Translation C-663/18 — 1

Case C-663/18

Request for a preliminary ruling

Date lodged:

23 October 2018

Referring court:

Cour d'appel d'Aix-En-Provence (France)

Date of the decision to refer:

23 October 2018

Appellants:

BS

CA

Respondent:

COUR D'APPEL

D'AIX-EN-PROVENCE

[...] [procedure]

[...] Delivered in open court, TUESDAY, 23 OCTOBER 2018,

[...] [procedure]

JUDGMENT ON THE SUBSTANCE On appeal from a judgment of the Tribunal Correctionnel (Criminal Court)

[...] [Or. 2-16] [...] [judgment in which the national court decides to make a reference to the Court of Justice for a preliminary ruling, and which contains an overall summary of the proceedings and a very detailed summary of the arguments of the parties. Since the relevant information is set out in the request for a preliminary ruling annexed to the judgment, there appears to be no need to translate the judgment making the reference, but only the request submitted to the Court, which appears in the annex]

ON THOSE GROUNDS:

[...] [procedure]

Before ruling on the substance;

Having regard to Article 267 TFEU;

Hereby requests the Court of Justice of the European Union (CJEU) to deliver a preliminary ruling on the interpretation of Articles 28, 29, 30 and 32 TFEU, of Regulations No 1307/2013 and No 1308/2013 and of the principle of the free movement of goods, referring to it the question whether those provisions must be interpreted as meaning that the derogating provisions introduced by the arrêté (Decree) of 22 August 1990, by limiting the cultivation, industrialisation and marketing of hemp solely to fibre and seeds, impose a restriction that is not in accordance with [EU] law;

Attaches as an annex to this judgment the request submitted to the CJEU;

[...] [procedure] [**Or. 17**]

[...] [composition of the court and procedure][Or. 18]

[...] [procedure]

Ordinary question referred to the Court of Justice of the European Union for a preliminary ruling

- 1 SAS Catlab, a company whose directors were Mr S B and Mr A C-A, was formed in 2014 for the marketing of Kanavape products, alpha-CAT kits for testing the quality of CBD (see paragraph 3 below) and hemp oil. It went into compulsory liquidation on 18 July 2016. Kanlaba SRO, a company whose registered office is in Prague (Czech Republic), was formed in 2014 by three partners: S B, A C-A and Ms B, for the purpose of marketing and distributing the product Kanavape.
- 2 Kanavape is an electronic cigarette, the liquid in which contains cannabidiol or CBD; it was to be distributed via the internet and a network of sellers of electronic cigarettes.
- 3 CBD is one of the compounds of cannabis, another of which, tetrahydrocannabinol (THC), is responsible for the psychotropic effects attributed to the plant and therefore for its classification in the category of narcotic drugs.

- CBD is usually extracted from Cannabis sativa L (sub-species sativa) or hemp since that variety naturally contains a high level of it, whilst containing a low level of THC.
- 4 An information campaign was conducted for the launch of Kanavape in December 2014; the product's relaxing properties were highlighted and also the fact that it was legal under French law. In that regard, the defendants referred to an arrêté ministériel (Ministerial Decree) of 22 August 1990, amended in 2004.
- 5 The Public Prosecutor attached to the Tribunal de grande instance de Marseille (Regional Court, Marseille), the court having territorial jurisdiction, then ordered an inquiry. At the same time, the matter was referred to the Agence nationale de sécurité du médicament (ANSM) (the National Agency for Medicinal Product Safety).
- 6 According to the evidence of the inquiry, the CBD used in Kanavape was produced in the Czech Republic using the whole of the plant Cannabis sativa L, grown locally; it was then imported into France by Catlab, which packaged it in cartridges for electronic cigarettes. The certificate issued by the Czech company producing the CBD confirmed that the whole plant was used. [Or. 2]
- 7 ANSM's testing laboratory stated that it had been able to test Kanavape cartridges available on the market and, although significant differences had been found in concentrations of CBD, the level of THC present in the products tested was always below the legally permitted threshold. In July 2016, following the meeting of the Committee on narcotic drugs and psychotropic substances, ANSM announced that it did not consider Kanavape to be a medicinal product, either by function or by presentation, and referred for the rest to the jurisdiction of the competition directorate.
- 8 A C-A and S B had suspended the marketing of their product pending the results of the judicial inquiry and also the administrative inquiry conducted by ANSM. Then, in 2016, having heard nothing from the authorities, they had resumed sales.
- 9—Proceedings were brought against S B and A C-A, under summonses of 21 December 2016 and 20 September 2017, before the Criminal Court, Marseille, relating to the offences of unauthorised possession of narcotic drugs attributed to S B alone, and of marketing a medicinal product without a marketing authorisation, opening a pharmaceutical establishment without authorisation, advertising a medicinal product without a marketing authorisation, deception as to the essential quality of a product and infringement of the regulations on the marketing and/or use of a medicinal product, plant, substance or preparation classified as poisonous, including one for infringement of the law on poisonous substances, attributed to both defendants.
- 10 The summons relating to the latter offences, which are the only ones to which the present question referred for a preliminary ruling relates, is worded as

