Reports of Cases

OPINION OF ADVOCATE GENERAL
MENGOZZI
delivered on 22 May 2014[1]

Case C-108/13

Mac GmbH
v
Ministère de l'Agriculture, de l'Agroalimentaire et de la Forêt

(Request for a preliminary ruling from the Conseil d'État (France))

(Free movement of goods — Quantitative restrictions — Measures having equivalent effect — Plant protection products — Marketing authorisation — Parallel importation — Requirement, in the exporting State, for a marketing authorisation granted in accordance with Directive 91/414/EEC)

I – **Introduction**

1. This request for a preliminary ruling, made by the French Conseil d'État (Council of State) in the course of a dispute between the company Mac GmbH ('Mac') and the Ministre chargé de l'agriculture et de la pêche (Minister for Agriculture and Fisheries) relating to the Minister's refusal to authorise the placing on the market in France as a parallel import a plant protection product covered by such an authorisation in the United Kingdom, concerns the interpretation of Articles 34 TFEU and 36 TFEU.

2. It raises the question whether the Treaty provisions on the free movement of goods preclude the legislation of a Member State under which a parallel import authorisation may be granted in accordance with a simplified procedure only to plant protection products which have, in the exporting Member State, a marketing authorisation granted in accordance with Directive 91/414/EEC[2] ('the Directive') thereby preventing the 'parallel reimportation' of those products.

1 — Original language: French.

2 — Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market (OJ 1991 L 230, p. 1). Directive 91/414 was amended several times and repealed by Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC (OJ 2009 L 309, p. 1).

II – **Legal context**

A – *EU law*

1. Primary law

3. Under Article 34 TFEU, quantitative restrictions on imports and all measures having equivalent effect are prohibited between Member States. Article 36 TFEU, provides that '[t]he provisions of Articles 34 and 35 shall not preclude prohibitions or restrictions on imports, exports or goods in transit justified on grounds of … the protection of health and life of humans, animals or plants … Such prohibitions or restrictions shall not, however, constitute a means of arbitrary discrimination or a disguised restriction on trade between Member States'.

2. The Directive

4. The Directive establishes uniform rules on the conditions and procedures for granting, reviewing and withdrawing marketing authorisations for plant protection products,[3] in order, first, to eliminate barriers to the free movement of those products and of plant products arising from the existence of divergent national rules[4] and, secondly, to ensure a high standard of protection of the health of humans and animals and also of the environment from the threats and risks arising from unrestricted use of plant protection products.[5]

5. In accordance with Article 3(1) of the Directive, 'Member States shall prescribe that plant protection products may not be placed on the market and used in their territory unless they have authorised the product in accordance with this Directive …'. Importation of a plant protection product into the territory of the Community is deemed to constitute placing on the market for the purposes of the Directive.[6]

6. Article 4(1) of the Directive lays down, in subparagraphs (b) to (f), the conditions relating, inter alia, to effectiveness and the absence of harmful effects on human and animal health and the environment, which plant protection products must fulfil in order to be authorised. In accordance with Article 4(3), Member States are to ensure that compliance with those requirements 'is established by official or officially recognised tests and analyses carried out under agricultural, plant health and environmental conditions relevant to use of the plant protection product in question and representative of these prevailing where the product is intended to be used, within the territory of the Member State concerned'.

7. The first subparagraph of Article 9(1) of the Directive provides that '[a]pplication for authorisation of a plant protection product shall be made by or on behalf of the person responsible for first placing it on the market in a Member State to the competent authorities of each Member State where the plant protection product is intended to be placed on the market'. Where a plant protection product is already authorised in another Member State, the Member State in which an application for authorisation is made must, under Article 10(1) of the Directive, refrain from requiring the repetition of tests and analyses already carried out, to the extent that agricultural, plant health and environmental

3 — Under Article 2(1) of the Directive, 'plant protection products' means 'active substances and preparations containing one or more active substances, put up in the form in which they are supplied to the user' intended to fulfil the functions listed in that Article.

4 — Fifth and sixth recitals.

5 — See in particular the ninth recital.

6 — Second sentence of Article 2(10).

(including climatic) conditions relevant to the use of the product are comparable in the regions concerned, and, subject to certain conditions, also authorise the placing of that product on the market in its territory. However, the Directive contains no provision governing the conditions for granting a marketing authorisation where the product is imported as a parallel import.

3. Regulation No 1107/2009

8. Although not applicable *ratione temporis* to the dispute in the main proceedings, Regulation No 1107/2009, which entered into force on 14 December 2009 and replaced the Directive, contains some provisions that merit consideration. Article 52 of that regulation, entitled 'Parallel trade', provides in paragraph 1 thereof as follows:

'1. A plant protection product that is authorised in one Member State (Member State of origin) may, subject to granting a parallel trade permit, be introduced, placed on the market or used in another Member State (Member State of introduction), if this Member State determines that the plant protection product is identical in composition to a plant protection product already authorised in its territory (reference product). The application shall be submitted to the competent authority of the Member State of introduction.'

