Reports of Cases

JUDGMENT OF THE COURT (First Chamber)

14 November 2019*

(Reference for a preliminary ruling — Regulation (EC) No 1107/2009 — Placing of plant protection products on the market — Parallel trade — Modification of the period of validity of the parallel trade permit — Identity of the plant protection product and the reference product — Conditions)

In Case C-445/18,

REQUEST for a preliminary ruling under Article 267 TFEU from the College van Beroep voor het bedrijfsleven (Administrative Court of Appeal for Trade and Industry, Netherlands), made by decision of 3 July 2018, received at the Court on 9 July 2018, in the proceedings

Vaselife International BV,

Chrysal International BV,

v

College voor de toelating van gewasbeschermingsmiddelen en biociden,

THE COURT (First Chamber),

composed of J.-C. Bonichot, President of the Chamber, R. Silva de Lapuerta, Vice-President of the Court, M. Safjan, L. Bay Larsen (Rapporteur) and C. Toader, Judges,

Advocate General: G. Hogan,

Registrar: M. Ferreira, Principal Administrator,

having regard to the written procedure and further to the hearing on 13 May 2019,

after considering the observations submitted on behalf of:

– Vaselife International BV, by O.P. Swens and A. Yildiz, advocaten,

– Chrysal International BV, by E. Broeren and A. Freriks, advocaten,

– the Netherlands Government, by M.K. Bulterman, M.H.S. Gijzen and C.S. Schillemans, acting as Agents,

– the European Commission, by A. Bouquet, I. Naglis and G. Koleva, acting as Agents,

after hearing the Opinion of the Advocate General at the sitting on 27 June 2019,

* Language of the case: Dutch.

gives the following

Judgment

1 This request for a preliminary ruling concerns the interpretation of Article 52 of 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).

2 The request has been made in proceedings between Vaselife International BV ('Vaselife') and Chrysal International BV ('Chrysal') and the College voor de toelating van gewasbeschermingsmiddelen en biociden (Netherlands Board for the Authorisation of Plant Protection Products and Biocides) ('the competent Netherlands authority'), concerning, primarily, the refusal by that authority to renew the parallel trade permit previously granted to Vaselife.

Legal context

3 Recitals 3, 8, 9, 24 and 31 of Regulation No 1107/2009 state:

'(3) In the light of experience gained from the application of [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)] and of recent scientific and technical developments, that Directive should be replaced.

…

(8) The purpose of this Regulation is to ensure a high level of protection of both human and animal health and the environment and at the same time to safeguard the competitiveness of Community agriculture. Particular attention should be paid to the protection of vulnerable groups of the population, including pregnant women, infants and children. The precautionary principle should be applied and this Regulation should ensure that industry demonstrates that substances or products produced or placed on the market do not have any harmful effect on human or animal health or any unacceptable effects on the environment.

(9) In order to remove as far as possible obstacles to trade in plant protection products existing due to the different levels of protection in the Member States, this Regulation should also lay down harmonised rules for the approval of active substances and the placing on the market of plant protection products, including the rules on the mutual recognition of authorisations and on parallel trade. The purpose of this Regulation is thus to increase the free movement of such products and availability of these products in the Member States.

…

(24) The provisions governing authorisation must ensure a high standard of protection. In particular, when granting authorisations of plant protection products, the objective of protecting human and animal health and the environment should take priority over the objective of improving plant production. Therefore, it should be demonstrated, before plant protection products are placed on the market, that they present a clear benefit for plant production and do not have any harmful effect on human or animal health, including that of vulnerable groups, or any unacceptable effects on the environment.

…

(31) Where identical plant protection products are authorised in different Member States, a simplified procedure for granting a parallel trade permit should be provided for in this Regulation, in order to facilitate the trade between Member States of such products.'

4 Article 28 of that regulation, entitled 'Authorisation for placing on the market and use', provides:

'1. A plant protection product shall not be placed on the market or used unless it has been authorised in the Member State concerned in accordance with this Regulation.

2. By way of derogation from paragraph 1, no authorisation shall be required in the following cases:

…

(e) placing on the market and use of plant protection products for which a parallel trade permit has been granted in accordance with Article 52.'

