely to 'courses', and not to 'disciplines'. Despite the fact that FEBEA accordingly proposes that the second question for a preliminary ruling be answered in the negative, it invites the Court to rule on the third question — which is submitted only if the second is answered in the affirmative — and to clarify the criteria by which a discipline may be considered to be 'similar' within the meaning of that provision.[38]

35 See, in addition to the provisions mentioned in footnote 31 to this Opinion, the fourth paragraph of the explanatory memorandum to the proposal for a regulation (COM(2008) 49, p. 4).

36 The French Government argues, rightly in my view, that the clarification provided in this regard by national provisions of general application, such as those of the contested order, helps to remove interpretative difficulties for actors in the cosmetics sector, for the other Member States and for the market supervisory authorities.

37 FEDEA considers that Member States may merely give an indicative list of such similar disciplines.

38 FEBEA argues that there is clearly an interest in these criteria being specified, so that interpretation by the various Member States is harmonised. On this point, see point 64 et seq. of this Opinion.

50. The French Government, on the other hand, alleges that paragraph 2 of Article 10 of Regulation No 1223/2009 authorises the Member States, when recognising courses as equivalent to those mentioned in that paragraph, to decide that a discipline is similar to pharmacy, toxicology or medicine, basing that decision on the knowledge that is covered by the discipline in question. Similarly, the Commission considers that the Member States are entitled to determine which disciplines are 'similar' within the meaning of Article 10(2) as well as the level of qualification required, provided that they have regard both to the objectives of that provision and to those pursued by Regulation No 1223/2009.

51. That is also my view, for the reasons which I shall set out below, which follow the rules of interpretation of EU law that have been repeatedly stated by the Court of Justice. [39]

52. *First of all*, I would observe that the *wording* of the provisions of Regulation No 1223/2009, and more specifically of Article 10 thereof, does not offer any guidance that is immediately helpful in answering the second and third questions referred for a preliminary ruling, inasmuch as the concept of a discipline 'similar' to pharmacy, toxicology or medicine is in no way defined therein.

53. Admittedly, paragraph 2 of Article 10 draws a distinction between qualifications obtained on completion of a 'university course … in pharmacy, toxicology, medicine or a similar discipline' and qualifications obtained on completion of 'a course recognised as equivalent by a Member State'. Nevertheless, I do not think it can be inferred from the distinction drawn in the wording of that provision that the Member States have no residual competence [40] to identify the disciplines which, in practice, may be considered to be 'similar' within the meaning of that provision.

54. *Secondly*, as regards the *history* of Article 10(2) of Regulation No 1223/2009, examining the legislative work which led to the adoption of that paragraph reveals nothing decisive, in my view.

55. I would observe that the form of words in question appeared in the Commission's initial proposal, but without any clarification as to what was meant by a discipline 'similar' to pharmacy, toxicology or medicine, either in the relevant passage of the text, [41] or in the explanatory memorandum to the proposal for a regulation. [42] The working paper which the Commission published at the same time as its proposal equally offers no clarification in this regard. [43] Similarly, the guidelines which the Commission drew up in 2013 for the application of Annex I to Regulation No 1223/2009 offer no precise description of this concept. [44]

56. I would emphasise that Directive 76/768, which Regulation No 1223/2009 recast, contained in Article 7a(1)(e) a form of words substantially the same as that used in Article 10(2) of the regulation, except that it included 'dermatology' [45] in addition to the three disciplines listed in the regulation. [46] The Commission stated at the hearing that the EU legislature had decided, during the course of the process of recasting directive 76/768, no longer to mention training in the field of dermatology simply in order to avoid a redundancy, since Directive 2005/36, adopted before Regulation No 1223/2009, had

39 See the case-law cited in connection with point 27 of this Opinion.

40 As regards the competence which Member States may have to supplement the content of a regulation, see point 58 et seq. of this Opinion.

41 See Article 7(2) of the proposal for a regulation, cited in footnote 20 of this Opinion.

42 The explanatory memorandum nevertheless stresses the importance of introducing 'clear minimum requirements for the cosmetics safety assessment' (COM(2008) 49 final, sections 3 and 6.2.1).

43 See the Commission staff working paper of 5 February 2008, *Impact assessment — Report on simplification of the 'Cosmetics Directive' — Directive 76/768/EEC*, p. 60, point 3, which emphasises the need to ensure that the cosmetic product safety assessor is sufficiently well qualified, without giving any further details in that regard.

