Reports of Cases

OPINION OF ADVOCATE GENERAL
SHARPSTON
delivered on12 March 2019[1]

Case C-616/17

Procureur de la République
v
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
Nicolas Benoit Rey
Eric Malek Benromdan
Olivier Eric Labrunie
Simon Joseph Jeremie Boucard
Alexis Ganter
Pierre André Garcia
joined parties:
Espace Émeraude

(Request for a preliminary ruling from the Tribunal correctionnel de Foix (Criminal Court, Foix, France))

(Preliminary reference — Environment — Placing on the market of plant protection products — Validity of Regulation (EC) No 1107/2009 with regard to the precautionary principle — Reliability and impartiality of the assessment procedure — Cumulative effect of active substances — Pesticides — Glyphosate)

1 Original language: English.

1. This reference from the Tribunal Correctionnel de Foix (Criminal Court, Foix, France; 'the referring court') concerns the procedures deployed to strike an appropriate balance between negative and positive effects of using chemicals in plant protection. A number of environmental activists ('the defendants') are charged with causing criminal damage to containers of herbicidal products (specifically 'Roundup') containing the chemical glyphosate. In their defence, they argue that the products present an unacceptable potential risk to human health and the environment and that the EU approval process is defective and therefore unlawful.

EU law

2. Because the essence of the defendants' case is that the system put in place by the EU legislator to vet and supervise the use of plant protection products containing certain substances is deficient, it is necessary to set out in some detail how that system works.

Treaty on the Functioning of the European Union

3. As regards the transparency required for the Union's activities, Article 15(1) TFEU establishes the principle that the 'Union's institutions, bodies, offices and agencies shall conduct their work as openly as possible'. Article 15(3) TFEU provides that the right of citizens to have access to documents of the Union's institutions, bodies, offices and agencies will be subject to 'general principles and limits on grounds of public or private interest as determined by the European Parliament and the Council, by means of regulations'. The principle of transparency thus underpins all of the EU's activities.

4. Article 168 TFEU requires the EU to ensure 'a high level of human health protection … in the definition and implementation of all Union policies and activities'. Article 191(2) TFEU requires that 'Union policy on the environment shall aim at a high level of protection taking into account the diversity of situations in the various regions of the Union' and that it 'shall be based on the precautionary principle and on the principles that preventive action should be taken, that environmental damage should as a priority be rectified at source and that the polluter should pay'.

Regulation (EC) No 1107/2009[2]

5. Article 1(3) of Regulation No 1107/2009 ('the PPP Regulation') states that its purpose 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 …'. Article 1(4) states that 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'.[3]

2 Regulation 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).

3 Recital 8 of Regulation No 1107/2009 indicates that 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' and furthermore that 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'.

6. Article 2(1) defines plant protection products as 'products, in the form in which they are supplied to the user, consisting of or containing active substances, safeners or synergists, and intended for … (a) protecting plants or plant products against all harmful organisms or preventing the action of such organisms … (b) influencing the life processes of plants … (c) preserving plant products … (d) destroying undesired plants or parts of plants, … [and] (e) checking or preventing undesired growth of plants …'.

7. Article 2 specifies the scope of the PPP Regulation. Thus, the rules that it lays down apply in the first instance to '*active substances*' ('substances,[4] including micro-organisms having general or specific action against harmful organisms or on plants, parts of plants or plant products': Article 2(2)). The regulation also applies to '*safeners*' ('substances or preparations which are added to a plant protection product to eliminate or reduce phytotoxic effects of the plant protection product on certain plants': Article 2(3)(a)), '*synergists*' ('substances or preparations which, while showing no or only weak activity … can give enhanced activity to the active substance(s) in a plant protection product': Article 2(3)(b)), '*co-formulants*' ('substances or preparations which are used or intended to be used in a plant protection product or adjuvant, but are neither active substances nor safeners or synergists': Article 2(3)(c)), and '*adjuvants*' ('substances or preparations which consist of co-formulants or preparations containing one or more co-formulants, in the form in which they are supplied to the user and placed on the market to be mixed by the user with a plant protection product and which enhance its effectiveness or other pesticidal properties': Article 2(3)(d)).

8. Article 4 lays down the approval criteria for active substances. Article 4(1) provides that active substances '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'.[5]

9. Article 4(2) requires that residues of the plant protection product containing the active substance 'consequent on application consistent with good plant protection practice and having regard to realistic conditions of use, … (a) 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 Authority[6] to assess such effects are available, or on groundwater' and that '(b) they shall not have any unacceptable effect on the environment'.

10. Article 4(3) requires that a plant protection product containing the active substance '(a) … shall be sufficiently effective; (b) … shall have no immediate or delayed harmful effect on human health, including that of vulnerable groups, or animal health, directly or through drinking water …, food, feed or air, or consequences in the workplace or through other indirect effects, taking into account known cumulative and synergistic effects where the scientific methods accepted by the Authority to assess such effects are available, or on groundwater; (c) … shall not have any unacceptable effects on plants or plant products; (d) … shall not cause unnecessary suffering and pain to vertebrates to be controlled; (e) … shall have no unacceptable effects on the environment …'.

4 'Substances' are further defined as 'chemical elements and their compounds, as they occur naturally or by manufacture, including any impurity inevitably resulting from the manufacturing process' (Article 3(2) of the regulation).

5 Article 25(1) of Regulation No 1107/2009 provides that safeners and synergists must follow the same approval procedure as for active substances. The rules and steps that are narrated in the following points thus equally apply to those substances.

6 The 'Authority' is the European Food Safety Authority as established by Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ 2002 L 31, p. 1).

11. Article 4(4) states that the 'requirements of paragraphs 2 and 3 shall be evaluated in the light of uniform principles as referred to in Article 29(6)'. The latter provision contains powers for regulations to be laid down to establish uniform principles for evaluation and authorisation and further states that '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'.[7]

12. Article 6 contains a non-exhaustive list of the types of restriction that may be imposed on an approval of an active substance, safener or synergist including 'any other particular conditions that result from the evaluation of information made available in the context of this Regulation' (Article 6(j)).

13. The PPP Regulation sets out in Chapter II, section 1, subsection 2: 'Approval procedure' the steps to be followed for the approval of an active substance. Under Article 7(1) of the regulation, the first step is that the producer[8] of the active substance submits an application together with a 'summary and complete dossier as provided for in Article 8(1) and (2)' to a Member State (the 'rapporteur Member State') demonstrating that the active substance concerned fulfils the Article 4 approval criteria. Article 8(1)(a) specifies that the summary dossier must include, inter alia, 'information with respect to one or more representative uses on a widely grown crop in each zone[9] of at least one plant protection product containing the active substance, demonstrating that the approval criteria provided for in Article 4 are met …'. Article 8(2) states that 'the complete dossier shall contain the full text of the individual test and study reports …'.

