Pesticide Action Network Europe

To: The Director of the National Pesticide Authorisation Body.

Concerning: EU Court verdict on recent scientific insights in pesticide authorisations.

Brussels, 17-02-2025.

Dear Director, the new EU Court verdicts on '*recent scientific insights*'[1],[2] mean that you will have to drastically change your pesticide authorisation policy. Every decision you take from now on will have to be based on current scientific insights. And a full assessment of the negative effects of the use of each active substance and its formulation on health and the environment is required in the national authorisation procedure. And these insights can only be considered properly if you do a full literature search for every single active substance and its coformulants to begin with.

Recently (April 2024) the EU Court published verdicts in cases run by PAN Europe on the interpretation of Art. 4 of Regulation 1107/2009. These verdicts are the preliminary ruling of EU Court of 25-4-2024 on Joined Cases C-309/22 and C-310/22[3], the preliminary ruling of EU Court of 25-4-2024 on Case C-308/22[4], the final ruling on 15-10-2024 of Dutch CBB on case AWB 20/280 PL[5], and the final ruling on 16-1-2025 of Dutch CBB on case AWB 20/80[6]. While to us the verdicts are crystal clear, Dutch Ctgb produced a wrong assessment in HLM[7]. We ask your attention for this misinterpretation of the Court's verdicts and thus the rule of law.

Art.4 states that decisions of pesticides need to be done "***in the light of current scientific and technical knowledge***". Quite normal. Why would one take decisions based on old scientific knowledge that is not in line with current findings? But unfortunately this was and is the case in national pesticide decisions for over 15 years. EU member state authorisation bodies many times authorised pesticides that are approved decades ago, ignoring research that might be published in the meantime. Even if dozens of articles are published demonstrating serious harm to humans (such as on the pesticide difenoconazole) the national pesticide authorities generally turn a blind

[1] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A62022CJ0309&qid=1738576901784
[2] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A62022CJ0309&qid=1738576901784
[3] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A62022CJ0309&qid=1738576901784
[4] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A62022CA0308&qid=1738577102420
[5] https://uitspraken.rechtspraak.nl/details?id=ECLI:NL:CBB:2024:698
[6] https://uitspraken.rechtspraak.nl/details?id=ECLI:NL:CBB:2025:17
[7] Presentation of Dutch authorisation body Ctgb in the High Level Meeting of Commission, EFSA and EU member states in December 2024.

eye to these data and fail to protect the public and its environment. The EU Court judgements and the opinion of the Advocate–General are contrary to these practices.

Current scientific knowledge can only be assessed if all member states start by performing a **full literature search** for any decision on a pesticide they take. And collect all national monitoring data and scientific reports from independent institutes. There is no alternative. Current scientific knowledge needs to be collected. Continuing the practice to base decisions on (decades-old) industry-generated studies and views only is not an option anymore. It is unlawful.

For PAN Europe, after having written several letters to Commission and the ScoPAFF committee without achieving a change in policy, there was all reason to consult Dutch court, which in turn consulted the EU Court. And, not surprisingly, EU Court in 2024 ruled that "*in the light of current scientific and technical knowledge*" means nothing less than "*in the light of current scientific and technical knowledge*". The assessment by Dutch authorisation body Ctgb in December 2024 in HLM promotes a new, wrong explanation of the rules on a range of elements of the judgements. We will do an effort to explain what court ruled.

1. **EU Member States have every right to deviate from previous scientific assessments**.

A member state can deviate from the risk assessment of another state such as a Rapporteur (see the verdict in the footnote[8]). Court notes that it is important that Member States are granted this power given the provisions in the Regulation that the protection of human and animal health and the environment **'must take priority'** over improving plant production[9]. Scientific and technical knowledge changes all the time[10] and this knowledge needs to be taken into account in every decision taken[11]. The Charter of Fundamental Rights of the European Union, Article 47 -Right to an effective remedy and to a fair trial- also provides that national authorities can substitute its own assessment for the previous one[12]. Based on Art. 36.3, authorities can even refuse the authorization. Court stresses again that a **high level of protection is the goal of the Regulation** and that the Precautionary Principle needs to be applied in case of

[8] Case C-380-22 (Closer), paragraph 70: whereas a Member State deciding on the authorization to place a plant protection product on the market in accordance with Article 36(2) of that Regulation may, in the cases referred to in the second subparagraph of Article 36(3) of that Regulation, derogate from the scientific assessment of the risks posed by this product carried out by the Member State examining the application for such authorization under Article 36(1) of that Regulation, in particular where it has the most reliable scientific and technical data, where the latter Member State has not taken into account in preparing its assessment and which shows that there is an unacceptable risk to human or animal health or to the environment.

