Reports of Cases

JUDGMENT OF THE COURT (Grand Chamber)

1 October 2019*

(Reference for a preliminary ruling — Environment — Placing of plant protection products on the market — Regulation (EC) No 1107/2009 — Validity — Precautionary principle — Definition of the concept of 'active substance' — Combination of active substances — Reliability of the assessment procedure — Public access to the dossier — Tests of long-term toxicity — Pesticides — Glyphosate)

In Case C-616/17,

REQUEST for a preliminary ruling under Article 267 TFEU from the tribunal correctionnel de Foix (Criminal Court of Foix, France), made by decision of 12 October 2017, received at the Court on 26 October 2017, in the criminal proceedings against

Mathieu Blaise,

Sabrina Dauzet,

Alain Feliu,

Marie Foray,

Sylvestre Ganter,

Dominique Masset,

Ambroise Monsarrat,

Sandrine Muscat,

Jean-Charles Sutra,

Blanche Yon,

Kevin Leo-Pol Fred Perrin,

Germain Yves Dedieu,

Olivier Godard,

Kevin Pao Donovan Schachner,

Laura Dominique Chantal Escande,

* Language of the case: French.

Nicolas Benoit Rey,

Eric Malek Benromdan,

Olivier Eric Labrunie,

Simon Joseph Jeremie Boucard,

Alexis Ganter,

Pierre André Garcia,

intervener:

Espace Émeraude,

THE COURT (Grand Chamber),

composed of K. Lenaerts, President, R. Silva de Lapuerta, Vice-President, J.-C. Bonichot, A. Arabadjiev, A. Prechal and K. Jürimäe, Presidents of Chambers, A. Rosas, E. Juhász, M. Ilešič, J. Malenovský, L. Bay Larsen (Rapporteur), P.G. Xuereb, N. Piçarra, L.S. Rossi and I. Jarukaitis, Judges,

Advocate General: E. Sharpston,

Registrar: V. Giacobbo-Peyronnel, administrator,

having regard to the written procedure and further to the hearing on 20 November 2018,

after considering the observations submitted on behalf of:

– Mathieu Blaise and Others, by G. Tumerelle, avocat,

– the French Government, by D. Colas, S. Horrenberger and A.-L. Desjonquères, acting as Agents,

– the Greek Government, by G. Kanellopoulos, E. Chroni and M. Tassopoulou, acting as Agents,

– the Finnish Government, by H. Leppo, acting as Agent,

– the European Parliament, by A. Tamás, D. Warin and I. McDowell, acting as Agents,

– the Council of the European Union, by A.-Z. Varfi and M. Moore, acting as Agents,

– the European Commission, by F. Castillo de la Torre, A. Lewis, I. Naglis and G. Koleva, acting as Agents,

after hearing the Opinion of the Advocate General at the sitting on 12 March 2019,

gives the following

Judgment

1 This request for a preliminary ruling concerns the validity 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 criminal proceedings brought against Mr Blaise and 20 other defendants charged with damaging or defacing property belonging to another person, while acting together.

Legal context

Directive 2003/4/EC

3 Article 4(2) of Directive 2003/4/EC of the European Parliament and of the Council of 28 January 2003 on public access to environmental information and repealing Council Directive 90/313/EEC (OJ 2003 L 41, p. 26) is worded as follows:

‘Member States may provide for a request for environmental information to be refused if disclosure of the information would adversely affect:

…

(d) the confidentiality of commercial or industrial information where such confidentiality is provided for by national or Community law to protect a legitimate economic interest, including the public interest in maintaining statistical confidentiality and tax secrecy;

…

The grounds for refusal mentioned in paragraphs 1 and 2 shall be interpreted in a restrictive way, taking into account for the particular case the public interest served by disclosure. In every particular case, the public interest served by disclosure shall be weighed against the interest served by the refusal. Member States may not, by virtue of paragraph 2(a), (d), (f), (g) and (h), provide for a request to be refused where the request relates to information on emissions into the environment.

…’

Regulation No 1107/2009

4 Recital 8 of Regulation No 1107/2009 states:

‘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. … 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.’

5 Article 1 of that regulation provides:

‘1. This Regulation lays down rules for the authorisation of plant protection products in commercial form and for their placing on the market, use and control within the Community.

2. This Regulation lays down … rules for the approval of active substances … which plant protection products contain or consist of …

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.

4. The provisions of this Regulation are underpinned by the precautionary principle in order to ensure that active substances or products placed on the market do not adversely affect human or animal health or the environment. In particular, Member States shall not be prevented from applying the precautionary principle where there is scientific uncertainty as to the risks with regard to human or animal health or the environment posed by the plant protection products to be authorised in their territory.'

6 Article 2(2) of that regulation is worded as follows:

'This Regulation shall apply to substances, including micro-organisms having general or specific action against harmful organisms or on plants, parts of plants or plant products, referred to as "active substances".'

7 Article 3 of that regulation contains a number of definitions for the purpose of that regulation.

8 Article 4(1) to (3) and (5) of Regulation No 1107/2009 is worded as follows:

'1. An active substance shall be approved in accordance with Annex II if it may be expected, in the light of current scientific and technical knowledge, that, taking into account the approval criteria set out in points 2 and 3 of that Annex, plant protection products containing that active substance meet the requirements provided for in paragraphs 2 and 3.

