Reports of Cases

JUDGMENT OF THE GENERAL COURT (Fifth Chamber)

13 July 2022 *

(Plant protection products – Active substance chlorpyrifos – Determination of maximum residue levels for chlorpyrifos in or on bananas – Regulation (EC) No 396/2005 – Scientific and technical knowledge available – Other legitimate factors)

In Case T-629/20,

Delifruit, SA, established in Guayaquil (Ecuador), represented by K. Van Maldegem, P. Sellar and S. Abdel-Qader, lawyers,

applicant,

v

European Commission, represented by F. Castilla Contreras, A. Dawes and M. ter Haar, acting as Agents,

defendant,

THE GENERAL COURT (Fifth Chamber),

composed of D. Spielmann, President, U. Öberg and M. Brkan (Rapporteur), Judges,

Registrar: S. Spyropoulos,

having regard to the written part of the procedure,

further to the hearing on 23 February 2022,

gives the following

Judgment

Background to the dispute

1 By its action based on Article 263 TFEU, the applicant, Delifruit, SA, seeks the partial annulment of Commission Regulation (EU) 2020/1085 of 23 July 2020 amending Annexes II and V to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards

* Language of the case: English.

maximum residue levels for chlorpyrifos and chlorpyrifos-methyl in or on certain products (OJ 2020 L 239, p. 7, corrigendum OJ 2020 L 245, p. 31) ('the contested regulation'), in so far as it sets the maximum residue level ('MRL') for chlorpyrifos in or on bananas at 0.01 mg/kg.

2 The applicant is an undertaking established in Guayaquil (Ecuador) which produces and exports bananas, in particular to the European Union.

3 Chlorpyrifos is an active substance, which comes within the category of chemical products called organophosphates, used in particular as pesticide on certain crops. That substance was included in Annex I 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) by Commission Directive 2005/72/EC of 21 October 2005 amending Directive 91/414 (OJ 2005 L 279, p. 63).

4 In June 2013, an application for renewal of the approval of chlorpyrifos was submitted under Article 1 of Commission Implementing Regulation (EU) No 844/2012 of 18 September 2012 setting out the provisions necessary for the implementation of the renewal procedure for active substances, as provided for in Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market (OJ 2012 L 252, p. 26).

5 The rapporteur Member State (the Kingdom of Spain), in consultation with the co-rapporteur Member State (the Republic of Poland), drew up a renewal assessment report, forwarded on 3 July 2017 to the European Food Safety Authority (EFSA) and the European Commission.

6 On 1 July 2019, the Commission invited EFSA to issue a statement on the results available of the assessment of risks to human health and to provide an indication as to whether the active substance was likely to meet the approval criteria applicable to human health set out in Article 4 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 (OJ 2009 L 309, p. 1).

7 On 31 July 2019, EFSA sent the Commission a statement entitled 'Statement on the available outcomes of the human health assessment in the context of the pesticides peer review of the active substance chlorpyrifos' (EFSA Journal 2019;17(5):5809) ('EFSA's statement of 31 July 2019 on chlorpyrifos'), in which it concluded that the approval conditions applicable to human health laid down in Article 4 of Regulation No 1107/2009 were not met.

8 On 10 January 2020, the Commission adopted Implementing Regulation (EU) 2020/18 concerning the non-renewal of the approval of the active substance chlorpyrifos, in accordance with Regulation No 1107/2009, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011 (OJ 2020 L 7, p. 14), by which the approval of chlorpyrifos was not renewed, with the result that the Member States were required to withdraw marketing authorisations for plant protection products containing that active substance by 16 February 2020 at the latest, with the possibility of granting a grace period which was due to expire on 16 April 2020 at the latest.

9 At the meeting of the Standing Committee on Plants, Animals, Food and Feed (SCOPAFF) on 25 and 26 November 2019, at which the Commission presented a draft regulation on the reduction of the MRL for chlorpyrifos to 0.01 mg/kg, the Member States supported that draft and asked the Commission to schedule its vote at the February 2020 meeting.

10 At the SCOPAFF meeting on 17 and 18 February 2020, the Member States issued an opinion in favour of the draft regulation amending the MRL for chlorpyrifos. Following that favourable opinion, the draft regulation was forwarded to the European Parliament and the Council of the European Union for review.

