Reports of Cases

JUDGMENT OF THE COURT (Second Chamber)

15 September 2022 *

(Reference for a preliminary ruling – Approximation of laws – Cosmetic products – Regulation (EC) No 1223/2009 – Article 27 – Safeguard clause – Article 27(1) – Scope – Provisional national safeguard measures – General measure – Application to a category of cosmetic products containing the same substance – Individual measure – Application to an identified cosmetic product – Provisional national measure imposing certain labelling requirements on a category of leave-on products containing phenoxyethanol)

In Case C-4/21,

REQUEST for a preliminary ruling under Article 267 TFEU from the Conseil d'État (France), made by decision of 23 December 2020, received at the Court on 4 January 2021, in the proceedings

Fédération des entreprises de la beauté

v

Agence nationale de sécurité du médicament et des produits de santé (ANSM),

THE COURT (Second Chamber),

composed of A. Prechal, President of the Chamber, J. Passer, F. Biltgen, N. Wahl (Rapporteur) and M.L. Arastey Sahún, Judges,

Advocate General: M. Campos Sánchez-Bordona,

Registrar: M. Krausenböck, Administrator,

having regard to the written procedure and further to the hearing on 20 January 2022,

after considering the observations submitted on behalf of:

– the Fédération des entreprises de la beauté, by A. Bost and M. Ragot, avocats,

– the French Government, by G. Bain and T. Stéhelin, acting as Agents,

– the Greek Government, by V. Karra, I. Kotsoni and O. Patsopoulou, acting as Agents,

* Language of the case: French.

– the European Commission, by E. Sanfrutos Cano and F. Thiran, acting as Agents,

after hearing the Opinion of the Advocate General at the sitting on 24 March 2022,

gives the following

Judgment

1 This request for a preliminary ruling concerns the interpretation of Article 27 of Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products (OJ 2009 L 342, p. 59).

2 The request has been made in proceedings between the Fédération des entreprises de la beauté (Federation of Beauty Companies) ('the FEBEA') and the Agence nationale de sécurité du médicament et des produits de santé (National Agency for the Safety of Medicinal Products and Health Products; ANSM) concerning the application for annulment of the latter's decision imposing certain labelling requirements on a category of leave-on products containing phenoxyethanol.

Legal context

3 Recitals 3, 4, 16, 17 and 58 of Regulation No 1223/2009 state as follows:

'(3) This Regulation aims at simplifying procedures and streamlining terminology, thereby reducing administrative burden and ambiguities. Moreover, it strengthens certain elements of the regulatory framework for cosmetics, such as in-market control, with a view to ensuring a high level of protection of human health.

(4) This Regulation 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.

…

(16) To ensure their safety, cosmetic products placed on the market should be produced according to good manufacturing practice.

(17) For the purpose of effective market surveillance, a product information file should be made readily accessible, at one single address within the Community, to the competent authority of the Member State where the file is located.

…

(58) In order to address cosmetic products which, despite complying with the provisions of this Regulation, might endanger human health, a safeguard procedure should be introduced.'

4 Article 1 of that regulation provides:

'This 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.'

5 Article 2(1)(a) to (c) of that regulation sets out the following definitions:

'(a) "cosmetic product" means any substance or mixture intended to be placed in contact with the external parts of the human body (epidermis, hair system, nails, lips and external genital organs) or with the teeth and the mucous membranes of the oral cavity with a view exclusively or mainly to cleaning them, perfuming them, changing their appearance, protecting them, keeping them in good condition or correcting body odours;

(b) "substance" means a chemical element and its compounds in the natural state or obtained by any manufacturing process, including any additive necessary to preserve its stability and any impurity deriving from the process used but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition;

(c) "mixture" means a mixture or solution composed of two or more substances.'

6 Article 4 of that regulation, entitled 'Responsible person', is worded as follows:

'1. Only cosmetic products for which a legal or natural person is designated within the Community as "responsible person" shall be placed on the market.

2. For each cosmetic product placed on the market, the responsible person shall ensure compliance with the relevant obligations set out in this Regulation.

…'

7 Article 5 of Regulation No 1223/2009, entitled 'Obligations of responsible persons', provides:

'1. Responsible persons shall ensure compliance with Articles 3, 8, 10, 11, 12, 13, 14, 15, 16, 17, 18, Article 19(1),(2) and (5), as well as Articles 20, 21, 23 and 24.

2. Responsible persons who consider or have reason to believe that a cosmetic product which they have placed on the market is not in conformity with this Regulation shall immediately take the corrective measures necessary to bring that product into conformity, withdraw it or recall it, as appropriate.