follows: '[...] did in ... Marseille, between 1 July 2014 and 22 December 2016, in any event on national territory and within the European Union and at a time not covered by a limitation period, in the context of a regulated activity, [infringe] the provisions adopted under Article L.5132-8 of the Code de la santé publique (Public Health Code) prohibiting operations relating to plants classified as poisonous, in the present case by cultivating, supplying, using — and using for industrial and commercial purposes — cannabis, the whole or part of the cannabis plant, or products containing it, or products obtained from cannabis or from the cannabis plant, in the present case the Kanavape vaporiser, or electronic cigarette, with hemp oil (in liquid form for an electronic cigarette), by failing to comply with the provisions of Article R.5132-86 of the Public Health Code (CSP) and of the Decree of 22 August 1990, as amended, implementing Article R.5181 (now Article R.5132-86 of the CSP) in respect of cannabis, in the present case by using in the manufacture of the ingredients of the electronic cigarette liquid cartridge for the Kanavape vaporiser parts of the plant Cannabis sativa that are prohibited by law, in particular the leaves, flowers, floral envelope, bracts, flowering tops or fruiting tops, whereas only the fibre and seeds of the varieties of Cannabis sativa listed in the Decree of 22 August 1990, as amended, may be used for industrial and commercial purposes; offences provided for by Articles L.5432-1 §1(1), L.5132-8 para.1, L.5132-1, R.5132-74, R.5132-88, R 5132-92 of the CSP and punishable under Articles L.5432-1 §1 para.1, para.5 and L.5432-4 of the CSP'. [Or. 3]

11 — Article R 5132-86 of the Public Health Code reads as follows:

I. — The following shall be prohibited: production, manufacture, transportation, importation, exportation, possession, supply, transfer, acquisition or use of: 1. cannabis, cannabis plants and cannabis resin, products containing cannabis or products obtained from cannabis, cannabis plants or cannabis resin; 2. tetrahydrocannabinols, with the exception of delta 9-tetrahydrocannabinol, of tetrahydrocannabinol esters, ethers and salts, and of salts of the aforementioned derivatives, and of products containing them.

II. — Derogations may be granted from the above provisions for research and testing purposes and the manufacture of derivatives authorised by the Director-General of the Agence nationale de sécurité du médicament et des produits de santé (National Agency for Medicinal Product and Health Product Safety).

The cultivation, importation, exportation and industrial and commercial use of cannabis varieties not possessing narcotic properties or of products containing such varieties may be authorised, on a proposal from the Director-General of the Agency, by decree of the Ministers with responsibility for Agriculture, Customs, Industry and Health.

III. — The following shall not be prohibited: operations in respect of manufacture, transportation, importation, exportation, possession, supply, transfer, acquisition or use, where they relate to proprietary medicinal products containing one of the

substances listed in subparagraphs 1 or 2 of this article which are the subject of a marketing authorisation issued in France in accordance with the provisions of Chapter 1 of Title II of the present Book or by the European Union under Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency.