…

2. The residues of the plant protection products, consequent on application consistent with good plant protection practice and having regard to realistic conditions of use, shall meet the following requirements:

(a) they shall not have any harmful effects on human health, including that of vulnerable groups, or animal health, taking into account known cumulative and synergistic effects where the scientific methods accepted by the [European Food Safety Authority] to assess such effects are available, or on groundwater;

…

3. A plant protection product, consequent on application consistent with good plant protection practice and having regard to realistic conditions of use, shall meet the following requirements:

…

(b) it shall have no immediate or delayed harmful effect on human health, … taking into account known cumulative and synergistic effects where the scientific methods accepted by the [European Food Safety Authority] to assess such effects are available …;

…

5. For approval of an active substance, paragraphs 1, 2 and 3 shall be deemed to be satisfied where this has been established with respect to one or more representative uses of at least one plant protection product containing that active substance.'

9 Article 7(1) of that regulation states:

'An application for the approval of an active substance … shall be submitted by the producer of the active substance to a Member State, (the rapporteur Member State), together with a summary and a complete dossier as provided for in Article 8(1) and (2) … demonstrating that the active substance fulfils the approval criteria provided for in Article 4.'

10 Article 8 of that regulation provides:

'1. The summary dossier shall include the following:

…

(b) for each point of the data requirements for the active substance, the summaries and results of tests and studies, the name of their owner and of the person or institute that has carried out the tests and studies;

(c) for each point of the data requirements for the plant protection product, the summaries and results of tests and studies, the name of their owner and of the person or institute that carried out the tests and studies, relevant to the assessment of the criteria provided for in Article 4(2) and (3) for one or more plant protection products …;

…

2. The complete dossier shall contain the full text of the individual test and study reports concerning all the information referred to in points (b) and (c) of paragraph 1. …

…

4. The data requirements referred to in paragraphs 1 and 2 shall contain the requirements for active substances and plant protection products as set out in Annexes II and III to [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 laid down in Regulations adopted in accordance with the advisory procedure referred to in Article 79(2) without any substantial modifications. Subsequent amendments to these Regulations shall be adopted in accordance with Article 78(1)(b).

5. Scientific peer-reviewed open literature, as determined by the [European Food Safety Authority], on the active substance and its relevant metabolites dealing with side-effects on health, the environment and non-target species and published within the last 10 years before the date of submission of the dossier shall be added by the applicant to the dossier.'

11 Article 10 of that regulation provides:

'The [European Food Safety Authority] shall without delay make the summary dossier referred to in Article 8(1) available to the public, excluding any information in respect of which confidential treatment has been requested and justified pursuant to Article 63, unless there is an overriding public interest in its disclosure.'

12 Article 11(1) to (3) of Regulation No 1107/2009 states:

‘1. Within 12 months of the date of the notification … the rapporteur Member State shall prepare and submit to the Commission, with a copy to the [European Food Safety Authority], a report, referred to as the “draft assessment report”, assessing whether the active substance can be expected to meet the approval criteria provided for in Article 4.

2. …

The rapporteur Member State shall make an independent, objective and transparent assessment in the light of current scientific and technical knowledge.

…

3. Where the rapporteur Member State needs additional studies or information, it shall set a period in which the applicant must supply those studies or that information. …’

13 Article 12(1) to (3) of that regulation is worded as follows:

‘1. The [European Food Safety Authority] shall circulate the draft assessment report received from the rapporteur Member State to the applicant and the other Member States … It shall ask the applicant to circulate an update of the dossier where applicable to the Member States, the Commission and the [European Food Safety Authority].

The [European Food Safety Authority] shall make the draft assessment report available to the public, after giving the applicant two weeks to request, pursuant to Article 63, that certain parts of the draft assessment report be kept confidential.

…

2. The [European Food Safety Authority] where appropriate shall organise a consultation of experts, including experts from the rapporteur Member State.

Within 120 days of the end of the period provided for the submission of written comments, the [European Food Safety Authority] shall adopt a conclusion in the light of current scientific and technical knowledge using guidance documents available at the time of application on whether the active substance can be expected to meet the approval criteria provided for in Article 4 and shall communicate it to the applicant, the Member States and the Commission and shall make it available to the public. …

…

3. Where the [European Food Safety Authority] needs additional information, it shall set a period of a maximum of 90 days for the applicant to supply it to the Member States, the Commission and the [European Food Safety Authority].

…

The [European Food Safety Authority] may ask the Commission to consult a Community reference laboratory … for the purposes of verifying whether the analytical method for the determination of the residues proposed by the applicant is satisfactory …’

14 Article 13(1) and (2) of that regulation provides:

‘1. Within six months of receiving the conclusion from the [European Food Safety Authority], the Commission shall present a report, referred to as “the review report”, and a draft Regulation to the Committee referred to in Article 79(1), taking into account the draft assessment report by the rapporteur Member State and the conclusion of the [European Food Safety Authority].

…

2. A Regulation shall be adopted in accordance with the regulatory procedure referred to in Article 79(3) … providing that:

(a) an active substance is approved, subject to conditions and restrictions, as referred to in Article 6, where appropriate;

(b) an active substance is not approved; or

(c) the conditions of the approval are amended.’

15 Article 21 of that regulation states:

‘1. The Commission may review the approval of an active substance at any time. It shall take into account the request of a Member State to review, in the light of new scientific and technical knowledge and monitoring data, the approval of an active substance. …

Where, in the light of new scientific and technical knowledge, it considers that there are indications that the substance no longer satisfies the approval criteria provided for in Article 4 … it shall inform the Member States, the [European Food Safety Authority] and the producer of the active substance, setting a period for the producer to submit its comments.

…

3. Where the Commission concludes that the approval criteria provided for in Article 4 are no longer satisfied, … a Regulation to withdraw or amend the approval shall be adopted in accordance with the regulatory procedure referred to in Article 79(3).

