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POSITION PAPER

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Persistence scientific assessment and risk management safeguards under the Pesticide authorisation framework

Executive summary

- Pesticide active ingredients meeting by chance the initial PFAS structural definition proposed by 5 MS, and which are evaluated as "persistent" under the provisions of the pesticide authorization framework are not to be confused with "forever chemicals". They do degrade in the environment even though their half-lives do not meet the very conservative persistence thresholds.
- Before approval, pesticide active ingredients are thoroughly evaluated against POP and PBT criteria as part of the standard regulatory decision making under Regulation 1107/2009. If they do meet the POP and PBT criteria, the evaluation of the submitted data package will just stop and no authorisation can be given.
- Regulation 1107/2009 requires a thorough evaluation of degradation in different environmental matrices and under different environmental and climatic conditions according to international experimental guidelines. Only if the environmental risk assessments based on these data confirm safe use at active ingredient as well as product level, approval will be granted.
- In the exceptional case of unanticipated effects identified after approval, Regulation 1107/2009 has provisions that require immediate reporting of such effects and provisions that allow authorities to request additional data, and even to suspend or cancel approvals as a precautionary measure.
- With the new transparency regulation, all safety related data will be made available to the general public and the scientific community for active substances – allowing further scrutiny by interested parties.
- Considering the comprehensive data requirements, the strict authorization criteria, and the wide range of regulatory options both pre- and post-approval, the pesticide authorisation framework is considered to adequately address the concerns regarding persistence that are behind the proposed PFAS REACH Restriction.

Approval criteria:

- If an active substance fulfills the criteria of a persistent organic pollutant (POP) it cannot be approved as a pesticide (cut-off criterion looked at first).
- The fate and behavior of active substances in the environment is compared to conservative persistence criteria. Compounds are identified as "persistent" if they fail the acceptable degradation of 50% (DT50) in water (40-60 days), soil and sediment (120-180 days).
- If an active substance is persistent, bioaccumulative, and toxic (PBT) it cannot be approved as a pesticide. If it is persistent and either bioaccumulative or toxic (PB or PT) it can be authorized only as a Candidate for Substitution (CfS); in this case the approval is for only 7 years and all products containing such a CfS are subject to a special assessment for alternatives during the approval process at national level (leading to substitution).

Data requirements: the regulatory assessments require provision of GLP studies following standard protocols in soil, aquatic systems as well as in air to establish an estimation of persistence.

- Experimental data under laboratory conditions must always be provided about degradation and metabolism in soil (aerobic and anaerobic metabolism and soil photolysis) and in water, in water/sediment systems, and under the conditions of hydrolysis and aqueous photolysis. Degradation in air is investigated by means of QSAR calculations.

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- In all studies, all significant metabolites must be identified (those which exceed either 5% or 10% of the applied compound, depending on the study type).
- If the lab DT50 in soil of the a.i. or any major metabolite exceeds 60 days (at 20°C), the degradation must be further investigated in field dissipation studies. If the DT90 under field conditions exceeds one year, the accumulation in soil must be investigated by long-term field studies or model calculations. In addition, post-registration monitoring can be required by authorities.
- The lab data for the active substance must be generated in at least four soils and in two aquatic systems. The field data must be generated at a minimum of four test sites across Europe. Generally, the data sets are more extensive, and typically also include degradation data from additional EU and non-EU soils (e.g., from North America).
- In addition, the lab or field DT50 values are used for exposure assessments, i.e., Predicted Environmental Concentrations (PEC) in soil, groundwater, surface water and sediment are calculated for the active substance and all major metabolites. The calculations are done with physically based, mechanistic models and the use of predefined realistic worst-case environmental scenarios (e.g., regarding soil and weather conditions) from across Europe. The PEC values fully consider potential accumulation.
- Exposure of non-target organisms to the relevant PEC must not result in an unacceptable risk to those organisms. The risk assessment is based on extensive effect data for a range of aquatic and terrestrial organisms across all trophic levels and uses appropriate safety factors (generally between 10 and 100). Risk assessments are done for the active substances as well as for all major metabolites.
- The results of a comprehensive search of the scientific literature are included in the authorization dossier, and all relevant published data with regard to exposure (including e.g. additional degradation data) and effects of a compound must be considered in the risk assessment. The same is true for monitoring data: All available monitoring must be collected and presented in the authorization dossier.

Guidance documents: available at EU level but often complemented by national guidance on:

- Experimental studies all follow the appropriate OECD guidelines and guidance documents
- Modelling studies follow EFSA guidance documents which also describe the scenarios to be used

Risk management safeguards under Regulation 1107/2009

Following the approval of an active ingredient at EU level, or the authorisation of a product in EU Member States, the Regulation provides several mechanisms allowing for the proper monitoring and rapid reaction of authorities should there be any new concern emerging.

