JUDGMENT OF THE COURT (Second Chamber)

2 June 2022 (*)

(Reference for a preliminary ruling – Directive 87/357/EEC – Article 1(2) – Scope – Non-food products that may be confused with foodstuffs – Concept – Risk of suffocation, poisoning, or the perforation or obstruction of the digestive tract – No presumption of danger – Proof)

In Case C-122/21,

REQUEST for a preliminary ruling under Article 267 TFEU from the Lietuvos vyriausiasis administracinis teismas (Supreme Administrative Court of Lithuania), made by decision of 24 February 2021, received at the Court on 26 February 2021, in the proceedings

Get Fresh Cosmetics Limited

 \mathbf{v}

Valstybinė vartotojų teisių apsaugos tarnyba,

intervening parties:

V. U.,

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. Szpunar,

Registrar: A. Calot Escobar,

having regard to the written procedure,

after considering the observations submitted on behalf of:

- Get Fresh Cosmetics Limited, by M. Inta, advokatas,
- the Lithuanian Government, by K. Dieninis and V. Kazlauskaitė-Švenčionienė, acting as Agents,
- the Greek Government, by V. Karra and O. Patsopoulou, acting as Agents,
- the European Commission, by G. Goddin, E. Sanfrutos Cano and A. Steiblytė, acting as Agents,

having decided, after hearing the Advocate General, to proceed to judgment without an Opinion,

gives the following

- This request for a preliminary ruling concerns the interpretation of Article 1 of Council Directive 87/357/EEC of 25 June 1987 on the approximation of the laws of the Member States concerning products which, appearing to be other than they are, endanger the health or safety of consumers (OJ 1987 L 192, p. 49).
- The request has been made in proceedings between Get Fresh Cosmetics Limited and the Valstybinė vartotojų teisių apsaugos tarnyba (State Consumer Rights Protection Authority, Lithuania) ('the Consumer Protection Authority'), concerning a prohibition imposed on Get Fresh Cosmetics on making certain cosmetic products available on the market.

Legal context

European Union law

Directive 87/357

According to the first to seventh recitals of Directive 87/357:

'Whereas in [several] Member States legal provisions or regulations are in force concerning certain products which, appearing to be other than they are, endanger the safety or health of consumers; whereas, however, these provisions differ in content, scope and field of application; whereas, in particular, these provisions concern in certain Member States all products which resemble foodstuffs while not being such whilst in other Member States they concern products likely to be confused with foodstuffs, especially confectionery;

Whereas this situation creates significant barriers to the free movement of goods and unequal competitive conditions within the Community without ensuring effective protection for consumers, especially children;

Whereas these obstacles to the establishment and operation of the common market must be eliminated and adequate protection ensured for consumers in accordance with the Council resolutions of 14 April 1975 and 19 May 1981 respectively on the first [OJ 1975 C 92, p. 1] and second programmes [OJ 1981 C 133, p. 1] of the European Economic Community for a consumer protection and information policy and the Council resolution of 23 June 1986 on a new impetus for consumer protection policy [OJ 1986 C 167, p. 1];

Whereas the health and safety of consumers should enjoy an equivalent level of protection in the different Member States;

Whereas to that end it is necessary to prohibit the marketing, import and both the production and the export of products which, since they can be confused with foodstuffs, jeopardise the health or safety of consumers;

Whereas provision should be made for controls to be carried out by the competent authorities of the Member States;

Whereas, in accordance with the principles embodied in the Council resolutions on consumer protection, dangerous products must be withdrawn from the market'.

- 4 Article 1 of that directive provides:
 - 1. This Directive applies to the products, defined in paragraph 2 below, which, appearing to be other than they are, endanger the health or safety of consumers.
 - 2. The products referred to in paragraph 1 above are those which, although not foodstuffs, possess a form, odour, colour, appearance, packaging, labelling, volume or size, such that it is likely that consumers,

especially children, will confuse them with foodstuffs and in consequence place them in their mouths, or suck or ingest them, which might be dangerous and cause, for example, suffocation, poisoning, or the perforation or obstruction of the digestive tract.'