14. The data requirements of the contents of the dossier are specified by Commission Regulation (EU) No 283/2013.[10] That regulation provides, inter alia, that 'the information shall be sufficient to evaluate the foreseeable risks, whether immediate or delayed …' (point 1.1 of the introduction to the Annex to Regulation No 283/2013); that 'any information on potentially harmful effects of the active substance, its metabolites and impurities on human and animal health or on groundwater shall be included' (point 1.2); that a summary of '… all relevant data from the scientific peer reviewed open literature on the active substance, metabolites and breakdown or reaction products and plant protection in products containing the active substance and dealing with side-effects on health, the environment and non-target species' must be included (point 1.4); that 'tests and analyses shall be conducted in accordance with the principles laid down in Directive 2004/10/EC[11] … where testing is done to obtain data on the properties or safety with respect to human or animal health or the environment' (point 3.1); and that 'the results of the long-term studies conducted and reported, taken together with other relevant data and information on the active substance…' shall be included 'sufficient to …

7 Commission Regulation (EU) No 546/2011 of 10 June 2011 implementing Regulation No 1107/2009 as regards uniform principles for evaluation and authorisation of plant protection products (OJ 2011 L 155, p. 127) provides in point A.1 of Part 1 of the Annex that 'the principles developed in this Annex aim to ensure that evaluations and decisions with regard to authorisation of plant protection products, provided they are chemical preparations, results in the implementation of the requirements of Article 29(1)(e) in conjunction with Article 4(3) and Article 29(1)(f), (g) and (h) of Regulation No 1107/2009 by all the Member States at a high level of protection of human and animal health and the environment'.

8 'Producer' is defined in Article 3(11) of the PPP Regulation as 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'. Throughout this Opinion, I shall refer to producers applying for approvals or authorisations as 'industry applicants'.

9 The EU is divided into three zones: Zone A — North: Denmark, Estonia, Latvia, Lithuania, Finland, Sweden; Zone B — Centre: Belgium, Czech Republic, Germany, Ireland, Luxembourg, Hungary, Netherlands, Austria, Poland, Romania, Slovenia, Slovakia, United Kingdom; and Zone C — South: Bulgaria, Greece, Spain, France, Italy, Cyprus, Malta, Portugal (Annex I to the regulation).

10 Regulation 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).

11 Directive 2004/10/EC of the European Parliament and of the Council of 11 February 2004 on the harmonisation of laws, regulations and administrative provisions relating to the application of the principles of good laboratory practice and the verification of their applications for tests on chemical substances (OJ 2004 L 50, p. 44).

identify adverse effects resulting from long-term exposure to the active substance' (point 5.5 of Part A of the Annex to Regulation No 283/2013). Point 2 of the introduction to the Annex to Regulation No 283/2013 states that 'the requirements set out in this Regulation shall represent the minimum data to be submitted'.

15. The second step under the PPP Regulation is that the rapporteur Member State reviews the dossier. Once it deems the dossier to be complete, and within 12 months of notifying the industry applicant, the other Member States, the European Commission and the European Food Safety Authority ('the Authority') that the application is admissible, the rapporteur Member State prepares a draft assessment report 'assessing whether the active substance can be expected to meet the approval criteria' and submits that report to the Commission 'with a copy to the Authority' (Article 11(1) of the PPP Regulation). The rapporteur Member State's assessment is to be 'independent, objective and transparent' and carried out 'in the light of current scientific and technical knowledge' (Article 11(2)).

16. The third step is for the Authority to review the draft assessment report. After circulating the draft assessment report to all other Member States, making a version of the report available to the public and allowing for a period of 60 days for the submission of written comments (Article 12(1) of the PPP Regulation), the Authority is to '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 …' (Article 12(2)).

17. The fourth step is that the Commission takes into account the Authority's conclusions and the draft assessment report [12] and drafts a 'review report' and a draft regulation proposing either to approve (with or without conditions) or not approve the active substance concerned (Article 13(1) of the PPP Regulation). Finally, on the basis of that report and on 'other factors legitimate to the matter under consideration and the precautionary principle', the committee referred to in Article 79(1) of the regulation adopts a regulation either approving with or without conditions, or not approving, the substance concerned (Article 13(2)).

18. The approval of an active substance may or may not be renewed further to an application from the producer(s) concerned under Article 14(1) of the PPP Regulation, depending on whether 'it is established that the approval criteria provided for in Article 4 are satisfied'.

19. The fact that an active substance has been approved is not, of itself, sufficient to allow a manufacturer to include that substance in a plant protection product and place that product on the market.

20. Article 28(1) of the PPP Regulation states that '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'. Article 29(1) provides that a plant protection product shall only be authorised where 'following the uniform principles referred to in paragraph 6', [13] it complies with the following (inter alia): '(a) its active substances, safeners and synergists have been approved; … (c) its co-formulants are not included in Annex III; [14] (d) its technical formulation is such that user exposure or other risks are limited as much as possible without compromising the functioning of the product; (e) in the light of

12 Both the evaluation by the Authority and by the rapporteur Member 'must be based on scientific principles and be made with the benefit of expert advice' (point 1.2 of Annex II to Regulation No 1107/2009).

13 See point 11 above.

14 Annex III to the PPP Regulation contains the 'list of co-formulants which are not accepted for inclusion in plant protection products as referred to in Article 27' (of the same regulation). As was pointed out at the hearing, however, that list is currently empty.

current scientific and technical knowledge, it complies with the requirements provided for in Article 4(3);[15] (f) the nature and quantity of its active substances, safeners and synergists and, where appropriate, any toxicologically, ecotoxicologically or environmentally relevant impurities and co-formulants can be determined by appropriate methods; …'.

21. Article 29(2) of the regulation requires the industry applicant to 'demonstrate that the requirements provided for in points (a) to (h) of paragraph 1 are met'. Article 29(3) requires that 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 ...'.

22. As with the procedure for the approval of an active substance at EU level, the PPP Regulation sets out a sequence of steps to be followed at Member State level for the authorisation of a plant protection product. The first step is that the industry applicant submits an application to each Member State 'where the plant protection product is intended to be placed on the market' (Article 33(1)). That application is accompanied by '(a) … 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 …' (Article 33(3)).

