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Court Upholds Restrictions on Neonicotinoids – A Precautionary Approach to Evidence

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I. Background

In August 2013, Bayer CropScience AG and Syngenta Crop Protection AG brought legal proceedings¹ against the European Commission seeking to annul the Commission's Implementing Regulation (EU) No 485/2013² that severely restricted the conditions of approval for three active substances – clothianidin, thiamethoxam, imidacloprid – used in plant protection products (PPPs).³ These substances are neonicotinoids (or 'neonics'), a category of insecticide. Their safety was assessed in the late 2000s, and a broad range of uses was approved at EU level for a period of ten years.⁴ The 2013 Implementing Regulation restricted such approvals because the neonics were found to pose a potential, yet uncertain, risk to non-target organisms and specifically to pollinators.⁵

The restrictions resulted from the decision of the Commission to re-evaluate the risks posed by neonics to bees, under the so-called 'review procedure'. Under Article 21 Regulation (EC) No 1107/2009, at any point during the ten year approval period, the Commission can re-assess hazards and associated risks posed by a substance, provided that new evidence becomes available to suggest that the health and environmental protection goals established by Article 4 of that Regulation are no longer met.

The applicants challenged the restrictions introduced by Regulation No 485/2013 and relied on similar pleas in law to bring their cases to the General Court. They argued, *inter alia*, that the Commission had no new evidence to justify the initiation of the review procedure, and that the relevant scientific data had been misinterpreted and ignored. They also submitted that the Commission had acted in breach of the precautionary principle and the principle of proportionality, in part because the Commission had not

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¹ Joined Cases T-429/13 and T-451/13, *Bayer CropScience AG and Others v European Commission* ECLI:EU:T:2018:280.

² Implementing Regulation (EU) 485/2013 amending Implementing Regulation (EU) No 540/2011, as regards the conditions of approval of the active substances clothianidin, thiamethoxam and imidacloprid, and prohibiting the use and sale of seeds treated with plant protection products containing those active substances, OJ L 139, 25.5.2013, p. 12-26.

³ Bayer markets clothianidin and imidacloprid; Syngenta markets thiamethoxam.

⁴ Directive 2006/41/EC amending Directive 91/414 to include clothianidin and pethoxamid as active substances; Commission Directive 2007/6/EC of 14 February 2007 amending Directive 91/414 to include metrafenone, *Bacillus subtilis*, spinosad and thiamethoxam as active substances; Commission Directive 2008/116/EC of 15 December 2008 amending Directive 91/414 to include aclonifen, imidacloprid and metazachlor as active substances, OJ L 187, 8.7.2006, p. 24-27.

⁵ More precisely, in the Implementing Regulation the Commission prohibited the use of neonics in bee-attractive crops (including maize, oilseed rape and sunflower), allowing some exception for winter cereals and for the treatment of some crops after flowering. The Regulation also permits uses in greenhouses.

carried out an impact assessment to evaluate the consequences of the Regulation No 485/2013 before its adoption. Furthermore, the applicants alleged that the Commission had infringed their right to be heard during the review procedure, and that the contested measure breached their right to property and freedom to conduct a business.

The General Court rejected all the claims made by the applicants.

This commentary focuses on three prominent themes: the interpretation of the precautionary principle; the implications of a lack of impact assessment for risk management decisions; and the legitimate use of scientific data in risk assessment. The final section provides brief concluding remarks.

II. Alleged Breach of the Precautionary Principle

The precautionary principle is intended to ensure a high level of environmental protection in all the EU's spheres of activity, by allowing EU institutions to take protective measures without having to wait until the reality and extent of those risks become fully apparent or until the adverse effects materialise.⁶ The principle is enshrined in the Treaty on the Functioning of the EU and is often included or reflected in EU secondary legislation.⁷ The parent Regulation of the contested measure explicitly states that its provisions 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'.⁸ The applicants claimed that, in imposing restrictions on the substances concerned, the Commission had made manifest errors of assessment and misapplied the precautionary principle.