5 Article 2 of that directive provides:

'Member States shall take all the measures necessary to prohibit the marketing, import and either manufacture or export of the products referred to in this Directive.'

6 Article 3 of that directive states:

'Member States shall in particular ensure that checks are carried out on products on the market to ascertain that no product falling within the scope of this Directive is being marketed and shall take all necessary measures to ensure that their competent authorities withdraw or cause to be withdrawn from their markets any product covered by this Directive.'

Regulation (EC) No 1223/2009

- Recitals 9 and 10 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), are worded as follows:
 - '(9) Cosmetic products should be safe under normal or reasonably foreseeable conditions of use. In particular, a risk-benefit reasoning should not justify a risk to human health.
 - (10) The presentation of a cosmetic product and in particular its form, odour, colour, appearance, packaging, labelling, volume or size should not endanger health and safety of consumers due to confusion with foodstuffs, in accordance with [Directive 87/357]'
- 8 Article 3(a) of that regulation, entitled 'Safety', provides:

'A cosmetic product made available on the market shall be safe for human health when used under normal or reasonably foreseeable conditions of use, taking account, in particular, of the following:

(a) presentation including conformity with [Directive 87/357];

...,

Lithuanian law

- Article 6 of the Lietuvos Respublikos maisto įstatymas (Law on foodstuffs of the Republic of Lithuania) regulates the restrictions on the placing on the market of foodstuffs and other products resembling foodstuffs. Paragraph 2 of that provision prohibits the placing on the market of products which resemble foodstuffs in form, odour, colour, appearance, labelling, packaging, size or in any other way to such an extent that consumers, especially children, might mistakenly consume such products as foodstuffs, thereby endangering their health or life.
- Under Article 9 of the Lietuvos Respublikos produktų saugos įstatymas (Law on product safety of the Republic of Lithuania; 'the Law on product safety'):

'The seller shall be obliged:

to place only safe manufactured goods on the market.

. . . :

11 Article 3(5) of the Law on product safety provides:

"Safe manufactured goods" shall mean any manufactured goods which, under conditions of use that are normal, set out by the producer or reasonably foreseeable, including long-term use, do not present any risk or only a risk to the life and health of consumers which is established by legislation to be acceptable and consistent with a high level of consumer protection, taking into account the following:

- (1) the characteristics of the manufactured goods, including their composition, packaging, instructions for assembly, use and maintenance;
- (2) the effect on other manufactured goods, in the case where it is reasonably foreseeable that they will be used with other manufactured goods;
- (3) the presentation of the manufactured goods to the consumer, notices on the manufactured goods or their packaging, instructions for their use and disposal and any other indication or information provided by the producer;
- (4) the category of consumers, in particular children, who are at an increased risk when using the manufactured goods.'