23. The data requirements of the contents of the dossier are specified by Commission Regulation (EU) No 284/2013.[16] Accordingly, the dossier must meet, inter alia, the following requirements: 'the information [in the dossier] shall be sufficient to evaluate efficacy and the foreseeable risks, whether immediate or delayed, which the plant protection product may entail for humans, including vulnerable groups, animals and the environment and contain at least the information and results of the studies referred to in this Annex' (point 1.1 of the introduction to the Annex to Regulation No 284/2013); 'any information on potentially harmful effects of the plant protection product on human and animal health or on groundwater shall be included as well as known and expected cumulative and synergistic effects' (point 1.2); 'any information on potentially unacceptable effects of the plant protection product on the environment, on plants and plant products shall be included as well as known and expected cumulative and synergistic effects' (point 1.3); 'the information shall include all relevant data from the scientific peer reviewed open literature on the active substance, metabolites and breakdown or reaction products and plant protection products containing the active substance and dealing with side-effects on health, the environment and non-target species' (point 1.4); and 'the information provided for the plant protection product and that provided for the active substance, shall be sufficient to: … (c) permit an evaluation of short and long-term risks for non-target species, populations, communities and processes; … (e) permit a risk assessment of acute and chronic consumer exposure, including, where relevant, a cumulative risk assessment deriving from exposure to more than one active substance…; (f) permit an estimation of acute and chronic exposure to operators, workers, residents and bystanders including, where relevant, the cumulative exposure to more than one active substance' (point 1.12).

24. As with applications for approval of an active substance, the contents of the dossier as specified by Regulation No 284/2013 are 'the minimum data to be submitted' (point 2 of the introduction to the Annex); and the 'tests and analyses shall be conducted in accordance with the principles laid down in Directive 2004/10/EC …' (good laboratory practice: point 3).

15 See point 10 above for a summary of the Article 4(3) criteria.

16 Regulation 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).

25. Under Article 36(1) of the PPP Regulation, the second step requires the Member State concerned to conduct 'an independent, objective and transparent assessment in the light of current scientific and technical knowledge using guidance documents available at the time of application …'). That Member State will apply the 'uniform principles for evaluation and authorisation of plant protection products, referred to in Article 29(6)' and it will also give 'all Member States in the same zone the opportunity to submit comments to be considered in the assessment'.

26. The third step is that the Member State(s) concerned either grant or refuse authorisations 'on the basis of the conclusions of the assessment' (Article 36(2) of the PPP Regulation).

27. Throughout both the approval and the authorisation procedure under the PPP Regulation, an industry applicant may request that the Member States concerned keep confidential certain data submitted by them in their applications and dossiers (Articles 7(3) and 33(4) of the PPP Regulation). The applicant makes that request by reference to Article 63 of the PPP Regulation, which provides that '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'. Article 63 is without prejudice to Directive 2003/4/EC on public access to environmental information. [17]

28. The approval of an active substance can always be reversed. Thus, Article 21(1) of the PPP Regulation provides that the 'Commission may review the approval of an active substance at any time' and '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 …'.

29. Finally, Article 69 of the PPP Regulation provides a mechanism for emergency measures 'where it is clear that an approved active substance, safener, synergist or co-formulant or a plant protection product which has been authorised in accordance with this Regulation is likely to constitute a serious risk to human or animal health or the environment, and that such risk cannot be contained satisfactorily by means of measures taken by the Member State(s) concerned'. In such circumstances, 'measures to restrict or prohibit the use and/or sale of that substance or product shall be taken immediately … either at the own initiative of the Commission or at the request of a Member State [but b]efore taking such measures the Commission shall examine the evidence and may request an opinion from the Authority'. In situations of 'extreme urgency', Article 70 permits 'emergency measures' to be taken after the Commission has consulted the Member State(s) concerned. Further, 'where a Member State officially informs the Commission of the need to take emergency measures and no action has been taken in accordance with Article 69 or 70, the Member State may adopt interim protective measures' (Article 71 of the PPP Regulation).

National law

30. Article 322-1 of the Code Pénal (French Criminal Code) provides that the destruction, defacing or damage of property belonging to other persons is punishable by a fine of up to EUR 30 000 and two years' imprisonment. If only minor damage is caused, falling into the category of a petty offence, the maximum penalty is EUR 1 500.

17 Directive 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).

31. Articles 40 and 40-1 of the Code de procédure pénale (French Code of Criminal Procedure) afford public prosecutors discretion as to how to treat complaints, accusations and official reports that they receive. Where the public prosecutor considers that the offence had been committed and there is no legal obstacle to prosecution, it is for the prosecutor to decide whether to prosecute or to close the case. Article 122-7 of the Criminal Code provides that the defence of necessity shall constitute a ground establishing the absence of criminal liability.

Facts and procedural history

32. On two separate occasions — 27 September 2016 and 1 March 2017 — the defendants, who were members of the activist group 'Voluntary Reapers of GMOs, Ariège department', entered three shops. In two of them, they defaced containers of herbicide products containing glyphosate (specifically, 'Roundup') with paint. In the third shop, they used paint and rollers from the shop itself to deface Roundup products and some display cabinets. At one of the shops, they distributed leaflets with the headline '*Roundup and Co, we can't and won't stand this any longer*'. Certain members of the group informed the police that their intention was to 'hammer home the point' that the rules requiring products containing glyphosate to be kept locked in glass cabinets and to be accompanied by the vendor's warning that glyphosate was carcinogenic were being broken.

33. The defendants were charged with degrading or deteriorating the property of another, acting in joint enterprise. At a hearing before the referring court on 17 August 2017, the defendants requested that that court refer questions to the Court under Article 267 TFEU. That request was not opposed by the public prosecutor on the basis that (i) if it were found that the glyphosate-containing products potentially posed risks to human health and the environment, he could have chosen not to prosecute the defendants; and that (ii) such a finding might remove the legal foundation on which the prosecution was based. The defendants also argued that, even were they to be convicted, such a finding could lead the referring court to grant an absolute discharge given the laudable motive for their acts.

34. The referring court expressed doubts as to (i) whether too much discretion is left to the industry applicant to define the active substance covered by the approval process, (ii) whether the rules permit industry applicants to conduct the tests and analyses contained in the dossier on their own and to use confidentiality rules to prevent independent counter-analysis of that dossier and (iii) whether sufficient testing is required of the actual plant protection product containing glyphosate which is placed on the market (both as regards the so-called 'cocktail effect' and in terms of long-term toxicity).