…’

16 Articles 25 to 27 of Regulation No 1107/2009 lay down the rules relating to the approval of safeners and synergists and the acceptance of co-formulants.

17 Article 29 of that regulation provides:

‘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;

…

(e) in the light of current scientific and technical knowledge, it complies with the requirements provided for in Article 4(3);

…

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. Subsequent amendments to these Regulations shall be adopted in accordance with Article 78(1)(c).

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.'

18 Article 33(1) and (3) of that regulation states:

'1. An applicant who wishes to place a plant protection product on the market shall apply for an authorisation …

…

3. The application shall be accompanied by the following:

(a) for the plant protection product concerned, a complete and a summary dossier for each point of the data requirements of the plant protection product;

(b) for each active substance, safener and synergist contained in the plant protection product, a complete and a summary dossier for each point of the data requirements of the active substance, safener and synergist;

…'

19 Article 36(1) of that regulation provides:

'The Member State examining the application shall make an independent, objective and transparent assessment in the light of current scientific and technical knowledge using guidance documents available at the time of application. …

…'

20 Article 37(1) of Regulation No 1107/2009 states:

'The Member State examining the application shall decide within 12 months of receiving it whether the requirements for authorisation are met.

Where the Member State needs additional information, it shall set a time limit for the applicant to supply it. …'

21 Article 44(1) and (3) of that regulation is worded as follows:

‘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.

…

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;

(b) false or misleading information was supplied concerning the facts on the basis of which the authorisation was granted;

…’

22 Article 63 of that regulation is worded as follows:

‘1. A person requesting that information submitted under this Regulation is to be treated as confidential shall provide verifiable evidence to show that the disclosure of the information might undermine his commercial interests, or the protection of privacy and the integrity of the individual.

2. Disclosure of the following information shall normally be deemed to undermine the protection of the commercial interests or of privacy and the integrity of the individuals concerned:

(a) the method of manufacture;

…

(f) information on the complete composition of a plant protection product;

…

3. This Article is without prejudice to Directive [2003/4].’

23 Point 1.2 of Annex II to Regulation No 1107/2009 states:

‘The evaluation by the [European Food Safety Authority] and the rapporteur Member State must be based on scientific principles and be made with the benefit of expert advice.’

24 Point 3.5 of that Annex provides:

‘3.5.1. The methods of analysis of the active substance, safener or synergist as manufactured and of determination of impurities of toxicological, ecotoxicological or environmental concern or which are present in quantities greater than 1 g/kg in the active substance, safener or synergist as manufactured, shall have been validated and shown to be sufficiently specific, correctly calibrated, accurate and precise.

3.5.2. The methods of residue analysis for the active substance and relevant metabolites in plant, animal and environmental matrices and drinking water, as appropriate, shall have been validated and shown to be sufficiently sensitive with respect to the levels of concern.

3.5.3. The evaluation has been carried out in accordance with the uniform principles for evaluation and authorisation of plant protection products referred to in Article 29(6).’

25 Points 3.6.3 and 3.6.4 of that Annex subject, inter alia, the approval of active substances to the results of assessments including testing of carcinogenicity and toxicity.

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

26 On 27 September 2016 Mr Blaise and 20 other individuals entered shops in the department of Ariège (France) and damaged cans of weed killer, containing glyphosate as well as glass display cases.

27 Those acts led to criminal proceedings being brought against those individuals before the tribunal correctionnel de Foix (Criminal Court of Foix, France), on charges of defacing or damaging the property of another, while acting in concert with others.

28 Before that court, the accused pleaded the defence of necessity and the precautionary principle, arguing that the aim of their actions had been to alert the shops concerned and their customers to the dangers associated with selling, without sufficient warnings, weed killers containing glyphosate, to prevent such sales, and to protect public health and their own health.

29 In order to give a ruling on whether that argument is well founded, the referring court is uncertain whether the EU legislation is capable of fully ensuring the protection of the human population and considers, therefore, that a ruling on the validity of Regulation No 1107/2009 in the light of precautionary principle is required.

30 In those circumstances, the tribunal correctionnel de Foix (Criminal Court of Foix) decided to stay proceedings and to refer the following questions to the Court for a preliminary ruling:

‘(1) Is Regulation [No 1107/2009] compatible with the precautionary principle when it provides no specific definition of an active substance, leaving it to the applicant to determine what it designates as the active substance in its product and granting it scope to focus its whole application dossier on a single substance, while its end product placed on the market is made up of several substances?

(2) Is the precautionary principle observed and impartiality of the authorisation to place products on the market maintained when the tests, analyses and evaluations necessary for [investigating] the dossier are conducted by the applicants alone, who may be biased in their presentation, without any independent counter-analysis or publication of the application reports on the pretext of protecting industrial secrecy?

(3) Is Regulation [No 1107/2009] compatible with the precautionary principle when it takes no account of there being multiple active substances or of their cumulative use, in particular when it makes no provision for any comprehensive specific analysis at European level of [the cumulative effect] of active substances within a single product?

(4) Is Regulation [No 1107/2009] compatible with the precautionary principle when, in Chapters III and IV, it exempts from toxicity tests (genotoxicity, carcinogenicity assessment, assessment of endocrine disruptors, etc.) pesticide products in the commercial formulations in which they are placed on the market and in which consumers and the environment are exposed to them, requiring only summary testing, which is [in any event] performed by the applicant itself?’

The admissibility of the request for a preliminary ruling

31 The European Parliament and the European Commission contest the admissibility of the request for a preliminary ruling.

