



Reports of Cases

JUDGMENT OF THE COURT (Second Chamber)

15 October 2015*

(Reference for a preliminary ruling — Directive 92/83/EEC — Harmonisation of the structures of excise duties on alcohol and alcoholic beverages — Article 27(1)(d) — Exemption from the harmonised excise duty — Ethyl alcohol — Use for cleaning and disinfection of equipment and facilities used for the production of medicines)

In Case C-306/14,

REQUEST for a preliminary ruling under Article 267 TFEU from the Varhoven administrativen sad, made by decision of 19 June 2014, received at the Court on 25 June 2014, in the proceedings

Direktor na Agentsia ‘Mitnitsi’

v

Biovet AD,

THE COURT (Second Chamber),

composed of R. Silva de Lapuerta (Rapporteur), President of the First Chamber, acting as President of the Second Chamber, J.L. da Cruz Vilaça, A. Arabadjiev, C. Lycourgos and J.-C. Bonichot, Judges,

Advocate General: Y. Bot,

Registrar: M. Aleksejev, Administrator,

having regard to the written procedure and further to the hearing on 30 April 2015,

after considering the observations submitted on behalf of:

- the Direktor na Agentsia ‘Mitnitsi’, by V. Tanov, S. Yordanova, N. Yotsova-Toteva and S. Genova,
- Biovet AD, by A. Ivanov,
- the Bulgarian Government, by E. Petranova, D. Drambozova and M. Georgieva, acting as Agents,
- the Portuguese Government, by L. Inez Fernandes, N. Vitorino and M. Rebelo, acting as Agents,
- the European Commission, by M. Wasmeier and D. Roussanov, acting as Agents,

after hearing the Opinion of the Advocate General at the sitting on 4 June 2015,

* Language of the case: Bulgarian.

gives the following

Judgment

- 1 This request for a preliminary ruling concerns the interpretation of Article 27(2) of Council Directive 92/83/EEC of 19 October 1992 on the harmonisation of the structures of excise duties on alcohol and alcoholic beverages (OJ 1992 L 316, p. 21).
- 2 The request has been made in proceedings between the Direktor na Agentsia 'Mitnitsi' (Director of the 'Customs' Agency; 'the Director') and Biovet AD ('Biovet') concerning the subjection of the ethyl alcohol used by Biovet for cleaning and disinfecting purposes to harmonised excise duty.

Legal context

EU law

- 3 The 19th and 20th recitals in the preamble to Directive 92/83 are worded as follows:

'... it is necessary to lay down at Community level the exemptions which apply to goods which are transported between Member States;

... however, it is possible to permit Member States an option to apply exemptions tied to end-uses within their territory'.
- 4 Under Article 19(1) of that directive, Member States are to apply an excise duty to ethyl alcohol.
- 5 Article 27(1) of the directive provides:

'Member States shall exempt the products covered by this Directive from the harmonised excise duty under conditions which they shall lay down for the purpose of ensuring the correct and straightforward application of such exemptions and of preventing any evasion, avoidance or abuse:

(a) when distributed in the form of alcohol which has been completely denatured in accordance with the requirements of any Member State, such requirements having been duly notified and accepted in accordance with paragraphs 3 and 4 of this Article. ...;

(b) when both denatured in accordance with the requirements of any Member State and used for the manufacture of any product not for human consumption;

...

(d) when used for the production of medicines defined by [Council Directive 65/65/EEC of 26 January 1965 on the approximation of provisions laid down by law, regulation or administrative action relating to medicinal products, OJ, English Special Edition, Second Series 1965-66, p. 20];

...'

6 Article 27(2)(d) of the directive provides:

‘Member States may exempt the products covered by this Directive from the harmonised excise duty under conditions which they shall lay down for the purpose of ensuring the correct and straightforward application of such exemptions and of preventing any evasion, avoidance or abuse, when used:

...

(d) in a manufacturing process provided that the final product does not contain alcohol.’

Bulgarian law

7 In accordance with Article 22 of the Law on excise duties and tax warehouses (Zakon za aktsizite i danachnite skladove, DV No 91 of 15 November 2005) in the version applicable to the main proceedings (‘ZADS’), excise duty which has been paid on ethyl alcohol which is denatured and used in a manufacturing process is to be refunded.