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

- Get Fresh Cosmetics is a company incorporated under English law which manufactures cosmetic products such as bath bombs. Those products are distributed in Lithuania, inter alia via a website.
- By letter of 2 May 2018, the Consumer Protection Authority contacted the distributor of the goods of Get Fresh Cosmetics in Lithuania, stating that it would carry out an inspection of the cosmetic products sold on the website concerned. It requested that distributor to provide it with the name and address of the manufacturer, the labels in the original language and in Lithuanian, other identification data, the International Nomenclature of Cosmetic Ingredients (INCI) and other information necessary for the purposes of that inspection in respect of certain randomly selected cosmetic products, namely different types of bath bombs ('the products at issue').
- By email of 3 May 2018, that distributor informed the Consumer Protection Authority that, several weeks earlier, after having been informed that the products at issue were similar to foodstuffs, the distributor had removed them from that website. The distributor also stated that all the products were referenced on the cosmetic product notification portal, were registered in the European Union and bore a label stating that they should not be placed in the mouth or swallowed. Lastly, it provided the Consumer Protection Authority with the documents requested.
- Following the inspection of the compliance of the products at issue with the requirements of Regulation No 1223/2009 and the Law on product safety and on the basis of the inspection report, the Consumer Protection Authority adopted decisions on 29 August 2018 finding that those products did not satisfy the requirements of Article 3(a) and Article 20(1) of Regulation No 1223/2009 on the ground that the products at issue imitated foodstuffs in appearance, odour, form and size and, by appearing to be other than they are, endangered the safety or health of consumers, in particular children and elderly people. By those decisions, the Consumer Protection Authority, first, prohibited the placing of the products at issue on the market and, second, required the distributor concerned to withdraw them from the market, to warn consumers about the risks associated with those products, to inform consumers about the possibility of returning those products to the seller and to provide information on the course of further action.
- The Vilniaus apygardos administracinis teismas (Regional Administrative Court, Vilnius, Lithuania) upheld in part the action brought by Get Fresh Cosmetics, annulling those decisions and requiring the Consumer Protection Authority to re-examine the question of the compliance of the products at issue with the requirement laid down in Article 3(a) of Regulation No 1223/2009.

- Ruling on an appeal brought by that authority, the referring court set aside that judgment and referred the case back to the Vilniaus apygardos administracinis teismas (Regional Administrative Court, Vilnius). That court dismissed the action brought by Get Fresh Cosmetics, which appealed against that judgment before the referring court on the ground, inter alia, that the Vilniaus apygardos administracinis teismas (Regional Administrative Court, Vilnius) had erred in law in the interpretation of Article 1 of Directive 87/357.
- Get Fresh Cosmetics submits that Article 1(2) of Directive 87/357 requires it to be demonstrated that the products at issue are non-food products possessing a form, odour, colour, appearance, packaging, labelling, volume or size, such that it is likely that consumers, especially children, will confuse them with foodstuffs and in consequence place them in the mouth, suck or ingest them, which might be dangerous and cause, for example, suffocation, poisoning, or the perforation or obstruction of the digestive tract.
- In that context, it submits that the Consumer Protection Authority could not merely establish that the products at issue could be confused with food products, but also had to demonstrate the danger posed by such confusion. It claims, to that end, that the Consumer Protection Authority had to carry out laboratory analyses and tests in order to determine whether the products at issue could be broken and whether they pose a danger of poisoning when placed in the mouth, sucked or swallowed.
- For its part, the Consumer Protection Authority submits that, since cosmetic products are not intended for consumption, the existence of a resemblance between such a non-food product and a food product, from which it follows that it is foreseeable that the cosmetic product will be placed in the mouth, is sufficient for it to be presumed that that product poses risks for the health of consumers.
- The referring court considers that it follows from the interpretation of Regulation No 1223/2009 and Directive 87/357, clarified by the *travaux préparatoires* which led to its adoption, that the resemblance between a cosmetic product and a foodstuff is a factor which *ipso facto* gives rise to a risk, or at least a potential risk, to the health or safety of consumers, in particular children.
- In that regard, the referring court notes that Article 1(2) of Directive 87/357 defines the scope of that directive such that it also applies to potential risks. In that context, it has doubts as to whether it is necessary to adduce evidence that the products covered by that provision actually present a danger. However, in the event that that provision were to be interpreted as requiring that the risk to health or safety be evidenced by objective and substantiated data, the referring court seeks to ascertain who would bear the burden of proof.
- In that regard, the referring court submits that, under Regulation No 1223/2009, the responsible person must ensure that cosmetic products comply with Directive 87/357 even before placing those products on the market and must, in particular, have information establishing that compliance.
- In those circumstances, the Lietuvos vyriausiasis administracinis teismas (Supreme Administrative Court of Lithuania) decided to stay the proceedings and to refer the following questions to the Court of Justice for a preliminary ruling:
 - '(1) Should Article 1(2) of [Directive 87/357] be interpreted as defining the products referred to in paragraph 1 of that article as being those which, although not foodstuffs, possess a form, odour, colour, appearance, packaging, labelling, volume or size, such that it is likely that consumers, especially children, will confuse them with foodstuffs and in consequence place them in their mouths, or suck or ingest them, which could be dangerous as it is demonstrated by objective and substantiated data that this may cause, for example, suffocation, poisoning, or the perforation or obstruction of the digestive tract?
 - (2) If the first question is answered in the affirmative, should the burden of proving this be borne by the competent supervisory authority of the Member State?'