32 The Parliament considers that the Court's reply to this request can have no effect on the outcome of the criminal prosecutions brought in the main proceedings. Although only a finding that the approval granted to glyphosate was invalid might possibly have some relevance in that regard, the request concerns solely the validity of Regulation No 1107/2009.

33 For its part, the Commission argues that the main proceedings concern a plant protection product authorised by the French Republic and that the referring court fails to explain how the invalidity of Regulation No 1107/2009 could have any effect on the classification as criminal offences of the acts allegedly committed by the accused or on the assessment of whether criminal prosecutions brought against them are appropriate.

34 It must be borne in mind that, in accordance with the Court's settled case-law, in the context of the cooperation between the Court and the national courts provided for in Article 267 TFEU, it is solely for the national court before which a dispute has been brought, and which must assume responsibility for the subsequent judicial decision, to determine in the light of the particular circumstances of the case both the need for a preliminary ruling in order to enable it to deliver judgment and the relevance of the questions which it submits to the Court. Consequently, where the questions submitted concern the interpretation or the validity of a rule of EU law, the Court is in principle bound to give a ruling (see, to that effect, judgments of 16 June 2015, *Gauweiler and Others*, C-62/14, EU:C:2015:400, paragraph 24, and of 4 December 2018, *Minister for Justice and Equality and Commissioner of An Garda Síochána*, C-378/17, EU:C:2018:979, paragraph 26).

35 It follows that questions relating to EU law enjoy a presumption of relevance. The Court may refuse to give a ruling on a question referred by a national court only where it is quite obvious that the interpretation, or the determination of validity, of a rule of EU law that is sought bears no relation to the actual facts of the main action or its purpose, where the problem is hypothetical, or where the Court does not have before it the factual or legal material necessary to give a useful answer to the questions submitted to it (see, to that effect, judgments of 16 June 2015, *Gauweiler and Others*, C-62/14, EU:C:2015:400, paragraph 25, and of 4 December 2018, *Minister for Justice and Equality and Commissioner of An Garda Síochána*, C-378/17, EU:C:2018:979, paragraph 27).

36 In this case, it is apparent from the order for reference and from the response of the referring court to a request for clarification that, according to that court, a declaration that Regulation No 1107/2009 is invalid might, pursuant to the rules of French criminal law, lead it to hold that the legal element that is a constituent of the crime that the accused are alleged to have committed is nullified, taking into consideration that the plant protection products at issue are harmful to human health.

37 In those circumstances, given that, first, in the procedure under Article 267 TFEU, the interpretation of national law is exclusively for the referring court (see, to that effect, judgment of 13 November 2018, *Čepelnik*, C-33/17, EU:C:2018:896, paragraph 24 and the case-law cited), and, second, Regulation No 1107/2009 establishes the rules whereby the harmfulness to human health or to animal health or to the environment of such products and the active substances of which those products are composed must be assessed before they can be authorised by a Member State, it cannot be held that questions seeking an examination of the compliance of that regulation with the precautionary principle manifestly bear no relation to the actual facts of the main action or its purpose.

38 The fact that the questions referred do not concern the validity of the EU acts approving the active substance contained in those products cannot lead to any other conclusion, since the main proceedings concern plant protection products which, as such, had to be authorised under that regulation.

39 Consequently, the request for a preliminary ruling is admissible.

Consideration of the questions referred

40 By its questions, which can be examined together, the referring court asks the Court, in essence, to assess the validity of Regulation No 1107/2009 in the light of the precautionary principle.

The scope of the precautionary principle and whether Regulation No 1107/2009 must comply with it

41 It must be noted, first, that, while Article 191(2) TFEU provides that the policy on the environment is to be based on, inter alia, the precautionary principle, that principle is also applicable in the context of other EU policies, in particular the policy on the protection of public health and where the EU institutions adopt, under the common agricultural policy or the policy on the internal market, measures for the protection of human health (see, to that effect, judgments of 2 December 2004, *Commission* v *Netherlands*, C-41/02, EU:C:2004:762, paragraph 45; of 12 July 2005, *Alliance for Natural Health and Others*, C-154/04 and C-155/04, EU:C:2005:449, paragraph 68; and of 22 December 2010, *Gowan Comércio Internacional e Serviços*, C-77/09, EU:C:2010:803, paragraphs 71 and 72).

42 There is therefore an obligation on the EU legislature, when it adopts rules governing the placing on the market of plant protection products, such as those laid down in Regulation No 1107/2009, to comply with the precautionary principle, in order to ensure, in particular, in accordance with Article 35 of the Charter of Fundamental Rights of the European Union and Article 9 and Article 168(1) TFEU, a high level of protection of human health (see, by analogy, judgment of 4 May 2016, *Pillbox 38*, C-477/14, EU:C:2016:324, paragraph 116).

43 That principle entails that, where there is uncertainty as to the existence or extent of risks to human health, protective measures may be taken without having to wait until the reality and seriousness of those risks become fully apparent. Where it proves to be impossible to determine with certainty the existence or extent of the alleged risk because the results of studies conducted are inconclusive, but the likelihood of real harm to public health persists should the risk materialise, the precautionary principle justifies the adoption of restrictive measures (see, to that effect, judgments of 22 December 2010, *Gowan Comércio Internacional e Serviços*, C-77/09, EU:C:2010:803, paragraphs 73 and 76; of 17 December 2015, *Neptune Distribution*, C-157/14, EU:C:2015:823, paragraphs 81 and 82; and of 22 November 2018, *Swedish Match*, C-151/17, EU:C:2018:938, paragraph 38).