9. Paragraph 2 of that article provides that a parallel trade permit is to be granted under a simplified procedure within 45 working days of receipt of a complete application and that Member States must, on request, provide each other with the information necessary to assess whether the product is identical to the reference product. Article 52(3)(a) to (c) sets out the conditions under which plant protection products are to be considered as identical to the reference products,[7] while Article 52(4) provides that '[t]he information requirements may be amended or completed and further details and specific requirements shall be established', inter alia, 'in cases of application for a plant protection product for which a parallel trade permit has already been granted'. Article 52(5) to (8) lays down the conditions for the placing on the market and use of plant protection products for which a parallel trade permit has been issued, the duration and conditions of validity of that permit, in particular where the authorisation holder of the reference product withdraws authorisation, as well as the rules applicable to such a permit and the conditions under which it may be withdrawn if the authorisation of the product is withdrawn in the Member State of origin. Article 52(9) provides that, where the product for which a permit is sought is not identical, in terms of paragraph (3), to the reference product, the Member State of introduction may only grant an authorisation after carrying out a full assessment in accordance with Article 29 of Regulation No 1107/2009, which reproduces, in essence, Article 4 of the Directive. Finally, Article 52(10) and (11) provide for certain exceptions to the application of the rules on parallel trade permits and set out provisions regarding public disclosure of information relating to parallel trade authorisations, respectively.

B – *National law*

10. Under Article L. 253-1 of the code rural (Rural Code), in the version in force when the administrative decision at issue in the main proceedings was adopted,[8] '[t]he placing on the market, use and possession by the end user of plant protection products are prohibited if those products do not have marketing authorisation …'

7 — Namely if: '(a) they have been manufactured by the same company or by an associated undertaking or under licence in accordance with the same manufacturing process; (b) they are identical in specification and content to the active substances, safeners and synergists, and in the type of formulation; and (c) they are either the same or equivalent in the co-formulants present and the packaging size, material or form, in terms of the potential adverse impact on the safety of the product with regard to human or animal health or the environment'.

8 — Version in force from 31 December 2006 to 14 July 2010.

11. Article R. 253-52 of the code rural, in the version in force when the administrative decision at issue in the main proceedings was adopted,[9] provides:

'The introduction into the national territory of a plant protection product from a State of the European Economic Area in which it already has a marketing authorisation issued in accordance with the Directive …, and identical to [the reference] product, shall be authorised on the following conditions:

The reference product must have a marketing authorisation granted by the minister responsible for agriculture …

Whether the product introduced into the national territory is identical to the reference product shall be assessed in the light of the following three criteria:

common origin of the two products in the sense that they have been manufactured by the same company or by an associated undertaking or under licence according to the same formulation;

manufacture using the same active substance or substances;

similar effects of the two products with due regard to differences which may exist in conditions relating to agriculture, plant health or the environment, in particular climatic conditions, connected with the use of the products.'

12. Under Article R. 253-53 of the code rural,[10] an order from the minister responsible for agriculture must establish the list of information to be provided in support of the application to place on the market in the national territory a plant protection product from a State of the European Economic Area, in particular information relating to the applicant for authorisation and the product covered by the application. That article provides that, in order to establish that the product introduced into the national territory and the reference product are identical, the minister responsible for agriculture may use the information contained in the reference product dossier, ask the holder of the authorisation for the reference product to provide the information in the holder's possession, and request information from the authorities of the State which authorised the product introduced into the national territory, as provided for in Article 9(5) of the Directive.

13. Article R. 253-55 of the code rural, in the version in force when the administrative decision at issue in the main proceedings was adopted,[11] provides:

'The marketing authorisation for the product introduced into national territory may be refused or withdrawn:

1. on grounds relating to the protection of human and animal health and the environment;

2. if that product is not identical, within the meaning of Article R. 253-52, to the reference product;

3. if the packaging and labelling do not comply with the conditions laid down in Articles 1 to 4 of the Decree of 11 May 1937 on the application of the Law of 4 August 1903 on the prevention of fraud in trade in products used for the destruction of crop pests.

Before a marketing authorisation is refused or withdrawn, the applicant for authorisation or authorisation holder shall be given the opportunity to submit observations to the minister responsible for agriculture.'

9 — Version in force from 20 March 2007 to 1 July 2012.

10 — Version in force from 20 March 2007 to 1 July 2012.

11 — Version in force since 23 September 2006.

III – **The facts, the main proceedings, the question referred for a preliminary ruling and the procedure before the Court**

14. At the material time, the plant protection product Cerone was covered by a marketing authorisation in France, granted to Bayer Cropscience France in accordance with the provisions of the Directive. That product was then authorised to be marketed in the United Kingdom as a parallel import under the name 'Agrotech Ethephon'. [12]

15. On 27 November 2007, Mac applied for a parallel import authorisation in France for Agrotech Ethephon with a view to marketing it under the name 'Mac Ethephone'.

16. On 20 February 2008, the Agence française de sécurité sanitaire des aliments (French Food Safety Agency) ('AFSSA') gave a positive opinion regarding that application, stating that the active substance of the product Agrotech Ethephon had the same origin as the reference product Cerone, and that the products could be regarded as identical in composition.

17. On 29 May 2009, the minister responsible for agriculture rejected the application because Agrotech Ethephon did not have a marketing authorisation in the United Kingdom granted in accordance with the Directive, contrary to the requirements laid down in Article R. 253-52 of the French code rural ('the decision refusing authorisation').

18. On 21 July 2008, Mac brought an action for annulment of the decision refusing authorisation, on the ground, inter alia, that Article R. 253-52 of the code rural was incompatible with Article 34 TFEU, inasmuch as it is not possible under that provision for a parallel import marketing authorisation to be granted for a product which already has such an authorisation in the exporting State.