Furthermore, where the cosmetic product presents a risk to human health, responsible persons shall immediately inform the competent national authorities of the Member States in which they made the product available and of the Member State in which the product information file is readily accessible, giving details, in particular, of the non-compliance and of the corrective measures taken.

3. Responsible persons shall cooperate with these authorities, at the request of the latter, on any action to eliminate the risks posed by cosmetic products which they have made available on the market. In particular, responsible persons shall, further to a reasoned request from a competent

national authority, provide it with all the information and documentation necessary to demonstrate the conformity of specific aspects of the product, in a language which can be easily understood by that authority.'

8 Article 6 of that regulation contains rules governing the obligations of distributors.

9 Article 8 of that regulation lays down rules on good manufacturing practice.

10 Under Article 9 of that regulation, entitled 'Free movement':

'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.'

11 Article 11 of that regulation, entitled 'Product information file', provides, in paragraphs 1 to 3:

'1. Where a cosmetic product is placed on the market, the responsible person shall keep an information file for it. The product information file shall be kept for a period of ten years following the date on which the last batch of the cosmetic product was placed on the market.

2. The product information file shall contain the following information and data which shall be updated as necessary:

(a) a description of the cosmetic product which enables the product information file to be clearly attributed to the cosmetic product;

(b) the cosmetic product safety report referred to in Article 10(1);

(c) a description of the method of manufacturing and a statement on compliance with good manufacturing practice referred to in Article 8;

(d) where justified by the nature or the effect of the cosmetic product, proof of the effect claimed for the cosmetic product;

(e) data on any animal testing performed by the manufacturer, his agents or suppliers, relating to the development or safety assessment of the cosmetic product or its ingredients, including any animal testing performed to meet the legislative or regulatory requirements of third countries.

3. The responsible person shall make the product information file readily accessible in electronic or other format at his address indicated on the label to the competent authority of the Member State in which the file is kept.

The information contained in the product information file shall be available in a language which can be easily understood by the competent authorities of the Member State.'

12 Article 13 of Regulation No 1223/2009, entitled 'Notification', states, in paragraphs 1 to 5 and 7:

'1. Prior to placing the cosmetic product on the market the responsible person shall submit, by electronic means, the following information to the [European] Commission:

(a) the category of cosmetic product and its name or names, enabling its specific identification;

(b) the name and address of the responsible person where the product information file is made readily accessible;

(c) the country of origin in the case of import;

(d) the Member State in which the cosmetic product is to be placed on the market;

(e) the contact details of a physical person to contact in the case of necessity;

(f) the presence of substances in the form of nanomaterials and:
(i) their identification including the chemical name (IUPAC) and other descriptors as specified in point 2 of the Preamble to Annexes II to VI to this Regulation;
(ii) the reasonably foreseeable exposure conditions;

(g) the name and the Chemicals Abstracts Service (CAS) or EC number of substances classified as carcinogenic, mutagenic or toxic for reproduction (CMR), of category 1A or 1B, under Part 3 of Annex VI to Regulation (EC) No 1272/2008 [of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ 2008 L 353, p. 1)];

(h) the frame formulation allowing for prompt and appropriate medical treatment in the event of difficulties.

The first subparagraph shall also apply to cosmetic products notified under [Council] Directive 76/768/EEC [of 27 July 1976 on the approximation of the laws of the Member States relating to cosmetic products (OJ 1976 L 262, p. 169)].

2. When the cosmetic product is placed on the market, the responsible person shall notify to the Commission the original labelling, and, where reasonably legible, a photograph of the corresponding packaging.

3. As from 11 July 2013, a distributor who makes available in a Member State a cosmetic product already placed on the market in another Member State and translates, on his own initiative, any element of the labelling of that product in order to comply with national law, shall submit, by electronic means, the following information to the Commission:

(a) the category of cosmetic product, its name in the Member State of dispatch and its name in the Member State in which it is made available, enabling its specific identification;

(b) the Member State in which the cosmetic product is made available;

(c) his name and address;

(d) the name and address of the responsible person where the product information file is made readily accessible.

4. Where a cosmetic product has been placed on the market before 11 July 2013 but is no longer placed on the market as from that date, and a distributor introduces that product in a Member State after that date, that distributor shall communicate the following to the responsible person:

(a) the category of cosmetic product, its name in the Member State of dispatch and its name in the Member State in which it is made available, enabling its specific identification;

(b) the Member State in which the cosmetic product is made available;

(c) his name and address.