11 On 21 May 2020, EFSA published on its website the study on 'genotoxicity of permethrin and clorpyriphos on human stem and progenitor cells at different ontogeny stages: implications in leukaemia development', carried out by the Josep Carreras Institute (the 'Josep Carreras study'), which it had commissioned from that institute under a contract for the provision of services signed following a negotiated procedure without prior publication of a contract notice.

12 On 23 July 2020, the Commission adopted the contested regulation.

13 Recitals 2 to 5 of the contested regulation state as follows:

> '(2) The approvals of the active substances chlorpyrifos and chlorpyrifos-methyl were not renewed by Commission Implementing Regulation (EU) 2020/18 … and Commission Implementing Regulation (EU) 2020/17 …, respectively.
>
> (3) All existing authorisations for plant protection products containing chlorpyrifos and chlorpyrifos-methyl have been revoked. It is therefore appropriate to delete the MRLs set out for these substances in Annex II to Regulation (EC) No 396/2005 in accordance with Article 17 of Regulation (EC) No 396/2005 in conjunction with Article 14(1)(a) thereof.
>
> (4) The Commission consulted the European Union reference laboratories as regards the need to adapt certain limits of determination (LODs) for the two substances. Those laboratories concluded that technical development permits the setting of LODs at 0.01 mg/kg for chlorpyrifos and chlorpyrifos-methyl in all products. Those default values should be listed in Annex V in accordance with Article 18(1)(b) of Regulation (EC) No 396/2005.
>
> (5) In the context of the non-renewal of the approval of chlorpyrifos and chlorpyrifos-methyl, [EFSA] published statements on the human health assessment for those active substances. In those statements [EFSA] confirmed developmental neurotoxicity of both active substances in children and could not exclude a genotoxic potential due to the exposure to residues of the two substances in food.'

14 The contested regulation states that it is to apply as of 13 November 2020.

15 The annex to the contested regulation provides, first, for the removal of the columns concerning chlorpyrifos and chlorpyrifos-methyl in Annex II to Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on [MRLs] of pesticides in or on food and feed of plant and animal origin and amending Directive 91/414 (OJ 2005 L 70, p. 1), and, second, for the addition of columns concerning chlorpyrifos and chlorpyrifos-methyl in Annex V to that regulation.

Forms of order sought

16 The applicant claims that the Court should:

– annul the contested regulation in so far as it sets the MRL for chlorpyrifos in or on bananas at 0.01 mg/kg;

– order the Commission to pay the costs.

17 The Commission contends that the Court should:

– dismiss the action;

– order the applicant to pay the costs.

Law

18 In support of its action, the applicant puts forward a single plea in law in which it submits, in essence, that the contested regulation is unlawful in that the Commission made a manifest error of assessment by failing to take into account the Josep Carreras study, which is a relevant factor which should have been taken into consideration when that regulation was adopted. In so doing, it infringed Article 14(2)(a) and (f) of Regulation No 396/2005. At the hearing, the applicant stated that the matter should have been referred to EFSA to assess the relevance of the Josep Carreras study before the adoption of the contested regulation. The Commission has disputed the admissibility of that argument.

Admissibility of the argument that the matter should have been referred to EFSA to assess the relevance of the Josep Carreras study before the adoption of the contested regulation

19 The Commission contends that the applicant's argument must be declared inadmissible on the ground that it is a new plea put forward at the hearing. The applicant disputes the alleged inadmissibility.

20 According to settled case-law concerning Article 84(1) of the Rules of Procedure of the General Court, no new plea in law may be introduced in the course of proceedings unless that plea is based on matters of law or fact which have come to light in the course of the procedure. However, a plea which constitutes an amplification of a plea made previously, whether directly or by implication, in the original application, and which is closely connected therewith, will be declared admissible. To be regarded as an amplification of a plea or a head of claim previously advanced, a new argument must, in relation to the pleas or heads of claim initially set out in the application, present a sufficiently close connection with the pleas or heads of claim initially put forward in the application in order to be considered as forming part of the normal evolution of debate in proceedings before the Court (see judgment of 5 October 2020, *HeidelbergCement and Schwenk Zement* v *Commission*, T-380/17, EU:T:2020:471, paragraph 87 (not published) and the case-law cited).