19. By order of 16 February 2011, the President of the Tribunal administratif de Paris (Administrative Court, Paris) referred the application to the Conseil d'État (Council of State), [13] which decided to stay the proceedings and to refer the following question to the Court for a preliminary ruling:

'Do Articles 34 TFEU and 36 TFEU preclude national legislation which makes, inter alia, the grant of a parallel import marketing authorisation for a plant protection product subject to the condition that the product in question should have, in the exporting State, a marketing authorisation granted in accordance with [the] Directive …, and which consequently does not permit the grant of a parallel import marketing authorisation for a product which has, in the exporting State, a parallel import marketing authorisation and which is identical to a product authorised in the importing State?'

20. Mac, the French Government and the European Commission lodged written observations before the Court and presented oral argument at the hearing on 6 March 2014.

IV – **Summary of the observations submitted by the parties**

21. Mac submits, as its main argument, that the requirement for a marketing authorisation granted in accordance with the Directive in the exporting Member State constitutes a restriction contrary to Article 34 TFEU. It takes the view that a distinction must be made between the placing of a plant protection product on the market in a Member State for the first time, which falls within the scope of the Directive, and the importation of a plant protection product as a parallel import of a product already covered by a marketing authorisation in the importing Member State, which falls within the scope of the principle of free movement of goods.

12 — The authorisation holder was the company Agrotech Trading GmbH. The reference product in the United Kingdom was Cerone, for which the marketing authorisation had been obtained by Bayer Cropscience Ltd.

13 — Pursuant to Article R. 351-2 of the Code de justice administrative (Administrative Code of Justice).

22. Mac points out, first, that the reference product for the product which it intends to import already has two marketing authorisations which were granted in accordance with the Directive, in France and in the United Kingdom, (under the name 'Cerone'), in addition to a parallel import authorisation in the United Kingdom (under the name 'Agrotech Ethephon'). In those circumstances, to make the grant of the import authorisation subject to the additional condition that the product to be imported should have a marketing authorisation granted in accordance with the Directive in the United Kingdom — which, moreover, could not have been fulfilled, since the Directive makes no provision for an authorisation procedure for parallel imports — constitutes a measure having an effect equivalent to a quantitative restriction under Article 34 TFEU and an incorrect application of the Directive.

23. Furthermore, the requirement for such an authorisation does not serve to achieve an objective of protecting human and animal health and the environment — to which, moreover, the decision refusing authorisation makes no reference —, since the analyses necessary to identify the risks presented by the imported product have already been carried out and similar analyses of the reference product have also been carried out. Even if it were justified by that objective, such a requirement would, in any event, be disproportionate, given that alternative measures exist which are less restrictive, such as the option of enlisting the help of the competent authorities in the exporting Member State under the information exchange system put in place by the Directive, which ensures that all plant protection products are traceable and provides an easy means of establishing whether the product for which authorisation is sought as a parallel import and the reference product are identical.

24. Secondly, Mac takes issue with the French authorities for refusing its application on the sole basis of the fact that the product at issue did not have, in the United Kingdom, a marketing authorisation granted 'in accordance' with the Directive, without establishing whether that product was identical to a product already on the French market and was, therefore, entitled to the benefit of the marketing authorisation issued for that product. It points out that the case-law of the Court has laid down specific rules for the placing on the market of plant protection products which are parallel imports, whereby the placing of those products on the market is subject only to the condition that a marketing authorisation has been issued in the importing Member State for a product which is identical to the imported product. That case-law should be extended to successive parallel imports, at the very least in circumstances such as those in the present case, namely where the product is reimported into the Member State in which the first marketing authorisation was granted in accordance with the Directive.

25. In the alternative, in the event that the Court takes the view that Articles 34 TFEU and 36 TFEU do not preclude the requirement of a marketing authorisation granted in accordance with the Directive, Mac maintains that the parallel import authorisation issued in the United Kingdom must be deemed to have been granted 'in accordance' with the Directive, for the purposes of the application of Article R. 253-52 of the code rural, as was found to be the case in the positive opinion given by the AFSSA, since that authorisation is based on the information exchange system put in place by the Directive. Mac contends that several Member States, including the French Republic, have authorised successive parallel imports of plant protection products on the basis of that system.

26. According to the French Government, a plant protection product cannot be granted a parallel import authorisation unless a marketing authorisation has been issued for the product in accordance with the Directive in the exporting Member State. That requirement, it argues, is justified by the need, in the context of parallel imports, to maintain a standard of protection for the environment and for human health which is at least equivalent to the standard guaranteed by the Directive. However, that would not be the case if the simplified authorisation procedure for parallel imports were used for a product which has not been the subject, in the exporting Member State, of a full assessment as required under Article 4(1) of the Directive. As case-law does not require the reference product and the product to be imported as a parallel import to be exactly the same, the latter could be different from the reference product in terms of both its composition and its packaging, labelling or container.

Without a full assessment in the exporting Member State, the authorities in the importing Member State may not have all the information necessary to compare the product at issue with the reference product which has been authorised in the importing Member State. Indeed, in the case of a product which is the subject of successive parallel imports, there would even be a risk of significant differences between that product and the reference product in the first exporting Member State.