On the basis of that communication, the responsible person shall submit to the Commission, by electronic means, the information referred to in paragraph 1 of this Article, where notifications according to Article 7(3) and Article 7a(4) of Directive 76/768/EEC have not been carried out in the Member State in which the cosmetic product is made available.

5. The Commission shall, without delay, make the information referred to in points (a) to (g) of paragraph 1, and in paragraphs 2 and 3 available electronically to all competent authorities.

That information may be used by competent authorities only for the purposes of market surveillance, market analysis, evaluation and consumer information in the context of Articles 25, 26 and 27.

…

7. Where any of the information set out in paragraphs 1, 3 and 4 changes, the responsible person or the distributor shall provide an update without delay.'

13 Article 14 of that regulation, entitled 'Restrictions for substances listed in the Annexes', provides, in paragraph 1:

'Without prejudice to Article 3, cosmetic products shall not contain any of the following:

(a) prohibited substances

– prohibited substances listed in Annex II;

(b) restricted substances

– restricted substances which are not used in accordance with the restrictions laid down in Annex III;

(c) colorants
(i) colorants other than those listed in Annex IV and colorants which are listed there but not used in accordance with the conditions laid down in that Annex, except for hair colouring products referred to in paragraph 2;

(ii) without prejudice to points (b), (d)(i) and (e)(i), substances which are listed in Annex IV but which are not intended to be used as colorants, and which are not used in accordance with the conditions laid down in that Annex;

(d) preservatives
(i) preservatives other than those listed in Annex V and preservatives which are listed there but not used in accordance with the conditions laid down in that Annex;
(ii) without prejudice to points (b), (c)(i) and (e)(i), substances listed in Annex V but which are not intended to be used as preservatives, and which are not used in accordance with the conditions laid down in that Annex;

(e) UV-filters
(i) UV-filters other than those listed in Annex VI and UV-filters which are listed there but not used in accordance with the conditions laid down in that Annex;
(ii) without prejudice to points (b), (c)(i) and (d)(i), substances listed in Annex VI but which are not intended to be used as UV-filters and which are not used in accordance with the conditions laid down in that Annex.'

14 The first paragraph of Article 22 of that regulation, entitled 'In-market control', provides:

'Member States shall monitor compliance with this Regulation via in-market controls of the cosmetic products made available on the market. They shall perform appropriate checks of cosmetic products and checks on the economic operators on an adequate scale, through the product information file and, where appropriate, physical and laboratory checks on the basis of adequate samples.'

15 Article 24 of the same regulation, entitled 'Information on substances', is worded as follows:

'In the event of serious doubt regarding the safety of any substance contained in cosmetic products, the competent authority of a Member State in which a product containing such a substance is made available on the market may by reasoned request require the responsible person to submit a list of all cosmetic products for which he is responsible and which contain this substance. The list shall indicate the concentration of this substance in the cosmetic products.

Competent authorities may use the information referred to in this Article for the purposes of in-market surveillance, market analysis, evaluation and consumer information in the context of Articles 25, 26 and 27.'

16 Under Article 25 of Regulation No 1223/2009, entitled 'Non-compliance by the responsible person':

'1. Without prejudice to paragraph 4, competent authorities shall require the responsible person to take all appropriate measures, including corrective actions bringing the cosmetic product into conformity, the withdrawal of the product from the market or its recall, within an expressly mentioned time limit, commensurate with the nature of the risk, where there is non-compliance with any of the following:

(a) the good manufacturing practice referred to in Article 8;

(b) the safety assessment referred to in Article 10;

(c) the requirements for the product information file referred to in Article 11;

(d) the provisions on sampling and analysis referred to in Article 12;

(e) the notification requirements referred to in Articles 13 and 16;

(f) the restrictions for substances referred to in Articles 14, 15 and 17;

(g) the animal testing requirements referred to in Article 18;

(h) the labelling requirements referred to in Article 19(1), (2), (5) and (6);

(i) the requirements related to product claims set out in Article 20;

(j) the access to information for the public referred to in Article 21;

(k) the communication of serious undesirable effects referred to in Article 23;

(l) the information requirements on substances referred to in Article 24.

…

3. The responsible person shall ensure that the measures referred to in paragraph 1 are taken in respect of all the products concerned which are made available on the market throughout the Community.

…'

17 Article 26 of that regulation, entitled 'Non-compliance by distributors', states:

'Competent authorities shall require distributors to take all appropriate measures, including corrective actions bringing the cosmetic product into conformity, the withdrawal of the product from the market or its recall, within a given reasonable time limit, commensurate with the nature of the risk, where there is non-compliance with obligations laid down in Article 6.'

