Reports of Cases

Case T-536/22

(publication by extracts)

Pesticide Action Network Europe (PAN Europe)
v
European Commission

Judgment of the General Court (Fourth Chamber) of 21 February 2024

(Plant protection products – Active substance cypermethrin – Implementing Regulation (EU) 2021/2049 – Request for internal review – Article 10(1) of Regulation (EC) No 1367/2006 – Rejection of the request – Identification of critical areas of concern by EFSA – Risk assessment and risk management – Precautionary principle – Discretion enjoyed by the Commission)

1. *Actions for annulment – Time limits – Point from which time starts to run – Date of notification of the decision – Commission's response to a request for internal review drafted in a language other than that of the request – Subsequent communication to the party making the request of a copy of that response in the language of the request – Period starting to run on the date of that subsequent communication*
(Art. 263, sixth para., TFEU; European Parliament and Council Regulation No 1367/2006; Council Regulation No 1, Art. 2)

(see paragraph 24)

2. *Environment – Aarhus Convention – Application to EU institutions – Ability of non-governmental organisations to request internal review of administrative measures in environmental matters – Administrative measure aimed at renewing the approval of an active substance – Subject of the review – Review of the approval*
(European Parliament and Council Regulation No 1367/2006, Art. 10(1))

(see paragraph 38)

3. *Action for annulment – Pleas in law – Action against a decision rejecting a request for review – Plea not presented in the request for review – Inadmissibility – Arguments constituting a mere amplification of a plea presented in the request for review – Admissibility – Limits – Plea not altering the object of the internal review procedure*
(Art. 263 TFEU; European Parliament and Council Regulation No 1367/2006, Art. 12)

(see paragraphs 41, 43, 46, 47)

4. *Environment – Aarhus Convention – Application to EU institutions – Ability of non-governmental organisations to request internal review of administrative measures in environmental matters – Statement of the grounds for review – Need to indicate factors likely to raise doubts as to whether the measure in question is well-founded*
(European Parliament and Council Regulation No 1367/2006, Art. 10(1))

(see paragraphs 42, 146)

5. *Action for annulment – Pleas in law – Action against a decision rejecting a request for internal review – Plea arising from that rejection decision and seeking to challenge its merits – Admissibility – Limits – Plea not altering the object of the internal review procedure*
(Art. 263 TFEU; European Parliament and Council Regulation No 1367/2006, Art. 12)

(see paragraph 45)

6. *Public health – Assessment of risks – Application of the precautionary principle – Scope – Concepts of risk and hazard – Determination of the level of risk judged unacceptable for society – Competence of the EU institution designated by the relevant legislation – Obligation to ensure a high level of protection of public health, safety and the environment*
(Arts 114(3), 168(1) and 191 TFEU)

(see paragraphs 77-87, 94, 97, 314)

7. *Agriculture – Approximation of laws – Placing on the market of plant protection products – Regulation No 1107/2009 – Renewal of the approval of an active substance – Discretion of the Commission – Obligation on the part of the Commission to follow the opinion of the European Food Safety Authority (EFSA) – None – Conditions*
(European Parliament and Council Regulation No 1107/2009; Commission Regulation No 844/2012, Art. 14(1))

(see paragraphs 89-93, 103, 104, 123, 127)

8. *Agriculture – Approximation of laws – Placing on the market of plant protection products – Regulation No 1107/2009 – Renewal of the approval of an active substance – Discretion of the Commission – Scientific assistance requested from the European Food Safety Authority (EFSA) in the absence of a specific legal basis – Admissibility*
(European Parliament and Council Regulation No 178/2002, Arts 23(c) and 29(1)(a))

(see paragraph 230)

9. *Agriculture – Approximation of laws – Placing on the market of plant protection products – Regulation No 1107/2009 – Renewal of the approval of an active substance – Discretion of the Commission – Assessment criteria – Guidelines adopted by the Commission – Binding effect – Age of the guidelines necessitating an update – Irrelevance*
(Commission Regulation No 844/2012, Art. 13(1))

(see paragraphs 391, 393, 401)

Résumé

In the context of an action for annulment concerning the renewal of the approval of the active substance cypermethrin, the General Court explains the rules governing the admissibility of such an action brought by a non-governmental organisation on the basis of Regulation No 1367/2006,[1] as well as the scope of the European Commission's discretion as risk manager in the light of the precautionary principle.

Cypermethrin is an insecticide used in the European Union, which was authorised for use in plant protection products in 2005.[2]

As part of the procedure for renewing the approval of cypermethrin, the European Food Safety Authority (EFSA) identified, in its scientific conclusions of July 2018, four critical areas of concern relating to that active substance. It then published a statement on risk mitigation measures on cypermethrin in September 2019.

Following that risk assessment, on 24 November 2021 the Commission adopted Implementing Regulation (EU) 2021/2049,[3] which renews the approval of cypermethrin, accompanied by a series of specific provisions.

On 20 January 2022, the applicant, the environmental organisation Pesticide Action Network Europe (PAN Europe), sent the Commission a request for an internal review[4] of Implementing Regulation 2021/2049.

By its decision of 23 June 2022, the Commission rejected that request.