27. The French Government points out that the position which it has taken has been adopted by the Commission in its Guidance document concerning the parallel trade of plant protection products under Regulation No 1107/2009 ('Guidelines on parallel trade'),[14] in which it states that, under Article 52 of that regulation, a parallel import permit cannot be granted for a product which is itself a parallel-traded product.

28. Finally, the French Government points out that the rules governing the placing of plant protection products on the market for the purposes of parallel trade constitute an exception to the principle, laid down in Article 3(1) of the Directive, to the effect that plant protection products may not be placed on the market and used in the territory of a Member State unless the authorities of that Member State have already granted a marketing authorisation in accordance with the Directive. In accordance with the principle that exceptions are to be strictly interpreted, the application of those rules should not be extended to successive parallel imports.

29. In its written observations, the Commission points out, first of all, that, although it is not applicable *ratione temporis* to the instant case, Article 52 of Regulation No 1107/2009, which governs the simplified procedure for granting parallel trade permits, may serve as an aid to interpretation for the purposes of answering the question referred by the Conseil d'État.

30. The Commission observes that, according to case-law, in particular the judgment in *British Agrochemicals Association*,[15] the provisions of the Directive are not applicable to the parallel imports of plant protection products and that, consequently, such imports must be assessed on the basis of Articles 34 TFEU to 36 TFEU, the Member States nevertheless being required to ensure that the obligations and prohibitions laid down by the Directive are complied with. The Commission states that it is apparent, in particular, from the judgment in *Escalier and Bonnarel*,[16] that an imported plant protection product must be regarded as having already been authorised in the importing Member State if an identical product already has a marketing authorisation in that State, unless that is precluded by considerations relating to the effective protection of human and animal health and of the environment. By comparison with a 'single' parallel import operation, it is necessary and sufficient, in the case of a 'double' parallel import operation, such as that in the present case, for the national authorities to ensure that the product in question is identical to the product which has already received a marketing authorisation in accordance with the Directive. The absolute refusal to import the product concerned constitutes a particularly severe restriction on the free movement of goods which goes far beyond checking that that product is identical to a reference product, a characteristic which has not, moreover, been called into question by the French authorities in this case.

31. At the hearing, the Commission clarified its argument, explaining that a situation such as that in the present case, in which a product imported as a parallel import into one Member State is reimported from that State back into the Member State from which it was originally exported, is not the same as a classic situation of double importation involving three Member States. The Commission

14 — Guidance document concerning the parallel trade of plant protection products, DG SANCO/10524/2012, of 31 May 2012, in particular page 4.

15 — C-100/96, EU:C:1999:129.

16 — C-260/06 and C-261/06, EU:C:2007:659.

is of the opinion that Articles 34 TFEU and 36 TFEU preclude national legislation, such as that at issue in the instant case, which makes the grant of a parallel import marketing authorisation subject to the condition that the reimported product should have, in the exporting State, a marketing authorisation granted in accordance with the Directive.

V – **Legal analysis**

32. By the question referred, the Conseil d'État is, in essence, asking the Court whether Articles 34 TFEU and 36 TFEU must be interpreted as precluding national legislation under which a parallel import authorisation may not be granted for a plant protection product which does not have, in the exporting Member State, a marketing authorisation granted in accordance with the Directive, but only a parallel import authorisation.

A – *Preliminary observations*

33. According to Articles 9 TFEU and 11 TFEU, in defining and implementing its policies and activities, the European Union must take into account requirements relating to the protection of human health and the environment. The protection of health and life of humans, animals or plants also constitutes one of the grounds of general interest set out in Article 36 TFEU which may justify national measures liable to obstruct trade between Member States. Similarly, according to case-law, overriding requirements relating to protection of the environment may constitute such justification. [17] Plant protection products, which are intended to protect plants against all harmful organisms and to destroy undesired plants, [18] do not simply have beneficial effects on plant production and their use may involve risks and hazards for humans, animals and the environment. Therefore, prior to being placed on the market, these products must be tested to establish whether they are safe, harmless and effective.

34. Parallel trade, so called because it takes place outside and in parallel with the distribution networks set up by manufacturers or suppliers, involves importing into a Member State in which a product is sold at a high price a like product made or bought in another Member State in which that product is sold at a lower price, for the purposes of making a profit. Since parallel trade relates only to genuine products and relies on the price differences between them, it must be distinguished from illegal trade in counterfeit goods. [19]

35. The Court has taken a relatively favourable view of parallel imports, as they are considered to play a role in market integration, the hallmark of the existence of lively competition. Parallel trade creates, in principle, healthy competition and price reductions for consumers and is a direct consequence of the development of the internal market, which guarantees the free movement of goods. [20] Hence, parallel imports enjoy a certain amount of protection in Community law because they encourage trade and help reinforce competition. [21]

17 — See, most recently, *Commission* v *Austria* (C-28/09, EU:C:2011:854, paragraph 125 and case-law cited).

18 — See Article 2(1) of the Directive.

19 — The system of administrative authorisation for plant protection products, the result of which is that a given product may be authorised in some Member States but not in others, has led to the emergence of cross-border trafficking and counterfeiting in the European Economic Area (EEA). According to a 2006 report of the European Crop Protection Association (ECPA), the sale of counterfeit products accounts for 5% to 7% of the European plant protection market (see the *ECPA Position Paper: Counterfeiting and Illegal Trade in Plant Protection Products Across the EU and European Region*, Brussels, August 2006 ECPA, ref. 15020).