44 See the extract from the guidelines set out in point 11 of this Opinion.

45 Point (e) provides that 'the qualified person or persons responsible for the assessment … must hold a diploma as defined in Article 1 of Directive 89/48/EEC in the field of pharmacy, toxicology, dermatology, medicine or a similar discipline'.

46 I would add that the Swedish version of the regulation also included dermatology in Article 10(2) until a corrigendum was made on 25 July 2017 (OJ 2017 L 193, p. 7).

classified that discipline among the 'courses in specialised medicine',[47] with the result that, from then on, the term 'medicine' used in the regulation encompassed dermatology. My analysis of the preparatory work for Directive 93/35/EEC,[48] which inserted Article 7a into Directive 76/768, has revealed nothing decisive that could assist the Court in ruling on the questions referred in the present case.[49]

57. *Thirdly*, as regards the *regulatory context* into which the specific requirements set out in Article 10(2) of Regulation No 1223/2009 fit, it may be observed that that instrument is intended to 'give [no] room for diverging transposition by Member States' and is aimed at 'comprehensively [harmonising] the rules in the [European Union] in order to achieve an internal market for cosmetic products', as is stated in recitals 2 and 4.

58. Nevertheless, I am of the opinion that that does not mean that the Member States do not have the power, or the duty even, in accordance with Article 291(1) TFEU and the principle of sincere cooperation laid down in Article 4(3) TEU,[50] to take national measures to supplement Regulation No 1223/2009 so as to enable it to be fully effective, provided that they observe the rules set out and have regard to the objectives fixed by the regulation.

59. As the French Government argues,[51] it is clear from the case-law of the Court of Justice that, where a provision of an EU legislative act, including one of a regulatory nature, calls for national implementing measures, the Member States must, in accordance with the abovementioned principle, take all appropriate measures, whether general or particular, to ensure the full and complete implementation of the provision in question. The Court has acknowledged that the Member States are to adopt such supplemental measures not only where the regulation in question expressly confers power on them to do so, leaving it to the national authorities to adopt the implementing rules,[52] but also where it proves necessary for them to take legislative action in order fully to satisfy their obligations under that regulation,[53] albeit that they must in no case jeopardise the scope and effectiveness of that act[54] or imperil its uniform application.[55]

60. In the present case, it may be observed that Regulation No 1223/2009 does not specify what is to be considered 'similar' to pharmacy, toxicology or medicine within the meaning of Article 10(2) of that regulation. The Commission infers from that, rightly in my view, that the Member States have a certain discretion in so far as concerns both the level of qualification required and the definition of the similar disciplines, provided that they have regard to the provisions and objectives of the regulation.

47 See Annex V ('Recognition on the basis of coordination of the minimum training conditions') to Directive 2005/36, Section V.1 ('Doctor of medicine'), point 5.1.3. The Commission has stated that the change in the wording of Article 10(2) of Regulation No 1223/2009 in no way altered the substance of that provision; nor was it the result of any wish on the part of the legislature to alter the list of minimum qualifications required.

48 Council Directive of 14 June 1993 amending for the sixth time Directive 76/768 (OJ 1993 L 151, p. 32).

49 The initial proposal which led to the adoption of Directive 93/35 merely required that the safety assessor should have received 'university training in the field of natural sciences' (see COM(90) 488 final, OJ 1991 C 52, p. 8), whereas the final version of the directive contained the list of disciplines set out in footnote 45 to this Opinion.

50 Article 291 TFEU provides that 'Member States shall adopt all measures of national law necessary to implement legally binding Union acts.'

51 With reference to the judgments of 20 October 1981, *Commission* v *Belgium* (137/80, EU:C:1981:237, paragraphs 8 and 9), and of 20 March 1986, *Commission* v *Netherlands* (72/85, EU:C:1986:144, paragraph 20).

52 See, in particular, judgments of 27 September 1979, *Eridania-Zuccherifici nazionali and Società italiana per l'industria degli zuccheri* (230/78, EU:C:1979:216, paragraphs 34 and 35, which states that 'there is no incompatibility between the direct applicability of a Community regulation and the exercise of the power conferred on a Member State to take implementing measures on the basis of that regulation'), and of 11 January 2001, *Monte Arcosu* (C-403/98, EU:C:2001:6, paragraph 26 et seq.).