18 Article 27 of that regulation, entitled 'Safeguard clause', provides:

'1. In the case of products meeting the requirements listed in Article 25(1), 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.

For the purposes of the first subparagraph, the information exchange system provided for in Article 12(1) of Directive 2001/95/EC [of the European Parliament and of the Council of 3 December 2001 on general product safety (OJ 2002 L 11, p. 4)] shall be used.

Article 12(2), (3) and (4) of Directive 2001/95/EC shall apply.

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 [Scientific Committee on Consumer Safety (SCCS)].

4. Where the provisional measures are justified, Article 31(1) 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.'

19 Article 28 of Regulation No 1223/2009, entitled 'Good administrative practices', provides:

'1. Any decision taken pursuant to Articles 25 and 27 shall state the exact grounds on which it is based. It shall be notified by the competent authority without delay to the responsible person, who shall at the same time be informed of the remedies available to him under the law of the Member State concerned and of the time limits to which remedies are subject.

2. Except in the case where immediate action is necessary for reasons of serious risk to human health, the responsible person shall have the opportunity to put forward his viewpoint before any decision is taken.

3. Where applicable, the provisions mentioned in paragraphs 1 and 2 shall apply with regard to the distributor for any decisions taken pursuant to Articles 26 and 27.'

20 Articles 29 and 30 of that regulation form Chapter IX thereof, relating to administrative cooperation, and establish, respectively, cooperation between the competent authorities of the Member States and with the Commission and cooperation regarding verification of product information.

21 Article 31(1) and (2) of that regulation, entitled 'Amendment of the Annexes', provides:

'1. Where there is a potential risk to human health, arising from the use of substances in cosmetic products, which needs to be addressed on a Community-wide basis, the Commission may, after consulting the SCCS, amend Annexes II to VI accordingly.

Those measures, designed to amend non-essential elements of this Regulation, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 32(3).

On imperative grounds of urgency, the Commission may use the urgency procedure referred to in Article 32(4).

2. The Commission may, after consulting the SCCS, amend Annexes III to VI and VIII for the purposes of adapting them to technical and scientific progress.

Those measures, designed to amend non-essential elements of this Regulation, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 32(3).'

22 Phenoxyethanol is classified at point 29 of Annex V to Regulation No 1223/2009, which establishes a list of preservatives allowed in cosmetic products and which requires that the concentration of that substance in ready-to-use cosmetic products be limited to 1% of the composition.

The dispute in the main proceedings and the questions referred for a preliminary ruling

23 By decision of 13 March 2019, the Director-General of the ANSM, seeking to implement the safeguard clause provided for in Article 27 of Regulation No 1223/2009, laid down specific conditions for the use of leave-on cosmetic products containing phenoxyethanol, relying, inter alia, on a risk assessment previously carried out by that authority ('the decision of 13 March 2019'). That decision required, as a precautionary measure, that the labelling of those products made available on the French market, with the exception of deodorants, hairdressing products and make-up products, and whatever their concentration of phenoxyethanol, should state, no later than nine months from the publication of that decision on that agency's website, that such products may not be used on the bottoms of children aged three years or less.

24 Following the communication of that decision to the Commission, 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 ('the letter of 27 November 2019'), informed the Director-General of the ANSM that the measure contained in the decision of 13 March 2019 was a measure of general application applying to a category of cosmetic products containing a certain substance and that, consequently, it could not be considered to be the implementation of the 'safeguard clause' in Article 27 of Regulation No 1223/2009. By letter of 6 December 2019, the Director-General of the ANSM replied that he intended to maintain, as a precautionary measure, his decision of 13 March 2019, pending the decision that the Commission was required to adopt in accordance with Article 27(3) of that regulation.

25 The FEBEA, the applicant in the main proceedings, brought an action before the referring court seeking annulment of the decision of 13 March 2019. It submits, in particular, that that decision infringes Regulation No 1223/2009, since it imposes, without the conditions for the application of the safeguard clause provided for in Article 27 of that regulation being met, a labelling requirement for which that regulation does not provide and which is thus contrary to the principle of the free movement of cosmetic products laid down in Article 9 of that regulation.

26 The referring court observes that the labelling imposed by the decision of 13 March 2019 constitutes a restriction on the placing on the market of leave-on cosmetic products containing phenoxyethanol which satisfy the requirements of Regulation No 1223/2009. In so far as such a restriction is contrary to Article 9 of that regulation, that court considers that its basis can be found only in Article 27 of that regulation.