35. Against a background of disputed science on glyphosate and noting that the PPP Regulation is based on the precautionary principle, the referring court considered that EU legislation, as it currently stands, might be insufficient to ensure that people and their environment are afforded full protection. Accordingly, it decided to refer the following questions:

'(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 compilation of 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 for any comprehensive analysis at European level of cumulation 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 anyway performed by the applicant itself?'

36. On 15 March 2018, the Court asked the referring court to indicate the specific impact that the answers to the questions submitted would have on the prosecutions brought against the defendants. The referring court replied by letter of 10 April 2018.

37. The defendants, the Finnish, French and Greek Governments, the European Parliament, the Council and the Commission submitted written observations. With the exception of the Finnish and Greek Governments, those parties made further submissions at the hearing held on 25 November 2018 and answered questions from the Court.

Admissibility

38. The Commission, the European Parliament and the French Government question whether the reference is admissible on the grounds that it is not clear how the answers to the questions — which concern the overall system of plant protection product regulation at the EU level — will have any effect on the criminal proceedings which concern damage to products whose active substance is glyphosate.

39. The referring court notes in its order for reference that the defendants pleaded a defence of necessity. In its reply to the Court's questions, it confirmed that, inter alia, 'positive answers to the questions … could have led … the court hearing the prosecutions to hold that the legal foundation of the offence was removed in light of the harmful nature of the marketed products damaged by all the defendants'. At the hearing, the French Government accepted that the answers could play a role in any sanction passed by the court. That is consistent with the argument in the alternative advanced by the defendants before the referring court as described in the order for reference.

40. It is settled law that in proceedings under Article 267 TFEU, the national court which alone has direct knowledge of the facts of the case is in the best position to assess, with full knowledge of the matter before it, the need for a preliminary ruling to enable it to give judgment. This Court is, in principle, bound to give a ruling. Nonetheless, the Court may decide to examine the circumstances in which the case was referred to it by the national court in order to assess whether it has jurisdiction. [18]

41. In my view the reference is plausibly admissible. In any event, the defendants argue, and the French Government concedes, that the Court's ruling may play a role in determining the sanction that the defendants may eventually face. There is no good reason to distinguish between the prosecution itself and the potential sentence for the purposes of preliminary reference proceedings under Article 267 TFEU. I make no comment on the plea of necessity and whether or not that is sustainable as a matter of national law: that is for the referring court alone to assess. In my view, therefore, the reference is admissible. [19]

18 Judgment of 22 November 2005, *Mangold*, C-144/04, EU:C:2005:709, paragraphs 34 to 36.

19 In analogous circumstances, the Court admitted a reference where it considered the argument that, regardless of the answer it gave, the criminal prosecution would still proceed. The reference was admissible there because it was 'not quite obvious that the questions referred for a preliminary ruling are not necessary for the national court …': judgment of 1 April 2004, *Bellio F.lli*, C-286/02, EU:C:2004:212, paragraphs 26 to 30.

Assessment

Preliminary observations

42. I have two observations to make on the context in which the questions referred came before the Court. The first concerns the use of the active substance glyphosate as an example of alleged failures in the overall system of plant protection product governance. The second is the role that the precautionary principle should play in the review of the validity of an EU legal act.

The use of glyphosate as an example

43. The defendants hold up glyphosate as the exemplar of what is wrong with the PPP Regulation. Although specific EU acts have been adopted by the EU institutions affecting the use of glyphosate,[20] the four questions referred do not mention — still less target — those acts. Instead, the focus is on the overall regulatory architecture established by the PPP Regulation affecting all plant protection products.

44. The validity of provisions 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.[21] In my view, that principle is particularly relevant here. Unless concerns relating to glyphosate are shown to be representative of a systemic and fundamental failure undermining the PPP Regulation and the aim that that regulation seeks to achieve, they cannot place in doubt the overall integrity of the prior approval system established by that regulation.

45. Thus, whilst evidence has been submitted showing differences in scientific opinion between third parties such as scientists[22] and international institutes[23] and the EU institutions, any alleged errors in the conclusions drawn by the latter are necessarily limited to the specific case of glyphosate. Similarly, the fact that there may or may not have been issues regarding independence and transparency during the assessments of glyphosate cannot be taken as evidence that each and every evaluation of an active substance under the regulation is tainted by the same alleged defects.[24]

46. The essential issue before the Court is simply whether any generic, systemic provisions of the PPP Regulation are flawed in such a manner as to render that regulation invalid.

20 Thus, glyphosate was first approved and included on the list of approved substances by Commission Directive 2001/99/EC of 20 November 2001 amending Annex I to Council Directive 91/414/EEC concerning the placing of plant protection products on the market to include glyphosate and thifensulfuron-methyl as active substances (OJ 2001 L 304, p. 14), as most recently renewed by Commission Implementing Regulation (EU) No 2017/2324 of 12 December 2017 renewing the approval of the active substance glyphosate in accordance with Regulation No 1107/2009, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011 (OJ 2017 L 333, p. 10).

21 Judgment of 29 May 2018, *Liga van Moskeeën en Islamitische Organisaties Provincie Antwerpen and Others*, C-426/16, EU:C:2018:335, paragraphs 72 to 74 and the case-law cited.

22 Various materials are cited by both the referring court and the defendants (inter alia, research from Dr Portier dated 29 May 2017, papers from Seralini in 2012 and 2016 and from Defarge in 2016 and 2018). Reference was also made to the 'Monsanto Papers', which emerged during litigation proceedings in the United States and which were, inter alia, specifically taken into account by the Authority in its assessment of glyphosate ('EFSA statement regarding the EU assessment of glyphosate and the co-called "Monsanto papers"').

23 Thus, the International Agency for Research on Cancer concluded in its overall evaluation of glyphosate that it was 'probably carcinogenic to humans': see point 6.3 on p. 78 of the updated monograph of 11 August 2016 (which can be accessed via this link: https://monographs.iarc.fr/iarc-monographs-on-the-evaluation-of-carcinogenic-risks-to-humans-4/.) That view was not shared by either the Authority or the European Chemicals Agency: see recital 4 of Commission Implementing Regulation (EU) 2016/1056 of 29 June 2016 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval period of the active substance glyphosate (OJ 2016 L 173, p. 52) and recital 15 of Implementing Regulation No 2017/2324 referred to in footnote 20 above.

24 See, inter alia, articles in *Le Monde* on 28 March 2016 and 16 September 2017 respectively entitled 'Roundup: le pesticide divise l'Union européene et l'OMS' and 'Glyphosate: expertise truffée de copiés-collés de documents Monsanto' which allege, in summary, that there are differences in scientific opinion, that Germany as rapporteur Member State 'copy-pasted' entire sections of scientific conclusions which had been reached by the industry applicant for the assessment of glyphosate, that there are conflicts of interest within the Authority affecting the impartiality of its work and that there is a difference in scientific opinion on glyphosate.

