



Reports of Cases

JUDGMENT OF THE COURT (Third Chamber)

7 December 2023*

(Reference for a preliminary ruling – Approximation of laws – Regulation (EC) No 1107/2009 – Placing of plant protection products on the market – Article 52 – Parallel trade – Regulation (EU) No 547/2011 – Labelling requirements for plant protection products – Annex I, paragraph 1(b) and (f) – Name and address of the holder of the authorisation – Batch number)

In Case C-830/21,

REQUEST for a preliminary ruling under Article 267 TFEU from the Hanseatisches Oberlandesgericht Hamburg (Higher Regional Court, Hamburg, Germany), made by decision of 9 December 2021, received at the Court on 23 December 2021, in the proceedings

Syngenta Agro GmbH

v

Agro Trade Handelsgesellschaft mbH,

THE COURT (Third Chamber),

composed of K. Jürimäe, President of the Chamber, N. Piçarra, M. Safjan, N. Jääskinen and M. Gavalec (Rapporteur), judges,

Advocate General: L. Medina,

Registrar: A. Calot Escobar,

having regard to the written procedure,

after considering the observations submitted on behalf of:

- Syngenta Agro GmbH, by P. Gey and H.-G. Kamann, Rechtsanwälte,
- Agro Trade Handelsgesellschaft mbH, by H.P. Koof, Rechtsanwalt,
- the Greek Government, by V. Karra, K. Konsta and E. Leftheriotou, acting as Agents,
- the Italian Government, by G. Palmieri, acting as Agent, and by A. Collabolletta, avvocato dello Stato,

* Language of the case: German.

- the Austrian Government, by A. Posch, J. Schmoll and V.-S. Strasser, acting as Agents,
- the European Commission, by A.C. Becker and M. Ter Haar, acting as Agents,

after hearing the Opinion of the Advocate General at the sitting on 20 April 2023,

gives the following

Judgment

- 1 This request for a preliminary ruling concerns the interpretation of Article 1 of, and paragraph 1(b) and (f) of Annex I to, Commission Regulation (EU) No 547/2011 of 8 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards labelling requirements for plant protection products (OJ 2011 L 155, p. 176).
- 2 The request has been made in proceedings between Syngenta Agro GmbH and Agro Trade Handelsgesellschaft mbH ('Agro Trade') as regards prohibiting the placing on the market of a plant protection product.

Legal context

European Union law

Regulation (EC) No 1107/2009

- 3 Recitals 8, 9 and 31 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) are worded as follows:
 - '(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. ...
 - (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.
 - ...
 - (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 1 of that regulation, entitled ‘Subject matter and purpose’ provides in paragraph (3):

‘The purpose of this Regulation is to ensure a high level of protection of both human and animal health and the environment and to improve the functioning of the internal market through the harmonisation of the rules on the placing on the market of plant protection products, while improving agricultural production.’

5 Article 3 of that regulation, headed ‘Definitions’, provides:

‘For the purposes of this Regulation, the following definitions shall apply:

...

(10) “authorisation of a plant protection product” means an administrative act by which the competent authority of a Member State authorises the placing on the market of a plant protection product in its territory;

(11) “producer” means a person who manufactures plant protection products, active substances, safeners, synergists, co-formulants or adjuvants on his own, or who contracts this manufacturing to another party, or a person designated by the manufacturer as his sole representative for the purpose of compliance with this Regulation;

...

(24) “authorisation holder” means any natural or legal person holding an authorisation of a plant protection product;

...’

6 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.’

7 Article 52 of Regulation No 1107/2009, entitled ‘Parallel trade’, is worded 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.

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. ...

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;
- (d) the original label and instructions for use with which the plant protection product to be introduced is distributed in the Member State of origin if it is considered as necessary for the examination by the competent authority of the Member State of introduction. This competent authority may require a translation of the relevant parts of the original instructions for use;
- (e) the name and address of the applicant;
- (f) the name to be given to the plant protection product to be distributed in the Member State of introduction;
- (g) a draft label for the product intended to be placed on the market;
- (h) a sample of the product which is intended to be introduced if it is considered as necessary by the competent authority of the Member State of introduction;
- (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. To facilitate monitoring and controls the Commission shall set out specific control requirements for the product to be introduced in a Regulation referred to in Article 68.