It is first worth noting that the Court's treatment of the precautionary principle covers largely familiar ground. There is a sizeable body of EU case law establishing that institutions acting on the precautionary principle are required to follow proper procedure. In line with previous cases, the Court explained that:

within the process leading to the adoption by an institution of appropriate measures to prevent specific potential risks to public health, safety and the environment by reason of the precautionary principle, three successive stages can be identified: first, identification of the potentially adverse effects arising from a phenomenon; second, assessment of the risks to public health, safety and the environment which are related to that phenomenon; and, third, when the potential risks identified exceed the threshold of what is acceptable for society, risk management by the adoption of appropriate protective measures.⁹

⁶ Cases T-429/13 and T-451/13, *Bayer CropScience AG and Others v European Commission* (n 1), para 110.

⁷ Treaty on the Functioning of the European Union, OJ C 326, 26.10.2012, p. 47-390, Article 191(2).

⁸ Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC, OJ L 309, 24.11.2009, p. 1-50, Art 1(4), see also recital 8.

⁹ *Ibid.*, para 111.

The risk assessment stage is subject to certain checks and balances.¹⁰ For example, the assessment is to be entrusted by the institutions to scientific experts, based on the best scientific data available and undertaken in an independent, objective and transparent manner.¹¹ Although the assessment is not required to provide the institutions with conclusive evidence, a preventive measure 'cannot properly be based on a purely hypothetical approach to risk, founded on mere conjecture which has not been scientifically verified'.¹² It follows that 'a preventive measure may be taken only if the risk ... appears nevertheless to be adequately backed up by the scientific data available at the time when the measure was taken'.¹³

The applicants alleged that the Commission's restriction of the three active substances infringed the precautionary principle because purely hypothetical risks were taken into account, there was no adequate risk assessment, and the measures taken were disproportionate.¹⁴

The Court separated out the claims into those relating to risk assessment and those relating to risk management. There is a long tradition in EU risk regulation of treating risk assessment and risk management as cleanly distinct stages in the decision-making process.¹⁵ Accordingly, risk assessment is conceived as technical, expert-driven and value-neutral, whereas risk management involves the exercise of political choice in determining the level of risk deemed unacceptable for society and the appropriate means of protection. This has consequences for the nature and intensity of judicial review of each of the respective stages, as these joined cases demonstrate. For current purposes, the point is to highlight that the line between risk assessment and risk management is not as clear-cut as suggested by the Court, because it falsely implies that certain decisions based on technical expertise do not also entail policy choices.¹⁶

The Court held that there was no manifest error at the risk assessment stage and that, in this regard, the Commission had not misapplied the precautionary principle.¹⁷ The Court found that the risk assessment did not fail to take account of important scientific data,¹⁸ nor did it reflect a purely hypothetical approach to risk.¹⁹ The risk assessment was, in the Court's view, conducted 'in accordance with the scientific rules'²⁰ and must be deemed to be scientifically sound since the applicants had not established that the

¹⁰ Ibid, para 112.

¹¹ Ibid, paras 115 and 117.

¹² Ibid, para 116.

¹³ Ibid, para 120.

¹⁴ Ibid, paras 334-335.

¹⁵ See, for example, European Commission, Communication on the Precautionary Principle COM(2000) 1 final, para 4.

¹⁶ For general discussion, see, for example, E. Fisher, 'Framing Risk Regulation: A Critical Reflection' (2013) 4(2) *European Journal of Risk Regulation* 125-132; S. Jasanoff, 'The Songlines of Risk' (1999) 8(2) *Environmental Values* 135-152.

¹⁷ Cases T-429/13 and T-451/13, *Bayer CropScience AG and Others v European Commission* (n 1), paras 580-582.

¹⁸ Ibid, paras 355-382.

¹⁹ Ibid, paras 383-415.

²⁰ Ibid, para 390.

assessment was defective.²¹ The Court cannot substitute its own assessment for that used by the Commission, and is empowered only to examine whether the risk assessment complied with what it called ‘general rules of evidence’²² and ‘important procedural guarantees ... whose purpose is to ensure the scientific objectivity’.²³ Through this, risk assessment comes to be seen as a predominantly cognitive process of factual assessment and interpretation, not as a source of discretion involving matters of political choice or volition.²⁴ In reality, however, technical assessments and policy choices are not so clearly separable.

