Case C-4/21

Request for a preliminary ruling

Date lodged:

4 January 2021

Referring court:

Conseil d'État (France)

Date of the decision to refer:

23 December 2020

Applicant:

Fédération des entreprises de la beauté

Defendant:

Agence nationale de sécurité du médicament et des produits de santé

CONSEIL D'ETAT

[…] **FRENCH REPUBLIC**

IN THE NAME OF THE FRENCH PEOPLE

FEDERATION DES ENTREPRISES DE LA BEAUTE

[…]

Decision of 23 December 2020

Having regard to the following procedure:

By an application, a reply and further pleadings registered on 8 April, 1 July, 23 September and 2 and 18 December 2019 […], the Fédération des entreprises de la beauté (Federation of Beauty Companies) claims that the Conseil d'État (Council of State, France) should:

(1) annul as *ultra vires* the decision of the Agence nationale de sécurité du médicament et des produits de santé (National Agency for the Safety of

Medicine and Health Products; 'the Agence') of 13 March 2019 laying down special conditions for the use of leave-on cosmetic products containing phenoxyethanol by the specification on their labels that they may not be used on the buttocks of children aged three or under;

(2) […] [claim in relation to costs]

It claims that:

– the decision at issue infringes Regulation No 1223/2009 of 30 November 2009 since it imposes, in a situation where the conditions for the application of the safeguard clause in Article 27 of that regulation are not met, a labelling obligation for which that regulation does not provide and which is thus contrary to Article 9 of that regulation; **[Or. 2]**

– it unlawfully uses the policing powers in health matters conferred on the Agence by Article L. 5312-1 of the code de la santé publique (Public Health Code) in that, on the one hand, it wrongly regards as satisfied the condition of danger to human health to which the use of those powers is subject and in that, on the other, the scope of the cosmetic products to which it applies is vitiated by a manifest error of assessment.

[…] The Agence contends that the application should be dismissed. It maintains that the pleas in law raised by the applicant are unfounded.

[…] [procedural matters]

Having regard to:

– the Treaty on the Functioning of the European Union, in particular Article 267 thereof;

– Regulation (EC) No 1223/2009 of 30 November 2009;

– the judgments of 9 March 1994, *TWD Textilwerke Deggendorf* (C-188/92), and of 22 October 2002, *National Farmers' Union* (C-241/01), of the Court of Justice of the European [Union];

– the Public Health Code;

– the code de justice administrative (Code of Administrative Justice) and Decree No 2020-1406 of 18 November 2020;

[…] [procedural matters]

Whereas:

1 On the one hand, under Article 1 of Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic

products, that 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*'. Recital 4 of that regulation states that it comprehensively harmonises the rules in the Community in order to achieve an internal market **[Or. 3]** for cosmetic products while ensuring a high level of protection of human health. On that basis, under the combined provisions of Article 14 of that regulation and Annex V thereto, cosmetic products may contain phenoxyethanol, classed as a preservative in point 29 of that annex, only if the concentration of that substance in the product does not exceed 1%, without any other restrictions related, inter alia, to age or the area of the body on which it is used.

2 On the other hand, under Article 9 of that regulation, '*Member States shall not, for reasons related to the requirements laid down in this regulation, refuse, prohibit or restrict the making available on the market of cosmetic products which comply with the requirements of this regulation.*' Article 27 of that regulation nevertheless contains a 'safeguard clause', pursuant to which, '*1. In the case of products meeting the requirements* [as to compliance incumbent on the responsible person], *where a competent authority ascertains, or has reasonable grounds for concern, that a cosmetic product or products made available on the market present or could present a serious risk to human health, it shall take all appropriate provisional measures in order to ensure that the product or products concerned are withdrawn, recalled or their availability is otherwise restricted. 2. The competent authority shall immediately communicate to the Commission and the competent authorities of the other Member States the measures taken and any supporting data. […] 3. The Commission shall determine, as soon as possible, whether the provisional measures referred to in paragraph 1 are justified or not. For that purpose it shall, whenever possible, consult the interested parties, the Member States and the SCCS. 4. Where the provisional measures are justified, Article 31(1)* [which provides for the possibility of amending the annexes to the regulation] *shall apply. 5. Where the provisional measures are not justified[,] the Commission shall inform the Member States thereof and the competent authority concerned shall repeal the provisional measures in question.*'

3 By a decision of 13 March 2019, which the Fédération des entreprises de la beauté is seeking to have annulled as *ultra vires*, the Agence, wishing to make use of that 'safeguard clause', laid down special conditions for the making available on the market of leave-on cosmetic products containing phenoxyethanol, by requiring, as a precautionary measure, pending the decision of the Commission, called upon to rule in the matter in accordance with Article 27 of Regulation (EC) No 1223/2009, that it be stated on the labels of those products, excluding deodorants, hair styling products and make-up, at the latest nine months from the date of the publication of that decision on the website of the Agence, that they may not be used on the buttocks of children aged three or under.