27 Furthermore, the referring court seeks to determine whether or not the letter of 27 November 2019 constitutes a measure which is preparatory to the decision by which the Commission must determine whether or not a provisional measure is justified under Article 27(3) of Regulation No 1223/2009. If that were the case, the referring court seeks to ascertain whether, pending the Commission's decision, the national court may rule on the lawfulness of a provisional measure and, if so, whether Article 27(1) of that regulation permits the adoption of provisional measures applying to a category of products containing the same

substance. If the letter of 27 November 2019 were to be classified as a 'final decision' of the Commission, the referring court asks whether, and if so under what conditions, the validity of such a decision could be challenged before the national court.

28 In those circumstances, the Conseil d'État (Council of State, France) decided to stay the proceedings and to refer the following questions to the Court for a preliminary ruling:

'(1) Must the letter of 27 November 2019 from the Head of the "Consumer, Environmental and Health Technologies" Unit of the [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 No 1223/2009], 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 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 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 [TFEU], in view of the fact that the wording of that letter suggested that it was merely a preparatory measure and that [the ANSM], 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 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 No 1223/2009] be regarded as contrary to that regulation from the outset or only as from the notification of that letter to [the ANSM], 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 ANSM], 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 No 1223/2009]"?'

Consideration of the questions referred

The third question

29 By its third question, which it is appropriate to examine in the first place, the referring court asks, in essence, whether Article 27(1) of Regulation No 1223/2009 must be interpreted as allowing the competent authority of a Member State to adopt general provisional measures applying to a category of products containing the same substance.

30 As a preliminary point, it should be noted that the concept of 'cosmetic product' is defined in Article 2(1)(a) of Regulation No 1223/2009 as 'any substance or mixture intended to be placed in contact with the external parts of the human body (epidermis, hair system, nails, lips and external genital organs) or with the teeth and the mucous membranes of the oral cavity with a view exclusively or mainly to cleaning them, perfuming them, changing their appearance, protecting them, keeping them in good condition or correcting body odours'.

31 Furthermore, the preamble to Annexes II to VI to that regulation, on the one hand, draws a distinction between rinse-off and leave-on products and, on the other hand, identifies and defines eight purposes for cosmetic products, namely hair products, skin products, lipstick products, face products, nail products, oral products, products applied on mucous membranes and eye products.

32 It must therefore be held that a cosmetic product is not limited to the substances of which it is composed, but is characterised, beyond those substances, by the category of cosmetic products to which it belongs and by the use for which it is intended.

33 It should also be noted that it follows from a reading of the provisions of Regulation No 1223/2009 as a whole, in particular its Article 1, read in the light of recitals 3 and 4 thereof, that that regulation has as its objective an exhaustive harmonisation of the rules in force in the European Union which is aimed at establishing an internal market for cosmetic products while, at the same time, ensuring a high level of protection for human health (judgment of 17 December 2020, *A.M. (Labelling of cosmetic products)*, C-667/19, EU:C:2020:1039, paragraph 27).

34 To that end, the EU legislature introduced, in Regulation No 1223/2009, requirements relating, inter alia, to the safety of cosmetic products for human health with which such products must comply, so that, in accordance with Article 9 thereof, Member States may not, for reasons related to the requirements laid down in that regulation, refuse, prohibit or restrict the making available on the market of cosmetic products which comply with the requirements thereof.

35 Thus, by means of the requirements set out in Regulation No 1223/2009, the EU legislature, without introducing a system of prior authorisation for cosmetic products, has reconciled the objective of free movement of cosmetic products with that of protecting human health.

36 In particular, it should be noted that, in order to ensure that high level of protection, any cosmetic product placed on the EU market must be safe for human health, its safety must be assessed on the basis of the relevant information and a safety report must be drafted and included in the cosmetic product information file (judgment of 12 April 2018, *Fédération des entreprises de la beauté*, C-13/17, EU:C:2018:246, paragraph 24 and the case-law cited).

37 It follows that any placement of a cosmetic product on the EU market, and its free movement on that market, presupposes that the safety of that product for human health has been assessed in accordance with the detailed rules specifically defined by Regulation No 1223/2009 (judgment of 12 April 2018, *Fédération des entreprises de la beauté*, C-13/17, EU:C:2018:246, paragraph 25).

38 Those requirements include, in particular, compliance with good manufacturing practices referred to in Article 8 of that regulation and compliance with the restrictions and prohibitions on the composition of cosmetic products set out in Article 14 of that regulation.