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. Without prejudice to Article 63, Member State authorities shall make publicly available information about parallel trade permits.'

8 Article 55 of that regulation, headed 'Use of plant protection products', provides:

'Plant protection products shall be used properly.

Proper use shall include the application of the principles of good plant protection practice and compliance with the conditions established in accordance with Article 31 and specified on the labelling. ...'

9 Article 56 of that regulation, entitled 'Information on potentially harmful or unacceptable effects', provides in paragraph 4:

'The holder of an authorisation for a plant protection product shall report annually to the competent authorities of the Member States which authorised his plant protection product if he has any information available relating to the lack of expected efficacy, the development of resistance and to any unexpected effect on plants, plant products or the environment.'

10 Article 65 of the regulation in question, entitled 'Labelling', states in paragraph 1:

'The labelling of plant protection products shall include the classification, labelling and packaging requirements of Directive 1999/45/EC [of the European Parliament and of the Council of 31 May 1999 concerning the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations (OJ 1999 L 200, p. 1)] and shall comply with the requirements set out in a Regulation adopted in accordance with the regulatory procedure with scrutiny referred to in Article 79(4).

...'

Regulation No 547/2011

- 11 Under Article 1 of Regulation No 547/2011:

‘The labelling of plant protection products shall comply with the requirements, as set out in Annex I, and contain, where appropriate, the standard phrases for special risks to human or animal health or to the environment, as set out in Annex II, and the standard phrases for safety precautions for the protection of human or animal health or of the environment, as set out in Annex III.’

- 12 Annex I to that regulation, entitled ‘Labelling requirements as referred to in Article 1’, provides in paragraph 1:

‘The following information shall be included clearly and indelibly on the packaging of plant protection products:

...

- (b) the name and address of the holder of the authorisation and the authorisation number of the plant protection product and, if different, the name and address of the person responsible for the final packaging and labelling or for the final labelling of the plant protection product on the market;

...

- (f) the formulation batch number and production date;

...’

Regulation (EC) No 1272/2008

- 13 Article 1 of Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ 2008 L 353, p. 1), entitled ‘Purpose and scope’, provides:

‘1. The purpose of this Regulation is to ensure a high level of protection of human health and the environment as well as the free movement of substances, mixtures and articles as referred to in Article 4(8) by:

...

- (b) providing an obligation for:

...

- (ii) suppliers to label and package substances and mixtures placed on the market;

...

...’

14 Article 2 of that regulation, entitled ‘Definitions’, provides:

‘For the purpose of this Regulation, the following definitions shall apply:

...

26. “supplier” means any manufacturer, importer, downstream user or distributor placing on the market a substance, on its own or in a mixture, or a mixture;

...’

15 Title III of that regulation, headed ‘Hazard Communication in the form of labelling’, includes Article 17, entitled ‘General Rules’, which is worded as follows:

‘1. A substance or mixture classified as hazardous and contained in packaging shall bear a label including the following elements:

(a) the name, address and telephone number of the supplier(s);

...’

German law

16 Paragraph 49(4) of the Gesetz zum Schutz der Kulturpflanzen (Law on the protection of cultivated plants) provides:

‘Permit holders which do not use the batch number of the holder of the authorisation for the plant protection product imported in parallel for the label referred to in Paragraph 47(1) must keep records, to be retained for at least five years, showing the correlation between the batch number which they use and the batch numbers of the holder of the authorisation of the plant protection product imported in parallel. ...’

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

17 Syngenta Agro is a distribution company that is part of the Syngenta group, which manufactures and distributes plant protection products in Germany and other Member States of the European Union.

18 Agro Trade is a trading company in the agricultural sector which distributes plant protection products, in particular plant protection products that have been imported in parallel.

19 The latter products include those of Syngenta Agro, which Agro Trade distributes in Germany in the original, unopened Syngenta Agro canisters, after it has replaced the original label with its own.