21 In this case, it must be held that it is true that, in its application, the applicant did not expressly rely on the need for a referral to EFSA for an opinion in order to carry out an assessment of the relevance of the Josep Carreras study. However, it referred to EFSA's failure to take that study

into consideration before the adoption of the contested regulation. Furthermore, in response to the Commission's line of argument, set out in its defence, referring to EFSA's role in the evaluation of the scientific studies and to the absence of any obligation to seek its opinion, the applicant submitted, in the reply, that the only bodies competent to examine the relevance of the Josep Carreras study were the rapporteur Member States or EFSA, and not the Commission, and stated that the failure to take that study into consideration was all the more serious given that EFSA had commissioned that study itself, which it then received before the adoption of the contested regulation, with the result that EFSA had the necessary time, from the receipt of the study to the adoption of the contested regulation, to examine its relevance.

22 It follows that the argument based on the obligation to refer the matter to EFSA for it to assess the relevance of the Josep Carreras study is an amplification of a plea made previously, whether directly or by implication, in the original application, and which, in this case, presents a sufficiently close connection with that plea in order to be considered as forming part of the normal evolution of debate in the context of these proceedings before the Court.

23 Accordingly, it must be held that that argument is admissible.

Substance

24 By its single plea in law, the applicant claims that the Commission made a manifest error of assessment on the ground that, by failing to take into account the Josep Carreras study when adopting the contested regulation, it failed to examine carefully and impartially all the aspects of the present case. Therefore, the applicant takes the view that the Commission infringed Article 14(2)(a) and (f) of Regulation No 396/2005, which sets out the factors to be taken into consideration in determining MRLs, namely 'the scientific and technical knowledge available' and 'other legitimate factors relevant to the matter under consideration'.

25 According to the applicant, in so far as the genotoxic potential constitutes, as is apparent from EFSA's statement of 31 July 2019 on chlorpyrifos and from the contested regulation, one of the grounds justifying the removal of the MRLs for chlorpyrifos, the Commission should have taken account, when that regulation was adopted, of the Josep Carreras study, which calls into question the genotoxic potential of chlorpyrifos.

26 In addition, the applicant takes the view that the only bodies competent to assess the relevance of the Josep Carreras study are the rapporteur Member States or EFSA and not the Commission. According to the applicant, the chronology of events should have enabled them to take that study into consideration for the purposes of the adoption of the contested regulation. In that regard, the applicant states that EFSA had commissioned the Josep Carreras study and that the data should have been available by 1 February 2020. It takes the view that EFSA knew that it had enough time to assess the relevance of the Josep Carreras study from its receipt to the adoption of the contested regulation. Moreover, in so far as the Josep Carreras study, commissioned by EFSA, was published on EFSA's website on 21 May 2020, that is to say, before the adoption of the contested regulation on 23 July 2020, the applicant claims that the Commission infringed Article 14(2)(a) and (f) of Regulation No 396/2005 on the ground that that study was not taken into consideration and that it did not refer the matter to EFSA to assess the study's relevance.

27 According to the applicant, even if the Commission may, pursuant to Article 17 of Regulation No 396/2005, remove MRLs following the revocation of an existing authorisation applicable to a plant protection product, without an EFSA opinion being sought, that provision does not relieve

it of its obligation to ensure that its decisions are based on the best scientific knowledge. In the event of a failure to comply with that obligation, the removal of MRLs would be arbitrary on account of a lack of an appropriate scientific basis.

28 The Commission disputes those arguments.

29 As a preliminary point, it should be borne in mind that the contested regulation was adopted on the basis of Regulation No 396/2005, itself adopted on the basis of Article 37 EC (now, after amendment, Article 43 TFEU), concerning the common agricultural policy, and Article 152(4)(b) EC (now, after amendment, Article 168(4)(b) TFEU), concerning public health.

30 As is apparent from recital 10 and Article 1 thereof, the objective of Regulation No 396/2005 is to ensure a high level of protection of human and animal health and the interests of consumers and to improve the functioning of the internal market by harmonising the rules on the MRLs for pesticides in or on food and feed of plant and animal origin.

