CROPLIFE LEGAL OPINION
14/06/2024 – LEG/24/LL/37880

CLE interpretation of ECJ judgements C-308/22, C-309/22 and C-310/22

KEY MESSAGES

C-308/22

- The ECJ confirmed that the system of division of work and mutual trust between Member States is retained. A concerned Member State ('cMS') cannot perform a re-assessment of the same factual circumstances and data that were already taken into account by the zonal Rapporteur Member State ('zRMS'). There are only very limited situations where a cMS may depart from the assessment of a zRMS. The cMS needs to show which specific environmental or agricultural circumstances prevail in its territory that allow it to depart from the zRMS' assessment and on the basis of which new reliable scientific and technical data.
- To enhance certainty, Member States should demonstrate in the preparation of their assessment that they have taken into account all available most reliable scientific and technical data. This would allow cMS to depart in the specific circumstances from the zRMS' conclusions only on the basis of reliable scientific and technical data which becomes available after the assessment of the zRMS.

C-309/22 & C-310/22

- Th ECJ found that, in case a Member States has to decide on an authorisation application for a product containing an active substance that has Endocrine Disrupting ('ED') properties, the Member State is required to take their potential adverse effects into account on the basis of the relevant and reliable scientific and technical knowledge. The ECJ did not, however, rule that such Member State has to conduct a *de novo* ED assessment for the active substance at national level.
- The obligation to take an active substance properties' potential adverse effects into account is limited to substances where it has been established that it has ED properties. A Member State may e.g. fulfil such obligation by taking note of the knowledge available at the time of its assessment (i.e. at the RMS / EFSA peer review level for the active substance) and, if necessary, consult with the RMS / EFSA.

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I. INTERPRETATION OF C-308/22

1. In C-308/22, PAN Europe challenged the decision of the Dutch Board for the Authorisation of PPPs and Biocides ('**CTGB**') to extend the authorisation for the placing on the Dutch market of a PPP marketed under the trade name Closer. PAN Europe argued that the CTGB should not have extended the authorisation as the assessment made by the zonal Rapporteur Member State ('**zRMS'**), which was followed by the CTGB, was not based on current scientific and technical knowledge.

2. In its judgement, the ECJ held that a concerned Member State ('**cMS'**) **may depart** from the scientific risk assessment carried out by the zRMS in the situations referred to in Art. 36(3), second paragraph of Regulation 1107/2009, in particular when the zRMS did not take into account the most reliable scientific and technical data which identifies an unacceptable risk to health or the environment.

3. It follows from the judgement that **only the situations referred to in Art. 36(3), second paragraph, of Regulation 1107/2009, may trigger the possibility to depart from the assessment of the zRMS**. This means that the cMS may only depart from the assessment of the zRMS where the concerns of a Member State relating to human and animal health or the environment cannot be controlled by national risk mitigation measures, and if, due to its specific environmental or agricultural circumstances, it has substantiated reasons to consider that the product in question poses an unacceptable risk to human or animal health or the environment which cannot be controlled by national risk mitigation measures.

4. The cMS may, therefore, depart where the zRMS did not consider the most reliable scientific and technical data in its assessment. Consequently, **cMS do not have a blank cheque to depart from the assessment of zRMS**. A cMS needs to show which specific environmental or agricultural circumstances prevail in its territory that allow it to depart from the zRMS' assessment and on the basis of which new reliable scientific and technical data.

5. While the ECJ did not clarify what constitutes the **'most reliable scientific and technical data**', data generated according to GLP or GEP should take priority over the rest and be considered as the most reliable data.

6. In this specific case, the zRMS had not used, in its assessment, the 2013 Bee guidance document, which had been published by the Commission but not fully endorsed by the SCoPAFF. The zRMS rather based its assessment on another GD, the Guidance Document on Terrestrial Ecotoxicology. The ECJ pointed out that neither the source of the available most reliable scientific and technical knowledge nor the time when it became available could preclude a cMS from using it. Further, in case a cMS considers that the documents used by the zRMS do not sufficiently reflect the current scientific and technical knowledge, the obligation to state reasons for decisions require the cMS to demonstrate this when departing from the assessment of the zRMS in the light of the concerns relating to health or the environment in connection with the environmental or agricultural circumstances specific to its territory.

7. To enhance certainty, Member States should demonstrate in the preparation of their assessment that they have taken into account all available most reliable scientific and

technical data. This would allow cMS to depart in the from the zRMS' conclusions only on the basis of reliable scientific and technical data which becomes available after the assessment of the zRMS.

II. INTERPRETATION OF C-309/22 AND C-310/22

8. In this case, PAN Europe challenged the decision of the CTGB to grant the authorisation for the placing on the Dutch market of PPPs marketed under the trade names Dagonis and Pitcher, respectively. PAN Europe argued that the CTGB failed to assess the Endocrine Disrupting ('**ED**') properties of the active substance contained in Pitcher and Dagonis, respectively, in the light of current scientific and technical knowledge at the time of the decision on that application.

9. In its judgement, the ECJ considered that the competent authority of a Member State, charged with the task of assessing an application for authorisation to place a PPP on the market, is required to take into account the adverse effects that the ED properties of the active substances contained therein may cause, having regard to the relevant and reliable scientific or technical knowledge available at the time of that examination and which is, in particular, reproduced in the criteria laid down in point 3.6.5 of Annex II to Regulation 1107.

10. This obligation, as it is formulated by the ECJ, applies only in cases where it has been established that the active substance contained in the product has ED properties that may cause adverse effects. Moreover, it is evident that the ECJ based its decision particularly on the fact that there was a **legislative addition of the criteria** (being the new technical knowledge) which was in place when the product authorisation decision was taken.

11. Furthermore, the "**taking into account**" requirement, as stated by the ECJ, must be interpreted in the light of standing principles of EU law like good administration, effectiveness and consistency. The Court's intention is not that a new risk assessment of an active substance at national level is necessary, including the generation of new data, in addition to what is already done at EU level. Otherwise, a *de novo* assessment at national level would infringe the fundamental set up and the allocation of competences and responsibilities under the PPP Regulation (which the ECJ cannot amend).

12. While the ECJ did not clarify what constitutes the '**relevant and reliable scientific and technical data**', it must be recalled that, under the EU level active substance ED screening program and Regulation 1107/2009, GLP studies are considered necessary for drawing such conclusions. Categorising a substance as an ED is an active regulatory step that must be taken appropriately. The criteria under Point 3.6.5. of Annex II are underpinned by significant guidance that sets out what may (or may not) comprise an adequate signal of ED effects, and the determination must ultimately be made by the competent risk assessor. A Member State may e.g. fulfil its obligations to take into account any adverse effects resulting from the active substances' ED properties by taking note of the knowledge available at the time of its assessment (i.e. at the RMS / EFSA peer review level for the active substance) and, if necessary, consult with the RMS / EFSA.