20 That label, inter alia, includes information on Agro Trade, in its capacity as importer and distributor, but has no information on Syngenta Agro, in its capacity as the holder of the authorisation of the plant protection product concerned in the Member State of origin. Agro

Trade also replaces the manufacturer's original batch number with its own identification number and keeps records showing the correspondence between that latter number and the original batch number.

- 21 Syngenta Agro brought proceedings before the Landgericht Hamburg (Regional Court, Hamburg, Germany) in order to have Agro Trade prohibited from placing parallel-imported Syngenta Agro plant protection products on the market on a commercial basis in Germany where the information on the name and address of the authorisation holder on the original packaging has been removed and/or where the formulation batch number displayed on that packaging has been removed and replaced by another identification number, on the ground that Agro Trade's conduct was in breach of Article 1 of Regulation No 547/2011 in conjunction with paragraph 1(b) and (f) of Annex I thereto.
- 22 The Landgericht Hamburg (Regional Court, Hamburg) upheld the claim put forward by Syngenta Agro in so far as it was based on paragraph 1(b) of Annex I to Regulation No 547/2011 and concerned the information on the name and address of the holder of the authorisation. However, it dismissed the claim in so far as it was based on paragraph 1(f) of that annex and concerned the batch number of the formulation concerned.
- 23 Syngenta Agro and Agro Trade appealed against the judgment of that court to the Hanseatisches Oberlandesgericht Hamburg (Higher Regional Court, Hamburg, Germany), which is the referring court in the present case.
- 24 That court harbours doubts as to the proper interpretation of paragraph 1(b) and (f) of Annex I to Regulation No 547/2011 since that regulation does not lay down any specific rule as regards the labelling of plant protection products which have been imported in parallel.
- 25 It is in those circumstances that the Hanseatisches Oberlandesgericht Hamburg (Higher Regional Court, Hamburg) decided to stay the proceedings and to refer the following questions to the Court of Justice for a preliminary ruling:
 - '(1) Is Article 1 of Regulation [No 547/2011], read in combination with paragraph 1(b) of Annex I thereto, to be interpreted as meaning that, in the case of a parallel import of a plant protection product, the name and address of the holder of the authorisation in the Member State of origin from which that plant protection product was imported must be stated on the packaging when it is distributed in another Member State?
 - (2) Is Article 1 of Regulation [No 547/2011], read in combination with paragraph 1(f) of Annex I thereto, to be interpreted as meaning that, in the case of a parallel import of a plant protection product, the batch number initially allocated by the manufacturer must be indicated on the packaging, or is it compatible with that provision for the parallel importer to remove the original batch number and to affix its own identification number to the packaging, where it keeps records showing the correlation between the batch numbers used by it and the batch numbers used by the holder of the authorisation of the plant protection product imported in parallel?'

Consideration of the questions referred

The first question

- 26 By its first question, the referring court asks, in essence, whether Article 1 of Regulation No 547/2011 and paragraph 1(b) of Annex I thereto must be interpreted as meaning that an importer introducing a plant protection product in a Member State, on the basis of a parallel trade permit, may, on the packaging of that product, replace the name and address of the holder of the authorisation in the Member State of origin with its own name and address.
- 27 In accordance with Article 65(1) of Regulation No 1107/2009, the labelling of plant protection products placed on the market or used pursuant to that regulation is to include the requirements of Directive 1999/45, which was repealed and replaced by Regulation No 1272/2008. That labelling must in addition comply with the requirements set out in Regulation No 547/2011, which was adopted on the basis of the aforementioned Article 65(1), in order to apply the labelling requirements for plant protection products foreseen by Regulation No 1107/2009.
- 28 Under Article 1 of Regulation No 547/2011, the labelling in question is to comply with the requirements set out in Annex I to that regulation.
- 29 It is evident from paragraph 1(b) of Annex I that the name and address of the holder of the authorisation are to be included clearly and indelibly on the packaging of plant protection products.
- 30 Neither Regulation No 1107/2009 nor Regulation No 547/2011 includes any specific provision concerning the labelling of plant protection products in respect of which a parallel trade permit has been applied for; Article 52(7) of Regulation No 1107/2009 merely provides that, inter alia, the general labelling provisions under Chapter VII of that regulation are to apply ‘correspondingly’ for those products.
- 31 In those circumstances, it must be observed that in interpreting a provision of EU law, it is necessary to consider not only its wording, by considering the latter’s usual meaning in everyday language, but also the context in which the provision occurs and the objectives pursued by the rules of which it is part (judgment of 22 June 2022, *Leistritz*, C-534/20, EU:C:2022:495, paragraph 18 and the case-law cited).
- 32 In addition, an implementing regulation must, if possible, be given an interpretation consistent with the basic regulation (judgment of 19 July 2012, *Pie Optiek*, C-376/11, EU:C:2012:502, paragraph 34 and the case-law cited).
- 33 It is in accordance with that case-law that it is necessary to determine how the expression ‘name and address of the holder of the authorisation’ in paragraph 1(b) of Annex I to Regulation No 547/2011 is to be understood in the context of the labelling of parallel traded plant protection products, within the meaning of Article 52(7) of Regulation No 1107/2009.
- 34 In the first place, as regards the literal interpretation of that expression, it must be stated that the wording of paragraph 1(b) of Annex I does not provide any useful information in that regard.