The applicant asks the General Court to annul that decision. In support of its action, it alleges infringement of the precautionary principle and of the European Union's obligation to ensure a high level of protection of human health and the environment. It claims, inter alia, that since EFSA had identified certain critical areas of concern in relation to cypermethrin, the Commission should not have renewed the approval of that substance. In that context, the Commission no longer has any discretion and cannot rely on its role as risk manager in that respect.

By its judgment, the Court of Justice dismissed the action in its entirety.

[1] Regulation (EC) No 1367/2006 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), in particular on the basis of Article 12 thereof.

[2] 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 2005/53/EC of 16 September 2005 amending Council Directive 91/414/EEC to include chlorothalonil, chlorotoluron, cypermethrin, daminozide and thiophanate-methyl as active substances (OJ 2005 L 241, p. 51).

[3] Commission Implementing Regulation (EU) 2021/2049 of 24 November 2021 renewing the approval of the active substance cypermethrin as a candidate for substitution 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, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011 (OJ 2021 L 420, p. 6).

[4] On the basis of Article 10(1) of Regulation No 1367/2006.

Findings of the Court

In the first place, the General Court provides procedural clarifications concerning the scope of the rule of concordance between the request for review and the action for annulment of the decision adopted in response to that request.

In that regard, the Court points out that such an action for annulment is admissible only if it is directed against the response to that request and if the pleas in law relied on in support of the annulment relate specifically to that response.

Such an action cannot be founded on new grounds or on evidence not appearing in the request for review, otherwise the requirement that reasons be given for such a request would be made redundant and the object of the procedure initiated by the request would be altered. [5]

Nevertheless, on the one hand, an applicant under Regulation No 1367/2006 must be able to raise, at the stage of the action before the General Court, arguments which seek to criticise, in law, the merits of the response to its request for review, provided that those arguments do not alter the subject-matter of the procedure initiated by that request. On the other hand, an argument which was not raised at the stage of the request for review does not constitute a new argument if it is simply an amplification of an argument already developed in the context of that request, that is to say, if it presents 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 the debate in proceedings before the Court.

In the second place, the Court points out that, if the Commission is to be able to pursue effectively the objectives assigned to it by Regulation No 1107/2009, it must be recognised as enjoying a broad discretion. That applies, in particular, to the risk management decisions which it must take pursuant to that regulation. [6]

Risk management corresponds to the body of actions taken by an institution faced with a risk in order to reduce it to a level deemed acceptable for society having regard to its obligation, in accordance with the precautionary principle, to ensure a high level of protection of public health, safety and the environment. [7]

That involves carrying out a prior assessment of the risks, which consists, first, in scientifically assessing those risks, based on the best scientific data available, and, second, in determining whether they exceed the level of risk deemed acceptable for society, which is a political choice of determining an appropriate level of protection for society.

[5] Judgment of 12 September 2019, *TestBioTech and Others* v *Commission* (C-82/17 P, EU:C:2019:719, paragraph 39).

[6] Judgment of 17 May 2018, *Bayer CropScience and Others* v *Commission* (T-429/13 and T-451/13, EU:T:2018:280, paragraph 143).

[7] Judgments of 12 April 2013, *Du Pont de Nemours (France) and Others* v *Commission* (T-31/07, not published, EU:T:2013:167, paragraph 148); of 17 May 2018, *Bayer CropScience and Others* v *Commission* (T-429/13 and T-451/13, EU:T:2018:280, paragraph 125); and of 17 March 2021, *FMC* v *Commission* (T-719/17, EU:T:2021:143, paragraph 78).

Accordingly, although, as part of the procedure for the renewal of active substances, the Commission must 'take into account', inter alia, EFSA's scientific conclusions,[8] it is not bound, as risk manager, by EFSA's findings. Such taking into account cannot be interpreted as an obligation on the part of the Commission to follow EFSA's conclusions in all respects.

However, the Commission's broad discretion in its capacity as risk manager remains governed by the need to comply with the provisions of Regulation No 1107/2009, in particular Article 4 of that regulation,[9] read in conjunction with Annex II thereto, and by the precautionary principle which underpins all the provisions of that regulation.

In those circumstances, the Commission can renew the approval of an active substance only if it is adequately demonstrated that, notwithstanding the identification of critical areas of concern, risk mitigation measures support the conclusion that the criteria of Article 4 of Regulation No 1107/2009 are fulfilled. Accordingly, the Commission's specific role is to determine the risks which are acceptable to society, with a higher tolerance threshold for environmental protection than as regards human or animal health, and taking into account management measures to mitigate the risks identified.

In the present case, the mere fact that EFSA identified four critical areas of concern in its conclusions as regards cypermethrin does not support the conclusion that the Commission, in its capacity as risk manager, no longer had any discretion, provided that it ensured that the criteria set out in Article 4 of Regulation No 1107/2009 were fulfilled. In other words, the Commission is not precluded from ascertaining, in compliance with the precautionary principle, whether the risk could have become acceptable by imposing certain measures.

[8] Under the terms of the second subparagraph of Article 14(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).

[9] According to that article, the approval of an active substance can be granted only if it is demonstrated that the conditions for approval provided for in paragraphs 2 and 3 are satisfied, under realistic conditions of use. A presumption is established that those conditions for approval are deemed to be met if it has been established that that is the case for at least one representative use of at least one plant protection product containing that active substance.