Consideration of the questions referred

The first question

- By its first question, the referring court asks, in essence, whether Article 1(2) of Directive 87/357 must be interpreted as meaning that it must be demonstrated by objective and substantiated data that placing in the mouth, sucking or ingesting products which, although not foodstuffs, possess a form, odour, colour, appearance, packaging, labelling, volume or size, such that it is likely that consumers, especially children, will confuse them with foodstuffs and in consequence place them in their mouths, or suck or ingest them may entail risks such as, suffocation, poisoning, or the perforation or obstruction of the digestive tract.
- In the present case, the referring court seeks, in particular, to determine whether Article 1(2) of Directive 87/357 established a presumption that products with the appearance of foodstuffs are dangerous or whether the hazardous nature of such products must be demonstrated by objective and substantiated data.
- In that regard, it should be noted, in the first place, that, under Article 1(1) of Directive 87/357, that directive applies to products which, appearing to be other than they are, endanger the health or safety of consumers.
- It should also be noted that, in accordance with paragraph 2 of that provision, products which, appearing to be other than they are, endanger the safety or health of consumers are those which, although not foodstuffs, possess a form, odour, colour, appearance, packaging, labelling, volume or size, such that it is likely that consumers, especially children, will confuse them with foodstuffs and in consequence place them in their mouths, or suck or ingest them, which might be dangerous and cause, for example, suffocation, poisoning, or the perforation or obstruction of the digestive tract.
- However, it must be noted that there is nothing in the wording of those provisions to indicate that they establish a presumption of danger as regards products appearing to be other than they are, or an obligation on the part of the competent national authorities to demonstrate by means of objective and substantiated data that placing such products in the mouth, or sucking or ingesting them might be dangerous and cause, for example, suffocation, poisoning, or the perforation or obstruction of the digestive tract.
- Article 1 of Directive 87/357 does not establish a direct cause and effect relationship between the fact that a product appears to be other than it is and the fact that it endangers the safety or health of consumers, but merely provides that a product falls within the scope of the prohibition on marketing, import, manufacture or export laid down by Directive 87/357 if four cumulative conditions are met.
- First, the product must be a non-food product possessing the form, odour, colour, appearance, packaging, labelling, volume or size of a foodstuff.
- Second, the characteristics referred to in the preceding paragraph must be such that it is likely that consumers, especially children, will confuse the product with a foodstuff.
- Third, it must be likely that, in consequence, consumers will place that product in their mouths, suck or ingest it.
- Fourth, placing the product in the mouth, sucking it or ingesting it may entail risks such as suffocation, poisoning, or the perforation or obstruction of the digestive tract.
- In the second place, it should be noted that Directive 87/357 does not contain any provision establishing a presumption of danger as regards products appearing to be other than they are, nor does it contain, in particular, a presumption that placing such products in the mouth, sucking or ingesting them entails such risks; the EU legislature requires, on the contrary, in respect of the latter condition, that such risks must be assessed on a case-by-case basis.