31 Regulation No 396/2005 thus applies Article 168(1) TFEU, which provides that a high level of human health protection is to be ensured in the definition and in the implementation of all policies and activities of the European Union. The protection of public health takes precedence over economic considerations, with the result that it may justify adverse economic consequences, even those which are substantial, for certain traders (judgments of 9 September 2011, *Dow AgroSciences and Others* v *Commission*, T-475/07, EU:T:2011:445, paragraph 143; of 12 April 2013, *Du Pont de Nemours (France) and Others* v *Commission*, T-31/07, not published, EU:T:2013:167, paragraph 132; and of 15 December 2016, *TestBioTech and Others* v *Commission*, T-177/13, not published, EU:T:2016:736, paragraph 87). In that regard, it should be noted that, under recital 5 of Regulation No 396/2005, since public health should be given priority over the interests of crop protection, pesticide residues should not be set at levels presenting an unacceptable risk to human beings, in particular vulnerable groups such as children and the unborn. Likewise, under recital 22 of Regulation No 396/2005, where pesticides are not authorised within the European Union, MRLs should be set at an appropriately low level to protect consumers from the intake of unauthorised or excessive levels of pesticides residues.

32 Furthermore, if the Commission is to be able to pursue effectively the objectives assigned to it by Regulation No 396/2005, namely, in particular, to ensure a high level of protection of human and animal health and the interests of consumers and to ensure the effective functioning of the internal market, and account being taken of the complex technical assessments which it must undertake, the Commission must be recognised as enjoying a broad discretion (see, by analogy, judgments of 18 July 2007, *Industrias Químicas del Vallés* v *Commission*, C-326/05 P, EU:C:2007:443, paragraph 75, and of 6 September 2013, *Sepro Europe* v *Commission*, T-483/11, not published, EU:T:2013:407, paragraph 38).

33 The exercise of that discretion is, however, not excluded from judicial review. In that regard, it follows from settled case-law that, in the context of such a review, the Courts of the European Union must verify whether the relevant procedural rules have been complied with, whether the facts found by the Commission have been accurately stated and whether there has been a manifest error of assessment or a misuse of powers (judgments of 22 October 1991, *Nölle*, C-16/90, EU:C:1991:402, paragraph 12, and of 9 September 2008, *Bayer CropScience and Others* v *Commission*, T-75/06, EU:T:2008:317, paragraph 83; see, to that effect, judgment of 25 January 1979, *Racke*, 98/78, EU:C:1979:14, paragraph 5).

34 In particular, where a party alleges that the competent institution has made a manifest error of assessment, the Courts of the European Union must review whether that institution has examined, carefully and impartially, all the relevant aspects of the individual case which support the findings reached from them (judgments of 21 November 1991, *Technische Universität München*, C-269/90, EU:C:1991:438, paragraph 14; of 9 September 2008, *Bayer CropScience and Others* v *Commission*, T-75/06, EU:T:2008:317, paragraph 84; and of 13 October 2021, *European Union Copper Task Force* v *Commission*, T-153/19, not published, EU:T:2021:688, paragraph 67).

35 The legal rules applicable to acts establishing, amending or removing MRLs are laid down in Article 14 of Regulation No 396/2005. Article 14(1)(a) of Regulation No 396/2005, as amended by Regulation (EC) No 299/2008 of the European Parliament and of the Council of 11 March 2008 (OJ 2008 L 97, p. 67), provides that, upon receipt of an opinion from EFSA and taking account of that opinion, the Commission is to adopt, without delay and at the latest within three months, a regulation on the setting, modification or deletion of an MRL. Under Article 14(2) of Regulation No 396/2005, for the purposes of setting, modifying or removing an MRL, account is to be taken of: (a) the scientific and technical knowledge available; (b) the possible presence of pesticide residues arising from sources other than current plant protection uses of active substances, and their known cumulative and synergistic effects, when the methods to assess such effects are available; (c) the results of an assessment of any potential risks to consumers with a high intake and high vulnerability and, where appropriate, to animals; (d) the results of any evaluations and decisions to modify the uses of plant protection products; (e) [an MRL set by the Codex Alimentarius Commission] or a [good agricultural practice] implemented in a third country for the legal use of an active substance in that country; (f) other legitimate factors relevant to the matter under consideration. Furthermore, since the contested regulation was adopted following the non-renewal of the approval of chlorpyrifos and the withdrawal of authorisations for plant protection products containing that substance, it should be noted that, under Article 17 of Regulation No 396/2005, the amendments made to Annexes II or III, necessary to remove an MRL following the revocation of an existing authorisation applicable to a plant protection product, may be adopted without EFSA's opinion being sought.

