

Sustainable Pesticide Use in EU - Quo Vadis?

By Lars Huber, Carla Lorenz and Annerie Liebenberg (SCC GmbH)



Dr. Lars Huber
Senior Manager, Team Lead
Biorationals, Biostimulants,
Fertilisers and IPM



Dr. Carla Lorenz
Manager Biorationals,
Biostimulants, Fertilisers
and IPM



Dr. Annerie Liebenberg
Senior Manager
Biorationals, Biostimulants,
Fertilisers and IPM

European farmer protests in 2024 and the subsequent withdrawal of the Sustainable (Pesticide) Use Regulation (SUR) by the EU Commission have sparked intensive discussions on the future of the European Green Deal, pesticide reduction goals, the Farm to Fork (F2F) and Biodiversity strategies, which directly impact the use of both chemical pesticides and biopesticides.

The withdrawal of the SUR has created the impression that sustainability efforts in the EU will come to a standstill or be significantly reduced, worsening the situation for biological crop protection and Integrated Pest Management (IPM). However, the SUR is only one part of the Green Deal that was politically quite easy to renounce, especially since this draft regulation was heavily criticized from the start. SUR was not a focal point of the farmer protests, which were directed more against the EU's Common Agricultural Policy (CAP), already existing administrative workloads, and subsidy cessation.

The EU's CAP, established in 1962, has undergone substantial changes. Initially, it aimed to boost agricultural productivity, stabilize markets, ensure fair incomes for farmers, and provide affordable food through guaranteed prices and import controls. This led to overproduction and various adverse environmental impacts, prompting policy adjustments. Starting in the 1980s, CAP shifted towards direct subsidies and land diversification. The 1990s saw further liberalization, removing market-stabilizing measures. By the 2000s, subsidies were decoupled from production volumes, prioritizing rural development. Recent CAP reforms (2021-2027) with reduced subsidies have pressured farmers' incomes and working conditions, resulting in widespread protests across Europe. Farmers argue that tax breaks on farm diesel, excessive regulations, documentation requirements for CAP payments and unfair competition from non-EU producers put them at a disadvantage.



European farmers have varying interests based on country or region. Large industrial farms benefit from substantial subsidies and support free trade due to their export capabilities. In contrast, smaller farms struggle with bureaucratic, administrative, and regulatory burdens, relying heavily on subsidies and generally opposing free trade agreements.

Intensive analysis of the EU's natural capital has driven CAP's push for greener agriculture through initiatives like the European Green Deal and the Farm to Fork Strategy, aiming to reduce pesticide use and promote sustainable farming practices. For example, the Integrated system for Natural Capital Accounting (INCA) project shows that nearly EUR 3.7 billion of the EU's annual agricultural output is directly attributed to pollinators (COM (2021) 261 final). However, these sustainability measures face resistance from farmers worried about productivity losses and increased costs. Rising energy and fertilizer prices, worsened by geopolitical tensions like the Russia-Ukraine conflict, have further strained farmers' finances. Climate change also presents significant challenges, with more frequent droughts and floods affecting crop yields, adding to the uncertainties faced by farmers.

The evolution of CAP underscores the complex relationship between agricultural policy, market forces, and environmental sustainability. The current dissatisfaction among farmers highlights the need for a more balanced approach that addresses both economic and ecological concerns. The future of CAP will likely continue to evolve in response to both internal and external pressures, shaping the landscape of European agriculture in the years ahead.