8 Article 22(7) of the ZADS states that, for the purposes of the application of Article 22(4)(4), alcohol and alcoholic beverages which are used as cleaning materials are deemed not to have been included or used in a manufacturing process.

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

9 Biovet manufactures medicinal products and markets veterinary medicinal products, agricultural products and medicinal products for human use.

10 In its manufacturing of medicinal products, Biovet uses ethyl alcohol, in the form of a 70% water-based solution of ethanol, to clean and disinfect technical equipment, production facilities and working areas and surfaces.

11 On 14 September 2012 Biovet applied for a refund of excise duty paid on 271 litres of ethyl alcohol which had been used for those purposes between 1 August and 31 August 2012.

12 By a decision of the Nachalnik na Mitnitsa ‘Plovdiv’ (Head of the Plovdiv Customs Office, Bulgaria), refund of the excise duty was refused. That decision was challenged by administrative appeal and confirmed by decision of the Director.

13 Biovet brought an action against that decision before the Administrativen sad Sofia-grad (Administrative Court, Sofia, Bulgaria), which held that cleaning and disinfection constitute different activities which form part of the process for the manufacture of a final product which does not contain alcohol, with the result that the excise duty which was paid on the acquisition of the alcohol used for disinfectant purposes was to be refunded pursuant to Article 22(4)(4) of the ZADS and was not covered by Article 22(7) thereof.

14 The Director appealed against the judgment of the Administrativen sad Sofia-grad to the referring court.

- 15 In those circumstances, the Varhoven administrativen sad (Supreme Administrative Court, Bulgaria) decided to stay proceedings and to refer the following questions to the Court for a preliminary ruling:
- (1) What is the meaning of the term “manufacturing process” in Article 27(2)(d) of Directive 92/83 and does that term include cleaning and/or disinfection as processes for achieving specific degrees of cleanliness which are prescribed by good practice in the production of medicines?
 - (2) Does Article 27(2)(d) of Directive 92/83 permit the enactment of a legal provision under which, after the Member States have introduced legislation exempting alcohol from harmonised excise duty on condition that the alcohol is used in a manufacturing process and that the end product does not contain any alcohol, alcohol used for cleaning is deemed, for the purposes of the application of that exemption, not to have been used in a manufacturing process?
 - (3) Having regard to the principles of legal certainty and the protection of legitimate expectations, is it permissible for a deeming provision such as that in Article 22(7) of the ZADS to be enacted with immediate effect (that is to say, without providing any reasonable period for market participants to adjust their behaviour) if it restricts refunds of excise duty on alcohol used as a cleaning material in the case where the exemption from excise duty has been enacted by the Member State within the scope of its discretion?

Consideration of the questions referred

The first and second questions

- 16 By its first and second questions, which it is appropriate to examine together, the referring court asks, in essence, whether Article 27(2)(d) of Directive 92/83 must be interpreted as meaning that, when a Member State adopts rules implementing the exemption provided for in that provision, ethyl alcohol used for cleaning and/or disinfecting equipment and facilities used in the production of medicines is covered by that exemption and whether, if so, that Member State may, in its implementation of that exemption, exclude from its scope ethyl alcohol used for such cleaning or disinfecting purposes.
- 17 It should be observed as a preliminary point that, according to the settled case-law of the Court, in the procedure laid down by Article 267 TFEU, providing for cooperation between national courts and the Court of Justice, it is for the latter to provide the referring court with an answer which will be of use to it and enable it to determine the case before it. To that end, the Court may have to reformulate the questions referred to it (see judgment in *Brasserie Bouquet*, C-285/14, EU:C:2015:353, point 15). The fact that a national court has, formally speaking, worded a question referred for a preliminary ruling with reference to certain provisions of EU law does not prevent the Court from providing that court with all the guidance on points of interpretation which may be of assistance in adjudicating on the case pending before it, whether or not it has referred to those points in its questions. In that regard, it is for the Court to extract from all the information provided by the national court, in particular from the grounds of the decision referring the questions, the points of EU law which require interpretation, having regard to the subject-matter of the dispute (see judgment in *Essent Energie Productie*, C-91/13, EU:C:2014:2206, point 36).
- 18 Since it is apparent from the order for reference that Biovet seeks reimbursement of the excise duty which it has paid on the ethyl alcohol used to clean or disinfect equipment and facilities as part of its medicinal product manufacturing activity, it is appropriate to examine whether a situation such as that at issue in the main proceedings is covered by Article 27(1)(d) of Directive 92/83. If that were the case, that alcohol would be mandatorily exempt from excise duty under that provision, so that it would no longer be necessary to ascertain whether Article 27(2)(d) of that directive applies to such a situation.