36 It is in the light of those considerations that the Court must examine the merits of the single plea in law raised by the applicant, alleging, first, infringement of Article 14(2)(a) of Regulation No 396/2005 and, second, infringement of Article 14(2)(f) of that regulation.

The complaint alleging infringement of Article 14(2)(a) of Regulation No 396/2005

37 It is necessary to ascertain whether, by failing to take into consideration the Josep Carreras study in the context of the procedure leading to the adoption of the contested regulation and by failing to refer the matter to EFSA for the relevance of that study to be assessed, the Commission infringed Article 14(2)(a) of Regulation No 396/2005, according to which, for the purposes of adopting a regulation setting, modifying or removing MRLs, account must be taken of 'the scientific and technical knowledge available'.

38 First, as regards the failure to take into account the Josep Carreras study, it should be noted that that study was published on EFSA's website on 21 May 2020, that is to say, before the adoption of the contested regulation but after the adoption of Implementing Regulation 2020/18, by which the approval of chlorpyrifos was not renewed on account of the concerns for human health identified in EFSA's statement of 31 July 2019 on chlorpyrifos. As apparent from its subject matter, that

study examines the effects of permethrin and chlorpyrifos on deoxyribonucleic acid (DNA) damage caused by topoisomerase II inhibition. In their conclusions, the authors of the study of the Josep Carreras study found as follows:

'Overall, our results suggest that despite the ability of [permethrin and chlorpyrifos] to induce breaks in the hot spot region of [the mixed lignemia leukaemia (MLL)] gene after a 24 hours hit, these compounds are not able to either induce detectable global DNA damage measures by γ-H2AX levels [or] act as [topoisomerase II] poisons. Furthermore, we do not detect [MLL] breaks after chronic treatment in our in vitro or in vivo systems, which indicates that lesions observed in single-pulse treatments are not enough to favour the enrichment of [MLL]-rearranged clones.'

39 It should be specified that, while it is true that the Josep Carreras study was commissioned by EFSA to investigate the genotoxic potential effect of two pesticides, permethrin and chlorpyrifos, in human stem cells at different ontogeny stages, and investigate their potential of inducing infant leukaemia in animal models, the fact remains that, as stated on its first page, that study constitutes a scientific study external to EFSA. Thus, as is apparent from the warning appearing, in particular on the second page, the Josep Carreras study does not constitute a document adopted by EFSA, with the result that its findings do not bind that authority.

40 It should be noted that, as regards chlorpyrifos, the contested regulation was adopted, as is apparent from recital 2 thereof, following the non-renewal of approval of that substance by Implementing Regulation 2020/18, so that, under Articles 3 and 4 of that regulation, authorisations for plant protection products containing chlorpyrifos have been withdrawn.

41 In those circumstances, to determine whether the failure to take into consideration the Josep Carreras study and the failure to refer the matter to EFSA to assess the study's relevance constitute, as claimed by the applicant, infringement of Article 14(2)(a) of Regulation No 396/2005, account must be taken of the specific rules applicable to the removal of MRLs following the non-renewal of the approval of an active substance.

42 In that regard, it should be noted that the establishment of an MRL for an active substance is inherently linked to the approval of that substance, on the basis of which marketing authorisations for plant protection products are granted. In particular, an MRL for an active substance, other than the default value provided for in Article 18(1)(b) of Regulation No 396/2005, is justified, in principle, only if plant protection products containing that substance are intended to be placed on the market (see, by analogy, judgments of 8 January 2002, *France* v *Monsanto and Commission*, C-248/99 P, EU:C:2002:1, paragraph 80, and of 12 July 2005, *Commission* v *CEVA and Pfizer*, C-198/03 P, EU:C:2005:445, paragraph 87).

43 Thus, where existing authorisations applicable to plant protection products are withdrawn following the non-renewal of the approval of an active substance, the objective of Article 17 of Regulation No 396/2005 is to enable the Commission to remove, as soon as possible, the MRLs for that active substance, in particular with the aim of protecting human health and consumers from the intake of unauthorised pesticide residues, in accordance with recitals 5 and 22 of that regulation. The exemption from an EFSA opinion laid down in that provision is explained by the fact that, since that authority has already had the opportunity to take a position on the concerns for human health linked to exposure to an active substance in the procedure which culminated in the non-renewal of the approval of such a substance, it would be superfluous to refer the matter to it once again to deliver a new opinion on that substance in the context of the procedure for the

removal of the MRLs, unless, before the adoption of a regulation removing the MRLs, reliable and new scientific elements show a significant evolution of scientific knowledge since the position taken by EFSA on that substance.

