Outstanding rulings on pesticides: What outcomes? What do they mean in practice and how do we utilise them?

Pesticide Action Network (PAN) Europe
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Pesticide Litigation| Case Blaise and Others, 2019, C-616/17

Main outcomes:

- *Question 1: Is the precautionary principle observed when Regulation 1107/2009 provides no definition of an active substance?*
    1) Court points out that Article 2(2) Reg 1107/2009 offers a definition (para 54)

    1) Read together with the data requirements of Article 78(1)(b)), the Court **denies that the absence of a definition would allow the applicant to freely choose which part of a formulation constitutes the active ingredient** (para 57).

    1) Finally, Court also points out that the Member States in their assessment are tasked with ensuring that each active substance in a PPP is approved (para 59).

Pesticide Litigation| Case Blaise and Others, 2019, C-616/17

Main outcomes:

- *Question 2: Is the precautionary principle observed when the Regulation takes no account of there being multiple active substances or of their cumulative use?*
    1) Court points to Article 4(2) and (3) require that the active substance 'known cumulative and synergistic effects' are taken into account with regard to the pesticide and its residues (para 68).
    2) On the authorisation of PPPs, the Court stresses that Article 4(3) must also be complied with (para 71–76).

> *Para 74: "The need to take into consideration the effects of the constituents of a plant protection product as a whole is, moreover, confirmed by the rules laid down in Articles 25 and 27 of Regulation, from which it is clear that the placing on the market of safeners, synergists and co-formulants contained in such a product must also be subject to assessments to determine whether they have any harmful effects".*

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Main outcomes:

- *Question 3: Is the precautionary principle observed when the tests, analyses and evaluations necessary are conducted by the applicants alone?*
    1) Court concludes that the submission of the assessment data by the applicant based on regulated and standardized methodologies [...] ensuring the quality of the scientific evidence, is not against the precautionary principle (para 79–87).

    1) Consequently, on the obligations of the Member States (and their authorities):
        - They must carry out **an independent, objective and transparent assessment of that application in the light of current scientific and technical knowledge** (para 88), including peer-reviewed literature (para 89).

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Main outcomes:

- *Question 3: Is the precautionary principle observed when the tests, analyses and evaluations necessary are conducted by the applicants alone?*

2) Obligations of the Member States and their authorities:

- They **cannot take into account data submitted** if there is no evidence that the data was generated in accordance with **accepted scientific methodology by reliable institutions**, and **must ask for additional information from the applicant if the evidence is insufficient** (para 91 and 92).

- **Relevant evidence other than the tests, analyses and studies submitted by the applicant that might contradict the latter** must be taken into account(para 93).

- They have a duty to take account of the **most reliable scientific data available and the most recent results of international research** and not to give in all cases preponderant weight to the studies provided by the applicant (para 94).

Pesticide Litigation| Case Blaise and Others, 2019, C-616/17

Main outcomes:

- *Question 3: Is the precautionary principle observed when the tests, analyses and evaluations necessary are conducted by the applicants alone?*
    3) Relation between the precautionary principle and the confidential nature of the dossier: The Court confirmed the ruling in *C-442/14*: clarified that the Directive 2003/4 on public access to environmental information applied to studies concerning the harm caused by the use of PPPs and residues in the environment (para 108).

- *Question 4: Is the precautionary principle observed when the Regulation exempts from toxicity tests pesticide products in the commercial formulations.*
    1) The Court refers to Articles 4(3)(b) and 29(1): to obtain authorisation, the product cannot have immediate or delayed harmful effect on human health (para 114).
    2) Additionally, according to the Court, **a pesticide 'cannot be considered to satisfy that condition where it exhibits any long-term carcinogenicity and toxicity**' (para 115).
    3) It is thus for **the competent authorities to examine that the submitted data sufficiently show that the product does not show risks for long-term carcinogenicity or toxicity** (para 116).

Pesticide Litigation| Case Blaise and Others, 2019, C-616/17

Transferability to national pesticide case

1. The Member States (and their authorities) must take into account the 'cocktail effects' of active substances, safeners, synergists and co-formulants → **Issue 1**

1. The Member States (and their authorities) must: → **Issue 2**
    a. carry out an independent, objective and transparent assessment in the light of current scientific and technical knowledge;
    b. disregard data if there is no evidence that it aligns with accepted scientific methodology;
    c. ask for additional information if the evidence is insufficient;
    d. take into account relevant evidence other than these submitted by the applicant;
    e. take account of the most reliable scientific data/results of international research.

1. The Member States (and their authorities) must consider long term carcinogenicity or toxicity in their assessment. → **Issue 1**

Pesticide Litigation| Case C-308/22 & Joined Cases C-309/22 and C-310/22

Pesticide Action Network Europe

Relevant facts:

- In 2019, the Dutch pesticide authorisation agency (CTGB) agreed to authorise the placing of three PPPs containing the active substances sulfoxaflor, difenoconazole and fludioxonil.
- PAN Europe lodged objections against such decisions, which were rejected as unfounded by the CTGB. As a consequence, PAN Europe sought annulment before the Dutch Court.
- PAN Europe claimed that the CTGB had
    - failed to use the most updated scientific knowledge available,
    - disregarded the most recent guidelines to evaluate endocrine disruption or the toxicity to bees
- The Dutch Court referred questions for a preliminary ruling to the Court of Justice of the EU, which resulted in two rulings delivered in April, 2024.