For example, one applicant alleged that the risk assessment was rushed because the Commission had imposed an excessively short deadline (five to eight months, depending on the starting date used), and that this undermined the quality and completeness of the scientific investigation.²⁵ The Court rejected the claim,²⁶ noting that the period allowed was ‘not unusual’.²⁷ Moreover, because the Commission enjoyed a broad discretion in relation to risk management, it was ‘fully entitled to take the view that the precautionary principle precluded the setting of a deadline ... that would enable later scientific knowledge to be taken into account’.²⁸ The point here is that the length of deadline will have materially affected the process if not the outcome of the risk assessment.²⁹ The deadline meant that the risk assessment was completed before a test guidance document was made available, which, the applicants claimed, ‘led to the facile and unscientific conclusion that a number of risks could not be excluded’.³⁰ The Court disagreed, finding that, had the Commission waited until the guidance was finalised, it would ‘necessarily have delayed the Commission’s becoming aware, however imprecisely, as risk manager, of the level of risk posed by the substances covered and, as a result, the taking of a decision’.³¹ This suggests that political and technical assessments are closely interconnected. The Commission’s decisions about deadlines and speed of process can hardly be described as merely technical or politically weightless – they involve value-laden choices about how quickly to respond, which in turn determines what is included and what is left out of the risk assessment.

III. Lack of Impact Assessment

The applicants further claimed that the Commission had breached the precautionary principle by failing to conduct an impact assessment of its restriction of the active

²¹ Ibid, para 390.

²² Ibid, para 142.

²³ Ibid, para 147.

²⁴ See J. Mendes, ‘Bounded Discretion in EU Law: A Limited Judicial Review Paradigm in a Changing EU’ (2017) 80(3) *Modern Law Review* 443-472.

²⁵ Cases T-429/13 and T-451/13, *Bayer CropScience AG and Others v European Commission* (n 1), paras 343-347.

²⁶ Ibid, paras 349-353.

²⁷ Ibid, para 351.

²⁸ Ibid, para 314.

²⁹ Ibid, see, for example, paras 365 and 393.

³⁰ Ibid, paras 306-310.

³¹ Ibid, para 309.

substances, 'which prevented [it] from appreciating the seriously damaging effects that the contested measure could have in economic and environmental terms'.³² Given that impact assessment falls within the remit of risk management (rather than of risk assessment), the Court examined not just the procedural guarantees but also the merits of the Commission's action. The Court noted that the 2000 Communication on the Precautionary Principle requires the Commission to have conducted a comparison of the most likely benefits and costs of action and lack of action, before taking any final decision as to the most appropriate course of action.³³ The Communication states that, where appropriate and feasible, the examination of pros and cons should include an economic cost-benefit analysis, and include consideration of wider, non-economic factors.³⁴ It is worth highlighting that more recent policy now makes clear that a proportionate impact assessment should be carried out 'for every decision invoking the precautionary principle'.³⁵ At the time, however, the authoritative statement on procedure was contained in the Communication, which does not prescribe a particular form of evaluation. Because of this, the Court held that 'it is not at all apparent that the authority concerned is obliged to initiate a specific assessment procedure culminating, for example, in a formal, written assessment report. In addition, it is apparent from the text that the authority applying the precautionary principle enjoys considerable discretion regarding methods of analysis'.³⁶ Moreover, the Court found that: 'it is not necessary for the economic analysis of the costs and benefits to be made on the basis of a precise calculation of the respective costs of the action proposed or of inaction. Such precise calculations will in most cases be impossible to make, given that, in the context of the application of the precautionary principle, their results depend on different variables which are, by definition, unknown'.³⁷

In other words, the Court found that the Commission had satisfied the requirements of the Communication on the Precautionary Principle because it had 'acquainted itself with the effects, positive and negative, economic and otherwise'.³⁸ Interestingly, the Commission in its 2017 Better Regulation Toolbox appears to interpret the Communication on the Precautionary Principle differently, as signalling that all acts based on the precautionary principle should be based on a formal impact assessment (not the general balancing of issues accepted by the Court here).³⁹

In assessing the merits of the Commission's examination of costs and benefits, the Court also concluded that the impact of the contested measure on agriculture and the environment seemed less significant than one of the applicants had claimed.⁴⁰ It was particularly relevant that several Member States had previously suspended certain uses of the substances concerned, and that none of them had reported negative effects on

³² Ibid, para 456.