12 — Under the derogations provided for by those provisions, the Decree of 22 August 1990, as amended on 21 March 2004, was adopted to implement Article R. 5132-86 of the Public Health Code in respect of cannabis; it reads as follows:

The following shall be authorised under Article R. 5181 of the above-mentioned code: cultivation, importation, exportation and industrial and commercial use (fibre and seeds) of varieties of Cannabis sativa L. meeting the following criteria:

- the delta-9-tétrahydrocannabinol content of those varieties does not exceed 0.20%;
- the determination of the delta-9-tétrahydrocannabinol content and the sampling for the purposes of such determination is carried out according to the Community method laid down in the annex.

Applications for the inclusion of a hemp variety in the list of varieties of Cannabis sativa L. contained in Article 2 must be accompanied by a report giving the results of the analyses carried out according to procedure B of the method described in the annex to the present decree and also by an information sheet describing the variety in question. [Or. 4]

13 — The Criminal Court acquitted the defendants of the charge of inciting the unlawful use of narcotic drugs and convicted S B and A C-A on the other charges. By way of punishment, the court ordered S B to serve a suspended term of eighteen months' imprisonment and to pay a fine of EUR 10 000 and A C-A to serve a suspended term of fifteen months' imprisonment and to pay a fine of EUR 10 000; it rejected an application for exemption from entry in Bulletin No 2 of the criminal record and ordered the forfeiture of the goods seized, and of the items to which official seals had been attached, and the publication of the judgment. The Criminal Court joined the National Council of the Order of Pharmacists in the case as a party claiming civil damages and ordered S B and A C-A, jointly and severally, to pay to it the sum of EUR 5 000 to compensate for its loss and EUR 600 under Article 475-1 of the Code of Criminal Procedure (Annex 2).

14 — Appeals were duly brought before the Court of Appeal, Aix-en-Provence, [...] [procedure], against a judgment of the Criminal Court, Marseille of 8 January 2018, by Mr A C-A and Mr S B regarding the civil and criminal provisions, and cross appeals were brought by the Public Prosecutor in respect of the criminal

provisions and by the National Council of the Order of Pharmacists in respect of the civil provisions.

- 15 With regard in particular to the proceedings concerning the law on poisonous substances and the subsequent deception, A C-A and S B claim that those proceedings should be dismissed.
- 16 Their arguments and pleas in law, which are set out in the body of the judgment which the Chamber delivered today, are, with regard to the question referred, that the Treaty on the Functioning of the European Union (TFEU), which lays down the rules of the common market, is, according to Article 38 thereof, applicable to agricultural products, which include 'true hemp (Cannabis sativa), raw' (Chapter 57 of Annex I), and that it establishes the principle that quantitative restrictions on imports and exports are prohibited between Member States (Articles 34 to 37 of the TFEU).
- 17 The defendants also point out that, although the Treaty provides the option for Member States to impose restrictions on grounds of 'public morality, public policy or public security; the protection of health and life of humans ...', the risk caused by the cultivation of hemp, in particular for public health, has been taken into account in regulations (in particular Regulations No 1307/2013 and No 1308/2013) in so far as they limit the cultivation of hemp on two conditions only: that seeds must be certified and that the level of THC present in the plants must not exceed 0.2%, and they do not mention any restriction in respect of certain parts of the plant, which is always envisaged in its entirety in the various texts.
- 18 The defendants contend that the Court of Justice of the European Union (CJEU) has already ruled on this point and found that the regulations relating to the common organisation of the market in hemp took public health-issues adequately into account (judgment of 16 January 2003, [Hammarsten, C-462/01, EU:C:2003:33]). [Or. 5]
- 19 They claim that France has put forward no justification for imposing a 'measure having equivalent effect to a quantitative restriction' on grounds of public interest, since CBD is not harmful relying in that regard on the fact that CBD, as such, is not classified as a narcotic substance in the Public Health Code, in contrast to THC and is already being marketed in several EU countries.
- 20 Thus, A C-A and S B claim that application of the Decree of 22 August 1990 should be excluded in favour of [EU] law or, in the alternative, that the court should refer a question to the CJEU for a preliminary ruling, since that regulatory provision cannot be justified on grounds of public interest in addition to those already pursued by the common organisation, and disproportionately undermines [EU] law.