5 Article 29 of that regulation, entitled 'Requirements for the authorisation for placing on the market', is worded as follows:

'1. Without prejudice to Article 50 a plant protection product shall only be authorised where following the uniform principles referred to in paragraph 6 it complies with the following requirements:

(a) its active substances, safeners and synergists have been approved;

(b) where its active substance, safener or synergist is produced by a different source, or by the same source with a change in the manufacturing process and/or manufacturing location:
   (i) the specification, pursuant to Article 38, does not deviate significantly from the specification included in the Regulation approving that substance, safener or synergist; and
   (ii) the active substance, safener or synergist has no more harmful effects within the meaning of Article 4(2) and (3) due to its impurities than if it had been produced in accordance with the manufacturing process specified in the dossier that supported the approval;

(c) its co-formulants are not included in Annex III;

(d) its technical formulation is such that user exposure or other risks are limited as much as possible without compromising the functioning of the product;

…

2. The applicant shall demonstrate that the requirements provided for in points (a) to (h) of paragraph 1 are met.

3. Compliance with the requirements set out in point (b) and points (e) to (h) of paragraph 1 shall be established by official or officially recognised tests and analyses …

…

6. Uniform principles for evaluation and authorisation of plant protection products shall contain the requirements set out in Annex VI to Directive 91/414/EEC and shall be laid down in Regulations adopted in accordance with the advisory procedure referred to in Article 79(2) without any substantial modifications. …

Following these principles, interaction between the active substance, safeners, synergists and co-formulants shall be taken into account in the evaluation of plant protection products.'

6 Article 43 of Regulation No 1107/2009, entitled ‘Renewal of authorisation’, provides:

‘1. An authorisation shall be renewed upon application by the authorisation holder, provided that the requirements referred to in Article 29 are still met.

…

5. Member States shall decide on the renewal of the authorisation of a plant protection product at the latest 12 months after the renewal of the approval of the active substance, safener or synergist contained therein.

6. Where, for reasons beyond the control of the holder of the authorisation, no decision is taken on the renewal of the authorisation before its expiry, the Member State in question shall extend the authorisation for the period necessary to complete the examination and adopt a decision on the renewal.’

7 Article 44 of that regulation, entitled ‘Withdrawal or amendment of an authorisation’, provides:

‘1. Member States may review an authorisation at any time where there are indications that a requirement referred to in Article 29 is no longer satisfied.

…

2. Where a Member State intends to withdraw or amend an authorisation, it shall inform the authorisation holder and give him the possibility to submit comments or further information.

3. The Member State shall withdraw or amend the authorisation, as appropriate, where:

(a) the requirements referred to in Article 29 are not or are no longer satisfied;

…’

8 Article 45 of that regulation, entitled ‘Withdrawal or amendment of an authorisation at the request of the authorisation holder’, states, in paragraphs 1 and 2 thereof, that ‘an authorisation may be withdrawn or amended at the request of the holder of the authorisation, who shall state the reasons for his request’, and that ‘amendments may only be granted where it is established that the requirements referred to in Article 29 continue to be met’.

9 Article 46 of that regulation, entitled ‘Grace period’, states:

‘Where a Member State withdraws or amends an authorisation or does not renew it, it may grant a grace period for the disposal, storage, placing on the market and use of existing stocks.

Where the reasons for withdrawal, amendment or non-renewal of the authorisation are not related to the protection of human and animal health or the environment, the grace period shall be limited and shall not exceed 6 months for the sale and the distribution and an additional maximum of 1 year for the disposal, storage, and use of existing stocks of the plant protection products concerned.’

10 Article 52 of Regulation No 1107/2009, entitled ‘Parallel trade’, provides:

‘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.

2. From receiving a complete application, a parallel trade permit shall be granted in a simplified procedure within 45 working days if the plant protection product to be introduced is identical in terms of paragraph 3. Member States shall on request provide each other with the information necessary to assess whether the products are identical within 10 working days of receiving the request. The procedure for granting a parallel trade permit is interrupted from the day the request for information is sent to the competent authority of the Member State of origin until the complete information required is delivered to the competent authority of the Member State of introduction.

3. Plant protection products shall be considered as identical to the reference products 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.

4. The application for a parallel trade permit shall include the following information:

(a) the name and registration number of the plant protection product in the Member State of origin;

(b) the Member State of origin;

(c) the name and address of the authorisation holder in the Member State of origin;

…

(e) the name and address of the applicant;

…

(i) the name and registration number of the reference product.