The role of the precautionary principle in judicial review of the validity of EU acts

47. All of the questions referred enquire as to the conformity of the PPP Regulation with the precautionary principle. The referring court does not, however, explain what it understands to be the components of that principle or indicate to what extent that principle is to be applied by the Court when considering whether an EU measure such as the PPP Regulation is invalid. An understanding of both those elements is necessary to establish the scope of the present review.

48. The correct application of the precautionary principle requires, first, identification of the potentially negative consequences for health (or the environment) of the proposed use of the substance at issue, and, secondly, a comprehensive risk assessment of the risk to health (or the environment) based on the most reliable scientific data available and the most recent results of international research.[25] Once those conditions have been satisfied, the competent authorities (whether at EU or Member State level) may then apply the precautionary principle in order 'take protective measures without having to wait until the reality and seriousness of those risks become fully apparent'.[26] The measures taken must also be proportionate in that they should not 'exceed the limits of what is appropriate and necessary in order to attain the legitimate objectives pursued by the legislation in question …'.[27]

49. Annulment actions may therefore be brought on the basis of the precautionary principle to challenge an act that is deemed too restrictive,[28] as opposed to an act that is deemed not to be restrictive enough.[29] In the case of the former, the question of whether there has been an infringement must essentially be framed in terms of whether the measure at issue infringes the principle of proportionality.[30] In the case of the latter, arguments concerning infringement of the precautionary principle have tended to 'serve merely to support pleas and arguments expressly raised elsewhere'.[31]

50. The PPP Regulation is itself a precautionary measure because it establishes a system of *prior approval* affecting a generic product category (plant protection products).[32] The text of the regulation indicates very clearly that it is based on the precautionary principle[33] and that measures adopted under it are to be based on the precautionary principle.[34]

25 Judgment of 22 December 2010, *Gowan Comércio Internacional e Serviços*, C-77/09, EU:C:2010:803, paragraph 75.

26 Judgment of 22 December 2010, *Gowan Comércio Internacional e Serviços*, C-77/09, EU:C:2010:803, paragraph 73 and the case-law cited. An early definition of the precautionary principle is found in the judgment of 5 May 1998, *National Farmers' Union and Others*, C-157/96, EU:C:1998:191, paragraph 63. A recent exposition is in judgment of 22 November 2018, *Swedish Match*, C-151/17, EU:C:2018:938, paragraph 38. The EU Treaties themselves contain no definition of the principle. Secondary legislation defines it to a limited extent: see, for example, Article 7(1) of Regulation No 178/2002.

27 Judgment of 9 June 2016, *Pesce and Others*, C-78/16 and C-79/16, EU:C:2016:428, paragraph 48.

28 See, inter alia, judgments of 22 December 2010, *Gowan Comércio Internacionale Serviços*, C-77/09, EU:C:2010:803; of 7 July 2009, *S.P.C.M. and Others*, C-558/07, EU:C:2009:430; and of 5 May 1998, *National Farmers' Union and Others*, C-157/96, EU:C:1998:191. In the General Court, see judgment of 17 May 2018, *Bayer CropScience and Others* v *Commission*, T-429/13 and T-451/13, EU:T:2018:280, and judgment of 11 September 2002, *Pfizer Animal Health* v *Council*, T-13/99, EU:T:2002:209.

29 See, for example, judgment of 11 July 2007, *Sweden* v *Commission*, T-229/04, EU:T:2007:217, paragraphs 191 and 262.

30 See, for example, judgment of 28 January 2010, *Commission* v *France*, C-333/08, EU:C:2010:44, paragraphs 85 to 110, in particular paragraph 95 et seq.

31 See judgment of 11 July 2007, *Sweden* v *Commission*, T-229/04, EU:T:2007:217, paragraph 128, where the General Court endorsed the common position of the parties on that point. Having conducted a very detailed examination of those other arguments, the General Court concluded that 'in the light of the foregoing … breach of the precautionary principle … must be substantially accepted' (at paragraph 262) and proceeded to annul the Directive at issue.

32 See judgment of 22 December 2010, *Gowan Comércio Internacional e Serviços*, C-77/09, EU:C:2010:803, paragraph 74, and, by analogy, judgment of 19 January 2017, *Queisser Pharma*, C-282/15, EU:C:2017:26, paragraph 58.

33 See Article 1(4) of the PPP Regulation. The legal bases of Regulation No 1107/2009 are Article 37(2) of the Treaty establishing the European Community ('TEC') (now Article 43 TFEU; the common agricultural policy), Article 95 TEC (now Article 114 TFEU; the internal market) and Article 152(4)(b) TEC (now Article 168 TFEU; public health). Requirements as to the EU policy of ensuring a high level of protection of human health, based on the precautionary principle, 'are a part of all the policies and actions of the Union': see judgment of 22 December 2010, *Gowan Comércio Internacional e Serviços*, C-77/09, EU:C:2010:803, paragraphs 71 to 72.

34 Article 13(2) of the PPP Regulation.

51. The referring court's questions do not suggest that the prior approval system established by the PPP Regulation per se infringes the precautionary principle. Rather, those questions concern alleged generic failures in the overall system of risk assessment of plant protection products — specifically, that the assessment is insufficiently comprehensive (Questions 1, 3 and 4) or independent and transparent (Question 2).

52. The area of law covered by the PPP Regulation is technically and scientifically complex. The EU institutions accordingly enjoy a particularly wide discretion in framing the measures they adopt. Such measures are susceptible to be annulled only where they are manifestly inappropriate or where the institutions have committed manifest errors in the light of the objective sought to be achieved. [35]

First and third questions

53. The first and third questions overlap in that they both raise doubts as to whether the 'cocktail effect' of an active substance (that is to say, the effect of exposure (i) to different plant protection products containing the same active substance or (ii) to different active substances contained in a single plant protection product) is fully assessed by the PPP Regulation. Since the concept of 'active substance' is left to the industry applicant to define, the national court is also concerned that the latter may enjoy too much discretion as to what is ultimately subject to assessment by the relevant authorities. [36]

54. I shall look first at the specific data requirements of the PPP Regulation, which do address both the identity of the active substance and the 'cocktail effect', and then examine the general safety-net mechanisms put in place by the regulation.