44 In that regard, it is clear from recital 8 and Article 1(4) of Regulation No 1107/2009 that the provisions of that regulation are based on the precautionary principle and that those provisions do not prevent the Member States from applying that principle where there is scientific uncertainty as to the risks with regard to human or animal health or the environment posed by the plant protection products to be authorised in their territory.

45 However, that finding cannot be sufficient to establish that that regulation complies with the precautionary principle.

46 A correct application of that principle in the area covered by Regulation No 1107/2009 presupposes, first, identification of the potentially negative consequences for health of the use of the active substances and plant protection products falling within its scope, and, second, a comprehensive assessment of the risk to health based on the most reliable scientific data available and the most recent results of international research (see, by analogy, judgments of 8 July 2010, *Afton Chemical*, C-343/09, EU:C:2010:419, paragraph 60, and of 22 December 2010, *Gowan Comércio Internacional e Serviços*, C-77/09, EU:C:2010:803, paragraph 75).

47 Consequently, since the purpose of Regulation No 1107/2009 is, as provided in Article 1(1) and (2) thereof, to lay down rules for the authorisation of plant protection products and the approval of active substances contained in those products, for their placing on the market, the EU legislature ought to establish a normative framework that ensures that the competent authorities have available to them, when they decide on that authorisation and that approval, sufficient information in order adequately to assess, in accordance with the requirements mentioned in paragraphs 43 and 46 of the present judgment, the risks to health resulting from the use of those active substances and those plant protection products.

48 It must also be recalled that the validity of a provision of EU law is to be assessed according to the characteristics of those provisions themselves and cannot depend on the particular circumstances of a given case (judgment of 29 May 2018, *Liga van Moskeeën en Islamitische Organisaties Provincie Antwerpen and Others*, C-426/16, EU:C:2018:335, paragraph 72).

49 It follows that the criticism expressed by the referring court in relation to the conduct of the procedure that led to the approval of glyphosate cannot, in isolation, lead to a finding that the general rules governing such a procedure are unlawful.

50 It must, moreover, be added that, in view of the need to strike a balance between several objectives and principles, and of the complexity of the application of the relevant criteria, judicial review by the Court must necessarily be limited to whether the EU legislature, in adopting Regulation No 1107/2009, committed a manifest error of assessment (see, to that effect, judgment of 21 December 2016, *Associazione Italia Nostra Onlus*, C-444/15, EU:C:2016:978, paragraph 46).

51 Accordingly, since the referring court considers that the general rules established by that regulation themselves do not satisfy the requirements arising from the precautionary principle, it is necessary to examine its criticism in order to determine whether that regulation is vitiated by a manifest error of assessment.

The identification of the active substances of a plant protection product

52 The referring court considers that Regulation No 1107/2009 provides no precise definition of the concept of an ‘active substance’. Accordingly, the referring court has doubts as to the compatibility with the precautionary principle of the fact that, according to that court, it is open to the applicant to shape the examination of an application for the authorisation of a plant protection product by choosing, at his discretion the constituent of the product which is to be described as its ‘active substance’.

53 In that regard, it must indeed be noted that Article 3 of that regulation, the purpose of which is to define a number of concepts for the purposes of that regulation, does not contain any definition of the expression ‘active substance’.

54 That said, first, it is clear from Article 2(2) of Regulation No 1107/2009 that substances, including micro-organisms, having general or specific action against harmful organisms or on plants, parts of plants or plant products are to be regarded as active substances, for the purposes of that regulation.

55 Second, it follows from Article 33 of that regulation that an applicant who wishes to place a plant protection product on the market must apply for an authorisation, and his application must contain the information required for the processing of that application. In particular, Article 33(3)(b) of that regulation provides that an application for authorisation of such a product must be accompanied, for each active substance contained in that product, by a complete and a summary dossier in respect of each point of the data requirements that apply to the active substance.

56 Further, in accordance with Article 78(1)(b) of Regulation No 1107/2009, read together with Article 8(4) of that regulation, the conditions which must be satisfied by the dossiers to be submitted in order to obtain the approval of active substances have been set out in detail, latterly, by Commission Regulation (EU) No 283/2013 of 1 March 2013 setting out the data requirements for active substances, in accordance with Regulation No 1107/2009 (OJ 2013 L 93, p. 1), which establishes, in particular, requirements, defined in section 1 of Part A of the Annex to that regulation, for the identification of those active substances. It is clear from those requirements that the information submitted must be sufficient to identify precisely each active substance and to define it in terms of its specification and nature.

57 It follows that an applicant is bound to identify, when submitting his application for authorisation of a plant protection product, any substance forming part of the composition of that product that corresponds to the criteria set out in Article 2(2) of Regulation No 1107/2009, so that, contrary to what is envisaged by the referring court, an applicant does not have the option of choosing at his discretion which constituent of that product is to be considered to be an active substance for the purposes of the examination of that application.

58 Further, it is not clearly evident that the criteria set out in that provision are insufficient to permit an objective determination of the substances concerned and to ensure that substances that actually play a role in the action of the plant protection products are actually taken into account in the assessment of the risks arising from the use of those products.

59 It must be added that it is the task of the competent authorities of the Member States to ensure that the obligation to identify the active substances contained in the plant protection product that is the subject of an application for authorisation has been met by the applicant, in order to be in a position to determine that that product satisfies the conditions laid down in Article 29 of that regulation, which imposes, inter alia, the requirement, in Article 29(1)(a), that each of those active substances has been approved.