53 See, in particular, judgments of 6 May 1982, *BayWa and Others* (146/81, 192/81 and 193/81, EU:C:1982:146, paragraph 20); of 21 September 1989, *Commission* v *Greece* (68/88, EU:C:1989:339, paragraph 23); and of 8 July 1999, *Nunes and de Matos* (C-186/98, EU:C:1999:376, paragraphs 9 to 14).

54 See judgments of 6 May 1982, *BayWa and Others* (146/81, 192/81 and 193/81, EU:C:1982:146, paragraph 29), and of 14 January 1993, *Lante* (C-190/91, EU:C:1993:11, paragraph 7 et seq.)

55 See, in particular, judgments of 11 February 1971, *Norddeutsches Vieh- und Fleischkontor* (39/70, EU:C:1971:16, paragraphs 4 and 5), and of 21 September 1983, *Deutsche Milchkontor and Others* (205/82 à 215/82, EU:C:1983:233, paragraph 17).

61. In so far as concerns the level of qualification required, I note that the specification of the duration of the training that was initially given in the Commission proposal that led to the adoption of Regulation No 1223/2009 [56] no longer appears in Article 10(2) of that regulation. It seems that the requirement of 'a period of at least three years of … study' was removed on account of concerns that such a level of qualification might be insufficient, which had been expressed during the negotiations. [57] That intentional omission on the legislature's part may, in my view, be made good by the Member States, provided that they observe the relevant requirements of EU law.

62. In so far as concerns the identification of the 'similar' disciplines to which Article 10(2) of Regulation No 1223/2009 refers, I share the French Government's view that, before recognising the equivalence of a course, as that provision expressly authorises them to do, the Member States must determine what the course in question is the equivalent of. That is to say, they must determine not only the appropriate level of qualification, but also the disciplines that must be mastered in order to carry out the task of assessing the safety of cosmetic products. Therefore, it is necessary, in order for that provision to be fully applied, for each Member State to identify the disciplines which it considers to be similar to pharmacy, toxicology or medicine, for the purposes of Regulation No 1223/2009, having regard to the objectives fixed by that regulation.

63. *Fourthly*, in light of the *objectives* of Regulation No 1223/2009, which I have already mentioned, [58] I consider, as do the French Government and the Commission, that, given the EU legislature's silence on the matter of the definition of 'similar' disciplines, the Member States may, and indeed must take all necessary measures to identify such disciplines, so that the regulation — which reserves competence to them to recognise equivalent courses — may be fully effective, albeit that the Member States must not exceed the discretion available to them and must therefore have regard to the objectives fixed by the regulation, in particular the objective of ensuring a high level of protection of human health.

64. *Finally*, the last question referred asks the Court to state what *criteria* the Member States must take into account in determining which disciplines are considered similar to pharmacy, toxicology or medicine, for the purposes of Article 10(2) of Regulation No 1223/2009.

65. I agree with the views consistently expressed in the observations submitted to the Court and think that, in order to establish whether a discipline is 'similar' to one of the three disciplines expressly mentioned in Article 10(2), the Member States must verify that it shares with one of those disciplines a common body of scientific knowledge that is indispensable in order to assess, with the greatest certainty possible, the safety of a cosmetic product, in so far as concerns not only its ingredients, but also the finished product itself. [59]

66. The objective of ensuring a high level of protection of human health which Regulation No 1223/2009 pursues cannot, in my view, be properly attained unless, as the French Government argues, that common body of scientific knowledge includes both knowledge of the human body and its pathologies and knowledge of the substances used in the manufacture of cosmetic products and their physical and chemical properties. [60] In addition, it is clear from the wording of Article 10(2) of the regulation that that knowledge must have been gained by theoretical study followed by practical application, inasmuch as that provision requires experience in both domains to have been acquired in the courses in pharmacy, toxicology and medicine.

56 See Article 7(2) of the Commission's proposal, cited in footnote 20.

57 Council working paper No 6972/09 of 26 February 2009 relating to the proposal for a regulation (p. 40, note 27) explains the removal of the stipulation thus: 'AT, DE emphasise need for a masters level of qualification'. See also note 1 *in fine* of the opinion of the rapporteur public of the Conseil d'État (Council of State) mentioned in footnote 12 to this Opinion.