…

5. A plant protection product for which a parallel trade permit has been issued shall be placed on the market and used only in accordance with the provisions of the authorisation of the reference product. …

6. The parallel trade permit shall be valid for the duration of authorisation of the reference product. If the authorisation holder of the reference product applies for a withdrawal of authorisation in accordance with Article 45(1) and the requirements of Article 29 are still fulfilled, the validity of the parallel trade permit shall expire by the date on which the authorisation of the reference product would normally have expired.

7. Without prejudice to specific provisions of this Article, Articles 44, 45, 46, and 55 and Article 56(4) and Chapters VI to X shall apply to parallel traded plant protection products correspondingly.

8. Without prejudice to Article 44, a parallel trade permit may be withdrawn if the authorisation of the introduced plant protection product is withdrawn in the Member State of origin because of safety or efficacy reasons.

9. Where the product is not identical, in terms of paragraph 3, to the reference product, the Member State of introduction may only grant the authorisation required for placing on the market and use in accordance with Article 29.

…'

11 Article 56 of that regulation, entitled 'Information on potentially harmful or unacceptable effects', is worded as follows:

'1. The holder of an authorisation for a plant protection product shall immediately notify the Member States that granted an authorisation of any new information concerning that plant protection product, … which suggests that [it] no longer complies with the criteria set out in Articles 29 and 4 respectively.

…

3. Without prejudice to the right of Member States to adopt interim protective measures, the Member State which first granted an authorisation within each zone shall evaluate the information received and inform the other Member States, belonging to the same zone, where it decides to withdraw or amend the authorisation under Article 44.

…'

12 Article 83 of that regulation, entitled 'Repeal', provides, in its first paragraph:

'Without prejudice to Article 80, Directives 79/117/EEC and 91/414/EEC, as amended by the acts listed in Annex V, are repealed with effect from 14 June 2011, without prejudice to the obligations of the Member States relating to the time limits for transposition into national law and application of the Directives set out in that Annex.'

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

13 By decision of 12 June 2015, entitled 'Decision on the parallel trade permit' ('Decision I'), the competent Netherlands authority granted Vaselife, which had submitted an application to that effect, a parallel trade permit for the product Vaselife Universal Bulb PHT ('the product Vaselife UB'), with the authorisation number 14878N, expiring on 31 December 2016.

14 It is apparent from that decision that the product Vaselife UB is imported from Italy, where it is registered or authorised as a plant protection product under the name Promalin. That product does not differ fundamentally from the reference product VBC-476, with the authorisation number 12865N, which is authorised in the Netherlands and manufactured, like Promalin, by Valent Biosciences, a division of Sumitomo Chemical Agro Europe SAS ('Sumitomo').

15 Following Sumitomo's application for re-registration of the authorisation for the plant protection product VBC-476, the competent Netherlands authority granted, by decision of 23 December 2015, the authorisation of that product under the same authorisation number 12865N as previously. That decision changes the holder of the authorisation for that product from Valent Biosciences to Sumitomo, and refers to 1 December 2025 as the expiry date.

16 By decision of 19 February 2016, changing the composition of the authorised plant protection product VBC-476, the competent Netherlands authority decided, at Sumitomo's request, to change that product. The authorisation for that product retains the number 12865N and the expiry date of 1 December 2025.

17 By decision of the competent Netherlands authority of 19 February 2016, transferring the authorisation 12865N for VBC-476, that authorisation was transferred to Chrysal at Sumitomo's request.

18 By decision of 1 March 2016, entitled 'Decision to renew the parallel permit' ('Decision II'), the competent Netherlands authority decided to renew the parallel trade permit issued for the product Vaselife UB by Decision I until 1 December 2025. To that end, that authority relied on Article 52 of Regulation No 1107/2009, considering that that product was manufactured by Valent Biosciences and therefore came from the same undertaking as the reference product.

19 Chrysal lodged a complaint against Decision II on 1 April 2016.

20 By decision of 26 April 2017, the competent Netherlands authority declared Chrysal's complaint against Decision II admissible and, in part, well founded, withdrew Decision II and rejected Vaselife's application for the renewal of Decision I.