55. Article 2(2) of the PPP Regulation makes it clear that any substance having 'general or specific action against harmful organisms or on plants, parts of plants or plant products' falls to be considered an 'active substance' to which the regulation applies. If such a substance fulfils that definition, it can only be lawfully placed on the EU market for any of the purposes mentioned in Article 2(1) of the regulation if the producer who wishes to do so has applied for and obtained approval. When he does so, it is clear that he will have to provide the relevant authorities with objectively derived data if he wishes to obtain approval. Specifically, he must provide detailed data on the identity of his substance, its molecular formula, specification of purity, relevant and significant impurities and additives (inter alia). [37] Thus, the system put in place by the PPP Regulation is designed to provide the relevant authorities with detailed knowledge of the precise make-up of the active substance, impurities included.

56. Similarly, it seems to me that the PPP Regulation and its related secondary legislation taken together should ensure that the possible 'cocktail effects' of both an active substance and a plant protection product will be included in the overall risk assessment conducted by the relevant authorities.

35 See, inter alia, judgments of 8 July 2010, *Afton Chemical*, C-343/09, EU:C:2010:419, paragraph 38; of 22 December 2010, *Gowan Comércio Internacional e Serviços*, C-77/09, EU:C:2010:803, paragraphs 55 to 56; of 21 December 2016, *Associazione Italia Nostra Onlus*, C-444/15, EU:C:2016:978, paragraph 46; and of 9 June 2016, *Pesce and Others*, C-78/16 and C-79/16, EU:C:2016:428, paragraph 49.

36 The referring court here cites Article 8 of Regulation No 1107/2009, which concerns the approval process for active substances. My Opinion on this question is accordingly limited to the rules relating to that approval process.

37 For all of the data requirements on identity of the active substance, see Section 1 of Part A of the Annex to Regulation No 283/2013. See also Commission Communication 2013/C 95/02 in the framework of the implementation of Regulation No 284/2013, in accordance with Regulation No 1107/2009 (OJ 2013 C 95, p. 21).

57. Thus, for active substances, Article 4(2) and (3) of the PPP Regulation provides that the assessment of an active substance includes taking 'into account known cumulative and synergistic effects where the scientific methods accepted by the Authority to assess such effects are available …'.[38] To enable that to take place, Regulation No 283/2013 requires that the data submitted by an industry applicant must be sufficient to 'permit a risk assessment of consumer exposure, including, where relevant, a cumulative risk assessment deriving from exposure to more than one active substance; [and] to permit an estimation of the exposure to operators, workers, residents and bystanders including, where relevant, the cumulative exposure to more than one active substance'.[39] Those data requirements and assessment aims are mirrored at Member State level when the latter are considering applications for authorisation of a plant protection product.[40]

58. The words 'cumulative' and 'synergistic' are, as I understand it, more scientific alternatives to the word 'cocktail'. Were there any doubts as to whether those words cover the 'cocktail effect', they are removed by Article 29(6) of the PPP Regulation. That article reemphasises that the assessment process at both EU and Member State level for approvals and authorisations extends beyond the particular attributes of an individual active substance acting alone by *requiring* that account also be taken of the 'interaction between the active substance, safeners, synergists and co-formulants'.

59. A fuller reading of the PPP Regulation therefore leads to the clear conclusion that the assessment process it lays down does take into account the 'cocktail effect'. When asked at the hearing what specific changes the legislator should make to the PPP Regulation in order to address its alleged failure to assess the cocktail effect, counsel for the defendants suggested imposing an additional requirement that industry applicants produce long-term toxicity testing data when seeking an authorisation of their plant protection products.[41] The wider, structural reading of the regulation that I have just outlined was not in truth contested.

60. Should an individual approval process fail adequately to take account of the cocktail effect, safety nets exist permitting restrictive measures to be taken on the basis of the precautionary principle. Thus, for example, the PPP Regulation allows for restrictions subsequently to be imposed on an approved active substance where 'the Commission concludes that the approval criteria provided for in Article 4 are no longer satisfied'. The overall system therefore ensures that problems which may slip through unidentified at the approval stage are caught at a subsequent stage.[42] Furthermore, precautionary measures can be taken independently of any risk assessment undertaken as part of the PPP Regulation approval and authorisation processes.[43] The PPP Regulation thus specifically permits relevant authorities at EU and Member State levels to invoke other assessments to justify precautionary measures where necessary.

38 The European Parliament's 'Report on the Union's authorisation procedure for pesticides' (2018/2153 (INI), 18 December 2018) states at point AC on p. 10 that 'such methodologies are now available …'.

39 Point 1.11(q) and (r) of the Introduction to the Annex to Regulation No 283/2013.

40 See, inter alia, Article 29(1)(e) of Regulation No 1107/2009 (which refers back to Articles 4(3) and 29(6) thereof) and points 1.2, 1.3 and 1.12(e) and (f) of the Introduction to the Annex to Regulation No 284/2013.

41 That echoes one of the recommendations of the European Parliament in its 'Report on the Union's authorisation procedure for pesticides' (2018/2153 (INI), 18 December 2018) at point 57 on p. 22. See also point 76 et seq. below.

42 That, indeed, is precisely what happened with glyphosate. During a review of that substance's initial approval, a restriction was adopted preventing the use of glyphosate in combination with the co-formulant 'POE-tallowamine' because 'concerns were highlighted as regards the potential of POE-tallowamine to negatively affect human health when used in plant protection products containing glyphosate': see Commission Implementing Regulation (EU) 2016/1313 of 1 August 2016 amending Implementation Regulation (EU) No 540/2011 as regards the conditions of approval of the active substance glyphosate (OJ 2016 L 208, p. 1).

43 See, for example, Articles 36(3), 56, and 69 to 71 of Regulation No 1107/2009. See also, by analogy, judgment of 9 September 2003, *Monsanto Agricoltura Italia and Others*, C-236/01, EU:C:2003:431, paragraphs 102 to 113.

61. In short, no material has been adduced showing that the PPP Regulation is vitiated by a manifest error such that assessments conducted under that regulation do not take account of the 'cocktail effect' or that an industry applicant is able to manipulate its data submission such that that effect is not assessed. The *system* put in place by the regulation is sound and permits errors of assessment in individual cases to be caught and corrected.

The second question

62. The second question proceeds on several assumptions: first, that an applicant seeking approval of its active substance or authorisation for its plant protection product may submit a biased data set to the authorities for assessment; second, that that data set is not 'counter-analysed' independently; and third, that applications for approval (and also for authorisation) are protected from third party scrutiny by application of industry-friendly confidentiality rules. If those assumptions are correct, the assessments conducted will not be impartial or transparent and thus may jeopardise regulatory recourse to the precautionary principle.

