Reports of Cases

Case T-476/17

Arysta LifeScience Netherlands BV
v
European Commission

Judgment of the General Court (Fourth Chamber), 19 September 2019

(Plant protection products — Active substance diflubenzuron — Review of approval — Article 21 of Regulation (EC) No 1107/2009 — Rights of the defence — *Ultra vires* — Manifest error of assessment — Procedure for renewal of approval — Article 14 of Regulation No 1107/2009 — Imposition, in the context of the review procedure, of additional restrictions limiting the use of the active substance at issue without waiting for the outcome of the renewal procedure — Proportionality)

1. *Agriculture — Approximation of laws — Placing of plant protection products on the market — Regulation No 1107/2009 — Review of approval of an active substance — Rights of the defence — Scope — Right to submit observations at each stage of the review procedure — Right to submit observations on the conclusions drawn by the rapporteur Member State during its final assessment — None*
(European Parliament and Council Regulation No 1107/2009, Arts 14 and 21; Commission Regulation 2017/855; Council Directive 91/414, Annex I)

(see paragraphs 63, 67-69, 74-76)

2. *Agriculture — Approximation of laws — Placing of plant protection products on the market — Regulation No 1107/2009 — Review of approval of an active substance — Renewal of approval — Commission decision imposing, in the context of the review procedure, restrictions on the use of the active substance diflubenzuron without waiting for the outcome of the renewal procedure — Concerns linked to consumer safety — Manifest error of assessment — None — Breach of the principle of proportionality — None*
(European Parliament and Council Regulation No 1107/2009, Arts 14 and 21; Commission Regulation 2017/855; Council Directive 91/414, Annex I)

(see paragraphs 93, 97, 99-101, 103-106, 109-112, 117-121)

Résumé

In the judgment in *Arysta LifeScience Netherlands* v *Commission* (T-476/17), delivered on 19 September 2019, the General Court dismissed the action for annulment brought against the Commission's implementing regulation on conditions of approval of the active substance diflubenzuron [1] and provided clarifications on, first, observance of the rights of defence in a procedure for reviewing the approval of an active substance and, second, the relationship between that procedure and the procedure for the renewal of approval of an active substance, governed, respectively, by Articles 21 and 14 to 20 of Regulation No 1107/2009 concerning the placing of plant protection products on the market. [2]

Having approved the active substance diflubenzuron, in accordance with the evaluation procedure provided for in Article 11 of the regulation concerning the continued evaluation of active substances, [3] the Commission decided to open the procedure for review of that active substance, provided for in Article 21 of the regulation concerning the placing of plant protection products on the market, in the light of its potential harmful effects on human health through possible exposure to the metabolite 4-chloroaniline (PCA) as a residue. In the context of that review procedure and before conclusion of the procedure for the renewal of approval for that active substance, the Commission adopted the implementing regulation on the conditions of approval of diflubenzuron, in which it concluded that exposure of consumers to PCA could not be excluded and that, as a result, the use of diflubenzuron should be restricted to non-edible crops.

As regards, in the first place, the infringement of the applicant's rights of defence, the Court states that observance of those rights during the procedure for reviewing the approval of an active substance, in accordance with Article 21 of the regulation concerning the placing of plant protection products on the market, must be assessed by taking into account the review procedure as a whole, not each stage of that procedure separately. Thus, the Court examines whether, in the circumstances of the case in question, observance of the right of the defence should be ensured specifically during a particular stage of the review procedure, in particular during the assessment by the rapporteur Member State. In that regard the Court notes, first, that the applicant does not provide any concrete evidence in support of its claim that it would not be possible to change the conclusions drawn by the rapporteur Member State in its final assessment during a later stage in the procedure. Second, the Court finds that, despite their materially different character as compared with the draft assessment on potential exposure of consumers to PCA submitted by the rapporteur Member State, the conclusions drawn by the latter in its final assessment cannot be considered to have raised a new concern that was previously unknown to the applicant and on which the applicant was entitled to be heard once again after that assessment. Third, the Court holds that the applicant provides no new relevant scientific information liable to disprove the conclusions drawn by the rapporteur Member State in its final assessment.

As regards, in the second place, the relationship between the review procedure and the renewal procedure, the Court states, first of all, that Regulation No 1107/2009 makes no provision for any such relationship.

[1] Commission Implementing Regulation (EU) 2017/855 of 18 May 2017 amending Implementing Regulation (EU) No 540/2011 as regards the conditions of approval of the active substance diflubenzuron (OJ 2017 L 128, p. 10).

[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 Regulation (EC) No 1490/2002 of 14 August 2002 laying down further detailed rules for the implementation of the third stage of the programme of work referred to in Article 8(2) of Council Directive 91/414/EEC and amending Regulation (EC) No 451/2000 (OJ 2002 L 224, p. 23).

Next, the Court examines whether the arguments raised by the applicant either call into question the Commission's decision to prioritise consumer safety by not waiting for the outcome of the procedure for the renewal of the approval of diflubenzuron, or demonstrate that such a decision is unreasonable and disproportionate. Rejecting all the arguments raised by the applicant in that regard, the Court concludes that the Commission was entitled to find, first, that consumer safety justified such a decision and, second, that that decision was proportionate.