21 In support of the decision of 26 April 2017, that authority noted, inter alia, the following:

– the early re-registration of the reference product changed the expiry date of the authorisation of that product from 31 December 2016 to 1 December 2025. As a result, the expiry date of 31 December 2016 provided for in the parallel trade permit is no longer in line with that of the reference product. The change in the expiry date of the authorisation of the reference product led the competent Netherlands authority, in agreement with Vaselife and at its request, to renew that permit until 1 December 2025;

– the decision of 19 February 2016, amending the composition of the reference product, relates to a minor change. Therefore, the product Vaselife UB is still identical to the reference product within the meaning of Article 52(3)(b) and (c) of Regulation No 1107/2009;

– Chrysal is not a company associated with Valent Biosciences. Nor does it work under a license granted by that company. In addition, it is apparent from the application for amendment of the name of the authorisation holder for the reference product that the place of manufacture of the reference product has changed. As a result, the reference product and the product Vaselife UB do not have a common origin and are therefore not 'identical products' within the meaning of Article 52 of Regulation No 1107/2009. Therefore, Chrysal's claim is well founded on that point; and

– a renewal of the parallel trade permit is not possible, because the conditions of Article 52 of Regulation No 1107/2009 are no longer satisfied. Since those conditions are no longer satisfied and the validity of Decision I expired on 31 December 2016, a grace period should be granted until 1 November 2017, pursuant to Article 46 of Regulation No 1107/2009, for consignments already imported and notified to the Nederlandse voedsel- en warenautoriteit (Netherlands Food and Consumer Product Safety Authority).

22 Vaselife appealed against the decision of 26 April 2017 to the College van Beroep voor het bedrijfsleven (Administrative Court of Appeal for Trade and Industry, Netherlands).

23 By decision of 3 June 2016, the competent Netherlands authority granted Chrysal's application to change the name of the product VBC-476 to Chrysal BVB.

24 In addition, the competent Netherlands authority, by decision of 20 July 2017, extended the effect of the grace period granted in the decision of 26 April 2017 in that, in addition to the two lots specifically indicated in that decision, the existing stock of the product Vaselife UB, with the lot number 272-994-S 4, could be delivered until 1 November 2017 and used until 1 November 2018.

25 Chrysal lodged an appeal against that decision.

26 In those circumstances the College van Beroep voor het bedrijfsleven (Administrative Court of Appeal for Trade and Industry) decided to stay the proceedings and to refer the following questions to the Court of Justice for a preliminary ruling:

'(1) Is the competent authority … authorised, after having taken a decision to re-register the reference product, whether or not of its own motion, to change the period of validity of a parallel trade permit as referred to in Article 52 of Regulation No 1107/2009, where that permit was granted before the re-registration decision, in accordance with the — later — date of the period of validity applying to the decision to re-register the reference product?

(2) If Question 1 is answered in the affirmative, is the change to the period of validity of a parallel trade permit an automatic consequence of a decision to re-register the reference product resulting from Regulation No 1107/2009 itself? Is the entry of the new date of the period of validity of the parallel [trade] permit into the database of the competent authority thus a purely administrative act, or does it require a decision taken by that authority of its own motion or in response to a request?

(3) If the answer to Question 2 is that a decision must be taken, does Article 52 of Regulation No 1107/2009, and, in particular, the third paragraph of that article, apply to that decision?

(4) If Question 3 is answered in the negative, which provision(s) is/are then applicable?

(5) Can a plant protection product already be considered not to be identical within the meaning of Article 52 of Regulation No 1107/2009 if the reference product does not (any longer) originate from the same undertaking? The Court of Justice is requested, in answering that question, also to consider whether the notion of an associated undertaking or of an undertaking operating under licence can also include an undertaking which produces the product according to the same recipe, with the consent of the right-holder. Is it relevant here whether the production process according to which the reference product and the parallel product which is to be introduced are manufactured is carried out by the same undertaking as far as the active substances are concerned?

(6) Is the mere changing of the location for the production of the reference product relevant to the assessment of whether the product is identical?

(7) If Questions 5 and/or 6 are/is answered in the affirmative, can the conclusion to be drawn therefrom ("not identical") be undermined by the fact that the competent authority has already established that, as regards its composition, the product has not undergone any change or has undergone only a slight change?