58 See point 43 et seq. of this Opinion.

59 Article 19(1)(g) of the regulation, which defines the concept of 'ingredients', for the purposes of packaging, draws a distinction between the manufacturing phase and the end result. The same distinction is drawn in Article 10(1)(a), with regard to the safety assessment.

60 The concept of 'substance', for the purposes of Regulation No 1223/2009, is defined in Article 2(1)(b) of the regulation.

67. In its written and oral observations, FEBEA has maintained that ecotoxicology cannot be regarded as a similar discipline to pharmacy, toxicology or medicine, since it involves the study of the impact of chemical substances on ecosystems or on the biosphere in general, rather than on human health.[61] More specifically, it has asserted that, despite the similarity of their names, ecotoxicology and toxicology are two completely different specialisations[62] which lead to different university qualifications. The French Government disputed those allegations at the hearing,[63] adding that, even if ecotoxicology was not a 'similar discipline' within the meaning of Article 10(2), it could be 'recognised as equivalent' by the French Republic, as is permitted by the last phrase of that provision.

68. Admittedly, the Court of Justice must, in my opinion, give the referring court all the guidance it needs in order to decide the case before it. However, it is solely for the referring court to give a ruling on the substance,[64] and, in particular, on the question of whether, having regard to the criteria which the Court may set out in the judgment which it will deliver, it was right or wrong to mention ecotoxicology in the French order the purpose of which was to define 'the courses recognised as being equivalent to the diplomas in medicine, pharmacy or toxicology that are required of assessors of the safety of cosmetic products for human health'.[65]

69. Consequently, I propose that the answer to the second and third questions referred for a preliminary ruling should be that Article 10(2) of Regulation No 1223/2009 authorises the Member States to determine the disciplines that are considered to be 'similar' to pharmacy, toxicology or medicine, for the purposes of that provision, provided that they have regard to the objectives fixed by that regulation, which consist, in particular, of ensuring that persons entrusted with the assessment of the safety of cosmetic products have received training, both theoretical and practical, that substantially corresponds to at least one of the three disciplines mentioned and is such as to ensure a high level of protection of human health.

V. Conclusion

70. In light of the foregoing considerations, I propose that the Court answer the questions referred by the Conseil d'État (Council of State, France) for a preliminary ruling as follows:

(1) Article 10(2) of Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products is to be interpreted in the sense that the concept of a 'course recognised as equivalent' used in that provision relates to the recognition of courses other than university courses, and not specifically of courses given in third countries.

(2) Article 10(2) of Regulation No 1223/2009 authorises the Member States to determine the disciplines that are considered to be 'similar' to pharmacy, toxicology or medicine, for the purposes of that provision, provided that they have regard to the objectives fixed by that regulation, which consist, in particular, of ensuring that persons entrusted with the assessment of

61 In its pleading, FEBEA has argued that recital 5 of Regulation No 1223/2009 distinguishes the aim of the regulation from the assessment of environmental safety. It has also referred to a note prepared by the European Chemicals Agency (ECHA) on 27 October 2014, which it alleges draws a distinction between tests to verify the harmlessness of products to human health and the study of the effects of products on the environment (see the communiqué entitled '*Clarity on interface between REACH and the Cosmetics Regulation*' and the factsheet available at: https://echa.europa.eu/view-article/-/journal_content/title/clarity-on-interface-between-reach-and-the-cosmetics-regulation).

62 According to FEBEA, the job of a safety assessor may be done by a toxicologist because he has been trained to measure the harmfulness of substances to living organisms, whereas an ecotoxicologist can only assess how a substance interacts with the environment (for example, whether it breaks down on contact with bacteria).

63 The French Government replied that ecotoxicology arose as a branch of toxicology in the 1970s and that, in France, the statute setting out the nomenclature for masters degrees lists a common qualification in 'toxicology and ecotoxicology', rather than one degree in toxicology and another in ecotoxicology.

64 In accordance with the rules on the division of jurisdiction which apply to the procedure laid down by Article 267 TFEU providing for cooperation between national courts and the Court of Justice (see, in particular, judgment of 26 October 2017, *BB construct*, C-534/16, EU:C:2017:820, paragraph 25).

65 This aim was mentioned in point 13 of this Opinion.

the safety of cosmetic products have received training, both theoretical and practical, that substantially corresponds to at least one of the three disciplines mentioned and is such as to ensure a high level of protection of human health.