39 It is apparent from Article 14 that, first, cosmetic products may not contain the prohibited substances listed in Annex II to that regulation, colorants, preservatives and UV-filters other than those listed respectively in Annexes IV, V and VI to that regulation and, second, that those products may not contain substances, colorants, preservatives being subject to restrictions which are not used in compliance with the restrictions set out, respectively, in Annexes III to VI to Regulation No 1223/2009.

40 In order to draw up the lists contained in those annexes and to adapt them to technical and scientific progress in the context of the entry into force and then the application of Directive 76/768 and, subsequently, of Regulation No 1223/2009, substances are subject to an assessment.

41 Furthermore, in order to ensure compliance with the requirements laid down by Regulation No 1223/2009 for the purposes, inter alia, of the protection of human health, the EU legislature has, on the one hand, established mechanisms for assessing the safety of cosmetic products made available on the market and, on the other hand, provided for two mechanisms enabling Member States to adopt measures in the event of a risk posed by cosmetic products.

42 Thus, under Articles 4 and 5 of that regulation, in order, inter alia, to ensure compliance with the safety assessment requirements for cosmetic products, a person responsible for ensuring compliance with the applicable obligations laid down in that regulation must be designated for each cosmetic product made available on the market.

43 Furthermore, Articles 25 and 26 of that regulation authorise Member States to require the responsible person and distributors respectively to take all appropriate measures, including corrective action bringing a cosmetic product into conformity, the withdrawal of the product from the market or its recall, within a reasonable period, commensurate with the nature of the risk, where there is non-compliance with the requirements of that regulation which are incumbent on the responsible person and the obligations incumbent on distributors.

44 Article 27(1) of Regulation No 1223/2009, the interpretation of which is sought by the referring court, provides that Member States are to adopt, in the case of products meeting the requirements listed in Article 25(1) of that regulation, and where they ascertain, or have 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, all appropriate provisional measures in order to ensure that the product or products concerned are withdrawn, recalled or that their availability is otherwise restricted.

45 The FEBEA and the Commission maintain that that provision permits only the adoption of individual provisional measures concerning a specific product made available on the market. On the other hand, the French and Greek Governments consider, relying in particular on the link between cosmetic products and substances established by Regulation No 1223/2009 and on the objective of protecting human health pursued by that regulation, that that provision must be interpreted as permitting the adoption of general provisional measures applying to a category of products containing the same substance.

46 Article 27(1) of that regulation cannot be interpreted as authorising Member States to adopt general provisional measures applying, not to one or more individually identified cosmetic products, but to a category of products containing the same substance.

47 In that regard, it should be borne in mind that, for the purposes of interpreting a provision of EU law the terms of which do not expressly refer to national law, it is necessary, in accordance with the settled case-law of the Court, to consider not only its wording but also its context and the objectives pursued by the rules of which it is part (see, to that effect, judgment of 17 December 2020, *A.M. (Labelling of cosmetic products)*, C-667/19, EU:C:2020:1039, paragraph 22 and the case-law cited).

48 In the first place, as regards the wording of Article 27(1) of that regulation, it must be stated that it refers only to cosmetic products to the exclusion of substances of which they are composed.

49 It is true, as the French Government submits, that Article 2(1)(a) of Regulation No 1223/2009, by defining the concept of 'cosmetic product' as 'any substance or mixture intended to be placed in contact with the external parts of the human body', establishes a link between the concept of 'cosmetic product' and that of 'substance'.

50 However, as has already been held in paragraphs 30 to 32 above, given the system established by that regulation, a cosmetic product is identified by its name and characterised not only by the substances of which it is composed, but also by the category of cosmetic products to which it belongs and by its intended use.

51 In the second place, the context of Article 27(1) of Regulation No 1223/2009 supports the interpretation of that provision according to which it does not authorise the competent authorities of the Member States to adopt general provisional measures applying to a category of products containing the same substance.

52 First, the scope of the possibility for the competent authorities of the Member States to adopt provisional safeguard measures provided for in that provision must be determined in the light of the system for regulating the use of substances in cosmetic products established in Articles 14 and 31 of that regulation.