(8) On whom and to what extent does the burden of proof lie to show that Article 52(3) of Regulation No 1107/2009 has been satisfied if the holders of the authorisation for the parallel product and for the reference product have a difference of opinion in that regard?'

Consideration of the questions referred

The first to fourth questions

27 By its first to fourth questions, which must be examined together, the referring court seeks, in essence, to ascertain:

– whether EU law and, in particular, Regulation No 1107/2009 must be interpreted as not precluding a national procedure under which the competent authority is empowered to take the initiative of its own motion to adapt the period of validity of a parallel trade permit to the period of validity of the renewed authorisation of the reference product;

– whether, if that is the case, Regulation No 1107/2009 and, in particular, Article 52 thereof, must be interpreted as meaning that the adaptation of the period of validity of a parallel trade permit automatically follows from the decision to renew the authorisation of the reference product or if it requires a separate decision to be taken in this respect;

– whether, in the event that a separate decision is required, Regulation No 1107/2009 must be interpreted as meaning that, where it concerns the adaptation of the period of validity of a parallel trade permit to the period of validity of the renewed authorisation of the reference product, it is the conditions for obtaining that permit laid down in Article 52(1) to (3) of Regulation No 1107/2009 or the conditions laid down in other provisions that must be satisfied.

28 It should be borne in mind that, under the first sentence of Article 52(6) of Regulation No 1107/2009, the parallel trade permit is to be valid for the duration of the authorisation of the reference product.

29 Pursuant to Article 43(1) of Regulation No 1107/2009, the authorisation is to be renewed upon application by the authorisation holder, provided that the requirements referred to in Article 29 of that regulation are still met, and compliance with them is intended to ensure, as is apparent, inter alia, from recital 24 of that regulation, a high level of protection of human and animal health and the environment.

30 By contrast, Regulation No 1107/2009 does not contain any express provision concerning the adaptation of the period of validity of a parallel trade permit to the period of validity of the renewed authorisation of the reference product.

31 However, just as, under Article 43(1) of Regulation No 1107/2009, the requirements for authorisation referred to in Article 29 of that regulation must be met when renewing an authorisation of the reference product, it may be deduced from the scheme of that regulation that, in accordance with Article 52(1) to (3) thereof, when it comes to adapting the period of validity of a parallel trade permit to the period of validity of the renewed authorisation of the reference product, the conditions for obtaining that permit laid down in those paragraphs must be satisfied.

32 Such a requirement is in line with the dual objective of Article 52 of Regulation No 1107/2009, which is, as is apparent, inter alia, from recitals 8, 9 and 31 of that regulation, to facilitate parallel trade in identical plant protection products authorised in different Member States, while ensuring a high level of protection of both human and animal health and the environment.

33 Such an interpretation of Article 52(1) to (3) of Regulation No 1107/2009 is also supported by Article 44 of that regulation, read in conjunction with Article 52(7) thereof. Just as, according to Article 44 of Regulation No 1107/2009, Member States may review an authorisation at any time where there are indications that a requirement referred to in Article 29 of that regulation is no longer

satisfied, Member States may, pursuant to Article 52(7) of that regulation, review a parallel trade permit at any time if there are indications that a requirement referred to in Article 52(1) to (3) of that regulation is no longer satisfied.

34 Thus, in so far as, when it comes to adapting the period of validity of a parallel trade permit to the period of validity of the renewed authorisation of the reference product, the conditions for obtaining that permit laid down in Article 52(1) to (3) of Regulation No 1107/2009 must be satisfied, it is for the competent authority of the Member State concerned to determine whether that is indeed the case.

35 However, such a determination by the competent authority of the Member State concerned precludes the possibility that the adaptation of the period of validity of a parallel trade permit automatically follows from the decision to renew the authorisation of the reference product, without any decision having to be taken, especially since such an adaptation is likely to adversely affect the rights of third parties.

36 Therefore, when the conditions noted in paragraph 34 above are satisfied, the adaptation of the period of validity of a parallel trade permit to the period of validity of the renewed authorisation of the reference product is to be given concrete expression in the granting of a new parallel trade permit.

