Für Mensch & Umwelt

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Phasing out animal testing in environmental risk assessment

- A competent authority's perspective

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Where we start from

We support the roadmap. Fewer animal tests are the right goal. Our condition: the level of protection for the environment must stay the same.

Pesticides are a special case. They are **designed to kill** organisms and are **spread on fields** on purpose. Our protection goal is usually the population - only in the acute risk assessment for birds and mammals it is the individual (i.e. no visible mortality).

We have almost no experience with non-animal methods. Today the data requirements prescribe the animal tests, and applicants submit them. Nobody has yet used a non-animal method in a pesticide environmental risk assessment.

A new method cannot be added by changing one document. Data requirements say which data to submit; the Uniform Principles and guidance say how to assess them. All three must change together, otherwise each Member State assesses differently.

Our rule: show the impact on the level of protection first - before you change the rules.

Question 1: which areas to prioritise first?

Area	Our view
Acute fish toxicity	Can start now. Methods exist: fish embryo test, fish cell line, QSAR. Before use: show they predict the fish test, and define when a fish test is still needed.
Bioaccumulation	Non-animal methods are emerging. Same prerequisites as for acute fish toxicity: show predictivity, define when the fish test is still needed.
Chronic fish toxicity	Too early. Many endpoints and modes of action; no method predicts them yet. Unexpected long-term effects are found in long-term studies.
Endocrine disruption	Right direction: extra parameters in existing tests; mechanistic assays as a supplement, not a replacement. Keep hazard-based identification and the link to population effects.
Birds and mammals	Start with acute tests alternatives - their readiness should to be evaluated first. Treat birds and mammals separately: mammal data do not predict effects in birds. Mind that ecologically relevant endpoints have to be derived from the alternatives methods.
Reproduction (fish, birds), higher-tier studies	Too early. Many endpoints and modes of action in reproduction studies.

Question 2: which measures help most?

1 Impact analysis first. For each new method, compare its results with the existing animal test data: how well does it predict, for which substances, with which uncertainty? Example: the fish embryo test uses zebrafish; the acute fish test often uses rainbow trout, which is considered the more sensitive species.

2 Clear triggers. From the impact analysis, define when the new method is enough and when the animal test is still required. Assessors must not decide this case by case.

3 Change the rules as one package. Data requirements, Uniform Principles and guidance together, so that the new method delivers an endpoint (LC50, NOEC) or a defined test strategy that fits the existing assessment. Then train the assessors.

4 Validation against a defined predictivity. OECD validation with a predefined criterion of adequate predictivity, as currently discussed for an endocrine disruptor hazard class under GHS. Register validation studies and publish negative results too.

5 Safe spaces: yes, but outside the authorisation procedure. Confidential pilot submissions help to develop and understand methods. Results relevant for a running assessment cannot be set aside.

Question 3: what is specific to pesticides?

Replacing a test is not the same as waiving it. A replacement gives us a new endpoint to assess. A waiver drops the test because a prediction says it is not needed. Waivers need the same impact analysis, and a test waived today is hard to bring back tomorrow.

Do not shift the decision burden to the Member States. If applicants may replace a test by weight of evidence and each Member State has to judge whether that is acceptable, we get thousands of case-by-case decisions and different outcomes.

 Procedures must not get more complex. The current system is at its limits.

Keep the link to the population. Our assessment goes from effect in the test to effect on the population, increasingly with population models. Mechanistic data alone (activity without adverse effect) cannot feed these models.

Chronic endpoints should be replaced with greatest care. Exposure is intended and repeated every season. Chronic fish, bird and reproduction endpoints are for us no candidates for the short-term basket of the roadmap implementation.

Perspective from the biocides section

The initiative is explicitly supported. However:

Comprehensive validation by an established international organisation (OECD, ISO) is essential, especially for non-testing methods such as QSAR: relevance and reliability must be shown.

Non-animal approaches must deliver an equivalent level of protection; this belongs in the validation process.

Funding of validation work is key and currently a major problem, especially for complex test methods: stronger support for validation initiatives like PEPPER.

Regular exchange on potential new methods in the technical committees of ECHA and EFSA, to confirm regulatory relevance and applicability early.

No artificial pressure: each task needs the time it requires (multi-laboratory validation, transferability to laboratories new to the method).

Live example: the proposed revision of BPR guidance (Vol. IV Part A, adoption planned 2027) already allows the fish embryo test and weight of evidence instead of the acute fish test. It shows how fast data requirements can change - the assessment rules must keep pace!

Take-home messages

1 We support the roadmap; the level of protection is the yardstick for every step.

2 Start with acute fish toxicity, with impact analysis and triggers. Chronic, birds, reproduction: later.

3 Change the data requirements, the Uniform Principles and the guidance documents - together.

4 Replacement is not waiving; do not overload Member States with case-by-case decisions.

5 Keep the link to the population level.

Thank you

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