60 In any event, the holder of an authorisation for a plant protection product who has not, in his application for authorisation, mentioned all the active substances contained in that product, would run the risk, under Article 44(3)(a) and (b) of that regulation, of his authorisation being withdrawn.

61 In the light of the foregoing, it cannot be held that the choices made by the EU legislature with respect to the obligations imposed on the applicant in relation to the identification of the active substances that form part of the composition of the plant protection product which is the subject of his application for authorisation are vitiated by a manifest error of assessment.

Whether the cumulative effects of constituents of a plant protection product are taken into account

62 The referring court is uncertain whether an alleged failure to take into account and undertake a specific analysis of the effects of a combination of a number of active substances contained in a plant protection product is compatible with the precautionary principle.

63 In that regard, it must be emphasised that Regulation No 1107/2009 makes provision for both a procedure for the approval of active substances, governed by Chapter II of that regulation, and a procedure for authorisation of plant protection products, governed by Chapter III of that regulation.

64 Those two procedures are closely linked, in that, in particular, the authorisation of a plant protection product presupposes, pursuant to Article 29(1)(a) of that regulation, that its active substances have previously been approved.

65 The EU legislature has imposed the requirement to take into account the potential effects of a combination of the various constituents of a plant protection product both in the procedure for the approval of the active substances and in the procedure for the authorisation of the plant protection products.

66 In accordance with Article 11(2) and Article 36(1) of Regulation No 1107/2009, the Member State dealing with an application for approval of an active substance or for authorisation of a plant protection product must undertake an independent, objective and transparent assessment of that application in the light of current scientific and technical knowledge.

67 In the procedure for the approval of an active substance, the aim of that assessment is, pursuant to Article 4(1) to (3) and (5) of that regulation, inter alia, to verify that one or more representative uses of at least one plant protection product containing that substance and the residues of such a product have no immediate or delayed harmful effect on human health.

68 Apart from the fact that it is inherent in such an assessment that it cannot be carried out in an objective fashion while failing to take into account the effects deriving from a possible combination of various constituents of a plant protection product, it must, in addition, be noted that Article 4(2) and (3) of that regulation explicitly provides that the possibility of that product or its residues having a harmful effect on human or animal health must be assessed taking into account 'known cumulative and synergistic effects', which implies, as stated by the Advocate General in point 58 of her Opinion, taking into consideration the effects caused by the interaction between a given active substance and, inter alia, the other constituents of the product.

69 That requirement also binds the European Food Safety Authority ('the Authority') where, in accordance with the second subparagraph of Article 12(2) of Regulation No 1107/2009, it adopts, in the light of current scientific and technical knowledge, conclusions in which it states whether the active substance can be expected to meet the approval criteria provided for in Article 4 of that regulation.

70 It must also be stated that, in accordance with Article 13(1) and (2) of Regulation No 1107/2009, the draft assessment report prepared by the rapporteur Member State and the conclusions of the Authority must be taken into account by the Commission in the review report that is to be the basis, when appropriate, for the adoption of a regulation approving the active substance concerned.

71 As regards the procedure for the authorisation of a plant protection product, taking into account the known cumulative and synergistic effects of the constituents of that product is again required, since, pursuant to Article 29(1)(e) of Regulation No 1107/2009, one of the requirements imposed if a plant protection product is to be authorised is that it must, in the light of current scientific and technical knowledge, comply with the conditions laid down in Article 4(3) of that regulation.

72 That requirement is, moreover, stated in Article 29(6) of Regulation No 1107/2009, from which it is apparent that, by virtue of the uniform principles for evaluation and authorisation of plant protection products that must be applied by the Member States, the interaction between the active substances, the safeners, the synergists and the co-formulants must be taken into account in such an assessment.

73 It is clear moreover from points 1.2 and 1.3 of the Annex to Commission Regulation (EU) No 284/2013 of 1 March 2013 setting out the data requirements for plant protection products, in accordance with Regulation No 1107/2009 (OJ 2013 L 93, p. 85) that, to obtain the authorisation of plant protection products, there must be submitted any information on potentially harmful effects of the plant protection product on human and animal health or on the environment, as well as known and expected cumulative and synergistic effects caused by such interaction.

74 The need to take into consideration the effects of the constituents of a plant protection product as a whole is, moreover, confirmed by the rules laid down in Articles 25 and 27 of Regulation No 1107/2009, from which it is clear that the placing on the market of safeners, synergists and co-formulants contained in such a product must also be subject to assessments to determine whether they have any harmful effects.

75 It follows from the foregoing that, contrary to the premiss which is the basis of the referring court's uncertainty as described in paragraph 62 of the present judgment, the procedures leading to the authorisation of a plant protection product must necessarily include an assessment not only of the specific effects of the active substances contained in that product, but also of the cumulative effects of those substances and their effects combined with other constituents of that product.

76 Consequently, it cannot be held that Regulation No 1107/2009 is vitiated by a manifest error of assessment in that it does not make sufficient provision for the combined effects of the various constituents of a plant protection product to be taken into account before the placing on the market of that product is authorised.

The reliability of the tests, studies and analyses taken into account for the authorisation of a plant protection product

77 The referring court is uncertain whether the fact that the tests, studies and analyses required in the procedures for the approval of an active substance and authorisation of plant protection products are submitted by the applicant, with no independent counter-analysis, is contrary to the precautionary principle, in that it implies that those tests, studies and analyses might be biased.