37 In this respect, it may be recalled that, under point 8 of the Guidance document concerning the parallel trade of plant protection products, published on 14 July 2015, 'upon the expiry date of a parallel trade permit a new application needs to be submitted according to the provisions of Article 52 of Regulation No 1107/2009. The assessment of these applications against the criteria of Article 52 will be conducted considering them as new applications. Therefore, a complete set of documents needs to be submitted'.

38 As to whether a new parallel trade permit, the period of validity of which is aligned with that of the renewed authorisation of the reference product, may be issued by the competent authority of the Member State concerned of its own motion, it is important to bear in mind, as noted in paragraph 30 above, that Regulation No 1107/2009 does not contain any express provision in this respect, as only the granting of a 'first' parallel trade permit has to be the subject, in accordance with Article 52(1) of that regulation, of an application submitted to the competent authority of the Member State of introduction.

39 Since the procedure whereby a new parallel trade permit may be obtained is not governed by Regulation No 1107/2009 and since whether it is initiated by the authorities of their own motion or on the initiative of the person concerned is, in essence, neutral in the light of the objectives of that regulation, as set out, inter alia, in recitals 8 and 9 thereof, it is for the Member States to organise that procedure in accordance with the principle of procedural autonomy, on condition, however, that that procedure is not less favourable than that governing similar domestic situations (principle of equivalence) and that it does not make it excessively difficult or impossible in practice to exercise the rights conferred by the EU legal order (principle of effectiveness) (see, to that effect, judgment of 15 March 2017, *Aquino*, C-3/16, EU:C:2017:209, paragraph 48).

40 However, EU law does not preclude a national procedure, such as that at issue in the main proceedings, under which the competent authority is empowered to take the initiative of its own motion to adapt the period of validity of such a permit to the new period of validity of the authorisation of the reference product. In that case, as is apparent from point 36 of the Advocate General's Opinion, the competent authorities must, in accordance with Article 44(2) of Regulation No 1107/2009, inform the holder of the parallel trade permit and give him or her the possibility to submit comments or further information.

41 In view of the foregoing, the answer to the first to fourth questions is that:

– EU law and, in particular, Regulation No 1107/2009 must be interpreted as not precluding a national procedure under which the competent authority is empowered to take the initiative of its own motion to adapt the period of validity of a parallel trade permit to the period of validity of the renewed authorisation of the reference product;

– Regulation No 1107/2009 and, in particular, Article 52 thereof, must be interpreted as meaning that the adaptation of the period of validity of a parallel trade permit does not automatically follow from the decision to renew the authorisation of the reference product, but requires that a decision be taken in this respect;

– Regulation No 1107/2009 must be interpreted as meaning that, when it comes to the adaptation of the period of validity of a parallel trade permit to the period of validity of the renewed authorisation of the reference product, the conditions for obtaining that permit laid down in Article 52(1) to (3) of Regulation No 1107/2009 must be satisfied and it is for the competent authority of the Member State concerned to determine whether that is indeed the case.

The fifth to seventh questions

42 By the fifth to seventh questions, which must be examined together, the referring court asks, in essence, whether Article 52(3)(a) of Regulation No 1107/2009 must be interpreted as including a situation in which the plant protection product authorised by the Member State of origin is manufactured by company A, while the reference plant protection product is manufactured, using the same process but in a different location from the former, by company B with the consent of company A.

43 It should be borne in mind that, under Article 52(1) and (2) of Regulation No 1107/2009, a plant protection product which is authorised in one Member State, namely the Member State of origin, may, subject to the granting of a parallel trade permit, be introduced, placed on the market or used in another Member State, known as the 'Member State of introduction', if the latter Member State determines that that product is identical, within the meaning of paragraph 3 of that article, to the plant protection product already authorised in its territory, namely the reference product. A parallel trade permit is to be granted under a simplified procedure within 45 working days of receipt of a complete application if the plant protection product to be introduced is identical within the meaning of paragraph 3 of that article.

44 Under Article 52(3) of that regulation:

'Plant protection products shall be considered as identical to the reference products 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.'

45 It is apparent from the documents before the Court and, in particular, from the order for reference that the dispute in the main proceedings concerns only the interpretation and application of the identity criterion contained in Article 52(3)(a) of Regulation No 1107/2009, as the product imported into the Netherlands by Vaselife and the reference product manufactured in the Netherlands by Chrysal were considered by the competent Netherlands authority to be 'identical' within the meaning of Article 52(3)(b) and (c) of that regulation, without this being called into question by the parties to the main proceedings.