- 21 Hemp gives rise to agricultural, industrial and commercial activity and has a number of uses in the textile and food industries and in the manufacture of building materials. France is a major producer of hemp, which has justified derogations from the general prohibition on all cannabis cultivation or trading, in order to permit the development of that industry, whilst protecting the market from the unlawful cultivation of that plant because of its closeness to the 'drug' plant.
- 22 CBD, for its part, does not appear to have any recognised psychoactive effects. In that regard, the court notes that, in a 2017 report, the World Health Organisation recommended removing CBD from the list of doping substances, that, following the meeting of the Committee on narcotic drugs and psychotropic substances on 25 June 2015, ANSM concluded that there were insufficient data to classify the product as harmful and did not consider it to be a medicinal product by function, and that Dr Maciuk, appointed in connection with the criminal inquiry that gave rise to the present proceedings, concluded that cannabinoids had 'little or no' effect on the central nervous system. CBD is not listed as such in the Single Convention on Narcotic Drugs, 1961.
- 23 CBD, which has only recently gained popularity, is not expressly referred to either in the texts applying to industrial hemp or in those relating to cannabis as a narcotic drug. Following the marketing of a number of CBD-based products, on 3 July 2018 the Minister for Justice adopted a circular advocating a strict application of the Decree of 22 August 1990; that circular, which applies specifically to Cannabis sativa L seeds and fibre, is not intended to allow natural CBD derived from the whole plant, and in particular from the flowers and leaves, to be regarded as legal. It is on that basis that the proceedings were brought in the case now before the Court of Appeal, due to the use in the manufacture of the product at issue of the whole hemp plant, including the leaves and flowers. [Or 6]
- 24 However, the marketing of synthetic CBD would not be covered by the law since CBD, unlike THC, is not classified as a narcotic drug.
- 25 As stated above, the TFEU puts in place a common market based on the free movement of goods, including agricultural products (Article 38). Chapter 57 of the annex to the TFEU expressly lists 'True hemp (Cannabis sativa), raw or processed but not spun; tow and waste of true hemp (including pulled or garnetted rags or ropes)'.
- 26 Dangerous goods, in the forefront of which are narcotic drugs, are, however, excluded from the notion of goods to which the common market applies. In order to be classified as a narcotic drug the product must meet two cumulative conditions, according to the CJEU: the harmfulness of the product must be demonstrated or generally recognised and its importation and marketing must be prohibited in all Member States (judgments in *Wolf* [judgment of 26 October 1982, 221/81, EU:C:1982:363] and *Evans* [judgment of 28 March 1995, C-324/93, EU:C:1995:84]).