Pesticide Litigation| Case C-308/22 & Joined Cases C-309/22 and C-310/22

Pesticide Action Network Europe

Main outcomes:

1) Court reminds that the (concerned) **Member States may depart from the scientific risk assessment carried out by the zonal Rapporteur Member State**, in particular where it has available **the most reliable scientific and technical data – which was not taken into account by the RMS** – which identifies an **unacceptable risk to human or animal health or to the environment** (case C-308/22, para 70).

   → Member State is responsible for its national authorisations and cannot blindly rely on the scientific evaluation from other Member States, even the RMS.

1) While Article 36(1) of Regulation 1107/2009 refers to the use of 'guidance documents available at the time of application', the Court states that the MS mustn't limit the risk assessment solely on the guidance documents available, **where it considers that such documents do not sufficiently reflect current scientific and technical knowledge** (case C-308/22, para 93).

Pesticide Litigation| Case C-308/22 & Joined Cases C-309/22 and C-310/22

Main outcomes:

3) It is the duty of the competent authorities to **take account of the most reliable scientific data available and the most recent results of international research, so it does not give in preponderant weight to the studies provided by the applicant.**

   the wording of the Articles 29(1)(e) and 36(2) of Regulation 1107/2009 does not preclude the most reliable scientific and technical information available – ***irrespective of the source of that information or the time when it became available*** *– from being submitted (Case C-308/22, para 109 - 110).*

3) The Court further declares that for the assessment of an application of a PPP must take into account the **adverse effects that the endocrine disrupting properties of an active substance contained in that product may cause for human beings,** considering the relevant and reliable scientific or technical knowledge available at the time of that examination *(as per the criteria laid down in point 3.6.5 of Annex II of Regulation 1107/2009)* (joined cases C-309/22 and C-310/22).

   → **Therefore, the Member States must ensure that the active substances contained in the formulations are not EDs.**

Pesticide Litigation| Case C-308/22 & Joined Cases C-309/22 and C-310/22

Main outcomes:

5) In regards to the principle of legal certainty, the Court states that **taking into account relevant and reliable scientific or technical knowledge which was not yet available at the time when the application was made cannot be regarded as being contrary to the principle of legal certainty** (case C-308/22 and joined cases C-309/22 and C-310/22).

5) It also confirms the **possibility for Member States to refuse to authorise a PPP in the their territories** due to environmental or agricultural circumstances specific to the territory or if the **high level of protection of human and animal health and the environment cannot be assured** (joined cases C309/22 and C310/22, para 91).

5) It is also interesting to note that both cases C-308/22 and joined cases C-309/22 and C-310/22 references the Case *Blaise and Others* (respectively para 90 and para 81).

Pesticide Litigation| Case C-308/22 & Joined Cases C-309/22 and C-310/22

Transferability to national pesticide litigation

1. Member States may depart from the scientific risk assessment of a product carried out by the zonal Rapporteur Member State. → **Issue 1 and 2**

1. Duty of the competent authorities to take account of the most reliable scientific data available and the most recent results of international research as to not to give in all cases preponderant weight to the studies provided by the applicant. → **Issue 2**

1. Member States when assessing a PPP must → **Issue 1 and 2**
   - Take into consideration the adverse effects that the endocrine disrupting properties of an active substance contained in that product may cause for human beings.
   - Take into account relevant and reliable scientific or technical knowledge which was not yet available at the time when the application was made.

1. Member States can refuse to authorise a PPP in their territories due to environmental or agricultural circumstances or if the high level of protection of human and animal health and the environment cannot be assured.

Pesticide Litigation| Case C-162/21, 2023

Relevant facts:

- The case followed a derogation given by Belgium for the use of bee-toxic neonicotinoid insecticides on sugar beets based on Article 53(1) of Regulation 1107/2009 in early 2019, following the ban on neonicotinoids from 2018.

Questions for preliminary ruling: Is it possible, on the basis of Article 53(1), to derogate from the prohibition to place on the market and outdoor use of seeds treated with these substances, expressly prohibited by an implementing regulation, by authorising :

- PPPs containing these active substances for seed treatment, and
- the placing on the market and use of treated seeds.

Main outcomes:

1) Court states that Article 53(1) **does not allow MS to derogate from EU legislation expressly designed to prohibit the marketing and use of seeds treated with these PPPs** (para 54).

   → Interpretation *rooted in the wording of Article 53 and in the objective of the Regulation :* to ensure a high level of protection for human and animal health and the environment based on the precautionary principle.

Pesticide Litigation| Case C-162/21, 2023

Main outcomes:

2) The Court also emphasises the **obligation of all Member States to take all necessary measures to promote low pesticide-input pest control,** giving priority wherever possible to non-chemical methods (para 44).
3) The Court further notes that EU lawmakers did envisage, in the context of Article 53(1), the situation of exceptional circumstances as a derogation. However, **in the present case, the Court considers that it was not the intention of lawmakers to allow Member States to derogate from such an express prohibition** (para 43).
4) For that purpose the Court adds that Article 53(1) cannot be interpreted in way [...] that would run counter to the objective of Regulation 1107/2009 and wouldn't give priority to the prevention of risks to human and animal health and the environment (para 50).

→ **Not limited to seeds but applies to all banned pesticides.**

Thank you for your attention!

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