- 35 In the second place, as regards the contextual interpretation, it is apparent from Article 3(10) and (24) and from Article 28(1) of Regulation No 1107/2009 that, in principle, the requirement to display the name and address of the holder of an authorisation on the packaging of plant protection products applies to the natural or legal person authorised by the competent authority of a Member State, by means of a specific administrative act, to place the plant protection product concerned on the market in the territory of that Member State.
- 36 As regards a parallel traded plant protection product, under Article 52 of Regulation No 1107/2009, it is the holder of the parallel trade permit who is responsible for placing that product on the market in the territory of the Member State of introduction, after an assessment has been made that that product and the reference product are identical.
- 37 Indeed, the Court has already held that the parallel trade permit is personal in nature and that only the holder of that permit may place a plant protection product on the market in the Member State which granted that permit (see, to that effect, judgment of 4 March 2021, *Agrimotion*, C-912/19, EU:C:2021:173, paragraphs 26 and 37).
- 38 It follows, as the Advocate General stated, in essence, in point 52 of her Opinion, that while an authorisation granted under Article 28(1) of Regulation No 1107/2009 links its holder to the Member State of origin, a parallel trade permit issued under Article 52 of that regulation links its holder to the Member State of introduction, and that an authorisation granted by the Member State of origin does not give rise to any rights or obligations as regards its holder in the Member State of introduction.
- 39 Consequently, it should be considered that the requirement set out in paragraph 1(b) of Annex I to Regulation No 547/2011, related to showing the name and address of the holder of the authorisation, is to be understood, in the context of parallel trade, as referring to the name and address of the holder of the parallel trade permit. The latter is therefore required to display its name and address on the label of the plant protection product placed on the market of the Member State of introduction, next to or in place of the name and address of the holder of the authorisation in the Member State of origin.
- 40 Furthermore, the provisions of Regulation No 1272/2008 confirm that interpretation of paragraph 1(b) of Annex I to Regulation No 547/2011.
- 41 Article 17(1)(a) of Regulation No 1272/2008 states that ‘a substance or mixture classified as hazardous and contained in packaging shall bear a label including ... the name, address and telephone number of the supplier(s)’.
- 42 It is apparent from Article 1(1)(b)(ii) of that regulation that the latter provides an obligation for suppliers to label and package substances and mixtures placed on the market, while, in accordance with the definition under Article 2(26) of that regulation, the concept of ‘supplier’ covers any manufacturer, importer, downstream user or distributor placing on the market a substance, on its own or in a mixture, or a mixture.
- 43 It follows from this that when an importer or distributor possessing a parallel trade permit places a plant protection product on the market in the Member State that granted that permit, that importer or distributor satisfies the labelling requirements provided for by Regulation No 1272/2008 if the packaging of that product bears a label including its name, address and telephone number.