- 19 Consequently, the first and second questions must be reformulated to ask, in essence, whether Article 27(1)(d) of Directive 92/83 must be interpreted as meaning that the obligation to exempt laid down in that provision applies to ethyl alcohol used by an undertaking for cleaning or disinfecting equipment and facilities used in the production of medicines.
- 20 In that regard, it is appropriate to note that the wording of that provision, which provides that the Member States are to exempt the alcohol products covered by Directive 92/83 from the harmonised excise duty when they are used for the production of medicines, does not make application of that exemption subject to a condition either that those products be used directly for the production of medicines or that they form part of the composition of the medicines for the production of which they are used.
- 21 In accordance with the settled case-law of the Court, the objective of the exemptions contained in Directive 92/83 is, in particular, to neutralise the impact of excise duties on alcohol used as an intermediate product in other commercial or industrial products (see order in *Asprod*, C-313/14, EU:C:2014:2426, paragraph 16 and the case-law cited).
- 22 That being said, that objective is not the only one pursued by those exemptions, since some of them, such as those laid down in Article 27(1)(a) and (b) of that directive, concerning alcohol which has been completely denatured in accordance with the requirements of a Member State and alcohol when thus denatured and used for the manufacture of any product not for human consumption, exempt the alcohol from the harmonised excise duty, even where it has not been used as an intermediary product forming part of the composition of other products.
- 23 That is also the case of the exemption provided for in Article 27(1)(d) of Directive 92/83, which seeks to neutralise the effect of the harmonised excise duty on alcohol used for the production of medicines, whether that alcohol forms part of the composition of those medicines or whether it is merely necessary to their production without forming part of their composition.
- 24 In the present case, it is not in dispute that it is in the course of its medicine production activity that Biovet sought reimbursement of the excise duty which it had paid on the ethyl alcohol used to disinfect its equipment and facilities.
- 25 It is apparent from the file submitted to the Court that the disinfection of material, equipment and facilities used for the production of medicines constitutes a necessary stage in the process of that production and that the use of ethyl alcohol is indispensable to such disinfection operations. In that regard, medicines have the peculiarity that, in comparison to other products, their production process is subject to compliance with very strict health rules. As the referring court notes, the disinfection operations at issue in the main proceedings seek in particular to eradicate pathogenic microorganisms, which are not permitted to be present in terms of the requirements regarding the germ content of medicinal products.
- 26 It follows therefrom that, in so far as that disinfection is inherent in the production process for medicines, the ethyl alcohol used for that purpose must be regarded as being used 'for the production of medicines' within the meaning of Article 27(1)(d) of Directive 92/83.
- 27 Consequently, in accordance with that provision, that alcohol must be exempt from the harmonised excise duty on the conditions laid down by the Member State concerned for the purpose of ensuring the correct and straightforward application of the exemption laid down in that provision and of preventing any evasion, avoidance or abuse.

- 28 In those circumstances, the answer to the first and second questions is that Article 27(1)(d) of Directive 92/83 must be interpreted as meaning that the obligation to exempt laid down in that provision applies to ethyl alcohol used by an undertaking for cleaning or disinfecting equipment and facilities used in the production of medicines.

The third question

- 29 In view of the answer given to the first and second questions, there is no need to answer the third question.

Costs

- 30 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)(d) of Council Directive 92/83/EEC of 19 October 1992 on the harmonisation of the structures of excise duties on alcohol and alcoholic beverages must be interpreted as meaning that the obligation to exempt laid down in that provision applies to ethyl alcohol used by an undertaking for cleaning or disinfecting equipment and facilities used in the production of medicines.

[Signatures]