44 In this case, as is apparent from recital 3 of the contested regulation, on the basis of Article 17 of Regulation No 396/2005, in conjunction with Article 14(1)(a) of that regulation, the Commission found that the MRLs established for chlorpyrifos in Annex II to Regulation No 396/2005 should be removed. In order to do so, it is apparent from recital 5 of the contested regulation that the Commission relied on EFSA's statement of 31 July 2019 on chlorpyrifos, which was published in the context of the non-renewal of the approval of that substance. It should be noted that that statement was drawn up on the basis of the results of an evaluation of that substance carried out by experts of the Panel on plant health, plant protection products and their residues, established on the basis of Article 28(4)(c) of 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 [EFSA] and laying down procedures in matters of food safety (OJ 2002 L 31, p. 1), as amended by Article 1(1) of Commission Regulation (EC) No 575/2006 of 7 April 2006 (OJ 2006 L 100, p. 3). Those experts examined, from the existing scientific literature, including recent scientific studies, various factors having an impact on human health. More specifically, the assessment of EFSA's experts related to several factors having an impact on human health, referred to in point 3.6 of Annex II to Regulation No 1107/2009, namely, in particular genotoxicity, reproductive toxicity, endocrine disruption and neurotoxicity. Following that assessment, EFSA's experts found that chlorpyrifos did not comply with the approval criteria applicable to human health set out in Article 4 of Regulation No 1107/2009.

45 In order to reach that conclusion, first of all, EFSA's experts noted that, on the basis of available public literature, a genotoxic potential of chlorpyrifos could not be ruled out. In particular, it is apparent from conclusions in EFSA's statement of 31 July 2019 on chlorpyrifos that the concerns relating to that genotoxic potential pertain, first, to studies showing chromosomal aberrations and, second, to studies reporting DNA damage caused either through oxidative stress or by topoisomerase II inhibition which was considered an initiating molecular event for infant leukaemia.

46 Next, EFSA's experts noted that there were concerns regarding the neurotoxicity of chlorpyrifos for children's development. On account of those neurotoxic effects, on the basis of an overall analysis of the available literature, the experts suggested that it would be appropriate for chlorpyrifos to be classified as a toxic substance for reproduction (REPRO 1B, H360D 'May damage the unborn child'), in accordance with the criteria set out in Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ 2008 L 353, p. 1).

47 Lastly, it should be noted that, on account of the unclear genotoxic potential and the significant uncertainties related to the neurological developmental toxicity study, in which effects have been observed for neurological development at low doses, EFSA's experts were not able to establish reference values on the basis of which exposure to chlorpyrifos would not pose a risk to human health and consumers.

48 Since EFSA's statement of 31 July 2019 on chlorpyrifos was issued by the experts of EFSA's scientific Panel on plant health, plant protection products and their residues, who assessed various risk factors for human health on the basis of an analysis of the available scientific data, it must be held, as the Commission rightly submits, that that statement constituted, at the time of the adoption of the contested regulation, both the most complete and the most recent assessment regarding all of the concerns relating to human health linked to exposure to that substance.

49 It must be stated that the applicant has not demonstrated that the Josep Carreras study which, as is apparent from paragraph 39 above, is a scientific report external to EFSA and which does not bind it, was an element capable of establishing that the state of scientific knowledge had evolved significantly since the adoption of EFSA's statement of 31 July 2019 on chlorpyrifos. It must be held that the applicant does not dispute that that study does not relate to the concerns regarding the neurotoxicity of chlorpyrifos for children's development. Moreover, as noted by the Commission, the scope of the Josep Carreras study is particularly limited in comparison with EFSA's findings, in so far as, as regards the genotoxic potential of that substance, which cannot be ruled out, the study relates only to the effects of chlorpyrifos on DNA damage caused by topoisomerase II inhibition, but does not concern EFSA's findings regarding the potential genotoxicity of chlorpyrifos related to chromosomal aberrations or DNA damage caused through oxidative stress.