53 By prohibiting the use of certain substances and by specifically regulating the use of substances authorised in the annexes to Regulation No 1223/2009, by indicating the type of products or parts of the body to which the substance is intended and the maximum concentration of the substance in ready-to-use preparations, the EU legislature has exhaustively harmonised the use of substances in cosmetic products at EU level. In drawing up the annexes to that regulation, the EU legislature also limited the scope of Article 27(1) of that regulation. A 'serious risk to human health' within the meaning of that provision concerns, as a result of the prohibitions and restrictions laid down in Annexes II to VI to that regulation, only certain cosmetic products containing a substance in a certain concentration, intended for a particular use or part of the body and, where appropriate, for a defined and identified group of consumers.

54 That interpretation is not called into question by the fact that, according to Article 27(4) of Regulation No 1223/2009, where the provisional measures are justified, Article 31(1) of that regulation is to apply, so that the Commission may, after consulting the SCCS, amend Annexes II to VI to that regulation accordingly.

55 That mechanism reflects the distinction drawn by Regulation No 1223/2009 between regulating the market in cosmetic products and surveillance of that market.

56 It follows from Chapter VII of that regulation that surveillance of the market in cosmetic products is a matter for the Member States. They are required, under Article 22 of that regulation, to carry out controls on cosmetic products made available on the market and, in accordance with Articles 23 and 24 of that regulation, to collect information on such products.

57 Those controls and information may, as is apparent from Article 23(5) and the second paragraph of Article 24 of Regulation No 1223/2009, be used inter alia for the purposes of in-market surveillance in the context of Articles 25 to 27 of that regulation.

58 Consequently, the possibility for the competent authorities of the Member States to adopt provisional safeguard measures provided for in Article 27(1) of that regulation is an instrument of the surveillance of the market in cosmetic products.

59 By contrast, the harmonisation of the rules governing the use of substances in cosmetic products established in Annexes II to VI to Regulation No 1223/2009 falls within the scope of the regulation of the market, which is a matter for the Commission.

60 Thus, the link established in Article 27(4) of Regulation No 1223/2009 between cosmetic products and substances reflects the fact that, as a general rule, the potential danger posed by a substance is detected by the Member States through the monitoring of cosmetic products and that it is remedied, at EU level, by the amendment of the relevant annex to that regulation.

61 It follows that, although the competent authorities of the Member States may, as part of their task of market surveillance, adopt, on the basis of Article 27(1) of Regulation No 1223/2009, individual provisional measures concerning one or more specific products made available on the market, they are not entitled unilaterally to call into question the exhaustive harmonisation provided for by that regulation, by, as in the present case, advising against certain specific uses of a substance or by prohibiting, even temporarily, the use of a substance authorised by that regulation.

62 Secondly, the interpretation of Article 27(1) of Regulation No 1223/2009 must not undermine the coherence of the system provided for by that regulation.

63 In that regard, it must be borne in mind that, according to Article 28(1) of that regulation, any decision taken pursuant to Articles 25 and 27 of that regulation is to be notified without delay by the competent authority to the responsible person. In addition, under Article 4 of Regulation No 1223/2009, a responsible person is responsible for a cosmetic product, and not for a substance.

64 It would be inconsistent to authorise, in the interests of speed, the competent authorities of the Member States to adopt general provisional measures applicable to a category of cosmetic products containing the same substance while requiring them to notify the person responsible for the cosmetic product.

65 In the third place, to interpret Article 27(1) of Regulation No 1223/2009 as meaning that the competent authorities of the Member States are empowered to adopt general provisional measures applying to a category of products containing the same substance would undermine the functioning of the internal market pursued by that regulation.

66 In that regard, it must be borne in mind that that regulation is intended comprehensively to harmonise the rules in the European Union in order to achieve an internal market for cosmetic products while ensuring a high level of protection of human health.

67 As is apparent from paragraphs 30 to 44 of the present judgment, compliance with and reconciling those two objectives are ensured by the requirements, in particular in terms of safety and composition, which cosmetic products must meet.

68 Thus, by drawing up lists of substances whose use in cosmetic products is prohibited and by regulating the use of certain substances in such products, Regulation No 1223/2009 seeks to ensure, at EU level, that cosmetic products which comply with Regulation No 1223/2009 and are made available on the market do not contain substances which are found to be dangerous and therefore ensures a high level of protection of human health.

69 Furthermore, since the use in cosmetic products of authorised substances is strictly regulated in the annexes to Regulation No 1223/2009, by indicating the type of products or parts of the body for which the substance is intended and the maximum concentration of that substance in ready-to-use preparations, cosmetic products which comply with the requirements of Article 25(1) of that regulation can present a ‘serious risk to human health’ within the meaning of Article 27(1) of that regulation only in defined circumstances.

