



CropLife Europe Annual Conference 2024

EU Harmonisation vs National Fragmentation



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EU Harmonization vs National Fragmentation of the Pesticide Framework

The Principle of Subsidiarity:

EU takes actions only if and insofar objective cannot sufficiently achieved by the Member States.

→ EU 1107/2009 a balanced system following the Principle of Subsidiarity:

European Union

- // Uniform **approval criteria** and **data requirements**
- // collaborative and joint **decision making**;
- // EU-wide effective **decisions**;
- // **centralized** active substance **approvals**,
- // **mutual recognition** of product registration,
- // centralized handling of **"issues"**

Member States

- // **Participation** in EU **decision making** and **peer review process**.
- // National **product registrations**
- // Mutual recognition based on **zonal system**
- // **Emergency authorizations**
- // **National enforcement** regarding products and **right to request EU-wide measures**

National Fragmentation → Caused by decisions ignoring the balanced system.

Objectives and purpose of EU 1107/2009 strive for broad Harmonisation

EU 1107/2009 Reasons of Commission's proposal and Recitals

Subsidiarity principle

The subsidiarity principle applies to the exclusive competence of the Community.

The objectives of the proposal cannot be sufficiently achieved by the Member States for the following reason(s).

Action by Member States only could lead to different levels of protection for human and animal health and for the environment. Recommendations or self-regulations would not guarantee a sufficient level of protection of human health or the environment.

It could also risk creating additional burden to industry when different requirements would apply. Competition conditions between farmers would be unequal if availability of plant protection products is very diverse.

Community action will better achieve the objectives of the proposal for the following reason(s):

Only Community action can lead to improvement of the completion of the internal market for plant protection products.

The large difference in authorisation of existing active substances shows that without further harmonisation the protection levels in Member States may vary a lot.



5) To simplify application of the new act and to ensure consistency throughout the Member States, it should take the form of a Regulation.

9) In order to remove as far as possible obstacles to trade in plant protection products existing due to the different levels of protection in the Member States, this Regulation should also lay down harmonised rules for the approval of active substances and the placing on the market of plant protection products, including the rules on the mutual recognition of authorisations and on parallel trade. The purpose of this Regulation is thus to increase the free movement of such products and availability of these products in the Member States.

10) Substances should only be included in plant protection products where it has been demonstrated that they present a clear benefit for plant production and they are not expected to have any harmful effect on human or animal health or any unacceptable effects on the environment. In order to achieve the same level of protection in all Member States, the decision on acceptability or non-acceptability of such substances should be taken at Community level on the basis of harmonised criteria. These criteria should be applied for the first approval of an active substance under this Regulation. For active substances already approved, the criteria should be applied at the time of renewal or review of their approval.

25) In the interest of predictability, efficiency and consistency, criteria, procedures and conditions for the authorisation of plant protection products should be harmonised, account being taken of the general principles of protection of human and animal health and the environment.

29) The principle of mutual recognition is one of the means of ensuring the free movement of goods within the Community. To avoid any duplication of work, to reduce the administrative burden for industry and for Member States and to provide for more harmonised availability of plant protection products, authorisations granted by one Member State should be accepted by other Member States where agricultural, plant health and environmental (including climatic) conditions are comparable. Therefore, the Community should be



Objectives and purpose of EU 1107/2009 strive for broad Harmonization

Key Aspects:

Better Risk Management

// **Common standards** and **harmonized criteria** lead to consistent and high level of protection for **consumers** and the **environment** by avoiding and avoiding different protection levels.

// → food safety, safeguard public health, protecting the environment.

Efficient Processes

// **Centralized system** (single assessment) for the approval of pesticides allows for a more efficient and coordinated evaluation process.

// → Avoids duplication of efforts and resources as well as conflicting assessments.

// → **reliability** for consumers / **predictability** for industry / **workload management** for authorities

Fostering EU Single Market

// Level playing fields for all **farmers** in the EU.

// Free Movement of Goods: Within the single market, pesticides authorized in one member state can generally be sold and used in all others.

// Reduced Trade Barriers caused by different protection levels.

// Fostering **foreign investments** (i.e. SMEs).

// **Preventing competition advantages compromising on safety**.

Safeguarding Political Integration

// The EU has evolved beyond a mere economic union to include **shared political institutions** and decision-making processes demonstrating the Union.



Any benefits from national fragmentation?

Here is what ChatGPT says:

National fragmentation in the EU pesticide regulatory system can be beneficial in certain contexts, particularly when it comes to tailoring regulations to specific national needs and circumstances:

Adaptation to Local Conditions

National fragmentation allows for the **adaptation of pesticide regulations to local conditions** like varying climates, soil types, and agricultural practices, ensuring that the regulations are more effective and relevant.

Cultural and Social Considerations:

National fragmentation can also **account for cultural and social factors that may influence pesticide use** (e.g. placing higher values on organic farming or environmental protection) which can help ensure greater compliance and acceptance among farmers and other stakeholders.

Flexibility in Implementation:

National fragmentation allows for **greater flexibility in the choosing and implementation of regulations, in particular** when dealing with emerging issues or new scientific evidence considering different approaches to risk assessment and risk management.

Experimentation and Innovation:

National fragmentation can also foster experimentation and innovation in pesticide regulation **by adopting different approaches to addressing similar problems** leading to the identification of best practices and innovative solutions that can be shared and adopted more widely.

Political and Administrative Considerations:

Finally, national fragmentation can also **reflect political and administrative realities within the EU** by taking different priorities and capacities into account.

ChatGPT



National Fragmentation of the Pesticide Framework

Does it happen? Only few examples:

National specific requirements, which require the submission of a **national addendum** in that country in addition to the core dossier.

Specific requirements linked to **biodiversity** in Germany, which trigger additional risk mitigation measures for non-target arthropods.

Specific rules on **groundwater metabolites** in some member states.

Export ban re AIs under discussion in Germany, Belgium and France.

Refusal of **mutual recognition** in Germany.

National deviations from **Annex III co-formulants**.

Attempts to **ban Glyphosate** in Austria and Luxembourg.

French **ban of all IRAC class 4 insecticides**

Deviations from the **One Substance One Assessment** approach as well as nationally uncoordinated implementation of **RAC classification proposals**.

Conclusion?

