Reports of Cases

JUDGMENT OF THE GENERAL COURT (Fourth Chamber)

28 May 2020*

(Plant-protection products — Active substance oxasulfuron — Non-renewal of approval for placing on the market — Obligation to state reasons — Article 41(2)(c) of the Charter of Fundamental Rights — Manifest error of assessment — Article 6(f) of Regulation (EC) No 1107/2009 and point 2.2 of Annex II to Regulation No 1107/2009 — Precautionary principle)

In Case T-574/18,

Agrochem-Maks d.o.o., established in Zagreb (Croatia), represented by S. Pappas, lawyer,

applicant,

v

European Commission, represented by A. Lewis, I. Naglis and G. Koleva, acting as Agents,

defendant,

supported by

Kingdom of Sweden, represented by A. Falk, C. Meyer-Seitz, H. Shev, J. Lundberg and H. Eklinder, acting as Agents,

intervener,

APPLICATION based on Article 263 TFEU, seeking annulment of Commission Implementing Regulation (EU) 2018/1019 of 18 July 2018 concerning the non-renewal of approval of the active substance oxasulfuron, 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 Commission Implementing Regulation (EU) No 540/2011 (OJ 2018 L 183, p. 14),

THE GENERAL COURT (Fourth Chamber),

composed of S. Gervasoni, President, L. Madise (rapporteur) and R. Frendo, Judges,

Registrar: E. Coulon,

gives the following

* Language of the case: English.

Judgment [1]

…

Law

…

Second plea in law: infringement of Article 6(f) of Regulation No 1107/2009, of point 2.2 of Annex II to that regulation and of the principle of proportionality with regard to the alleged data gaps

…

98 Finally, the applicant adds that, with regard to the approval or the renewal of the approval of an active substance, the completeness of the dossier is checked definitively by the rapporteur Member State at the admissibility stage of the application. Following that stage, the admissibility of the application can no longer be questioned. EFSA can ask for further information which must be provided within 90 days (approval) or one month (renewal), but it cannot call into question the actual admissibility of the application for renewal of the substance

…

106 In the third place, the applicant's argument that, since the rapporteur Member State declared the renewal application admissible in accordance with Article 8 of Implementing Regulation No 844/2012, EFSA can no longer call into question the completeness of the information communicated by the applicant, is unfounded. The fact that the dossier formally contains all the items referred to in Article 7 of that regulation does not in itself constitute a decision on the quality of those items from a scientific point of view, which may necessitate an in-depth study and may result in diverging assessments by the rapporteur Member State and EFSA with regard to whether or not they are sufficient to allow a renewal application. It must be observed in that regard that Article 7 of Implementing Regulation No 844/2012 requires only that the items referred to in its provisions for the purposes of setting up a 'supplementary' dossier be communicated. In accordance with Article 8 of that regulation, this is a condition for the admissibility of the application and therefore a formal requirement which, if satisfied, triggers the substantive assessment of the dossier, referred to in Chapter 2 of that regulation. It must be pointed out that the fact that the application is formally declared to be admissible for the purposes of Article 8 of Implementing Regulation No 844/2012 does not preclude the Member State from requiring additional information in accordance with Article 11(5) of that regulation, or EFSA from requiring additional information in accordance with Article 13(3) of that regulation. Moreover, that was the situation in the present case since, by communication of 13 July 2016, the applicant received a letter from EFSA requiring further information concerning oxasulfuron.

…

On those grounds,

THE GENERAL COURT (Fourth Chamber)

1 Only the paragraphs of the present judgment which the Court considers it appropriate to publish are represented here.

hereby:

1. **Dismisses the action;**

2. **Orders Agrochem-Maks d.o.o. to bear its own costs and to pay those incurred by the European Commission in the present action and in the proceedings for interim measures;**

3. **Orders the Kingdom of Sweden to bear its own costs.**

Gervasoni Madise Frendo

Delivered in open court in Luxembourg on 28 May 2020.

[Signature]