BRIEFING NOTE
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EU MRL Policy Changes: Why a Comprehensive Impact Assessment Matters

Ensuring that any changes to the EU framework are science-based, proportionate and coherent with food security, trade and competitiveness objectives.

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Executive Summary

Potential changes to the EU Maximum Residue Level (MRL) framework for on-approved active substances could have consequence far beyond residue policy. They may affect consumer confidence, food and feed supply, affordability, farmers' competitiveness innovation, international trade, development objectives and the EU's credibility as a science-based regulator.

For that reason, the European Commission announced it intended to carry out an Impact Assessment, which was broad in scope, evidence-based and cross-sectoral, in line with the EU's Better Regulation [1].

This paper sets out why the assessment must go beyond a narrow competitiveness lens:

- why a narrow or purely competitiveness-driven assessment would be insufficient.
- which impact dimensions must be examined to allow an informed policy choice; and
- why alternative, less trade-distorting policy options should be assessed alongside any proposal to default MRLs to the limit of quantification ("technical zero").

1. Purpose and Scope of this Paper

The purpose of this paper is to contribute constructively to the design of the European Commission's announced Impact Assessment on potential changes to the EU MRL framework affecting substances not approved in the EU.

The paper does not prejudge the outcome of the Impact Assessment. Instead, it highlights why the assessment must:

- reflect the full range of economic, legal, social and international impacts;
- distinguish clearly between hazard-based approval decisions and risk-based residue management; and
- assess whether proposed measures are necessary, proportionate and effective in achieving their stated policy objectives.

2. Policy Context

The Commission's Vision for Agriculture and Food establishes a principle *that the most hazardous pesticides banned in the EU for health and environmental reasons are not allowed back to the EU through imported products*. The Vision explicitly recognises the need for an Impact Assessment to evaluate impacts on:

- EU competitiveness,
- international trade, and
- the broader legal framework.

[1] European Commission (2021) *COMMISSION STAFF WORKING DOCUMENT*

Better Regulation Guidelines

At the same time, discussions around the Food & Feed Safety Omnibus raise concerns that substantive changes to Regulation (EC) No 396/2005 could be advanced before the completion of the announced assessment.

Against this background, the Impact Assessment is not a procedural formality but a central safeguard for evidence-based policymaking.

3. Overarching Principles for the Impact Assessment

A robust assessment should be guided by the following principles:

1. **Science-based decision-making:** Consumer protection under the EU MRL regulation is already ensured through rigorous EFSA risk assessment. Any policy change must be assessed against demonstrable risk reduction, not assumptions.
2. **Proportionality and necessity:** Measures must be shown to be effective and necessary to achieve their intended objectives; those affecting trade and market access must be no more restrictive than necessary to achieve legitimate policy objectives.
3. **Policy coherence:** The assessment must consider consistency with EU objectives on agriculture, trade, food security, innovation and development.
4. **Legal certainty and predictability:** Regulatory stability is essential for farmers, supply chains, innovators and trading partners.

4. Key Impact Areas to Be Assessed

4.1 Consumer Safety and Public Health

MRLs under Regulation (EC) No 396/2005 function as harmonised market access standards. They define the maximum legally permitted residue levels in food and feed placed on the EU market in a way that ensures consumer exposure remains within safe limits. Using MRLs primarily to pursue objectives other than consumer exposure and safety would risk blurring their role and could weaken confidence in the coherence of the EU's regulatory system.

A robust assessment should examine:

- whether existing MRLs for non-approved substances already ensure consumer safety, as confirmed by EFSA.
- whether defaulting MRLs to the LOQ provides any additional, measurable health benefit.
- the implications of replacing risk-based decision-making with a hazard- or policy-driven approach.

4.2 EU Agricultural Competitiveness

MRL policy cannot be a substitute for addressing the underlying causes of EU farmers' competitiveness such as loss of plant protection tools, lack of innovation uptake, climatic pressures, production costs and slow access to alternatives. Competitiveness challenges rooted in internal regulatory asymmetries cannot be resolved through trade-restrictive residue measures.

A robust assessment should analyse:

- whether restricting import MRLs effectively addresses the competitiveness challenges faced by EU farmers.
- the relative contribution of MRL-related measures compared to other drivers, such as:
    - shrinking availability of plant protection tools in the EU.

    - agronomic and climatic constraints.
    - input costs and innovation gaps.
    - regulatory and administrative burden.
- impacts on EU farmers relying on imported feed and raw materials.
- availability of effective alternatives, where relevant.

4.3 Food and Feed Security and Affordability

Even temporary or theoretical restrictions can lead to permanent supply chain shifts, with consequences for food affordability and resilience.

