

Conflicting European principles: Update on ongoing Dutch court cases and opinion of Advocate General Medina

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Authorization of plant protection principles: Conflicting principles and ambiguities in interpretation

Principle of harmonization



Precautionary principle

Consideration of new scientific and technical knowledge



Cut-off date for documents to be considered

In Germany: Deviation from decisions of zRMS only in exceptional cases (principle of harmonization)

- Generally **no deviation** from authorization decision regarding a plant protection product (PPP) of **zRMS** according to established case law in Germany on interpretation of Art. 36 para. 2 and 3 of Regulation (EC) 1107/2009
- A **cMS** may **review** the authorization decision of a zRMS authority only
 - when the **rules** of Regulation (EC) 1107/2009 are being **violated or ignored** by zRMS **systematically**); or
 - if the specific conditions of Art. 36 para 3 Regulation (EC) 1107/2009 are fulfilled (risk mitigation measures deriving from **specific conditions of use** or due to **specific environmental or agricultural circumstances** in Germany posing an unacceptable risk)
- **Administrative Court** of Braunschweig (competent for review of decisions of German Federal Office for Consumer Protection and Food Safety Law) repeatedly refers to **principle of harmonization** as **justification** that cMS may generally **not deviate** from the decision of zRMS

Initiation of preliminary ruling procedures by Dutch court regarding interpretation of – inter alia – Art. 36 para 2 of Regulation (EC) 1107/2009

- Dutch court initiated **3 ECJ proceedings**: C-308/22 (Closer/**Corteva**); C-309/22 (Pitcher/**Adama**); C-310/22 (Dagonis/**BASF**)
- In each national proceeding, PAN (Pesticide Action Network Europe) challenged the decision of the Dutch CTB (Plant Protection Products and Biocides Approval Board) to extend the authorization of the respective PPP to include the requested use in the Netherlands
- In a nutshell, the Dutch Court has asked the ECJ whether the cMS which decides on the **authorization of a PPP** under **Art. 36 para 2** of Regulation (EC) 1107/2009, has any **discretion to depart** from the assessment of the zRMS that examined the application under Art. 36 para 1 of that regulation and, if so, what the margin of that discretion is

Margin of discretion of cMS given according to opinion of Advocate General (AG) Medina in case C-308/22

- AG Medina states that **zRMS** conducts **risk assessment for zone** and **cMS** conducts final approval (**no automatic approval**)
- According to AG Medina, **conclusions by zRMS** are **just one of the documents** that cMS must consult (also available guidance documents as well as **other more recent information**)
- AG Medina is of opinion that particularly Art. 44 Regulation (EC) 1107/2009 support conclusion that **cMS has a margin of discretion**
 - As Art. 44 Regulation (EC) 1107/2009 **allows Member States** to **withdraw authorization** if requirements laid down in Art. 29 Regulation (EC) 1107/2009 are no longer fulfilled, cMS must also be able to refuse an authorization in first place if requirements are not met (regardless of the assessment by the zRMS)

Conclusion of AG Medina (C-308/22): Deviation from zRMS possible if current scientific or technical knowledge asks for it

- **Art. 36 para 2** Regulation (EC) 1107/2009 must be interpreted as
 - **allowing the cMS**, when examining an application for authorisation of a PPP, **to depart from the assessment of the zRMS**, and
 - as giving it a **right to refuse a requested authorisation** in a situation **where current scientific or technical knowledge** indicates that the requirement (no harmful effect on human or animal health or unacceptable effect on the environment) is not satisfied.
- **Art. 36 para 1** Regulation (EC) 1107/2009 must be interpreted as follows: in examining an application for authorisation of a PPP a Member State should **take into account**
 - any **pertinent and reliable current** (that is to say the **most recent**) **scientific and technical knowledge**
 - **regardless of the source or document** from which it comes

Opinion of AG Medina further elaborated in cases C-309/22 / C-310/22

- According to AG Medina, objective of protecting human and animal health and environment should "**take priority**" over the other objectives
- **Independently** of fact that **active substance is approved at EU level**, competent authority of Member State has to take into account and assess risk on the basis of **current and reliable information** indicating that an active substance contained in product could disrupt endocrine system
- Neither Regulation (EC) 1107/2009 nor Regulation (EU) 2018/605 deprive Member State of competence to **adopt appropriate measures** in order to comply with all the requirements of the PP-Regulation on the basis of "current scientific and technical knowledge"; that knowledge must be "**most recent**" or "**latest**"
- Otherwise, Member State would disregard requirements of the PP-Regulation as well as the **precautionary principle**

Conclusion of AG Medina (C-309/22 & C-310/22): Challenge of approval of active substance possible

- Art. 29 para 1 lit. e Regulation (EC) 1107/2009, read in conjunction with Art. 4 para 1 Regulation (EC) 1107/2009 (...) must be interpreted as meaning that:
 - **where the competent authority of a Member State**, responsible for assessing an application for the authorization of a PPP, **has pertinent and reliable information** that is based on **current** (that is to say the **most recent**) scientific or technical **knowledge**,
 - **regardless of the source of such information**, that indicates that an active substance contained in the product in question could disrupt the endocrine system,
 - that authority **must take into account the risk** (...), assess that risk and take an appropriate decision.

Critical analysis of opinion of AG Medina (C-308/22) (1/2)

(Biased) premise of AG Medina:

- Conclusion (C-308/22) does **not contain opinions of all Member States**
- **Doubtful** if AG fulfilled duty to provide **impartial** and **independent** conclusion as she **premises** that **use of plant protection products** should be **restricted** anyways

Explanation contra legem:

- Substantive considerations clearly contrary to Regulation (EC) 1107/2009, particularly **contradictory** to **wording of Art. 36 para. 2 and 3**
- cMS has to **grant** or **refuse** application “**accordingly**” and “**on the basis of**” conclusions of zRMS
- **AG stretches conditions** set out in Art. 36 para. 3

Incompatibility with principle of harmonization:

- **Opinion contrary to main rule** that cMS follows assessment of zRMS and that **cMS may not duplicate assessment by zRMS** due to principle of harmonization (zRMS to take into consideration all **comments and concerns** raised **by cMS**)

Critical analysis of opinion of AG Medina (C-308/22) (2/2)

Problematic interpretation of case law :

- AG Medina puts **cited judgments** (Bayer C-499/18, EU:C:2021:367, Blaise C-616/17, EU:C:2019:800) in **wrong context**; **judgments did not concern national authorization** of a PPP
 - Bayer (C-499/18): involved **review of active substance**; review procedure – and associated assessment framework – is **not directly applicable** to (national) authorization of PPP
 - Blaise (C-616/17): also involved **review of active substance**; ECJ **did not rule on interpretation of scientific and technical knowledge** to be taken into account in application for authorisation of PPP

Unworkable and incompatible answers :

- Answers **do not resolve** alleged **ambiguity** raised by preliminary questions
- If limit to possibility of refusal of admission by cMS **no longer lies exclusively in conditions of Art. 36 para. 3**, unclear when cMS can proceed to refusal
- **Unclear which documents** an applicant shall **submit** and which (other) documents should/may the cMS **independently consult**

Outlook: How will the conflicting principles be reconciled in the future?

- Decision by ECJ will bring more clarity
- New decision by General Court (T-536/22) might shed light on position of European courts
- Will precautionary principle prevail over principle of harmonization?
- ...

Thank you very much for your attention!



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Questions / Open Discussion



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