[9] Case Closer, C-308/22, paragraph 3. See also: Judgement of 19 January 2023, Pesticide Action Network Europe ao., C-162/21, EU:C:2023:30, paragraphs 46 and 48

[10] Case C-309/22 and C-310/22, paragraph 98: any applicant wishing to place a plant protection product on the market can expect that the state of scientific and technical knowledge will change during the course of the authorization procedure or during the period for which an active substance has been approved or a plant protection product has been authorized

[11] Case C-309/22 and C-310/22, paragraph 99: The taking into account of relevant and reliable scientific and technical knowledge that was not yet available at the time of submission of the application for authorization to place a plant protection product on the market cannot therefore be considered to be contrary to the principle of legal certainty.

[12] Case C-308/22, paragraph 40, 57 and 59.

uncertainty[13]. **Assessing recent scientific and technical knowledge in decisions**, **contributes** to the goal of a high level of protection[14].

2. Current scientific insights not limited to endocrine effects.

Dutch Ctgb claims in its presentation at HLM that the ECJ judgments are limited to available knowledge on endocrine properties for humans. This is not the case. EU Court ruled that it is crystal clear from the wording of Article 29(1)(a) and (e) and Article 4(3)(b) of Regulation No 1107/2009 that any national decision needs to be based on current scientific and technical insights[15],[16]. On endocrine properties, but also on any other harmful effect such as carcinogenicity, neurotoxicity, immunotoxicity, etc. In the judgement on Closer (25-4-2024) Court also doesn't limit the assessment to endocrine disruption but rules that all scientific and technical knowledge needs to be assessed, including the results of international research[17]. Court additionally rules that all scientific and technical knowledge needs to be taken into account, scientific publications, guidelines, models, etc. and not only "certain categories[18]". In the final verdict on Closer (15-10-2024) Court similarly rules that available scientific knowledge

[13] Case C-308/22, paragraph 102: this Regulation aims to ensure a high level of protection of human and animal health and the environment. Furthermore, as stated in Article 1(4) of that Regulation, those provisions are based on the precautionary principle and do not prevent Member States from applying that principle where there is scientific uncertainty as to the risks to human or animal health or the environment of the plant protection products to be authorized on their territory.

[14] Case C-308/22, paragraph 103: The possibility of submitting to the authorities and courts of the Member State concerned referred to in Article 36(2) of that Regulation all relevant, reliable and up-to-date scientific and technical knowledge for the purpose of authorizing a plant protection product in the territory of that Member State contesting contributes to the achievement of that goal, taking into account the precautionary principle.

[15] Case C-309/22 and C-310/22, paragraph 72: It is therefore clear from the wording of Article 29(1)(a) and (e) and Article 4(3)(b) of Regulation No 1107/2009 that a competent national authority may authorize a plant protection product in particular where all active substances in that product have been approved and, according to the state of scientific and technical knowledge, that product has no immediate or delayed harmful effect on human health.

[16] Case C-309/22 and C-310/22, paragraph 81: it should be noted that, under Article 29(1)(e) of Regulation No 1107/2009, Member States must, when examining an application for authorization to place a plant protection product on the market, verify whether the product meets the requirements of Article 4(3) of this Regulation. The Court has already clarified that, according to Article 29(1)(e) of that regulation, the authorization to place a plant protection product on the market requires, inter alia, that the product must, on the basis of the state of scientific and technical knowledge, meets the requirements of Article 4(3) of the same Regulation. Under those provisions, such a product may be authorized only if it is established that it has no immediate or delayed adverse effect on human health (see, to that effect, judgment of 1 October 2019, Blaise and Others, C-616/17, EU:C :2019:800, paragraphs 71 and 114).