20 — See Enterprise and Industry DG of the European Commission, *Guide to the application of the provisions of the Treaty of Lisbon governing the free movement of goods*, 2010, p. 24, at http://ec.europa.eu/enterprise/policies/single-market-goods/files/goods/docs/art.34-36/new_guide_fr.pdf.

21 — Judgments in *Sot. Lélos kai Sia and Others* (C-468/06 to C-478/06, EU:C:2008:504, paragraph 37), *X* (C-373/90, EU:C:1992:17, paragraph 12) and the Opinion of Advocate General Tesauro in that case (EU:C:1991:408), points 5 and 6).

36. Given that such protection cannot operate to the detriment of health and environmental protection requirements, there is necessarily tension between the various objectives listed above (as well as between the underlying conflicting economic interests), as clearly illustrated by the present case. That tension makes it necessary to strike a balance between those various objectives and interests, which is often a delicate matter. Finding that balance forms the basis of the case-law of the Court which is briefly set out in the following points.

B – *Review of the case-law relating authorisation to place plant protection products on the market as parallel imports*

37. Unlike Regulation No 1107/2009, the Directive contains no provisions on parallel trade in plant protection products. It was in *British Agrochemicals Association* [22] that the Court considered this issue for the first time, applying, *mutatis mutandis*, the same reasoning in the context of trade in plant protection products as it had applied to pharmaceutical products in *De Peijper* [23] and *Smith & Nephew and Primecrown*. [24] Since the Directives relating to pharmaceutical products [25] and plant protection products pursue relatively similar objectives of protecting public health and eliminating barriers to trade, the Court has drawn parallels between the two authorisation regimes. [26]

38. The Court has thus held that the provisions of the Directive do not apply 'where a plant protection product covered by marketing authorisation granted in accordance with the provisions of the Directive in one Member State is imported into another Member State as a parallel import of a plant protection product already covered by a marketing authorisation in the Member State of importation', [27] but that such a situation is governed by the Treaty provisions on the free movement of goods. According to the Court, 'where two marketing authorisations are granted in accordance with the Directive, the objectives which it pursues as to protection of human and animal health and of the environment do not call for the same treatment', 'with the result that [i]n such a situation, application of the Directive's provisions concerning the procedure for the grant of marketing authorisation would go beyond what is necessary to achieve those objectives and could, without justification, run counter to the principle of the free movement of goods laid down in Article 30 of the Treaty [34 TFEU]'. [28]

39. On that basis, the Court established a 'simplified' procedure for authorising the placing on the market of plant protection products as parallel imports, whereby it is for the competent authority of the importing Member State to ascertain whether the product to be imported, 'if not identical in all respects to a product already authorised within [the] Member State [of importation], at least shares a common origin with that product in that it has been manufactured by the same company or by an associated undertaking or under licence according to the same formulation, was manufactured using the same active ingredient and also has the same effect with due regard to differences which may exist in conditions relating to agriculture, plant health and the environment, in particular climatic

22 — EU:C:1999:129.

23 — 104/75, EU:C:1976:67. In that case, the Court held, in the context of Articles 30 and 36 of the EC Treaty, that if, as a result of a previous importation which gave rise to their granting a marketing authorisation, the public health authorities of the importing Member State are already in possession of all the particulars necessary for checking that the product is effective and safe, it is clearly not necessary, for the purpose of protecting the health and life of humans, for those authorities to require a second trader who has imported a medicinal product which is in every respect the same or which has no differences altering the therapeutic effect, to submit those particulars to them again.

24 — C-201/94, EU:C:1996:432. In that case, the Court held that Council Directive 65/65/EEC of 26 January 1965 on the approximation of provisions laid down by law, regulation or administrative action relating to proprietary medicinal products (OJ, English Special Edition 1965-1966, p. 20), was not applicable to a proprietary medicinal product covered by a marketing authorisation in one Member State which is being imported into another Member State as a parallel import of a proprietary medicinal product already covered by a marketing authorisation in that other Member State, since that imported product cannot, in such a case, be regarded as being placed on the market for the first time in the importing Member State.

25 — Directive 65/65.

26 — *British Agrochemicals Association* (EU:C:1999:129, paragraph 30). See also *Commission* v *Germany* (C-114/04, EU:C:2005:471, paragraph 24).

27 — *British Agrochemicals Association* (EU:C:1999:129, paragraph 31).

28 — Ibidem, paragraph 32.

conditions, relevant to the use of the product'.[29] If, on completion of that examination, the competent authority of the importing Member State finds that all the criteria are fulfilled, 'the plant protection product to be imported must be considered to have already been placed on the market of the Member State of importation and, accordingly, must be able to benefit from the marketing authorisation granted in respect of the plant protection product already on the market, unless that is precluded by considerations concerning the effective protection of human and animal health and of the environment'.[30]