70 In that context, in order to reconcile the two objectives pursued by Regulation No 1223/2009 and taking account of the safeguards established by the lists drawn up in Annexes II to VI to that regulation, the scope of Article 27(1) of that regulation is necessarily limited, so that it does not authorise disproportionate infringements, even temporary, of the free movement of cosmetic products and can therefore relate only to specific cosmetic products covered individually.

71 The practical difficulties relied on by the French Government do not call into question that interpretation of Article 27(1).

72 First, it must be stated that the concerns of that government as regards the number of products which may be affected by a provisional measure adopted on the basis of Article 27(1) of Regulation No 1223/2009 are unfounded. As is apparent from paragraph 69 above, the serious risk to human health which may lead to the adoption by the competent authority of a Member State of a provisional safeguard measure under Article 27(1) of that regulation concerns, as a matter of

principle, only a very limited number of cosmetic products falling within a certain category of cosmetic products intended for a particular use and for certain parts of the body and including a substance in an amount equal to a certain concentration. Therefore, interpreting that provision as permitting only the adoption of individual provisional measures concerning one or more specific products made available on the market does not have the effect of obliging the national authorities to adopt a disproportionate number of provisional measures and does not generate an administrative overload for those authorities or for the Commission.

73 Secondly, even though Regulation No 1223/2009 does not provide for a mechanism of prior authorisation for the marketing of cosmetic products, the mechanisms provided for by that regulation allow the competent authorities of the Member States quickly to identify products intended for the same use and containing a certain substance and to adopt, in accordance with Article 27(1) of Regulation No 1223/2009, appropriate provisional measures to ensure that the product or products concerned are withdrawn, recalled or that their availability is otherwise restricted.

74 Regulation No 1223/2009 establishes mechanisms for centralisation and exchange of information relating to cosmetic products ensuring, through administrative cooperation between the competent authorities of the Member States and with the Commission, that that information is rapidly and easily accessible to the competent national authorities.

75 Thus, those authorities are, in accordance with Article 30 of that regulation, required to cooperate in order to ensure verification of the information file provided, pursuant to Article 11 of that regulation, for each cosmetic product made available on the market by the responsible person. Furthermore, the information referred to in Article 13 of Regulation No 1223/2009, which is transmitted to the Commission and centralised by it, must, in the context of the cooperation established by Article 29 of that regulation, be exchanged in order to be used, if necessary, for the purposes of market surveillance in the context of Articles 25 to 27 of that regulation.

76 Moreover, the competent authorities of the Member States in which a product containing a substance is made available on the market may, on the basis of Article 24 of Regulation No 1223/2009, require the responsible person to submit a list of all cosmetic products for which he or she is responsible and which contain that substance.

77 In the light of all the foregoing considerations, the answer to the third question is that Article 27(1) of Regulation No 1223/2009 must be interpreted as not allowing the competent authority of a Member State to adopt general provisional measures applying to a category of products containing the same substance.

The first, second and fourth to sixth questions

78 By its first and second questions, the referring court asks the Court, in essence, what classification should be given to the letter of 27 November 2019 and, in the event that that letter is classified as a ‘preparatory measure’ for the decision by which the Commission determines whether or not a provisional measure of a Member State is justified on the basis of Article 27(3) of Regulation No 1223/2009 and that, consequently, the Commission has not adopted a final decision, what the arrangements are for the national court to review such a provisional measure.

79 By its fourth to sixth questions, in the event that the letter of 27 November 2019 is classified as a 'Commission decision' under Article 27(3) of Regulation No 1223/2009, the referring court asks about the conditions for challenging the legality of that decision and the consequences thereof for the validity of the provisional national measure.

80 Those questions are based on the premiss that Article 27 of Regulation No 1223/2009 is applicable in the context of the dispute in the main proceedings. It follows from the answer to the third question referred that Article 27(1) of Regulation No 1223/2009 does not allow the competent authority of a Member State to adopt general provisional measures applying to a category of products containing the same substance, with the result that the decision of 13 March 2019 does not fall within that provision.

81 It follows that, in view of the answer given to the third question, it is not necessary to answer the first, second, and fourth to sixth questions.

Costs

82 Since these proceedings are, for the parties to the main proceedings, a step in the action pending before the national court, the decision on costs is a matter for that court. Costs incurred in submitting observations to the Court, other than the costs of those parties, are not recoverable.

On those grounds, the Court (Second Chamber) hereby rules:

Article 27(1) of Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products must be interpreted as not allowing the competent authority of a Member State to adopt general provisional measures applying to a category of products containing the same substance.

[Signatures]