[17] Case C-308/22, paragraph 90: that, in accordance with Article 36(1) of Regulation No 1107/2009, the Member State to which an application for authorization of a plant protection product has been submitted must carry out an objective and transparent assessment of that application on the basis of the state of scientific and technical knowledge. Competent authorities should pay particular attention to the most reliable scientific information available and the most recent results of international research, and should not automatically attach greater importance to studies submitted by the applicant (see, to that effect, judgment of 1 October 2019, Blaise and others, C-616/17, EU:C:2019:800, paragraphs 66 and 94).

[18] Case C-380-22 (Closer), paragraph 91: It follows that neither the wording of Article 29(1)(e) of Regulation No 1107/2009 nor that of Article 36(2) indicates that the authorities and courts of the Member State concerned, when an administrative or judicial decision has to be taken on the authorization of a plant protection product on its national market, must take into account only certain categories of scientific and technical knowledge, depending on the source of it or the moment at which that knowledge became available.

always needs to be taken into account[19]. The wording of Article 29(1)(e) of Regulation No 1107/2009 nor that of Article 36(2) allow for a limitation to endocrine disruption. Moreover, the pesticide data requirements already obliged member states to take into account all relevant scientific and technical information[20].

3. Not only pending product applications

Ctgb claims that the ruling only applies to pending product applications. Again not true. The previous paragraph shows that Court rules that all scientific and technical knowledge needs to be assessed in all authorisation decisions (the obligation "to always make a decision tailored to the specific substance in question and the intended use against the background of the available scientific knowledge[21]"). This counts for any decision based on applications for extension, mutual recognition, minor use, etc. But also for a decision of the authorization body on a request for withdrawal of a pesticide from an external organization based on Art.44. Any decision needs to be assessed in the light of current scientific and technical knowledge.

4. Not only guidelines

Ctgb claims that "Scientific technical knowledge" should be understood as study(s) based on European or international guidelines for conducting tests and conducted by a contract laboratory or academic institution. Not true. In question nr. 4 on Closer national court asks if only guidelines 'taken note' should be considered[22]. EU Court rules that all scientific and technical knowledge needs to be taken into account, and not solely on available guidelines[23], [24]. Taking note or not is not relevant. If guidelines are available they should be considered.

5. Not only industry studies

Ctgb claims that for the endocrine assessment (in case of European procedure not finalised) they can check the EFSA peer review or the RAR (Revised Assessment Report) for the national assessment. Meaning limiting the assessment to industry-submitted studies and views. Again a false opinion. Court rules that authorities should pay attention to "the most reliable scientific information available and the most recent

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[19] Case Closer, 15-10-2024, paragraph 10: The applicable assessment framework for the Ctgb entails the obligation to always make a decision tailored to the specific substance in question and the intended use against the background of the available scientific knowledge.

[20] Case C-309/22 and C-310/22, paragraph 85: in accordance with paragraph 2(c) of Title A of Part I of this Annex, when examining applications for authorization and granting authorizations, Member States must take into account other relevant technical and scientific information which they may reasonably have available in relation to the possible adverse effects of the plant protection product itself or its components.

[21] Case Closer, 15-10-2024, paragraph 10: The applicable assessment framework for the Ctgb entails the obligation to always make a decision tailored to the specific substance in question and the intended use against the background of the available scientific knowledge.

[22] Case Closer, paragraph 44.

[23] Case Closer C-308/22, paragraph 92: The wording of Article 29(1)(e) and Article 36(2) of Regulation No 1107/2009 does not therefore prevent those authorities and courts from having the most reliable scientific and technical information is put forward to contest the authorization of that product in the territory of the Member State concerned, regardless of the source of that information or the time at which it became available.

[24] Case Closer, paragraph 93: The fact that Article 36(1) of that Regulation requires use of the guidelines available at the time of the application does not alter that interpretation. It cannot be inferred from that provision that the Member State examining that application must base its risk assessment solely on the available guidelines if it considers that those documents do not sufficiently reflect the state of scientific and technical knowledge on the basis of which it must carry out its assessment.

results of international research, and should **not automatically attach greater importance to studies submitted by the applicant**[25]".