50 Accordingly, in the circumstances of this case, the Commission was entitled, without infringing Article 14(2)(a) of Regulation No 396/2005, (i) to adopt the contested regulation, without taking into consideration the Josep Carreras study, in order to remove the MRLs for chlorpyrifos from Annex II to that regulation on account of the concerns for human health identified in EFSA's statement of 31 July 2019 on chlorpyrifos and (ii), in the absence of any reference values on the basis of which exposure to chlorpyrifos did not present a risk to human health and consumers, to set, under Article 18(1)(b) of Regulation No 396/2005, the default value for chlorpyrifos residues at 0.01 mg/kg.

51 Second, it follows from the foregoing that, contrary to what is claimed by the applicant, the Commission cannot be required to have referred the matter to EFSA to assess the relevance of such a study, published during the period which separated the adoption of the regulation by which the approval of an active substance was not renewed and the adoption of the regulation removing the MRLs for that substance. Otherwise, Article 17 of Regulation No 396/2005 would be deprived of its effectiveness in so far as, in the event of the publication of any new study relating to a substance during that period, the Commission could not remove the MRLs for that active substance, whose approval had not been renewed, without first referring the matter to EFSA, even though that new study did not significantly alter the state of scientific and technical knowledge.

52 Furthermore, as regards chlorpyrifos, it should be noted that, under Article 3 of Regulation 2020/18, Member States were to withdraw authorisations for plant protection products containing that substance by 16 February 2020 at the latest, with the possibility of granting a grace period which, under Article 4 of that regulation, was due to expire by 16 April 2020 at the latest. Accordingly, as from 17 April 2020, products containing chlorpyrifos could no longer be marketed or used within the European Union. Since the use of that substance is still authorised in some third countries, until the MRLs for chlorpyrifos had been removed it remained possible lawfully to import into the European Union foodstuffs, such as the bananas produced by the applicant, in or on which residues of that substance were found at levels likely to present risks to

human health and consumers. In such circumstances, as is apparent from paragraph 42 above, to be able to remove as soon as possible the MRLs for an active substance, Article 17 of Regulation No 396/2005 allows the Commission to adopt a regulation for that purpose without it being necessary to submit a request for an opinion to EFSA.

53 In view of the concerns for human health identified by EFSA as regards exposure to chlorpyrifos, the SCOPAFF, at its meeting on 26 and 27 September 2019, agreed that the actions necessary to establish the MRL for that substance should be treated with high priority and, at its meeting on 17 and 18 February 2020, delivered an opinion in favour of the draft regulation submitted by the Commission to that end. Accordingly, if, as submitted by the applicant, the Commission had been required, following the publication of the Josep Carreras study on 21 May 2020, to refer the matter to EFSA so that that authority could rule on the study's relevance, it would have been necessary to interrupt the procedure for the adoption of the contested regulation, which would have significantly delayed its entry into force, thus extending the period during which foodstuffs in or on which chlorpyrifos residues could be found could be legally imported into the European Union, in particular on the bananas produced by the applicant for which the MRL was set at 4 mg/kg. Thus, in such circumstances, the Commission was entitled to consider that a referral to EFSA to assess the relevance of that study would have involved an extension of the procedure to remove the MRLs for chlorpyrifos, contrary to the objective pursued by Regulation No 396/2005 to ensure a high level of protection of human health and of consumers (see, to that effect and by analogy, judgments of 17 March 2021, *FMC* v *Commission*, T-719/17, EU:T:2021:143, paragraph 188, and of 6 October 2021, *Sipcam Oxon* v *Commission*, T-518/19, not published, EU:T:2021:662, paragraph 100).

54 Accordingly, by adopting the contested regulation without referring the matter to EFSA to assess the relevance of the Josep Carreras study, the Commission did not infringe Article 14(2)(a) of Regulation No 396/2005.

55 It follows from the foregoing that the applicant's arguments alleging infringement of Article 14(2)(a) of Regulation No 396/2005 must be rejected as unfounded.

The complaint alleging infringement of Article 14(2)(f) of Regulation No 396/2005

56 It is necessary to ascertain whether, by failing to take into consideration the Josep Carreras study in the context of the procedure which culminated in the adoption of the contested regulation, the Commission infringed Article 14(2)(f) of Regulation No 396/2005, according to which, for the purposes of adopting a regulation setting, modifying or removing MRLs, 'other legitimate factors relevant to the matter under consideration' must be taken into consideration.