40. Those principles were confirmed in *Escalier and Bonnarel*,[31] in which the Court held that an operator who is importing plant protection products solely for the needs of his farm, and not for the purposes of placing them on the market, is also required to obtain a parallel import authorisation under the simplified procedure described in *British Agrochemicals Association*. The Court restated its case-law in an action for failure to fulfil obligations brought against the French Republic, in which the Commission took the view that the French legislation in question unreasonably restricted eligibility for the simplified authorisation procedure for parallel imports of plant protection products to cases in which the imported product and the reference product had a common origin.[32] The Court dismissed the action, stating, in particular, that '[i]n order to verify whether a product authorised in another Member State in accordance with [the] Directive … is to be regarded as having already been authorised in the Member State of importation, it is for the competent authorities of that Member State (i) to ascertain whether the importation … constitutes a parallel import of a product already covered by a marketing authorisation in the Member State of importation, and (ii) to examine, when requested by the parties concerned, whether the product concerned may have the benefit of the marketing authorisation issued in favour of a plant protection product already on the market of the Member State of importation'.[33]

C – *Analysis of the question referred*

41. It is clear from this brief outline that the simplified authorisation procedure for the placing on the market or use of a product imported as a parallel import of a reference product is based on the assumption that, where certain conditions are fulfilled, the product to be imported *does not require a marketing authorisation* because it 'must be considered to have *already been placed on the market of the Member State of importation*'.[34]

42. In that regard, I am not convinced that the case-law cited above should be construed, as the French Government suggests in its observations, as a derogation from or exception to the principle laid down in Article 3(1) of the Directive to the effect that any product placed on the market of a Member State must first have been authorised by the authorities of that State in accordance with the Directive. Rather, it seems to me that that case-law should be interpreted as an *application of that principle* to situations which are not covered by the Directive and are governed, under EU law, only by the Treaty provisions on the free movement of goods. It is clear from that line of case-law that the purpose of the simplified control procedure is to verify whether the product to be imported may have the benefit of a marketing authorisation issued for a product already on the market of that State.[35] If

29 — Paragraph 40.

30 — Paragraph 36.

31 — EU:C:2007:659.

32 — *Commission* v *France* (C-201/06, EU:C:2008:104).

33 — Paragraph 37. In contrast to the statement made in *Kohlpharma* (C-112/02, EU:C:2004:208, paragraph 21), in relation to importation of pharmaceutical products the Court found that France was entitled to require, for the purpose of the grant of a parallel import authorisation for a plant protection product, that that product and the product already authorised in that Member State have a common origin. According to the Court, if the two products do not have a common origin because they were manufactured by two competing undertakings, 'the imported product must, at first sight, be regarded as separate from the reference product and, consequently, as having been placed on the market of the Member State of importation for the first time'.

34 — See *British Agrochemicals Association* (EU:C:1999:129, paragraph 36) and *Escalier and Bonnarel* (EU:C:2007:659, paragraph 32).

35 — See, in particular, *Escalier and Bonnarel* (EU:C:2007:659, paragraph 32).

that is the case, it is, therefore, *under cover of that marketing authorisation*, granted in accordance with the Directive, that the imported product may be placed on the market and used in the importing Member State. That interpretation is, moreover, supported by paragraph 29 of *Escalier and Bonnarel*, in which the Court stated that Member States must carry out the checks required under the simplified control procedure 'since they are obliged to *ensure that the obligations and prohibitions laid down by the Directive are complied with*'.[36]

43. Accordingly, the case-law cited above stated that a plant protection product introduced into the territory of a Member State as a parallel import cannot, 'automatically or absolutely and unconditionally, have the benefit of a marketing authorisation issued to a plant protection product already on the market of that State'.[37] First, all importers must obtain an authorisation, granted following a control procedure, whether or not the product is being imported for the purposes of being placed on the market. Secondly, the imported product must fulfil certain conditions intended to determine whether it is identical to the reference product. Thirdly, even when those conditions are fulfilled, the imported product cannot have the benefit of the marketing authorisation issued to the reference product if that is precluded by considerations relating to the effective protection of human and animal health and of the environment.[38]

44. In that context, it is essential to establish that the product to be imported is identical to the reference product, since it is only if they have been found to be identical that the product may be considered to have already been authorised in the importing Member State and therefore benefit from the marketing authorisation for the reference product. The control mechanism established in *British Agrochemicals Association* is based on the notion that, if the product to be imported may be regarded as identical to the reference product and there are no grounds relating to the protection of human or animal health or of the environment for denying that product the benefit of the marketing authorisation granted for the reference product, to make importation conditional on the product to be imported being subject to an examination procedure under Article 4 of the Directive would constitute a restriction on trade between Member States, which is prohibited by Article 34 TFEU. The authorities in the importing Member State are entitled (or, rather, obliged), for the purposes of authorising the importation, to ensure that the conditions laid down by the Directive are complied with only if the product to be imported and the reference product are found not to be identical or it is impossible to establish whether or not they are identical.[39]

45. In the present case, the question that arises is whether the simplified control procedure described above may be used only for plant protection products which have been authorised in accordance with the Directive in the exporting Member State.

46. According to the French Government, it follows from the case-law cited in this Opinion that that question should be answered in the negative. Unlike the French Government, I do not believe there are any clear indications to that effect — or to the contrary — in that case-law.

47. To date, the Court has had to deal only with situations in which parallel import products benefited, in the exporting Member State, from a marketing authorisation granted in accordance with the Directive, which may, in my view, explain the terminology used by the Court in the various passages of the judgments cited in points 37 to 39 above, which do seem to limit the application of the simplified control procedure to those situations alone.[40] Moreover, although the complaint on which

36 — Emphasis added. See also paragraph 35 of that judgment. I would point out, however, that *British Agrochemicals Association* (EU:C:1999:129, paragraph 36) seems, on the other hand, to be based on the principle of an exception to the rule: see, to that effect, for example, paragraph 41.