- As stated in **Article 1** the provisions of Regulation 1107/2009 are underpinned by the precautionary principle that ensures substances or products placed on the market do not adversely affect the health of humans, animals or the environment, including situations where scientific uncertainty about risks exists. Further detail is given in the '*Communication from the Commission on the precautionary principle*' of 02.02.2000.
- The evaluation system of AIs already involves numerous actors which increase the overall scrutiny: a Rapporteur Member States conducts the main evaluation in conjunction with the co-Rapporteur Member State. All others Member States as well as the public are able to comment on this evaluation. Then the European Food Safety Authorities will organise a peer review of this work and produce dedicated conclusions. Based on the EFSA Conclusion the EU Commission will recommend approval or non-approval of a substance, based on available risk management options. Such recommendation will finally be voted on by all EU Member States.
- **Article 4(6)** sets out detailed requirements to be met, among others, to avoid unacceptable effects on the environment.
- **Article 6** allows to grant approval with conditions and restrictions to limit the use of plant protection products or to impose risk mitigation measures and monitoring.
- **Article 14** sets maximum periods not exceeding 15 years for approval after which a full review is again required. Under special derogations, a review after a maximum of 5 years is required.
- **Article 21** provides specific measures to review an existing approval **at any time**. A Member State can request such review to the Commission in the light of new scientific and technical knowledge and monitoring data.
- Products containing an authorised active ingredient also need to be approved individually afterwards in each Member States receiving an applicant's product dossier: additional scientific information need to be provided also to satisfy national specific requirements (e.g. NL and water protection; DK and

persistence). Member States can also impose specific exposure mitigation measures or monitoring requirements.

- **Article 24** lays down conditions of a limited approval period if the conditions of a "candidate for substitution" are met, e.g. persistence and toxicity exceeding the relevant threshold levels. Against the context of alternative treatment methods with a more acceptable risk profile, these 'candidates for substitution' may be restricted in use or discontinued entirely. According to Article 50, EU Member States are required to carry out a comparative assessment that weighs up the risks and benefits of uses or entire products. Accordingly, authorisations may be amended or withdrawn.
- **Article 29** sets out requirements to be met for plant protection products in each EU Member State following a review of the active substance contained therein at EU level.
- Under **Article 36** a Member State can refuse authorisation of a plant protection product authorised in another Member State if it considers that the product in question still poses an unacceptable risk to human or animal health or the environment.
- **Under Article 43** a Member State can refuse the renewal of an authorisation after review of an application if certain requirements are not met.
- **A Member State can withdraw an authorisation at any time** if it considers the requirements are not meant anymore or new concerns emerge (**Article 44**).
- Applicants are obliged under **Article 56** to report to EU Member States any new information that suggests the product no longer complies with existing requirements. EU Member States may adopt interim protective measures, amend or withdraw the authorisation to avoid any unexpected effect on the environment.
- Emergency measures are also foreseen (**Article 69**) should immediate EU level action be needed if a substance is likely to constitute a serious risk, and that such risk cannot be contained satisfactorily by means of measures taken by the Member State(s) concerned.
- The European Commission is also empowered to act on its own in cases of extreme urgency (**Article 70**).
- Interim protective measures are also possible at Member State level should a rapid response be needed (**Article 71**).

Further to the elements provided by regulation 1107/2009, the Transparency Regulation 2019/1381 is also adding an extra layer of scrutiny by having the application dossier for an active ingredient made available to the public at the beginning of the evaluation process. Coupled with the public consultations foreseen by this Regulation, the level of access by academics, other regulators and the public to underlying scientific data will reinforce the scrutiny and ensure all external contributions are considered in the scientific evaluation process.

Risk management safeguards under the Water Framework Directive (Directive 2000/60/EC)

The purpose of this Directive is to establish a framework for the protection of different types of surface waters and groundwater to protect and enhance the protection and improvement of the aquatic environment through specific measures for the progressive reduction of discharges, emissions and losses of priority substances as well as the pollution of groundwater.

- **Article4** requires EU Member States to implement the necessary measures to prevent deterioration of the status of all water bodies. With the aim to progressively reduce pollution, emissions from (hazardous) priority substances may be ceased or phased out.
- Under **Article 8** EU Member States shall ensure the establishment of programmes for the monitoring of water status, which distinguishes between point and diffuse sources as stated in **Article 10**.
- **Article 11** describes the 'Programme of measures' in which national control programs have to be developed and regularly be reported to the EU Commission. Causes of pollution have to be assessed and measures taken to control these. Where monitoring or other data indicate reason for concern, EU Member States are required to review permits, adjust monitoring programs and take additional measures to stop deterioration.
- Not all issues may be solved by individual EU Member States (**Article 12**) and may be reported to the EU Commission and any other EU Member State with a recommendation for its resolution.
- The EU Parliament and the EU Council are mandated to adopt specific measures against pollution of water as outlined in **Article 16**. These measures have to be included in the national programmes of measures.
- The EU Commission is regularly updating the list of priority substances, related to **Annex X** of this Directive, to adjust to newly identified threats of pollution, requiring EU Member States to adapt their programmes of measures to these changes.