57 In that regard, it is apparent from both the wording and the scheme of Article 14(2) of Regulation No 396/2005 that the factors to be taken into consideration in the context of Article 14(2)(f) are necessarily different from those referred to in Article 14(2)(a) to (e) of that regulation.

58 In view of its scientific nature, it must be found that the Josep Carreras study, which relates to the effects of active substances on DNA damage caused by topoisomerase II inhibition, does not come within the factors set out in Article 14(2)(b) to (e) of Regulation No 396/2005, referred to in paragraph 35 above. By contrast, that study, as a scientific element, may fall within the scope of Article 14(2)(a) of Regulation No 396/2005. In that regard, as is apparent from paragraph 55 above, it has been found that, in the circumstances of this case, the failure to take that study into

consideration cannot constitute infringement of that provision. However, that study cannot be regarded as coming under 'other legitimate factors relevant to the matter under consideration' within the meaning of Article 14(2)(f) of Regulation No 396/2005.

59 It should be noted that, under recitals 9 and 11 and Article 1 thereof, Regulation No 396/2005 is established in accordance with the general principles of food law set out in Articles 5 to 8 of Regulation No 178/2002. Therefore, to preserve the coherence of the concepts applicable to phytosanitary matters, Regulation No 396/2005 must be interpreted in the light of equivalent concepts as defined in Regulation No 178/2002.

60 It is apparent from Article 6 of Regulation No 178/2002, which lays down the principles applicable to risk analysis, in particular paragraph 3 thereof, that 'other legitimate factors' are factors which must be taken into consideration in the context of 'risk management', which, under Article 3(12) of that regulation, is defined as the process, distinct from risk assessment, of weighing the various policy alternatives in consultation with interested parties, considering risk assessment and other legitimate factors and, if need be, selecting appropriate prevention and control measures. In that regard, it is apparent from recital 19 of Regulation No 178/2002 that those other relevant factors which should legitimately be taken into account in the context of risk management correspond to societal, economic, traditional, ethical and environmental factors and the feasibility of controls.

61 It must be stated that the Josep Carreras study does not concern such factors of a socioeconomic, traditional, ethical or environmental nature or falling within the feasibility of controls which should be taken into account by the Commission in the context of risk management when it adopts a regulation seeking to set, modify or remove MRLs.

62 It follows that the Josep Carreras study cannot come within the 'other legitimate factors relevant to the matter under consideration' within the meaning of Article 14(2)(f) of Regulation No 396/2005.

63 Accordingly, the applicant's arguments alleging infringement of Article 14(2)(f) of Regulation No 396/2005 must be rejected as unfounded.

64 Furthermore, as regards the argument that the Commission failed to fulfil its duty of diligence by not taking into consideration the Josep Carreras study when adopting the contested regulation, it must be stated that that argument overlaps with the arguments relating to infringement of Article 14(2)(a) and (f) of Regulation No 396/2005 and has no autonomous scope.

65 Therefore, since, in the context of this case, the Commission was entitled to find that the Josep Carreras study did not show significant developments in the scientific and technical knowledge available, it was entitled to consider that it was not a relevant factor to be taken into consideration to comply with its obligation to examine carefully and impartially all the relevant aspects of the individual case.

66 Lastly, in so far as the applicant claims that the Commission made a manifest error of assessment when adopting the contested regulation, it must be held that such a substantive argument is not substantiated in any way and must therefore be rejected as unfounded.

67 It follows from all of the foregoing that the single plea in law put forward by the applicant must be rejected as unfounded, without it being necessary to examine whether it is ineffective, as contended by the Commission, and that, accordingly, the action must be dismissed.

Costs

68 Under Article 134(1) of the Rules of Procedure, the unsuccessful party is to be ordered to pay the costs if they have been applied for in the successful party's pleadings. Since the applicant has been unsuccessful, it must be ordered to bear its own costs and to pay those incurred by the Commission, in accordance with the form of order sought by the latter.

On those grounds,

THE GENERAL COURT (Fifth Chamber)

hereby:

1. Dismisses the action;

2. Orders Delifruit, SA to pay the costs.

Spielmann Öberg Brkan

Delivered in open court in Luxembourg on 13 July 2022.

E. Coulon S. Papasavvas
Registrar President