37 — *Escalier and Bonnarel* (EU:C:2007:659, paragraph 30).

38 — Ibidem.

39 — See *Escalier and Bonnarel* (EU:C:2007:659, paragraph 30) and *British Agrochemicals Association* (EU:C:1999:129, paragraph 37).

40 — In other passages, however, the Court refers, more generally, to products which are 'already authorised in another Member State'; see, for example, *Escalier and Bonnarel* (EU:C:2007:659, paragraph 28).

the action in *Commission* v *France* (EU:C:2008:104) was based did indeed concern a case of 'double importation' — the product in question having been parallel-imported first from Germany to Austria and then from Austria to France —,[41] the claim that France had failed to fulfil its obligations was based on the requirement for the imported product and the reference product to have a common origin, which meant that both the discussion between the parties and the judgment of the Court related to that single issue alone.[42]

48. In *British Agrochemicals Association*, the Court held that a plant protection product *from a third country*, which is not therefore covered by a marketing authorisation granted in accordance with the Directive, may not be placed on the market of a Member State as a parallel import under the simplified control procedure even if it has been established that it is identical to a product already authorised in that Member State. By converse inference, it might be concluded that, in addition to the conditions and limits set out in point 43 above, case-law requires that, in order for a product imported as a parallel import to be able to benefit from the marketing authorisation granted for the reference product, it must also have been authorised *in accordance with the Directive* in the Member State or in the EEA State in which it originates.

49. However, such a conclusion seems to me to be excessive. By excluding parallel imports originating in third countries from the simplified control procedure, the Court intended, in my view, to reserve the application of that procedure exclusively for products which have already been lawfully placed on the market of a Member State and benefit from the Treaty provisions on the free movement of goods.[43] That limitation is justified, in essence, by the fact that, as there is no harmonisation at international level of the conditions under which plant protection products may be placed on the market, products from third countries do not offer the same guarantees, in terms of the protection of human and animal health and of the environment, as products governed by the harmonised authorisation system established within the EU.[44] Products for which a parallel import authorisation has been granted by a Member State on the basis of the simplified control procedure form part of such a system and, in principle, offer the same guarantees as those covered by a marketing authorisation granted in accordance with the Directive. Although they have not been the subject of an authorisation procedure in accordance with the Directive in the Member State into which they were imported as parallel imports, they have none the less been subject to such a procedure in the Member State where they were placed on the EU market for the first time.

50. The reason given by the French Government to justify its refusal to authorise the parallel importation of plant protection products which have been granted only a parallel import authorisation in the exporting Member State is that those products do not offer the same guarantees as regards the protection of human health and of the environment as products authorised in accordance with the Directive. Those products could be different from the reference product authorised in the exporting Member State in the way in which they are presented, packaged and labelled, with the result that the authorities in the importing Member State 'may not have all the information necessary to compare th(ose) product(s) with the reference product which they have authorised'.

51. As indicated above, a parallel import authorisation may be granted only if it can be demonstrated that the product to be imported is identical to the reference product authorised in the importing Member State. As the French Government is correct to observe, the authorities of the importing Member State cannot carry out such an assessment unless they have all the information necessary for that purpose.

41 — Point 13 of the Advocate General's Opinion.

42 — I would nevertheless point out that the French Republic had initially granted a parallel import marketing authorisation for the product in question, but this was subsequently withdrawn because the French authorities had doubts as to whether that product and the reference product had a common origin.

43 — Points 43 and 44.

44 — See points 41 to 43.

52. However, as the Court has pointed out on several occasions, those authorities normally have the legislative and administrative means of compelling the manufacturer, his duly appointed representative or the licensee for the plant protection product already covered by marketing authorisation to supply information in their possession which they consider necessary.[45] Those authorities may also consult the file submitted in connection with the application for marketing authorisation in respect of that product[46] and request information from the authorities in the Member State where the product to be imported has been authorised.[47] Where such a product has been authorised only as a parallel import, that information may relate both to that product itself and to the product which served as the reference product for the purposes of the parallel importation. Information may also be obtained, by means of the information exchange system established by the Directive, from the Member State from which the product was exported for the first time and in which it is covered by a marketing authorisation granted in accordance with the Directive. Furthermore, in circumstances such as those in the present case, in which a product which has been authorised in one Member State in accordance with the Directive is imported as a parallel import into that Member State after having been exported from there and imported into another Member State as a parallel import, the information necessary to carry out the checks required under the simplified control procedure should, in principle, be easier to find, given that the reference product in the importing Member State is the same as the product which was first exported from there.

53. Under those circumstances, a total ban on the parallel importation of plant protection products which have been imported as parallel imports into the Member State from which they were exported, such as the prohibition in force in France, which is based on an alleged systemic inadequacy in the information that can be made available to the importing Member State or on the mere 'possibility' of such inadequacy, cannot be justified, at least in cases of 'parallel reimportation' such as that at issue here.

54. With regard, more particularly, to the information relating not to the active ingredient or the origin of the product to be imported but to its co-formulants, packaging, labelling and container, it is, admittedly, true that, as maintained by the French Government, that information is not necessarily obtained as part of the checks carried out under the simplified control procedure introduced by the case-law cited above,[48] since the sole purpose of that procedure is to establish whether the product imported as a parallel import may be covered by the marketing authorisation granted for the reference product.