46 Therefore, it is in the light of Article 52(3)(a) of that regulation that it is appropriate to examine the fifth to seventh questions.

47 In that regard, it is appropriate to refer to the Court's case-law on parallel imports of plant protection products under Directive 91/414 (repealed and replaced by Regulation No 1107/2009 in accordance with recital 3 and the first paragraph of Article 83 of that regulation), which did not provide for a simplified procedure for the granting of marketing authorisations for plant protection products imported in parallel.

48 According to that case-law, where the competent authority of a Member State finds that a plant protection product imported from a Member State in which it is already covered by a marketing authorisation granted in accordance with Directive 91/414, 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 conditions, relevant to the use of the product,

that product must be able to benefit from the marketing authorisation already granted in the Member State of importation, unless this is precluded by considerations concerning the protection of human and animal health and of the environment (see, to that effect, judgments of 11 March 1999, *British Agrochemicals*, C-100/96, EU:C:1999:129, paragraph 40, and of 21 February 2008, *Commission* v *France*, C-201/06, EU:C:2008:104, paragraph 39).

49 It is on that basis that the Court found that, by requiring, for the purpose of granting an authorisation for the parallel import of a plant protection product that the imported product and the product already authorised in France must have a common origin, in the sense that they have been manufactured according to the same formulation by the same company or by an associated undertaking or under licence, the French Republic had not failed to fulfil its obligations under Article 28 EC (judgment of 21 February 2008, *Commission* v *France*, C-201/06, EU:C:2008:104, paragraphs 30 and 45).

50 Thus, under Directive 91/414, plant protection products were regarded as identical if, at least, they shared a common origin in that they had been manufactured by the same company or by an associated undertaking or under licence according to the same formulation, were manufactured using the same active ingredient, and also had the same effect with due regard to differences which might exist in conditions relating to agriculture, plant health and the environment, in particular climatic conditions, relevant to the use of the product (judgment of 6 November 2014, *Mac*, C-108/13, EU:C:2014:2346, paragraph 24).

51 It therefore appears that Article 52(3) of Regulation No 1107/2009, which, like Directive 91/414, pursues in particular the objectives of protecting public health and eliminating barriers to trade between Member States, was largely prompted by that case-law.

52 It follows that that provision lays down as a criterion for the identity of the plant protection product authorised by the Member State of origin and the reference plant protection product that those products have been manufactured by the same company or by an associated company or that they have been manufactured under licence using the same manufacturing process.

53 As regards the expression 'manufactured under licence in accordance with the same manufacturing process' found in Article 52(3)(a) of Regulation No 1107/2009, it must be considered, as the Advocate General noted, in essence, in point 47 of his Opinion, that it also includes situations where the plant protection product authorised by the Member State of origin is manufactured by a different company from that which manufactures the reference product, using the same process and with the consent of the first company, even if that arrangement does not, as such, consist in a formal licensing arrangement, provided that that arrangement is a long-term arrangement similar to a licensing arrangement.

54 Such an interpretation of Article 52(3)(a) of Regulation No 1107/2009 ensures both the common origin of the plant protection product authorised by the Member State of origin and of the reference plant protection product, as a specific objective of that provision, and a high level of protection of human and animal health and the environment, while respecting the free movement of those products, as general objectives of that regulation.

55 Moreover, a change in the place of manufacture of the reference product is, in itself, irrelevant for the purpose of assessing whether the plant protection product authorised by the Member State of origin and the reference plant protection product are identical in the light of Article 52(3)(a) of Regulation No 1107/2009, in that they were manufactured by the same company or by an associated company or in that they are manufactured under licence using the same manufacturing process.

56 In view of all of the foregoing, the answer to the fifth to seventh questions is that Article 52(3)(a) of Regulation No 1107/2009 must be interpreted as including a situation in which the plant protection product authorised by the Member State of origin is manufactured by company A, while the reference plant protection product is manufactured, using the same process but in a different location from the former, by company B with the consent of company A, provided that that arrangement is a long-term arrangement similar to a licensing arrangement.