Irrespective of future changes to the CAP, the farmers' protests have clearly highlighted the high level of bureaucracy as one of the main weaknesses of European agricultural policy. Various EU Member States have already reacted and initiated programs to reduce the administrative burden for farmers. Additionally, the discussion on the SUR has made

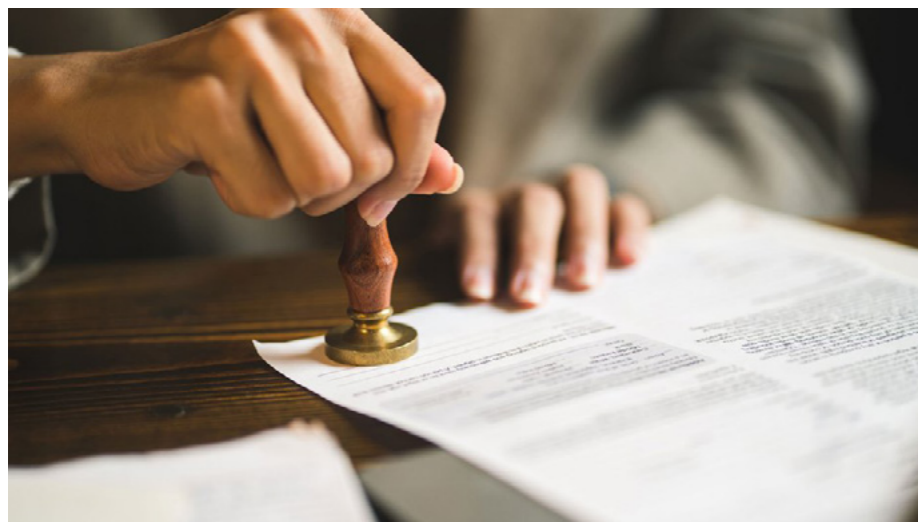


it clear that the administrative and bureaucratic burden also represents considerable barriers in other areas, such as the authorization of plant protection products, especially of biopesticides and low-risk plant protection products, delaying new developments and innovations, and significantly impeding the implementation of the Green Deal.

Considering the registration and market introduction of biopesticides, the administrative workload for applicants and authorities and the resulting long duration of the authorization procedure are among the most criticized issues. Recent experience with the registration of microbial plant protection active substances and products has shown that new data requirements for microorganisms introduced in 2022, while generally a huge improvement, have increased the workload and administrative tasks. The revised data requirements (Part B of Regulations 283/2013 and 284/2013) for the approval of microbial pesticides focus on the biological properties of microorganisms, adopting a "fit-for-purpose" approach. This shift from a box-ticking approach is helpful for microbial pesticide applications, as a single set of rules cannot be applied to different types of microorganisms. However, the flexibility of the data requirements also leaves room for interpretation, potentially leading to unharmonized acceptance or rejection of certain conditional requirements.

Performing extensive literature

searches on the microorganism in question has become essential to gather information on its biological properties and can significantly reduce the number of required studies. For unknown or novel microorganisms, however, available data might be limited, necessitating adapted search criteria to include subspecies or genus-level data. Additionally, two new guidance documents addressing the assessment of secondary metabolites and antimicrobial resistance genes entered into force in 2021 (SANCO/2020/12258 and SANTE/2020/12260). The assessment of possible secondary metabolites involves a stepwise approach, starting with gathering literature information on potential metabolites and their hazards using available literature and whole genome sequencing (WGS) data. Limited strain-level information often necessitates extending searches to species or subspecies levels, leading to unmanageably high volumes of publications, especially for well-researched species. For taxonomically reclassified microorganisms, searches must include multiple species or even genera. Once a list of potential metabolites is set up, further literature searches are needed to determine each metabolite's antimicrobial activity or hazardousness (Mombert et al., 2022). Finding possible secondary metabolites and performing additional searches for each one is labour-intensive, potentially



leading to hundreds of thousands of articles to assess. In 2022, the Plant Protection Product Unit of Spain's National Institute for Agricultural and Food Research and Technology (INIA-CSIC) published their first experience with guidance SANCO/2020/12258 using *Bacillus amyloliquefaciens* and *Beauveria bassiana* as case studies. They concluded that the exhaustive list of metabolites lacked specific information about their synthesis under production conditions or *in situ*, and that additional literature searches for each identified metabolite required a tremendous amount of work (Mombert et al., 2022). WGS data plays a crucial role in both assessments, though it is not a mandatory requirement. The use of genomic data to predict secondary metabolite production has limitations, especially for novel microorganisms with limited information. Screening genomes for secondary metabolite-associated genes is only useful when there is proof of the gene's absence. However, gene presence does not guarantee expression, requiring intensive literature searches to

build scientific arguments for non-relevance, increasing administrative work.