³³ Ibid, para 458.

³⁴ Communication on the Precautionary Principle (n 16), para 6.3.4.

³⁵ European Commission, *Better Regulation Toolbox* (European Commission 2017) 93.

³⁶ Cases T-429/13 and T-451/13, *Bayer CropScience AG and Others v European Commission* (n 1), para 459.

³⁷ Ibid, para 460.

³⁸ Ibid, para 460.

³⁹ Better Regulation Toolbox (n 37), 93 footnote 101.

⁴⁰ Cases T-429/13 and T-451/13, *Bayer CropScience AG and Others v European Commission* (n 1), para 463.

productivity or the environment. The applicant took issue with this because the Commission ‘failed to conduct any investigation in that respect’ and ‘if one does not look one will not find’.⁴¹ The Court, however, took the absence of Member States reports to be crucial, concluding that the Commission ‘was entitled to rely on that silence and assume that there were no such consequences or, in any event, that they were insignificant’.⁴²

IV. Selection of Evidence in Article 21 Review Procedure

The definition of the knowledge-base for risk assessment is a very sensitive issue. EU pesticide regulations establish in detail the data requirements for the approval and renewal of approval of substances.⁴³ Conversely, criteria for the review of approvals are only partially defined: whereas there are indications of the data required to start a review, the evidence-base for the review itself is left unspecified. It is not surprising therefore that it became a matter of controversy in the context of the legal cases on neonicotinoids.⁴⁴

Article 21(1) Regulation (EC) No 1107/2009 establishes the conditions to be met to start the review of the conditions of approval of a substance before its legal expiry date: the existence of ‘new scientific and technical knowledge and monitoring data’ that indicate that the substance might no longer satisfy the approval criteria. In the joined cases under discussion, the Commission was prompted to act by three peer-reviewed studies published in 2012,⁴⁵ as well as by monitoring data gathered by national authorities.⁴⁶ The applicants objected that such papers did not constitute ‘new’ evidence, because in their view they did not contain any new relevant scientific information.⁴⁷ In rejecting this claim, the Court observed that ‘new’ has both a substantial and a temporal meaning. In

⁴¹ Ibid, para 465.

⁴² Ibid, para 465.

⁴³ Commission Regulation (EU) No 283/2013 setting out the data requirements for active substances, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, OJ L 93, 3.4.2013, p. 1-84; Commission Implementing Regulation (EU) No 844/2012 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 L 252, 19.9.2012, p. 26-31.

⁴⁴ It might be useful to recall that the preliminary completeness check of a dossier is often controversial, even in the case of procedures of approval carried out according to detailed rules as set by Regulation 283/2013. See E. Bozzini, *Assessing Criteria and Capacity for Reliable and Harmonised ‘Hazard Identification’ of Active Substances* (European Parliament Research Service 2018).

⁴⁵ In a first study, Henry and colleagues found that exposure to a non-lethal dose of thiamethoxam can impair the capacity of honey bees to safely return to their hive, thus increasing mortality rate and possibly leading to colony collapse. In a second study, Whitehorn and colleagues calculated that the growth rate of colonies of bumble bees treated with imidacloprid was significantly reduced compared to control colonies. Imidacloprid also had an impact on the production of new queens that was 85% lower in treated colonies compared to control ones. A third study published by Schneider et al. found that a decrease in foraging activities in bees exposed to sub-lethal doses of imidacloprid and clothianidin.

⁴⁶ See for example APENET, 2011. “Effects of coated maize seed on honeybees” Report based on results obtained from the third year (2011) activity of the APENET project.