- 44 In the third place, the interpretation of paragraph 1(b) of Annex I to Regulation No 547/2011 supported in paragraph 39 above 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 latter 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 (see, to that effect, judgment of 14 November 2019, *Vaselife International and Chrysal International*, C-445/18, EU:C:2019:968, paragraph 32).
- 45 First, it must be stated that a reference to the name and address of the holder of the parallel trade permit of a plant protection product, on the label thereof, is not in any way an impediment to the parallel trade of that product in that it does not, in and of itself, impose any conditions for trading that product outside the Member State of origin.
- 46 Second, as regards human and animal health and the environment, it should be observed, as the Greek Government has done, that a high level of protection thereof is ensured by the controls of the proper use of plant protection products required by Article 55 of Regulation No 1107/2009, which is applicable to parallel traded plant protection products under Article 52(7) of that regulation.
- 47 Such a control is to be carried out with regard to the content of the parallel trade permit of the plant protection product concerned, while that content, with respect to the conditions for the placing of that product on the market and its use, is to correspond, in accordance with the first sentence of Article 52(5) of that regulation, to that of the authorisation of the reference product in the Member State of introduction.
- 48 Furthermore, under the first sentence of Article 52(6) of that regulation, the period of validity of the parallel trade permit of a plant protection product is to correspond, in principle, to that set in the authorisation of the reference product in the Member State of introduction.
- 49 Consequently, both for the competent authority of the Member State of introduction and for the distributors and users of a parallel traded product, the most important indications and information concerning that product are to be found solely in the parallel trade permit of that product.
- 50 Those indications and that information include the name and address of the holder of the parallel trade permit of the plant protection product concerned which, as is apparent from paragraph 37 above, is solely responsible for placing that product on the market in the territory of the Member State of introduction.
- 51 Similarly, when a user in the Member State of introduction wishes to obtain information on the crops for which a parallel traded plant protection product is authorised or on the conditions for applying and the dosing of that product, the name and address given on the label affixed thereto should be that of the holder of the parallel trade permit of that product, since it is that holder which is able to provide that information and not the holder of the authorisation in respect of the same product in the Member State of origin.
- 52 That information is of vital importance with respect to achieving the objective pursued by Regulation No 1107/2009 of ensuring a high level of protection of both human and animal health and the environment in the Member State of introduction.

- 53 Lastly, as regards the possibility of the authorisation of the introduced plant protection product being withdrawn in the Member State of origin because of safety or efficacy issues, it is sufficient to state that the competent authority of the Member State of introduction has at its disposal, in accordance with Article 52(4) of Regulation No 1107/2009, the information needed to trace that product and to identify the holder of the authorisation in the Member State of origin. In those circumstances, that authority has the ability, if necessary, to withdraw the parallel trade permit, in accordance with Article 52(8) of that regulation.
- 54 In those circumstance, the answer to the first question is that Article 1 of Regulation No 547/2011 and paragraph 1(b) of Annex I thereto must be interpreted as meaning that an importer introducing a plant protection product in a Member State, on the basis of a parallel trade permit, may, on the packaging of that product, replace the name and address of the holder of the authorisation in the Member State of origin with its own name and address.

The second question

- 55 By its second question, the referring court asks, in essence, whether Article 1 of Regulation No 547/2011 and paragraph 1(f) of Annex I thereto, must be interpreted as meaning that an importer introducing a plant protection product in a Member State, on the basis of a parallel trade permit, is obliged to display, on the packaging of that product, the formulation batch number initially allocated by the manufacturer.
- 56 As is apparent from paragraphs 27 and 28 above, the labelling of plant protection products placed on the market or used under Regulation No 1107/2009 must comply with the requirements set out in Annex I to Regulation No 547/2011, paragraph 1(f) of which provides that ‘the formulation batch number and production date’ must be included clearly and indelibly on the packaging of those products.
- 57 As regards the concept of ‘batch number’ it should be observed that neither Regulation No 547/2011, Regulation No 1107/2009 nor Regulation No 1272/2008 define that concept.
- 58 It is apparent from the case-law referred to in paragraph 31 above that in order to determine how that concept is to be understood, it is necessary to take into account the wording thereof, by considering the latter’s usual meaning in everyday language, its context and the objectives pursued by the rules of which it is part.
- 59 According to the meaning of the words ‘batch number’ in everyday language, they relate to a series of identification numbers and/or letters, allocated to a set of products having the same characteristics and which are manufactured during the same production operation.
- 60 It should be observed, as the Austrian Government has done, that paragraph 1(f) of Annex I to Regulation No 547/2011 refers specifically to the ‘formulation batch number’, making an inextricable link between the ‘batch number’ and ‘the formulation’ manufactured by its producer.
- 61 Furthermore, the meaning referred to in paragraph 59 above is reflected, inter alia, in Article 2(m) of Commission Implementing Regulation (EU) 2021/1280 of 2 August 2021 as regards measures on good distribution practice for active substances used as starting materials in veterinary medicinal products in accordance with Regulation (EU) 2019/6 of the European Parliament and of the Council (OJ 2021 L 279, p. 1), which defines a batch as ‘a defined quantity of starting