63. In my view, those assumptions do not survive examination. I shall take each in turn.

64. All assessments conducted under the PPP Regulation, whether at EU or Member State level, depend upon the submission of complete dossiers of data. If the rules are followed, those data will be of a certain standard set by that regulation and its related secondary legislation. Thus, for example, 'scientific peer-reviewed open literature' must be placed by the industry applicant in its dossier for the approval of an active substance [44] together with, as appropriate, 'official or officially recognised tests'; [45] and such tests and analyses must be conducted according to the rules on good laboratory practice. [46]

65. Those express requirements preclude an industry applicant from itself conducting the necessary studies against its own (biased) protocols and (partial) standards and choosing which data it prefers to submit in its dossier. Rather, it is clear to me that the PPP Regulation directly mandates the opposite by imposing objective requirements on the quality of data to be submitted.

66. Once submitted, the data set supporting the application for approval is required by the PPP Regulation to be assessed by a series of public authorities. Thus, the data for active substances are reviewed by a rapporteur Member State and thereafter that assessment is reviewed by the other Member States and by the Authority. [47] For plant protection products, the assessment is conducted by a Member State and thereafter that assessment is reviewed by the other Member States in the same geographic zone. [48] All of those assessments are conducted 'in the light of current scientific and technical knowledge'. [49] Similarly, all of those assessments are conducted 'independently, objectively and transparently'; those by the Member States because Regulation No 1107/2009 so requires; [50] and those by the Authority because that Authority was made subject to those requirements on its establishment. [51]

44 Article 8(5) of Regulation No 1107/2009.

45 Article 29(3) of Regulation No 1107/2009.

46 See point 3.1 of the introduction to the Annex to both Regulation No 283/2013 and Regulation No 284/2013. Aside from being a requirement that such data are submitted, there is also a commercial incentive for industry applicants to do so: Article 59(1)(b) of Regulation No 1107/2009 allows those applicants to protect their data from being referred to by other industry applicants who are submitting separate applications but only where, inter alia, those data were 'certified as compliant with the principles of good laboratory practice or of good experimental practice'.

47 Articles 11(2) and 12(2) of Regulation No 1107/2009.

48 Article 36(1) of Regulation No 1107/2009.

49 See Articles 11(2), second indent, and 12(2), second indent, of Regulation No 1107/2009.

50 Articles 11(2), second indent, and 36(1) of Regulation No 1107/2009.

51 See, inter alia, Articles 22(2), 23(k), 28(3) and (4) and 37(1) and (2) of Regulation No 178/2002.

67. There is, in other words, at all levels of the approval or authorisation process under the PPP Regulation a degree of scrutiny which the law requires to be of a certain objective standard and which I accept provides systemic independent analysis of the material submitted by an industry applicant. [52]

68. It is therefore immaterial that the industry applicant can choose in which Member State to start the assessment process for its active substance. All Member States are under the same obligations of scrutiny. Should the rapporteur Member State fail for whatever reason to conduct an adequate independent analysis of the industry applicant's data set, the safety net is found in the requirements for other Member States together with the Authority to conduct a further review under the same obligations.

69. Accordingly, I consider that no material has been adduced to undermine the conclusion that the *system* of structured assessment at EU and Member State levels laid down by the PPP Regulation is both appropriate and sufficient to achieve the high level of environmental and human health protection sought. If correctly applied, that regulatory system will generate a comprehensive risk assessment that can be relied upon by the competent authorities to justify adopting precautionary measures where appropriate.

70. What of the assertion that the confidentiality rules in the PPP Regulation can be invoked by the industry applicant to prevent publication of aspects of its applications for approval and thus potentially frustrate third party review?

71. In my view, those rules do not mean that the assessment produced is generically insufficiently transparent or independent.

72. Those rules operate by way of exception from the general principle of access to information and documents. That is evident from Article 63(3) of the PPP Regulation, which states that the rules of confidentiality are without prejudice to Directive 2003/4. That directive establishes the rights and obligations of Member State authorities when they receive a request for access to environmental information. The Court has consistently held that that directive aims 'to ensure a general principle of access to environmental information held by or for public authorities and … to achieve the widest possible systematic availability and dissemination to the public of environmental information'. [53] Any derogation based on public or private interest from that general principle must be interpreted and applied restrictively. [54] The equivalent rules covering applications for disclosure of the same type of information by EU institutions are found in Regulation (EC) No 1367/2006. [55] The same principles of widest possible access and narrowly interpreted exceptions apply. [56]

52 I add that my narration of the layers of scrutiny established by Regulation No 1107/2009 is not exhaustive. For example, Article 12(3), third indent, of the regulation permits the Authority to '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 …'.

53 Judgment of 23 November 2016, *Bayer CropScience and Stichting De Bijenstichting*, C-442/14, EU:C:2016:890, paragraph 55.

54 See, inter alia, judgment of 23 November 2016, *Bayer CropScience and Stichting De Bijenstichting*, C-442/14, EU:C:2016:890, paragraph 56. See also, by analogy to Regulation (EC) No 1049/2001 regarding public access to European Parliament, Council and Commission documents (OJ 2001 L 145, p. 43), and judgment of 13 July 2017, *Saint-Gobain Glass Deutschland* v *Commission*, C-60/15 P, EU:C:2017:540, paragraphs 61 to 63.

55 Regulation of the European Parliament and of the Council of 6 September 2006 on the application of the provisions of the Aarhus Convention on Access to Information, Public Participation in Decision-making and Access to Justice in Environmental Matters to Community institutions and bodies (OJ 2006 L 264, p. 13).

56 Judgment of 23 November 2016, *Commission* v *Stichting Greenpeace Nederland and PAN Europe*, C-673/13 P, EU:C:2016:889, paragraphs 52 and 53.

73. Article 63 of the PPP Regulation does not detract from those long-established principles. Rather, Article 63(1) states that claims from the industry applicant for confidentiality of information on the grounds that disclosure of that information 'might undermine his commercial interests or the protection of privacy and the integrity of the individual' must be accompanied by 'verifiable evidence'.[57] Moreover, claims to confidentiality over the specification of an impurity or a method of analysis of an impurity will fall if those impurities or those methods 'are considered to be toxicologically, ecotoxicologically or environmentally relevant' (Article 63(2)(b) and (d)).

