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04 June 2024

CropLife Europe - Zonal evaluation process in the Southern Zone

Dear members of the Southern Zone Steering Committee,

CropLife Europe (CLE) would like to discuss the zonal evaluation process in the Southern Zone, especially in relation to those situations where **concerned Member States (cMS) are not accepting the zonal evaluation**, e.g. when concerned Member States consider that their comments are not properly addressed by the zRMS. This letter is specifically focusing on cases when **France** is acting as concerned Member State as these reveal the most critical elements, yet the overarching principle remains valid no matter which country is involved.

In principle, we believe that the final evaluation at zonal level (including the requested and agreed actions) should be applicable to all cMS. Prerequisite is that where a cMS does not agree with the zonal evaluation this should be flagged during commenting, and all cMS comments should be properly addressed by the zRMS before finalising the evaluation. Where no agreement amongst MSs can be reached on the zonal level, a national evaluation of the specific topic should be proposed.

In contrast to this ideal situation, CropLife Europe member companies reported similar cases where a registration has been granted by the zRMS (and other SZ cMS) while refused by France as cMS. According to ANSES's own website, since January 2023, it seems that out of 15 submissions (registrations granted by zRMS with France as cMS), only 7 were granted in France.

The provided reasons for the refusals are usually based on a non-finalization by ANSES DEPR, generally stating that the dossier submitted by the applicant does not fulfil the criteria of Regulation 1107/2009 or does not follow the latest guidance documents. For illustration purposes, please find below specific cases in which the reasons for non-finalization were the results of comments submitted by ANSES during the commenting period and addressed by the zRMS as followed (3 examples provided):

> **1st example:**
> FR (cMS): Application dates considered for vines, pome/stone fruit and citrus uses do not fully cover the intended application periods. Additional calculations would be necessary to cover the possible applications close to the end of application period.
> zRMS: The application dates used by the Applicant are correctly selected based on the AppDate tool. No further calculations are required in the core dossier. If necessary, a National Addendum for France may be provided.
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> **2nd example:**
> In the tox part of the dRR, the proposed dermal absorption rates for the active substance were based on dermal absorption studies on a formulation which was considered equivalent due to a minor change formulation from the one to be registered. The bridging was not considered acceptable by FR as cMS whilst it was considered equivalent in the rest of the zone and by the zRMS.
> In that same dossier, an evaluation of a specific metabolite was not performed by the zRMS although included in original dossier. When FR pointed out to the zRMS the need to include the evaluation on the metabolite, the zRMS disagreed and considered this as new data on the AS which should be included and evaluated in the next renewal package and closed the point. FR did not accept the zRMS position and did *also* not perform a local assessment considering that the risk assessment could not be finalized at national level. In the end, the product was not authorised in France.
>
> **3rd example:**
> FR (cMS): This dossier was originally submitted in 2021. Therefore according to EFSA Guidance on DegT50 (2014)**[1]**, geometric mean Kfoc values should be reported in point 8.5 and used in PEC calculations for the active substance and its metabolites. Because of these deviations, FR considers the

[1] EFSA Journal 2014;12(5):3662

PECsw/sed values are not acceptable and without additional PECsw calculations, the risk assessment for non-target aquatic organisms could not be finalised at FR national level.
zRMS: zRMS agrees, nevertheless, no significant changes in PECgw results are expected. If necessary, a National Addendum for France may be provided.

Based on the comments from France and the feedback provided by the zRMS to the applicant, the applicant's approach was to contact ANSES asking if further data could or should be provided during the national phase. The clear answer of ANSES was that the evaluation will be performed following the conclusions made by the zRMS. However, these applicants subsequently were faced with negative conclusions from FR, highlighting a non-finalization for the parts where ANSES had made comments, despite the zRMS granting registrations. Please note in addition that none of the non-finalized sections are linked to national issues, but linked to national interpretations which cannot easily be anticipated as these are not made publicly available.

CropLife Europe consider these situations to go against the provisions and procedures of the zonal system, including options provided in both Regulation 1107/2009 and the guidance document on zonal evaluation (SANCO/13169). The zonal system is supposed to encourage trust between Member states when acting alternatively as zRMS and as cMS. Applicants understand the difficulties in the zonal evaluation process, but Member States need to find a way to solve evaluation and interpretation divergencies without a negative impact for applicants, aligned with the zonal process. **We believe that whenever a cMS does not agree with the zonal evaluation, there should be an option to complete the evaluation at national level, during the national phase, as allowed in Reg. 1107/2009. This should be applicable in all Member States.**

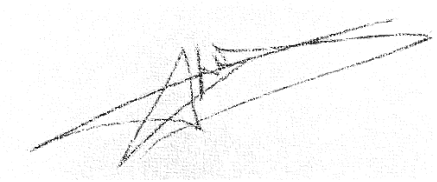
Currently, we fail to see what applicants could have done differently to obtain their registrations in France. ANSES' scientific opinions are clearly acknowledged, and we understand it can differ from other authorities' viewpoint. However, without the possibility to submit the required information in the national phase, CropLife Europe believes that this situation will create issues with farmers' competitiveness in Southern Europe. Without a solution to get authorisations in France as cMS when a zonal application is submitted in the Southern zone, applicants will only have two (highly inefficient) options left:

- Resubmit an updated dossier in France as zRMS (and only cMS) after receiving the initial refusal. However, this seems to be against the intentions of Regulation 1107/2009 and will result in an extra workload for the French Authorities due to the number of dossiers to be evaluated only for France.
- Always submit two applications in parallel: one only for France according to national interpretations of guidance and data requirements and another one in the rest of the zone. Also here, this would constitute unnecessary work to be done by at least two authorities for getting the same product authorized in the same zone.

For all these reasons, **we call upon the Southern Zone Steering Committee to discuss this important topic**, for French farmers, for the industry, and for their own sake, together with all the countries in the Southern Zone, and agree on a harmonized approach that is accepted and implemented by all SZ MSs when zonal applications are submitted. Following previous Southern Zone Steering Committee communications, we understood that in general the cMS will follow zRMS decisions unless linked to national specificities. We certainly are convinced this principle should still hold true.

If you need more information about the examples, this letter, the individual submissions and refusals, CLE is available to have a meeting or to submit any additional information that could be useful when seeking a sustainable solution for the zone.

Yours sincerely



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cc. Karin Nienstedt (European Commission)
Christian Prohaska (Chair of PAI)

This letter will be published on the CropLife Europe website and will be available at:
https://croplifeeurope.eu/resources-library/