material, packaging material or product processed in a single process or series of processes, so that it is expected to be homogeneous’, and in Article 2(p), which defines a ‘batch number’ as ‘a distinctive combination of numbers or letters that uniquely identifies a batch’.

- 62 It follows that the concept of ‘batch number’, within the meaning of paragraph 1(f) of Annex I to Regulation No 547/2011, is to be understood as the batch number initially allocated to a plant protection product by its manufacturer.
- 63 That interpretation is confirmed by the fact that the ‘production date’ refers unequivocally to the act of manufacturing by the ‘producer’, within the meaning of Article 3(11) of Regulation No 1107/2009. However, persons who relabel or repackage products cannot be considered as being a ‘producer’ within the meaning of that provision.
- 64 The interpretation in paragraph 62 above is also borne out by the objective pursued by Regulation No 1107/2009, namely, in particular, as observed in paragraph 44 above, of ensuring a high level of protection for both human and animal health and the environment, which assumes that plant protection products may be traced and subjected to effective controls.
- 65 As regards, in particular, the traceability of those products, it must be pointed out that in the event of an anomaly affecting such a product, it is the initial batch number of the formulation concerned that is the only relevant reference and that, in the event of an urgent situation, it is solely that number that allows the competent authorities to withdraw that product from the market in a targeted and immediate manner.
- 66 By contrast, if a parallel importer were permitted to remove the initial batch number of the formulation concerned and replace it with a new personal identification number, it would be possible to trace the plant protection product concerned only by means of a database showing how those numbers correspond with each other, which would cause a possible withdrawal of that product from the market to be slower and more complicated.
- 67 Consequently, as the Advocate General stated, in substance, in point 81 of her Opinion, national legislation that permits a parallel importer to replace, on the packaging of a parallel traded plant protection product, the initial batch number of the formulation concerned with an identification number of its own is contrary to the objective pursued by Regulation No 1107/2009, regardless of the fact that that legislation obliges the parallel importer in question to keep records showing the correlation between the initial lot numbers and the personal identification numbers of that parallel importer.
- 68 In those circumstances, the answer to the second question is that Article 1 of Regulation No 547/2011 and paragraph 1(f) of Annex I thereto must be interpreted as meaning that an importer introducing a plant protection product in a Member State, on the basis of a parallel trade permit, is obliged to display, on the packaging of that product, the batch number of the formulation concerned initially allocated by the manufacturer.

Costs

- 69 Since these proceedings are, for the parties to the main proceedings, a step in the action pending before the referring 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 (Third Chamber) hereby rules:

- 1. Article 1 of, and paragraph 1(b) of Annex I to, Commission Regulation (EU) No 547/2011 of 8 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards labelling requirements for plant protection products,**

must be interpreted as meaning that an importer introducing a plant protection product in a Member State, on the basis of a parallel trade permit, may, on the packaging of that product, replace the name and address of the holder of the authorisation in the Member State of origin with its own name and address.

- 2. Article 1 of Regulation No 547/2011 and paragraph 1(f) of Annex I thereto**

must be interpreted as meaning that an importer introducing a plant protection product in a Member State, on the basis of a parallel trade permit, is obliged to display, on the packaging of that product, the batch number of the formulation concerned initially allocated by the manufacturer.

[Signatures]