74. There is no absolute public right to access all of the data in an industry applicant's dossier. Such an absolute right would jar with EU primary law, in the shape of Article 15(3) TFEU, which allows the EU institutions in their regulations to prescribe 'limits on grounds of public or private interest' to the general principle of widest possible access.[58] A third party does not have an absolute right to conduct a counter risk assessment by reference to the industry applicant's dossier of raw data. The role of third parties in the risk assessment process is however guaranteed through other mechanisms within the PPP Regulation, such as the public dissemination of the industry applicant's summary dossier (Article 10 of the PPP Regulation) and of the draft assessment report with a timeline for comments (Article 12 of the PPP Regulation).

75. In my view, the provisions adopted by the EU institutions in the PPP Regulation regarding the public's access to data submitted by the industry applicant are consistent with Article 15(3) TFEU and with the general principles laid down in the Court's case-law.[59] They are, accordingly, appropriate and not vitiated by manifest errors.

The fourth question

76. The fourth question proceeds on the basis that the PPP Regulation 'dispenses' with the requirement for industry applicants to submit data on 'long-term toxicity analysis for pesticides found on the market and to which people are exposed' (that is to say, there is no need to submit such data for applications for authorisations of plant protection products). Specifically, no full genotoxicity, carcinogenicity, endocrine disruption (and similar) tests need to be undertaken, summary testing being considered sufficient. That 'dispensation' contrasts with data requirements for applications for active substance approval.

77. The legal requirements on data relating to human health toxicity testing do indeed differ depending on whether it is an active substance[60] or a plant protection product for which an application is being submitted. Strictly speaking there is no 'dispensation' per se from submitting such data for plant protection products. Rather, the PPP Regulation and Regulation No 284/2013 establish that the data set to be submitted for plant protection products must show that the product 'shall have no immediate or delayed harmful effect on human health, including that of vulnerable groups, or animal health, directly or through drinking water (taking into account substances resulting from water treatment), food, feed or air, or consequences in the workplace or through other indirect effects, taking into account known cumulative and synergistic effects …'.[61] The data requirements specified by Regulation No 284/2013 are the minimum demanded.[62] However, the reviewing authorities have the

57 For an example of what the obligation to produce 'verifiable evidence' entails, see judgment of 14 December 2018, *Arysta LifeScience Netherlands* v *EFSA*, T-725/15, EU:T:2018:977, paragraphs 105 to 130.

58 Article 339 TFEU also places an obligation on the 'members of the institutions of the Union, the members of committees, and the officials and other servants of the Union shall be required … not to disclose information of the kind covered by the obligation of professional secrecy, in particular information about undertakings, their business relations or their cost components'.

59 See point 72 above.

60 Section 5 of Part A of the Annex to Regulation No 283/2013 requires a series of long-term toxicity tests (including on carcinogenicity) to be part of the dossier submitted to the relevant authorities.

61 Article 4(3) of Regulation No 1107/2009 to which Article 29(1)(e) cross-refers.

62 See points 1.1 and 2 of the Introduction to the Annex to Regulation No 284/2013.

express power to require additional data. For example, they may ask for 'supplementary studies … taking into account the results of the acute toxicity studies of the individual plant protection products and the toxicological properties of the active substances, the possibility for exposure to the combination of the products concerned, with particular regard to vulnerable groups, and available information or practical experience with the products concerned or similar products'.[63]

78. Should an assessment show that there is a risk to human health due (for example) to long-term toxicity but it is not clear how serious that risk is, nothing in the PPP Regulation inhibits the relevant authorities from rejecting the application for authorisation of that plant protection product, in application of the precautionary principle.

79. Self-evidently, it is always possible to impose more stringent data requirements. Requiring a long-term toxicity analysis *before* a plant protection product is authorised to be placed on the market involves both incurring additional costs and delaying the moment at which farmers have access to that product to protect their crops. As with many things in life, regulation here involves striking a balance between two competing desiderata: an appropriately high level of protection for humans, animals and the environment[64] and enabling products that can enhance agricultural productivity to be placed on the market. No material has been adduced to support the conclusion that the EU legislator has committed a manifest error in striking that balance in Regulation No 1107/2009.

Temporal effect of invalidity

80. The Commission has submitted that, should the Court find that the regulation is invalid, the effects of the regulation should nevertheless be maintained whilst the necessary remedial steps are taken by the EU institutions concerned.

81. Should the Court disagree with my analysis above, I would endorse that submission given the complexity of this particular area of law together with the potential ancillary consequences for related measures whose legal basis is Regulation No 1107/2009. Continuity in the plant protection product programme is also arguably essential.[65]

Postscript

82. At the hearing, the defendants placed considerable reliance upon the European Parliament's 'Report on the Union's authorisation procedure for pesticides'.[66] That report notes that 'although the EU has one of the most stringent systems in the world, both the regulation as such and its implementation need to be improved for it to achieve its purpose'.[67] A series of recommendations is accordingly made.

83. The publication of that report is an excellent indication that the scrutiny and review procedures foreseen by the EU's institutional arrangements are working as they should. Nothing I have said in this Opinion should be read as suggesting that it would be appropriate for the EU legislator to sit back complacently and pay no attention when issues are raised concerning potential risks to human

63 See points 7.1.7 and 7.1.8 of Section 7 of Part A of the Annex to Regulation No 284/2013.

64 On the quintessentially political decision as to what that level should be, I refer to the illuminating article of my colleague in the General Court, Judge Ian Forrester, in his essay 'The Dangers of too Much Precaution' (Hoskins and Robinson, '*A True European*', Hart Publishing, Oxford and Portland, Oregon, 2003, p. 203) in which he discusses the dicta of Chief Justice Burger in *Industrial Union Department, AFL-CIO* v. *American Petroleum Institute et al.* 448 US 607 (1980) at 664 that 'perfect safety is a chimera; regulation must not strangle human activity in the search for the impossible' (p. 213).

65 See, by analogy, judgment of 5 July 1995, *Parliament* v *Council*, C-21/94, EU:C:1995:220, paragraph 31 and the case-law cited.

66 See footnote 38 above.

67 At point 1 on p. 17.

and animal health and the environment from the use of advanced chemical preparations in agriculture. However, the fact that recommendations are made suggesting that an existing law could with advantage be improved does not necessarily mean that that existing law is so flawed that it should be struck down. Most laws are capable of improvement; and the PPP Regulation is probably no exception to that general rule. Having examined the regulation in detail in the light of the questions referred, I conclude that it is *not* vitiated by a manifest error and that, accordingly, no issue arises as to its validity.

Conclusion

84. In the light of the foregoing considerations, I propose that the Court should give the following answer to the four questions referred for a preliminary ruling by the Tribunal Correctionnel de Foix (Criminal Court, Foix, France):

Examination of the material before the Court has disclosed no factor 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.