⁴⁷ Cases T-429/13 and T-451/13, *Bayer CropScience AG and Others v European Commission* (n 1), para 177.

substantial terms, the Court accepted the argument proposed by the Commission – that, since the studies employed an innovative methodology, they provided the regulators with new knowledge, and more importantly with more reliable knowledge on the effects of neonics on bees.⁴⁸ Furthermore, the Court observed that the studies were new in a temporal sense, because they had been published after the submission of the original dossier at the time of the first approval, which could therefore be taken as a reference date.⁴⁹ In this sense, the term ‘new’ was understood in relation to the timing of the evaluation procedure of a specific substance. The Court therefore judged that the studies singled out by the Commission constituted a proper evidence-base lawfully to initiate the Article 21 review procedure.

The review procedure was not, however, meant to be limited to the evaluation of the studies that prompted it, as these constituted only a limited selection of the available studies that might have qualified as ‘new’ according to the definition endorsed by the Court.⁵⁰ Moreover, the review was not limited to an evaluation of new evidence – the European Food Safety Authority (EFSA) (the expert body responsible for completing the assessment in this instance) also completed a re-assessment of the original dossier submitted by the applicants and of the data submitted to national authorities for the initial authorisation of the substances. EFSA therefore performed a re-evaluation of (old) data already assessed by national and EU authorities, this time taking into account new legal requirements regarding pollinators⁵¹ as well as more recent criteria detailed by EFSA in its 2012 Opinion.⁵²

This brings us to discussion of a second claim advanced by the applicants in this context, namely that the re-evaluation was partial and ignored relevant scientific evidence (favourable to neonics) from literature data and monitoring studies. In the remainder of this section, we will focus on the claim that EFSA ‘decided to forgo entirely the customary detailed review of relevant peer-reviewed scientific literature’.⁵³ Indeed, EFSA says it had taken into account ‘some literature data’,⁵⁴ but there are no indications that a proper

⁴⁸ Ibid, para 178 and 179.

⁴⁹ Ibid, para 172.

⁵⁰ A subsequent review on neonicotinoids carried out between 2015 and 2018 included hundreds of papers published since the mid-2000s. Fryday, S., Tiede, K. and Stein, J. (2015). ‘Scientific services to support EFSA systematic reviews: Lot 5 Systematic literature review on the neonicotinoids (namely active substances clothianidin, thiamethoxam and imidacloprid) and the risks to bees’, *EFSA supporting publication* 2015:EN-756 EFSA, 2018. Evaluation of the data on clothianidin, imidacloprid and thiamethoxam for the updated risk assessment to bees for seed treatments and granules in the EU. EFSA supporting publication 2018:EN-1378. 31 pp. doi:10.2903/sp.efsa.2018.EN-1378

⁵¹ See point 3.8.3 Annex II Regulation (EC) 1107/2009.

⁵² EFSA. (2012). ‘Scientific Opinion on the science behind the development of a risk assessment of Plant Protection Products on bees (*Apis mellifera*, *Bombus* spp. and solitary bees)’, *EFSA Journal* 10, (5) pp. 2668

⁵³ Cases T-429/13 and T-451/13, *Bayer CropScience AG and Others v European Commission* (n 1), para 354

⁵⁴ EFSA. (2013b). ‘Conclusion on the peer review of the pesticide risk assessment for bees for the active substance clothianidin’, *EFSA Journal* 11, (1:3066); EFSA. (2013a). ‘Conclusion on the peer review of the pesticide risk assessment for bees for the active substance thiamethoxam’, *EFSA Journal* 11, (1:3067); EFSA. Ibid. ‘Conclusion on the peer review of the pesticide risk assessment for bees for the active substance imidacloprid’, (1:3068)

search for the relevant open literature – according to the criteria laid down in EFSA Guidelines – had been undertaken.⁵⁵