- 27 In the present case, it appears that hemp with a THC level below 0.2% should be considered to be non-psychoactive. It also appears that it is marketed freely in several European countries, including the Czech Republic, the source of the product incorporated into the Kanavape liquid. Consequently, there appears to be no reason for placing CBD in the category of narcotic drugs excluded from the list of goods covered by the common market.
- 28 A number of regulations have laid down the conditions for implementing the common market and two regulations in particular are currently applicable to hemp: Regulations [EU] No 1307/2013 and [(EU) No 1308/2013].
- 29 The first of these sets out, in recital 28, the objective of ensuring the use of 'varieties of hemp offering ... guarantees with regard to its psychotropic substance content'. Recital 31 states that the Commission may adopt delegated acts in order to preserve public health by 'defining the procedure for the determination of hemp varieties and the verification of their THC content'. Article 32(6) provides that the varieties used must have a THC content not exceeding 0.2% (otherwise the areas will not be considered eligible under the CAP). Article 35 provides that, 'in order to preserve public health, the Commission shall be empowered to adopt delegated acts in accordance with Article 70 ... making the granting of payments conditional upon the use of certified seeds of certain hemp varieties ... and the verification of their THC content referred to in Article 32(6)'.
- 30 The Commission subsequently applied that option in Regulation 2017/1155, which lays down rules for controlling the THC content of plants without, however, distinguishing between the parts of the plant; each Member State is required to control 30% of cultivated areas. [Or. 7]
- 31 The second, [Regulation] [EU] No 1308/2013, which amends the conditions of the common agricultural policy, provides in Article 1 that it applies to agricultural products, and in the annexes reference is made, with regard to products covered by the CAP, to 'True hemp (Cannabis sativa), raw or processed but not spun; tow and waste of true hemp (including pulled or garnetted rags or ropes)'.
- 32 Article 189 of the regulation: (a) expressly allows importation of raw hemp meeting the conditions laid down in Article 32(6) and in Article 35 of Regulation [EU] No 1307/2013; (b) lays down limits relating to seeds for sowing (certified seeds with a THC content below 0.2%); and (c) lays down limits on seeds other than those for sowing, which may be imported only by importers authorised by the Member State.
- 33 [Article 189(2)] states that 'this Article shall apply without prejudice to more restrictive rules adopted by Member States in compliance with the TFEU and the obligations under the WTO Agreement on Agriculture'.

- 34 Both the Treaty itself and Regulation No 1308/2013 allow Member States to take more restrictive measures with regard to hemp, but the cumulative conditions imposed by the CJEU mean that those considerations must not have been taken into account already by European legislation, that the Member State has a separate interest and also that the response provided complies with the principle of proportionality.
- 35 European legislation regulates the cultivation and marketing of hemp due to its closeness to toxic, illicit plants, first by making reference to limiting its scope of application to 'varieties providing ... safeguards to be determined in respect of the content of intoxicating substances' then by adopting, first, a restriction regarding seeds and, secondly, a requirement regarding a low level of THC of the hemp, which has been the subject of several regulations that have progressively lowered the admissible THC level from 0.3% (EEC No 2059/84) to 0.2% (EC No 1420/98) the latter level being the one that is still currently in force.
- 36 Consequently, the public-health objective, assuming it is the justification for the restriction imposed by the Decree of 22 August 1990 on the legislation concerning the common market and on the TFEU, appears to have already been taken into account by that same EU legislation and cannot, it would seem, justify a measure having equivalent effect to a restriction on the free movement of goods, a principle that has direct effect in the Member States, since in the present case the CBD present in Kanavape was imported from the Czech Republic and that was in the context of intra-Community trade.
- 37 Nor would it appear possible to rely on the principle of proportionality, since, in its circular of 23 July 2018 in particular, in order to justify the prohibition on natural CBD, the French State relies on a prohibition which would not apply to the marketing of synthetic CBD with the same characteristics and effects. [Or. 8]
- 38 Consequently, the question which arises is whether the Decree of 22 August 1990, as amended, complies with international law in so far as it restricts the free movement of hemp products, in addition to the European restrictions relating to seeds and THC content, solely to trade in fibre and seeds and not to products derived from the whole plant.
- 39—It is therefore necessary, before ruling on the substance of the case, to refer the following question to the Court of Justice of the European Union regarding the scope and interpretation of [EU] law and the compatibility of the French legislation with the Treaty on the Functioning of the European Union and the [EU] regulations:
- 40 Must Regulations No 1307/2013 and No 1308/2013, and the principle of the free movement of goods, be interpreted as meaning that the derogating provisions introduced by the Decree of 22 August 1990, by limiting the cultivation, industrialisation and marketing of hemp solely to fibre and seeds, impose a restriction that is not in accordance with [EU] law?

Aix-en-Provence

23 October 2018

[...] [name and signature of the President]

