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Judgment of the General Court in Case T-77/20 | Ascenza Agro and Industrias Afrasa v Commission

The General Court dismisses the action against the non-renewal of the approval of the active substance chlorpyrifos-methyl, used in plant protection products

Two manufacturers of plant protection products, the Portuguese company Ascenza Agro and the Spanish company Industrias Afrasa, have challenged before the General Court of the European Union the non-renewal by the Commission, in January 2020 [1], of the approval of the active substance chlorpyrifos-methyl ('CHP-methyl'). CHP-methyl' is an active substance used in plant protection products to control pests and to treat stored cereal grain and empty warehouses against such organisms. It belongs to a group of chemicals called organophosphates to which another active substance called chlorpyrifos also belongs.

In the context of **the human health assessment** of CHP-methyl, the European Food Safety Authority (EFSA) **considered that EU requirements for the protection of human health** [2] **were not met.** Indeed, it is apparent, in particular, from that assessment that the genotoxic potential of CHP-methyl could not be ruled out and that concerns regarding the developmental neurotoxicity of that substance had been raised.

At a meeting of the **Standing Committee on Plants, Animals, Food and Feed**, the Member States subsequently issued, by qualified majority, in December 2019, a positive opinion on the non-renewal of the approval of CHP-methyl.

On 10 January 2020, the Commission decided not to renew the approval of CHP-methyl or that of chlorphyrifos [3]. Ascenza and Afrasa subsequently brought an action before the Court in respect of CHP-methyl.

By today's judgment, **the Court dismisses that action**.

This case gives the Court the opportunity to rule on a number of issues that have not previously been addressed in the context of plant protection products.

In the first place, in respect of procedure, the Court clarifies the concept of **a 'conclusion' adopted by EFSA** within

[1] Commission Implementing Regulation (EU) 2020/17 of 10 January 2020 concerning the non-renewal of the approval of the active substance chlorpyrifos-methyl, 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 2020 L 7, p. 11). The Commission's approval of CHP-methyl, which was initially due to expire on 30 June 2016, was extended on three occasions and finally expired on 31 January 2020.

[2] Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC (OJ 2009 L 309, p. 1).

[3] Commission 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 Implementing Regulation No 540/2011 (OJ 2020 L 7, p. 14).

the meaning of the rules on the procedure for renewal of approval of an active substance [4]. Contrary to what Ascenza and Afrasa maintain, the Court finds that **EFSA did, in the present case, adopt a conclusion since it took the view that CHP-methyl did not satisfy the approval criteria with regard to human health.** Indeed, **the decisive factor for establishing the existence of a conclusion is the expression of an opinion by EFSA as to the potential of an active substance to meet those criteria, irrespective of the name given to the document in question (in the present case, two 'statements').**

In addition, the Court clarifies the impact that the reasons for a Member State's vote in the context of the opinion adopted by the standing committee before the Commission took its decision on the renewal of the active substance in question have on the lawfulness of the Commission's decision. [5]

Ascenza and Afrasa claim that an irrelevant factor, namely the voting instruction given by the United Kingdom in respect of its vote within the standing committee, which they claim was based on political considerations, played a decisive role in the decision taken by the Commission. The Court states that although it is true that a favourable opinion from the standing committee was obtained with the United Kingdom's vote, which made it possible to achieve the required qualified majority, **the factors taken into account by the United Kingdom in relation to its vote were not taken into account by the Commission when it adopted its decision not to renew the approval of CHP-methyl. The same applies to the vote within the standing committee.**

In the second place, **as regards the substance, the Court provides, first, clarification regarding the application of the transparency obligation and of the precautionary principle in the context of plant protection products.**

The Court recalls in particular that **it is incumbent on an affected party who invokes infringement of the transparency obligation in support of an action for annulment brought against an act of the European Union of general application to rely on an express provision conferring on it a procedural right and falling within the legal framework governing the adoption of that act.**

As regards the precautionary principle, it states that, contrary to what Ascenza and Afrasa maintain, the precautionary principle may be applied during the risk assessment phase. The Court considers that **the approach adopted in the procedure that led the Commission** to adopt the decision not to renew the approval of CHP-methyl **is consistent with the precautionary principle. That principle requires the authorities responsible for the risk assessment, such as EFSA, to communicate to the Commission also the findings of uncertainty they have reached, in order to enable it to adopt restrictive measures if necessary. The Court notes that the risk assessment carried out in the present case revealed uncertainties in relation to human health linked to the proposed use of CHP-methyl.**

Second, the Court takes the view that **the approaches employed by EFSA during the risk assessment [6]**could be used in the context of the review of the renewal of approval of an active substance in order to assess the risks that substance presents for human health. In particular, it states that **the use of those approaches is provided for by EU law because they are considered sufficiently reliable from a scientific point of view.** The Court also notes that in order for an application for approval of an active substance or for renewal of such approval to be rejected, it is sufficient that mere uncertainty as to the presence of a risk to health can be identified. Moreover, **those approaches help to reduce animal testing, with the result that they contribute to the achievement of the objectives pursued by the applicable regulations on the renewal of approval of an active substance.**

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[4] 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 No 1107/2009 (OJ 2012 L 252, p. 26).

[5] In the form of a regulation such as the contested implementing regulation.

[6] Namely, in the present case, the read-across approach, which allows account to be taken, for the purposes of the risk assessment, of data from studies carried out with a similar active substance (in the present case chlorpyrifos), and the weight-of-evidence approach.

NOTE: An action for annulment seeks the annulment of acts of the institutions of the European Union that are contrary to EU law. The Member States, the European institutions and individuals may, under certain conditions, bring an action for annulment before the Court of Justice or the General Court. If the action is well founded, the act is annulled. The institution concerned must fill any legal vacuum created by the annulment of the act.

NOTE: An appeal, limited to points of law only, may be brought before the Court of Justice against the decision of the General Court within two months and ten days of notification of the decision.

The full text and, as the case may be, the abstract of the judgment is published on the CURIA website on the day of delivery.

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