Another example of administrative burden comes from the new Transparency Regulation (Regulation (EU) 2019/1381), published in 2019 and enforced in 2021. It mandates that all studies started after March 27, 2021, and used in EU procedures (including active substance renewals, new active substances, and MRL applications) must be notified to EFSA before their start date. Additionally, the dossier format has changed to IUCLID (International Uniform Chemical Information Database), already used for chemicals (REACH) and biocides, but now also for plant protection. All dossier information, including studies, is made publicly available, with few exceptions. Applicants must redact business-confidential and personal information, providing justifications reviewed by EFSA. These obligations require in-depth knowledge of Regulation 1107/2009 and related legislation, posing challenges for small and medium-sized companies

without the capacity to navigate the complex European legal framework for registration of active substances and plant protection products.

However, the farmer protests and SUR withdrawal have intensified efforts to improve the situation for farmers and applicants registering biological plant protection products. Germany's 'Plant Protection Product Authorization 2030' initiative, for example, aims to modernize the authorization process nationally and at the EU level, prioritizing environmentally friendly alternatives to synthetic chemical products. This initiative looks to improve authorization efficiency, predictability, and communication, and prioritize biological active substance applications through legal amendments. The initiative also suggests reviewing the definitions of plant strengtheners and biostimulants to allow a 'dual use' approach and adapt efficacy assessment criteria for low-risk active substances, considering their importance for organic farming and IPM.

Despite these challenges, ongoing efforts aim to reduce bureaucratic and administrative burdens, enhancing the availability and use of low-risk biological pesticides. This is crucial for the sustainable use of pesticides, reinforcing the necessity of increased availability and use of biological alternatives. The future of European agriculture will likely continue to evolve, responding to both internal and external pressures, shaping its landscape in the years ahead. ^{AP}



REFERENCES

- BVL (Bundesamt für Verbraucherschutz und Lebensmittelsicherheit; 2024): Pflanzenschutzmittel-Zulassung 2030. https://www.bvl.bund.de/SharedDocs/Fachmeldungen/04_pflanzenschutzmittel/2024/2024_07_09_Fa_Zulassung_2030_Abschlussbericht.html.
- COM(2021) 261 final: Report from The Commission to The European Parliament, The Council, The European Economic and Social Committee and The Committee Of The Regions - Progress in the implementation of the EU Pollinators Initiative.
- Mombert, P., Díaz-Otero, P.G., Alonso-Prados, J.L. (2022) Study of the different evaluation areas in the pesticide risk assessment process. Focus on pesticides based on microorganisms EFSA Journal 20(S1) Special Issue: EU-FORA Series 4.
- SANCO/2020/12258 Rev 1 (21 March 2024) Guidance on the risk assessment of metabolites produced by microorganisms used as plant protection active substances in accordance with Art. 77 of Reg. (EC) 1107/2009.
- SANTE/2020/12260 (23 October 2020) Guidance on the approval and low-risk criteria linked to "antimicrobial resistance" applicable to microorganisms used for plant protection in accordance with Reg. (EC) 1107/2009.



Streamlining your regulatory strategy for future market success

FORWARD-THINKING REGULATORY STRATEGIES AND SCIENTIFIC ADVICE FOR:

- Biocontrol solutions
- Basic and low-risk substances
- Biostimulants and fertilisers
- Organic/precision farming and IPM

SCC Scientific Consulting Company
Chemisch-Wissenschaftliche Beratung GmbH
Am Grenzgraben 11 • 55545 Bad Kreuznach • Germany
scc@scc-gmbh.de • www.scc-gmbh.de