55. However, I would point out, first, that that fact alone does not rule out the possibility that that information may, in any event, have been acquired when those checks were carried out[49] or that the Member State into which the product is imported may obtain it, for example by consulting the file submitted in connection with the application for a marketing authorisation in the Member State from which the product was first exported. In the case of the 'parallel reimportation' of a product, that information may, in principle, be easily obtained from the file relating to the reference product in the State of reimportation.

45 — See *British Agrochemicals Association* (EU:C:1999:129, paragraph 37); *De Peijper* (EU:C:1976:67, paragraph 27); and *Smith & Nephew and Primecrown* (EU:C:1996:432, paragraph 26).

46 — See *British Agrochemicals Association* (EU:C:1999:129, paragraph 34).

47 — In that regard I would point out that, under Article 9(5) of the Directive, Member States must, on request, make available to the other Member States the files which they are required to compile on each application for authorisation by supplying to them all the information necessary for full comprehension of those applications. It was, moreover, this provision which the AFSSA relied on in order to obtain the information necessary to determine whether Agrotech Ethephon was identical to the reference product Cerone. A procedure for the ad hoc exchange of information between Member States is provided for in Article 52 of Regulation No 1107/2009.

48 — I would point out, incidentally, that the conditions for the grant of a parallel trade permit under Article 52 of Regulation No 1107/2009 are stricter than those established by the case-law in *British Agrochemicals Association*. Article 52(3)(c) provides that plant protection products must be regarded as identical to the reference products 'if they are either the same or equivalent in the co-formulants present and the packaging size, material or form, in terms of the potential adverse impact on the safety of the product with regard to human or animal health or the environment'.

49 — As explained in the preceding footnote, that information must of necessity be included in applications for a parallel import permit submitted under Article 52 of Regulation No 1107/2009.

56. Secondly, I would point out that the legislation on parallel imports of plant protection products in force in France at the time of the decision refusing authorisation did not provide that the checks carried out under the simplified authorisation procedure should also cover the co-formulants or the packaging of the product to be imported, the purpose of those checks being restricted to what was required in *British Agrochemicals Association*. Accordingly, there was no requirement for any checks to be carried out in relation to those factors at the time when the AFSSA gave its opinion regarding the parallel import authorisation for the product in question in the main proceedings.

57. Thirdly, if, on completion of the control procedure, the authorities in the importing Member State were to conclude, on the basis of the information made available to them, that the product to be authorised has undergone changes in the course of previous parallel importations, to the extent that it can no longer be regarded as constituting a parallel import of the reference product, or if they were to consider that the information available is not sufficient to establish that the product in question is identical to the reference product, or if they were to take the view that the product does not guarantee an adequate level of protection of human or animal health or of the environment, they would be justified in rejecting the application for authorisation to import the product.

58. In the light of those circumstances, the arguments put forward by the French Government regarding the alleged difficulty of measuring the potential adverse impact of any changes which may have been made to a product which has been the subject of successive parallel importations, in terms of its presentation and/or packaging, are also incapable of justifying a total ban on reimportation, at the very least in a case such as that before the referring court.

59. By definition, a total ban on the importation of a given product falls within the scope of Article 34 TFEU and constitutes the most restrictive measure, in terms of its effect on the free movement of goods, that a Member State can adopt in pursuit of the objectives laid down in Article 36 TFEU. The systematic refusal on the part of the authorities of the Member State concerned to grant the permit required in order to be able to import products subject to administrative authorisation regimes with a view to marketing and using them in that Member State constitutes a measure having an effect equivalent to such a ban. In general, such a total ban on importation or use cannot be considered to be proportionate if there exist alternative measures that are also capable of attaining the objectives invoked by the Member State concerned while at the same time having a less restrictive effect on intra-Union trade.[50] As the Commission was correct to point out in its written observations, the Court stated, in *Escalier and Bonnarel* (EU:C:2007:659), that, while it is for the national authorities 'to ensure that the primary objective of the Community legislation, namely the safeguarding of human and animal health and of the environment, is fully complied with', 'the principle of proportionality requires that, in order to protect the free movement of goods, the legislation in question be applied within the limit of what is necessary in order to achieve the aim of protection of the environment and of human and animal health that is legitimately being pursued'.

60. For all the reasons given above, I am of the view that the national legislation at issue, in so far as it precludes the grant of a parallel import authorisation under the simplified control procedure established in *British Agrochemicals Association* (EU:C:1999:129), for plant protection products from another Member State into which they were previously imported as parallel imports from France, thereby preventing their reimportation into that Member State, goes beyond what is necessary to protect human or animal health and the environment.

50 — See, for example, *Commission* v *Belgium* (C-100/08, EU:C:2009:537) and *Kakavetsos-Fragkopoulos* (C-161/09, EU:C:2011:110).

VI – **Conclusion**

61. In the light of the foregoing, I propose that the Court reply to the question referred for a preliminary ruling by the Conseil d'État as follows:

Articles 34 TFEU and 36 TFEU preclude the legislation of a Member State which makes the grant of a parallel import marketing authorisation for a plant protection product which has been reimported into that Member State after being imported as a parallel import into another Member State subject to the condition that the product should have, in the exporting State, a marketing authorisation granted in accordance with Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market.