4 It is apparent from the documents in the case file that, following the communication to the Commission of the decision at issue, the Head of the

'Consumer, Environmental and Health Technologies' Unit of the Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs, by letter of 27 November 2019, indicated to the Chief Executive of the Agence that the measure taken, since it applied to a category of products, was not among the measures which could be taken on the basis of Article 27 of Regulation (EC) No 1223/2009, such that there was no legal basis for that measure in that article. The Chief Executive of the Agence replied to him by letter of 6 December 2019, refuting the analysis carried out in the letter of 27 November 2019 and concluding that he intended to maintain, as a precautionary measure, his decision of 13 March 2019, pending the decision of the Commission taken in accordance with the provisions of Article 27 of Regulation (EC) No 1223/2009. **[Or. 4]**

5 It is not disputed that the labelling required by the decision at issue constitutes a restriction on the making available on the market of leave-on cosmetic products containing phenoxyethanol which comply with the requirements of Regulation (EC) No 1223/2009, including as regards the maximum concentration of that substance. It follows that, regardless of the extent of the policing powers conferred on the Agence by Article L. 5312-1 of the Public Health Code in respect of the products falling within its competence and presenting a danger to human health or suspected of presenting such a danger, that decision, since it is contrary to Article 9 of Regulation (EC) No 1223/2009, can be taken, in the absence of any other legal basis capable of so permitting, without infringing that regulation only on the basis and under the conditions of Article 27 of that regulation.

6 In those circumstances, a decisive factor in the resolution of the dispute, first, is whether the letter of 27 November 2019 must be regarded as a measure which is preparatory to the decision by which the Commission determines whether a provisional measure is justified or not, on the basis of Article 27(3) of Regulation (EC) No 1223/2009, or as such a decision, expressing the final position of the European Commission. In view of the wording of that letter and the absence of any evidence showing that authority has been delegated to its signatory to take a decision on behalf of the Commission, that question presents serious difficulties. It is necessary, consequently, to refer it to the Court of Justice of the European Union under Article 267 of the Treaty on the Functioning of the European Union.

7 Second, should the letter of 27 November 2019 have to be regarded as a preparatory measure with no legal effect, it would be necessary to consider whether, when it is asked to rule on the legality of a provisional measure taken by a national authority on the basis of Article 27 of Regulation (EC) No 1223/2009, a national court may, pending determination by the Commission of whether that measure is justified or not, rule on its compliance with that article and, if so, to what extent and on which points, or whether, for as long as the Commission has not declared it to be unjustified, the provisional measure must be treated as compliant with that article. Should it be for the national court to determine whether the provisional measure is among the measures which a competent authority may take on the basis of Article 27 of the regulation, it would be necessary to ask whether that article must be interpreted as allowing provisional

measures to be taken which apply to a category of products containing the same substance, since it refers to the scenario where '*a cosmetic product or products made available on the market present or could present a serious risk to human health*', and, if the provisional measures are justified, as meaning that it is for the Commission, on the basis of Article 31(1) of the regulation, to amend Annexes II to VI to that regulation, which list the substances which are prohibited or subject to restrictions in all cosmetic products which may contain them. Those questions, which play a decisive role in the resolution of the dispute, present serious difficulties. It is necessary, consequently, to refer them also to the Court of Justice of the European Union pursuant to Article 267 of the Treaty on the Functioning of the European Union.

8 Third, should the letter of 27 November 2019 have to be regarded as a decision expressing the final position of the Commission on the provisional measure at issue, it would be necessary, first of all, to consider whether the validity of that decision may be contested before the national court. In accordance with the case-law arising from the judgment of 9 March 1994, *TWD Textilwerke Deggendorf* (C-188/92), of the Court of Justice of the European [Union] and illustrated, in particular, by that Court's judgment of 22 October 2002, **[Or. 5]** *National Farmers' Union* (C-241/01), a Member State which is a party to a dispute before a national court is not permitted to plead the unlawfulness of a decision of the European Commission addressed to it in respect of which it has not brought an action for annulment on the basis of Article 263 of the Treaty on the Functioning of the European Union. However, in the present case, on the one hand, the wording of the letter of 27 November 2019 suggested that it was merely a preparatory measure and, on the other, the Agence, the competent authority, to which the letter was addressed, had replied to it, expressing its disagreement and indicating that it was maintaining its provisional measure until the European Commission gave its final decision, and the European Commission did not express any further views thereafter. If the answer to that question were in the affirmative, it would be necessary to consider whether the letter of 27 November 2019 was signed by a member of staff to whom authority had been delegated to take the decision on behalf of the Commission and is valid inasmuch as it is based on the assertion that 'the safeguard clause mechanism laid down in Article 27 of Regulation (EC) No 1223/2009 on cosmetic products covers individual measures concerning cosmetic products made available on the market and not general measures which apply to a category of products containing a certain substance', in view of the interpretation which must be given to the provisions of that Article 27, combined with those of Article 31 of that regulation, referred to in paragraph 7. Those two questions, which play a decisive role in the resolution of the dispute, present serious difficulties. It is necessary, consequently, to refer them to the Court of Justice of the European Union under Article 267 of the Treaty on the Functioning of the European Union.