The eighth question

57 By its eighth question, the referring court, in essence, asks the Court to interpret Article 52(2) to (4) of Regulation No 1107/2009 in order to determine who is responsible for demonstrating, and to what extent, that the products concerned are still 'identical', within the meaning of Article 52(3) of that regulation, when the authorisation holder of the reference product and the holder of the parallel trade permit disagree in that regard.

58 Since, as noted in paragraph 41 above, the adaptation of the period of validity of a parallel trade permit to the period of validity of the renewed authorisation of the reference product requires a fresh decision to be taken in this respect, it follows from Article 52(2) of Regulation No 1107/2009 that it is for the holder of the parallel trade permit to submit a new complete application in order to demonstrate that the products concerned are still 'identical' within the meaning of paragraph 3 of that article.

59 In that event, Article 52(4) of Regulation No 1107/2009 lists the information that the application for a parallel trade permit must contain. In addition, in accordance with Article 52(2) of that regulation, the competent authority may request the Member State of origin of the imported product to provide the information necessary for assessing whether the products concerned are identical.

60 Moreover, in the absence of EU rules concerning the procedural requirements attaching to the burden of proof in the context of processing an application for a parallel trade permit or a challenge to a decision granting such a permit, it is for the domestic legal system of each Member State to determine those requirements in accordance with the principle of procedural autonomy, provided that it respects the principles set out in paragraph 39 above.

61 Therefore, if the holder of the authorisation for the reference product challenges the decision granting the parallel trade permit, the national rules of the Member State concerned are to apply concerning the burden of proof, provided that those rules respect the principle of equivalence and do not make it excessively difficult or impossible in practice to exercise the rights conferred by the EU legal order.

62 Accordingly, the answer to the eighth question is that Article 52(2) to (4) of Regulation No 1107/2009 must be interpreted as meaning that it is for the holder of the parallel trade permit to submit a new complete application, providing the information referred to in Article 52(4) of that regulation, in order to demonstrate that the products concerned are still 'identical' within the meaning of paragraph 3 of that article, without prejudice to the competent authority being able to request the Member State of origin of the imported product to provide the information necessary for assessing whether those products are identical. In the event of a challenge to the decision granting the parallel trade permit, the national rules of the Member State concerned are to apply as regards the burden of proof, provided that those rules respect the principle of equivalence and do not make it excessively difficult or impossible in practice to exercise the rights conferred by the EU legal order.

Costs

63 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 (First Chamber) hereby rules:

1. **European Union law and, in particular, 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 must be interpreted as not precluding a national procedure under which the competent authority is empowered to take the initiative of its own motion to adapt the period of validity of a parallel trade permit to the period of validity of the renewed authorisation of the reference product.**

   Regulation No 1107/2009 and, in particular, Article 52 thereof, must be interpreted as meaning that the adaptation of the period of validity of a parallel trade permit does not automatically follow from the decision to renew the authorisation of the reference product, but requires that a decision be taken in this respect.

   Regulation No 1107/2009 must be interpreted as meaning that, when it comes to the adaptation of the period of validity of a parallel trade permit to the period of validity of the renewed authorisation of the reference product, the conditions for obtaining that permit laid

down in Article 52(1) to (3) of Regulation No 1107/2009 must be satisfied and it is for the competent authority of the Member State concerned to determine whether that is indeed the case.

2. **Article 52(3)(a) of Regulation No 1107/2009 must be interpreted as including a situation in which the plant protection product authorised by the Member State of origin is manufactured by company A, while the reference plant protection product is manufactured, using the same process but in a different location from the former, by company B with the consent of company A, provided that that arrangement is a long-term arrangement similar to a licensing arrangement.**

3. **Article 52(2) to (4) of Regulation No 1107/2009 must be interpreted as meaning that it is for the holder of the parallel trade permit to submit a new complete application, providing the information referred to in Article 52(4) of that regulation, in order to demonstrate that the products concerned are still 'identical' within the meaning of paragraph 3 of that article, without prejudice to the competent authority being able to request the Member State of origin of the imported product to provide the information necessary for assessing whether those products are identical. In the event of a challenge to the decision granting the parallel trade permit, the national rules of the Member State concerned are to apply as regards the burden of proof, provided that those rules respect the principle of equivalence and do not make it excessively difficult or impossible in practice to exercise the rights conferred by the EU legal order.**

[Signatures]