A robust assessment should assess:

- EU import dependency for key commodities (e.g. feed proteins, tropical crops, processing inputs).
- risks of supply disruption, price volatility and reduced availability - also taking seasonal variance into account.
- the asymmetry between immediate market reactions to regulatory signals and the long timelines of assessments, derogations or exceptions.

4.4 Trade and International Relations

MRLs function as market access conditions. Systematic recourse to “technical zero” without risk justification risks being perceived as unjustified barriers to trade.

A robust assessment should evaluate:

- compatibility with WTO SPS and TBT obligations, including necessity, proportionality and non-discrimination.
- risks of dispute settlement, retaliation measures and erosion of trust with trading partners.
- impacts on EU agri-food exports, external market access and any potential spillover effects on EU Free Trade Agreements.

4.5 Innovation and Investment

Regulatory uncertainty and decoupling MRLs from risk assessment discourage long-term R&D investment and widen the competitiveness gap.

A robust assessment should examine:

- effects on incentives to invest in crop protection innovation for EU and global markets.
- interaction with existing barriers under Regulation (EC) No 1107/2009.
- spill-over effects on innovation uptake in exporting countries.

4.6 Regulatory Coherence and Legal Certainty

Regulatory incoherence undermines trust among operators, Member States and international partners.

A robust assessment should analyse:

- the integrity of the long-standing distinction between hazard-based approvals and risk-based MRLs.
- implications for Regulation (EC) No 396/2005 as a predictable, science-based framework.

- assess whether the hazard based LOQ option constitutes a Non Product Related Process and Production Methods (NPR- PPMs) and whether adequate justification, feasibility, and nexus exist[2].
- legal risks associated with conflating food safety, environmental and competitiveness objectives within MRL policy.
- operational risks and feasibility of implementing such a Regulation across the supply chain.

4.7 Impact on Developing Countries and Sustainability Objectives

Unintended external impacts risk contradicting EU development and cooperation objectives.

A robust assessment should assess:

- social and economic impacts on developing-country exporters, with special attention to smallholder farmers, where relevant.
- risks of exclusion from EU markets due to “technical zero” standards which are not realistically achievable considering climatic differences and different pest pressures.
- consistency with EU commitments on Policy Coherence for Development and sustainable value chains.

4.8 Identification of Affected Substances and Transparency of Selection Criteria

Without a clearly defined and transparent scope of affected substances, it will not be possible to meaningfully assess economic, trade, food security or innovation impacts in a robust and quantifiable manner. Early clarity on the substances concerned is also essential for ensuring predictability and allowing stakeholders and trading partners to provide informed input into the Impact Assessment process.

The Impact Assessment should therefore:

- provide a transparent list of the active substances which, in the Commission’s preliminary view, could fall within the envisaged policy change.
- explain in detail the criteria and methodology used to identify these substances, including the interpretation of hazard classifications and their interaction with the MRL framework.
- clarify whether and how substances never approved or not re-submitted in the EU, substances currently under assessment, and substances with existing import tolerances or Codex MRLs are expected to be treated.

5. Assessment of Policy Alternatives

In line with Better Regulation requirements, the Impact Assessment should explore alternatives to across-the-board defaulting to the LOQ, including:

- targeted, risk-based approaches within the existing legal framework.
- enhanced cooperation with Codex and trading partners, not only internal regulatory considerations.

[2] WTO trade rules distinguish between two kinds of import restrictions. The first targets the product itself (measurable residues, contamination, safety standards you can test at the border). The second targets how a product was made, in ways that leave no detectable trace on the product. These are called Non-Product-Related Process and Production Methods.

- measures directly addressing EU farmers' competitiveness (innovation, resilience, access to tools).
- transitional mechanisms that prevent immediate market disruption.

6. Process and Sequencing

The Commission's Better Regulation Toolbox (Tool #15) specifies that impact assessments must be completed before policy proposals are finalised, and that stakeholder consultation must meaningfully inform both problem definition and options analysis.

To preserve credibility and legal robustness:

- the Impact Assessment should be completed and published before any legislative changes are agreed.
- all relevant Commission services should be meaningfully involved.
- stakeholder input, including from trading partners, should be systematically considered.

Advancing legislative changes while the Impact Assessment is ongoing would reverse the proper policy sequence and undermine evidence-based decision-making.

7. Conclusion

Any future change to the EU MRL framework should be grounded in evidence, proportionate to the objective pursued, and aligned with the EU's commitments on consumer safety, food security, competitiveness, trade, innovation and sustainability.

A comprehensive, cross-DG Impact Assessment is therefore not optional but essential. Without it, there is a real risk of unintended consequences for food security, international trade relations and the EU's credibility as a science-based regulator, without delivering tangible benefits for consumer protection or farmer competitiveness.