9 Next, should the letter of 27 November 2019 have to be regarded as binding on the Conseil d'État (Council of State), either because it is a decision of the European Commission which has become final since it has not been the subject of

an action for annulment, or because it is valid, it would be necessary to consider whether the provisional measure at issue must be regarded as contrary to Regulation (EC) No 1223/2009 from the outset or only as from the notification of that letter to the Agence, or even as from a reasonable period of time after that notification, intended to allow it to be repealed, in the light, also, of the uncertainty as to the significance of that letter and of the fact that the Commission did not reply to the Agence, which indicated that it would 'maintain, as a precautionary measure, its decision of 13 March 2019, pending the decision of the Commission taken in accordance with the provisions of Article 27 of Regulation (EC) No 1223/2009'. That question, which plays a decisive role in the resolution of the dispute, presents serious difficulties. It is necessary, consequently, to refer it to the Court of Justice of the European Union under Article 267 of the Treaty on the Functioning of the European Union.

10 […] [stay of proceedings]

DECIDES AS FOLLOWS:

Article 1: The proceedings brought by the Fédération des entreprises de la beauté shall be stayed until the Court of Justice of the European Union has ruled on the following questions: **[Or. 6]**

1. Must the letter of 27 November 2019 from the Head of the 'Consumer, Environmental and Health Technologies' Unit of the European Commission's Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs be regarded as a measure which is preparatory to the decision by which the Commission determines whether a provisional measure of a Member State is justified or not on the basis of Article 27(3) of Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products, in view of the wording of that letter and the absence of any evidence showing that authority has been delegated to the member of staff who signed it to take a decision on behalf of the Commission, or must it be regarded as such a decision, expressing the final position of the Commission?

2. Should the letter of 27 November 2019 have to be regarded as a measure which is preparatory to the decision by which the Commission determines whether a provisional measure of a Member State is justified or not on the basis of Article 27(3) of Regulation (EC) No 1223/2009, when a national court is asked to rule on the legality of a provisional measure taken by a national authority on the basis of Article 27(1) of that regulation, may that court, pending the Commission's reaching its decision, rule on that provisional measure's compliance with that article and, if so, to what extent and on which points, or must that court, for as long as the Commission has not declared it to be unjustified, treat the provisional measure as compliant with that article?

3. If the answer to the preceding question is in the affirmative, must Article 27 of Regulation (EC) No 1223/2009 be interpreted as allowing provisional measures to be taken which apply to a category of products containing the same substance?

4. Should the letter of 27 November 2019 have to be regarded as a decision expressing the final position of the Commission on the provisional measure at issue, may the validity of that decision be contested before the national court, even though it has not been the subject of an action for annulment on the basis of Article 263 of the Treaty on the Functioning of the European Union, in view of the fact that the wording of that letter suggested that it was merely a preparatory measure and that the Agence, to which that letter was addressed, replied to it, expressing its disagreement and indicating that it was maintaining its provisional measure until the Commission gave its final decision, and the Commission itself did not reply to that letter?

5. If the answer to the preceding question is in the affirmative, was the letter of 27 November 2019 signed by a member of staff to whom authority had been delegated to take the decision on behalf of the Commission and is it valid inasmuch as it is based on the assertion that the safeguard clause mechanism laid down in Article 27 of Regulation (EC) No 1223/2009 'covers individual measures concerning cosmetic products made available on the market and not general measures which apply to a category of products containing a certain substance', in view of the interpretation which must be given to the provisions of that article, combined with those of Article 31 of that regulation?

6. If the answer to the preceding question is in the affirmative, or if the letter of 27 November 2019 may no longer be contested as part of the present dispute, must the provisional measure taken on the basis of Article 27 of Regulation (EC) No 1223/2009 be regarded as contrary to that regulation from the outset or only as from the notification of that letter to the Agence, or even as from a reasonable period of time after that notification, intended to allow it to be repealed, in the light, also, of the uncertainty as to the significance of that letter and of the fact that the Commission did not reply to the Agence, which indicated that it would 'maintain, as a precautionary measure, its decision of 13 March 2019, pending the decision of the Commission taken in accordance with the provisions of Article 27 of Regulation (EC) No 1223/2009'?

[…] [notification to the parties]

[…] [procedural matters]