- Furthermore, to interpret Article 1(2) of Directive 87/357 as introducing such a presumption would amount to prohibiting de facto the marketing of such products.
- 37 The purpose of Directive 87/357 is not to prohibit, as a matter of principle, the marketing of all products which are not foodstuffs and which may be confused with foodstuffs.
- It follows from the second to fifth recitals of that directive that it was adopted in order to eliminate obstacles to free movement resulting from national provisions concerning certain products which, appearing to be other than they are, endanger the health or safety of consumers while ensuring the health and safety of consumers and guaranteeing that they are subject to an equivalent level of protection in the various Member States.
- In the third place, it follows from Article 1 of Directive 87/357 and, in particular, from the four conditions referred to in paragraphs 31 to 34 of the present judgment that, as the European Commission has argued, that directive applies to an indefinite number of products with certain characteristics and for which it is necessary to determine, on a case-by-case basis and on the basis of each Member State, whether they may entail the risks referred to in that directive.
- 40 Thus, Directive 87/357 presupposes that the competent national authorities assess, in each individual case, whether the conditions set out in Article 1 of that directive are met and that they justify the adoption of a decision prohibiting a product based on Article 2 of that directive so that that decision can be subject to administrative or judicial review.
- To that end, they must assess, where the product at issue has the appearance or odour of a foodstuff, not only the likelihood that it will be confused with a foodstuff and, thereby, placed in the mouth, sucked or ingested, but also the risks of such an action.
- That assessment must, first, be based on the objective characteristics of the products concerned. Thus, a product that only roughly resembles the appearance or odour of a foodstuff is unlikely to be mistaken for that foodstuff. Such characteristics, and in particular the materials and composition of a non-food product, which it is for the person marketing the product to communicate, where appropriate, must also serve to determine whether placing that product in the mouth, sucking it or ingesting it may entail risks such as suffocating, poisoning, or the perforation or obstruction of the digestive tract.
- Second, that assessment must take into account the vulnerability associated with the categories of persons and consumers likely to be faced with products with the appearance of foodstuffs, including in particular children, as is apparent from the very wording of Article 1(2) of Directive 87/357.
- In the fourth place, although that assessment must relate to the four conditions laid down in Article 1(2) of Directive 87/357, neither that provision nor any other provision of that directive requires the competent national authorities to demonstrate by objective and substantiated data that consumers will confuse the products with foodstuffs and that the risks of suffocating, poisoning, or the perforation or obstruction of the digestive tract have been established.
- It follows from the wording of that provision that it is sufficient that the action of placing the product concerned in the mouth, sucking it or ingesting it is likely to entail such risks. Furthermore, to impose an obligation to demonstrate the certainty that those risks will materialise would conflict with the requirement of protection of individuals and consumers pursued by Directive 87/357 and would not ensure a fair balance between that requirement and that of the free movement of products, an objective pursued by that directive, as is apparent from the second to fifth recitals thereof.
- In the light of all the foregoing considerations, the answer to the first question is that Article 1(2) of Directive 87/357 must be interpreted as meaning that it is not necessary to demonstrate by objective and substantiated data that placing in the mouth, sucking or ingesting products which, although not foodstuffs, possess a form, odour, colour, appearance, packaging, labelling, volume or size, such that it is likely that

consumers, especially children, will confuse them with foodstuffs and in consequence place them in their mouths, or suck or ingest them may entail risks such as suffocation, poisoning, or the perforation or obstruction of the digestive tract. Nevertheless, the competent national authorities must assess on a case-by-case basis whether a product meets the conditions listed in that provision and justify their assessment that that is the case.

The second question

In view of the answer given to the first question, there is no need to reply to the second question.

Costs

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 1(2) of Council Directive 87/357/EEC of 25 June 1987 on the approximation of the laws of the Member States concerning products which, appearing to be other than they are, endanger the health or safety of consumers must be interpreted as meaning that it is not necessary to demonstrate by objective and substantiated data that placing in the mouth, sucking or ingesting products which, although not foodstuffs, possess a form, odour, colour, appearance, packaging, labelling, volume or size, such that it is likely that consumers, especially children, will confuse them with foodstuffs and in consequence place them in their mouths, or suck or ingest them may entail risks such as suffocation, poisoning, or the perforation or obstruction of the digestive tract. Nevertheless, the competent national authorities must assess on a case-by-case basis whether a product meets the conditions listed in that provision and justify their assessment that that is the case.

[Signatures]

Language of the case: Lithuanian.