6. **Full scientific assessment needed for every decision**

Court ruled that national authorities themselves have to assess the applications and not automatically copy-paste the assessments at European level[26],[27]. A full new scientific assessment is needed in every decision taken at national level. Also if an assessment at European or zonal level has been performed. Ctgb is wrong to claim "we follow the usual EU processes" and "we adopt outcome of expert meeting".

This means that all data need to be considered in any decision and this can only be achieved if a full literature search is performed for the active substances' toxicity, for instance on PUBMED[28]. The first step for an authorisation body for any new authorisation therefore is to perform a full literature search on independent scientists' studies. And also consider monitoring data and studies form independent institutes. Not automatically copy-paste the assessment from the approval decision or RAR.

7. **Recent scientific assessment only stops at stage of a decision on objection.**

Dutch Ctgb and industry argued that taking into account scientific knowledge stops at the moment when industry submits its application. Court ruled that this is unlawful. An applicant knows that during the assessment scientific knowledge can change[29]. Any new scientific and technical knowledge need to be assessed until the moment of decision-making[30], including when a decision is contested. In conclusion, for every decision taken by a national authorisation body, the requirement of deciding based on "*in the light of current scientific and technical knowledge*" counts, including the moment an

[25] Case C-308/22, paragraph 90: that, in accordance with Article 36(1) of Regulation No 1107/2009, the Member State to which an application for authorization of a plant protection product has been submitted must carry out an objective and transparent assessment of that application on the basis of the state of scientific and technical knowledge. Competent authorities should pay particular attention to the most reliable scientific information available and the most recent results of international research, and should not automatically attach greater importance to studies submitted by the applicant (see, to that effect, judgment of 1 October 2019, Blaise and others, C-616/17, EU:C:2019:800, paragraphs 66 and 94).

[26] Case Pitcher and Dagonis (C-309/22 and C-310/22), paragraph 82: Consequently, while Member States cannot, when examining an application for authorization to place a plant protection product on the market, revise the Commission's approval of the active substance it contains, the authorization of that product cannot be regarded as a purely automatic implementation of the Commission's approval of an active substance contained in that product (see, to that effect, judgment of 28 October 2020, Associazione GranoSalus v Commission, C-313/19 P, EU:C:2020:869, paragraphs 55 and 58).

[27] Case Pitcher and Dagonis (C-309/22 and C-310/22), paragraph 83: As the Advocate General noted in paragraph 58 of her Opinion, it follows that, although Regulation No 1107/2009 precludes a Member State from authorizing a plant protection product containing an active substance that has not been approved, a Member State is not obliged, conversely, to authorize a plant protection product all the active substances of which have been approved if scientific or technical knowledge is available showing that the use of that product poses an unacceptable risk to the health of to humans or animals or to the environment.

[29] Case C-308/22, paragraph 108: any applicant wishing to place a plant protection product on the market can expect that the state of scientific and technical knowledge will change during the course of the authorization procedure or during the period for which an active substance has been approved or a plant protection product has been authorized.

[30] Case C-308/22, paragraph 110: …..in order to contest the authorization of a plant protection product in the territory of the Member State which decides on such authorization in accordance with the latter provision, the most reliable scientific and technical data available may be relied on before the authorities or courts of that Member State in order to show that the scientific risk assessment carried out on that plant protection product by the Member State examining the application under Article 36(1) of this Regulation is inadequately substantiated.

authorisation body takes a decision after an external organisation made an objection to the authorisation decision[31].

We are looking forward to your reaction to our interpretation of the rulings and we are curious to know how you will change your authorisation policy in the light of the rulings.

Sincerely yours,

Hans Muilerman,
Maarten Baneke,
Pesticide Action Network Europe,
Brussels.

[31] Case AWB 20/80 (Dagonis), verdict 16-1-2025, paragraph 10: However, it follows from the system of the procedure that the investigation ends as soon as the Member State responsible for the assessment makes a decision pursuant to Article 36(2) over the admission.