78 It is apparent, admittedly, from Article 7(1) and from Article 8(1) and (2) of Regulation No 1107/2009, that the tests, studies and analyses required to permit the approval of an active substance must be provided by the applicant. The same is true in the procedure for authorisation of a plant protection product, pursuant to Article 33(3)(a) and (b) of that regulation, read together with Article 8(1) and (2) thereof.

79 Those rules constitute the corollary of the principle, set out in Article 7(1) and in Article 29(2) of that regulation, that it is for the applicant to prove that the active substance or plant protection product that is the subject of an application for approval or authorisation fulfils the relevant criteria laid down by that regulation.

80 That obligation contributes to achieving compliance with the precautionary principle by ensuring that there is no presumption that active substances and plant protection products have no harmful effects.

81 Further, it cannot be held that the body of rules established by Regulation No 1107/2009 enables an applicant to submit tests, studies and analyses that are biased in order to obtain, on that basis, the approval of an active substance or the authorisation of a plant protection product.

82 In that regard, it must, first, be stated that the EU legislature sought to control the quality of the tests, studies and analyses submitted in support of an application based on that regulation.

83 Accordingly, Article 8(1) of that regulation provides, inter alia, that the summary dossier submitted by the applicant must contain, in respect of each point of the data requirements that apply to the active substances and the plant protection products, the summaries and results of tests and studies, the name of their owner and of the person or institute that has carried out the tests and studies.

84 Likewise, as regards the procedure for the approval of the active substances, point 3.5 of Annex II to Regulation No 1107/2009 requires that the methods of analysis of the active substance and its residues should be validated and that the sufficiency of those methods to achieve various objectives should be demonstrated.

85 As regards the procedure for the authorisation of plant protection products, Article 29(3) of Regulation No 1107/2009 provides that compliance with a number of requirements, including the requirement that the product concerned has no harmful effects, is to be established by 'official or officially recognised tests and analyses', which necessarily precludes tests or analyses which do not sufficiently provide the guarantees of impartiality, objectivity or transparency from being accepted.

86 Further, while, for the remainder, Regulation No 1107/2009 does not directly establish standards stipulating in detail the manner in which the tests, studies and analyses submitted by the applicant are to be carried out, Article 8(4) of that regulation provides that rules are to be adopted with respect to the data requirements for the active substances and the plant protection products in the light of current scientific and technical knowledge.

87 Such standards have been adopted and are to be found in point 3 of the Annex to Regulation No 283/2013 and in point 3 of the Annex to Regulation No 284/2013.

88 Second, it must be recalled, as stated in paragraphs 66 and 69 of the present judgment, that the Member State to which an application is submitted must undertake an independent, objective and transparent assessment of that application in the light of current scientific and technical knowledge, while the Authority must adopt a decision in the light of current scientific and technical knowledge.

89 Meeting those requirements is assisted by Article 8(5) of Regulation No 1107/2009, which obliges the applicant to add to the dossier the scientific peer-reviewed open literature, as determined by the Authority, on the active substance and its relevant metabolites, dealing with side-effects on health, the environment and non-target species, and published within the last 10 years.

90 Further, point 1.2 of Annex II to Regulation No 1107/2009 provides that the evaluation of an active substance by the Authority and the rapporteur Member State must be based on scientific principles and be made with the benefit of expert advice.

91 It follows, in the first place, that, in order to be satisfied that an applicant has established, as required by Article 4(3)(b) and Article 29(1)(e) of that regulation, that a plant protection product has no harmful effects, the competent authorities cannot rely on tests, analyses and studies for which the applicant has not submitted evidence to demonstrate that those tests, analyses and studies were carried out by a reliable institution on the basis of methods that comply with accepted scientific principles.

92 If those authorities consider that the evidence submitted in that regard by the applicant is insufficient, they are under an obligation to request, pursuant to Article 11(3), Article 12(3) and Article 37(1) of that regulation, that additional information be provided by the applicant.

93 In the second place, as part of the assessment that those authorities must undertake, since, as stated in paragraph 88 of the present judgment, that assessment must be, in particular, independent and objective, those authorities are of necessity bound to take into account relevant evidence other than the tests, analyses and studies submitted by the applicant that might contradict the latter. Such an approach is compatible with the precautionary principle.

94 With that in mind, it is the duty of the competent authorities, in particular, to take account of the most reliable scientific data available and the most recent results of international research and not to give in all cases preponderant weight to the studies provided by the applicant.

95 In the event that the competent authorities come to the conclusion that, having regard to all the information at their disposal, an applicant has not established to the required standard that the conditions governing the approval or authorisation applied for are satisfied, they are bound to decide that the application should be rejected, there being no need, in order to reach that conclusion, to undertake a second assessment.

96 Third, it is clear that various provisions of Regulation No 1107/2009 play a part in ensuring that the assessment made by the competent authorities can rely on information other than merely the tests, analyses and studies submitted by the applicant.

97 Thus, it follows from Article 11(1) and from Article 12(1) of that regulation that, before the approval of an active substance, the rapporteur Member State is to prepare a draft assessment report which is to be sent to the other Member States and to the Authority.

98 In addition, in order to determine its conclusions, the Authority has the option, in accordance with Article 12(2) and (3) of that regulation, of organising a consultation of experts and of asking the Commission to consult a Community reference laboratory, to which the applicant may be required to submit samples and analytical standards. The conclusions are, moreover, communicated to the Member States.