The Court rejected this second claim, on the ground that there are no specific provisions under Article 21 Regulation (EC) No 1107/2009 stating which types of evidence are to be included and excluded from the re-assessment. Accordingly, there were no obligations to include a literature review in the EFSA procedure. At the same time, the Court affirmed that ‘however, that does not mean that the relevant scientific literature does not have to be taken into consideration’.⁵⁶ Where there is a lack of specific criteria for the selection of evidence in such a review procedure, some general principles hold; in particular, the Court observed that any assessment ‘should be based on the best scientific data available’.⁵⁷ In addition, following the reasoning proposed by the Court in its discussion on the temporal dimension of the term ‘new’, it seems sensible to conclude that the review could include all studies on the particular active substances published since the original dossiers were submitted.⁵⁸

Both the general criteria for the quality of risk assessment and the logic of the argumentation advanced in the judgment could lead to the conclusion that a comprehensive assessment of the available scientific literature is necessary under the Article 21 review procedure, as it is in approval and renewals. This might prove crucial for the legitimacy and the transparency of the review, especially in cases like these discussed here, characterised by high levels of scientific uncertainty, or in cases where a weight of evidence approach is to be applied as in the evaluation of endocrine disrupting properties of chemicals.⁵⁹ The Court, however, did not elaborate on this point, and in this sense the criteria for the legitimate selection of evidence in the context of a review procedure remain under-specified.

Conclusions

In substantial terms, the judgment will be of little consequence. In the time since the cases were brought in 2013, the regulatory debate on each of the three active substances has progressed substantially and the contested measure has now been superseded by new Implementing Regulations introduced by the Commission in 2018. The new measures are even more restrictive than the previous ones; notably, the

⁵⁵ EFSA. (2011). ‘Submission of scientific peer-reviewed open literature for the approval of pesticide active substances under Regulation (EC) No 1107/2009’, *EFSA Journal* 9, (2) pp. 2092 The guidelines establish rules for searching in scientific databases (like PubMed, Web of Science), for the evaluation of the relevance of each paper retrieved, for the reporting on the search strategy, etc.

⁵⁶ Cases T-429/13 and T-451/13, *Bayer CropScience AG and Others v European Commission* (n 1), para 358.

⁵⁷ *Ibid*, para 117, 289 and 354.

⁵⁸ it could be noted that, since the four chemicals were first assessed under Directive 414/1991/EEC which did not require any analysis of open peer review literature, any paper published on the substances under review could be considered new and therefore be potentially of relevance for the re-assessment.

⁵⁹ See Annex to Commission Regulation (EU) 2018/605 amending Annex II to Regulation (EC) No 1107/2009 by setting out scientific criteria for the determination of endocrine disrupting properties, OJ L 101, 20.4.2018, p. 33-36.

Regulations forbid all outdoor uses of the three neonics.⁶⁰ Yet, the judgment is of relevance for its discussion of some of the most controversial topics in pesticides regulation and more broadly risk regulation.⁶¹

The Court followed a well-established line of reasoning, especially in its discussion of the precautionary principle. It also left some issues open and ultimately unresolved. The Court affirmed that the impacts of a proposed Implementing Regulation must be assessed at the risk management stage but did not accept that such an evaluation had to take a particular form.⁶² As noted, things have moved on since the Court heard and decided on the issues in these cases, and the updated Better Regulation package clarifies that a formal impact assessment is now expected whenever the precautionary principle is invoked – presumably this would also include its invocation in implementing measures. Furthermore, the Court did not fully clarify data requirements under the Article 21 review procedure. The judgment signals that in many respects the adoption of implementing acts through comitology remains an obscure process.

⁶⁰ For details of each substance, see the EU pesticide database at <http://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/public/?event=activesubstance.selection&language=EN>

⁶¹ See the evaluation reports published in Spring 2018: European Parliament Research Service. (2018). "Regulation (EC) 1107/2009 on the Placing of Plant Protection Products on the Market. European Implementation Assessment." EPRS, Bruxelles; Scientific Advice Mechanism. (2018). "EU Authorisation processes of Plant Protection Products." Group of Scientific Advisors, Bruxelles.

⁶² It is of note that in a parallel case on the substance fipronil, the applicant, BASF Agro BV, had its request for annulment of the restrictive Implementing Regulation accepted on the basis of the lack of impact assessment in the risk management stage. See Case T-584/13, *BASF Agro BV and Others v European Commission* ECLI:EU:T:2018:279.