99 Fourth, it is apparent from Article 21(1) and (3) of Regulation No 1107/2009 that the Commission may review the approval of an active substance at any time, including where, in the light of new scientific and technical knowledge, there are indications that the substance no longer satisfies the approval criteria laid down in Article 4 of that regulation. Likewise, it follows from Article 44(1) and (3) of that regulation that the authorisation of a plant protection product may be reviewed, then amended or withdrawn, where, inter alia, it is apparent from developments in scientific and technical knowledge that the product does not satisfy or no longer satisfies the requirements for a marketing authorisation laid down in Article 29 of that regulation, including the requirement that it has no immediate or delayed harmful effect on human health.

100 In the light of all the foregoing, it does not appear that Regulation No 1107/2009 is vitiated by a manifest error of assessment in that it provides that the tests, studies and analyses necessary in the procedures for approval of an active substance and for authorisation of a plant protection product are to be submitted by the applicant, but does not systematically require that an independent counter-analysis be carried out.

Whether the authorisation application dossier should be public

101 The referring court expresses doubts as to the compatibility with the precautionary principle of the fact that the dossier lodged by the applicant as part of the procedures established by Regulation No 1107/2009 is confidential.

102 In that regard, while it is not inconceivable that increased transparency in those procedures may be such as to permit an even better assessment of the risk to health resulting from the use of a plant protection product, by enabling the public concerned to put forward arguments opposing the grant of the approval or authorisation sought by an applicant, it must, in any event, be held that that regulation permits, to a great extent, the public to obtain access to the dossier lodged by the applicant.

103 First, as regards the procedure for the approval of an active substance, Article 10 of that regulation establishes the general rule that the Authority is without delay to make the summary dossier referred to in Article 8(1) of that regulation available to the public, that dossier containing, inter alia, the summaries and the results of the tests and studies submitted by the applicant.

104 Likewise, Article 12(1) of Regulation No 1107/2009 provides, inter alia, that the Authority is to make the draft assessment report received from the rapporteur Member State available to the public. That draft assessment report, the purpose of which is, in accordance with Article 11(1) of that regulation, to assess whether the active substance can be expected to meet the approval criteria provided for in Article 4 of that regulation, necessarily includes an analysis of the dossier submitted by the applicant.

105 Second, Article 63(1) of Regulation No 1107/2009 provides that a person requesting that information submitted under that regulation should be treated as confidential is to provide verifiable evidence to show that the disclosure of that information might undermine his commercial interests, or the protection of privacy and the integrity of the individual, that risk being presumed, however, with respect to information specified in Article 63(2) of that regulation.

106 Third, Article 63(3) of Regulation No 1107/2009 states that that article is to be without prejudice to the application of Directive 2003/4, which means that requests for access by third parties to the information contained in authorisation application dossiers are subject to the general provisions of that directive (see, to that effect, judgment of 23 November 2016, *Bayer CropScience and Stichting De Bijenstichting*, C-442/14, EU:C:2016:890, paragraph 44).

107 It is clear from the penultimate sentence of Article 4(2) of that directive that Member States may not provide that a request for access which concerns information on emissions into the environment should be refused on grounds based on protection of the confidentiality of commercial or industrial information.

108 That specific rule is applicable, in particular, to a great extent, to the studies designed to assess the harm that may be caused by the use of a plant protection product or the presence in the environment of residues after the application of that product (see, to that effect, judgment of 23 November 2016, *Bayer CropScience and Stichting De Bijenstichtin*g, C-442/14, EU:C:2016:890, paragraphs 79, 87, 91 and 95).

109 In those circumstances, it cannot be held that the rules put in place by the EU legislature to ensure public access to information in application dossiers that is relevant to an assessment of the risks arising from the use of a plant protection product are vitiated by a manifest error of assessment.

The claim that no studies of carcinogenicity and toxicity are required for the authorisation procedure

110 The referring court considers that Regulation No 1107/2009 merely requires an applicant to carry out cursory tests of the plant protection product that is the subject of an application for authorisation and that it exempts him from carrying out tests of long-term carcinogenicity and toxicity. Consequently, the referring court is uncertain whether those rules are compatible with the precautionary principle.

111 In that regard, it is clear that that regulation does not prescribe in detail the nature of the tests, analyses and studies to which plant protection products must be subject if they are to obtain authorisation.

112 While points 3.6.3 and 3.6.4 of Annex II to that regulation list explicitly some of the tests to which active substances must be subject before their approval, that regulation contains no comparable provisions with respect to plant protection products.

113 Nonetheless, it cannot be concluded that Regulation No 1107/2009 exempts the applicant from submitting tests of long-term carcinogenicity and toxicity relating to the plant protection product that is the subject of an application for authorisation.

114 In that context, it must be recalled that, in accordance with Article 4(3)(b) and Article 29(1)(e) of that regulation, such a product can be authorised only if it is established that it has no immediate or delayed harmful effect on human health, the burden of adducing proof of that lying, in accordance with Article 29(2) of that regulation, on the applicant.

115 A plant protection product cannot be considered to satisfy that condition where it exhibits any long-term carcinogenicity and toxicity.

116 It is therefore the task of the competent authorities, when examining an application for the authorisation of a plant protection product, to verify that the material submitted by the applicant, and primarily the tests, analyses and studies of the product, is sufficient to exclude, in the light of current scientific and technical knowledge, the risk that that product exhibits such carcinogenicity or toxicity. In that context, the 'cursory tests' mentioned by the referring court would not suffice to perform that verification properly.

117 In the light of all the foregoing, the answer to the questions referred is that an examination of those questions has revealed nothing capable of affecting the validity of Regulation No 1107/2009.

Costs

118 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 (Grand Chamber) hereby rules:

An examination of the questions referred for a preliminary ruling has revealed nothing capable of affecting the validity 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.

[Signatures]