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#### The future of pesticide regulation in the EU – Between precaution and proportionality

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Abstract. The article analyzes current developments in European pesticide regulation. It explains how stricter authorization criteria and recent case law by the European Court of Justice on access to justice of environmental NGOs, emergency authorizations and scientific evidence may contribute to a further decline in the number of authorized plant protection products. It also analyzes the consequences of revocation or non-renewals in agricultural law, food law and civil law and discusses them with regard to fundamental principles of EU law. It calls for more proportionality especially when setting Maximum Residue Levels (MRLs) to avoid economic and enforcement challenges. Clear statutory information obligations for both manufacturers and public advisory services could also help to improve compliance and realize environmental and public health objectives.

Pesticide regulation in the EU is undergoing dynamic change. Whilst the ambitious reduction targets of the Farm to Fork strategy have not been repeated in the European Commission's new Vision for Agriculture and Food, and the proposal for Sustainable Use Regulation has been withdrawn in 2024, various developments may lead to revocations and non-renewals of plant protection products in the coming years. These developments are of particular significance for the wine sector where pesticide intensity and political sensitivites around the issue are very high.

The following paper gives an overview on various relevant issues: It first describes legal developments that contribute to a decline of authorized products, especially three recent ECJ judgements on access to justice, emergency authorizations and standards of evidence (section 1). It then analyzes the consequences of nonrenewals and revocations in agricultural law (section 2), food law (section 3) and civil law (section 4). It discusses them in light of general principles of EU law, namely legal certainty, precaution and proportionality (section 5). It finishes by drawing some tentative conclusions, namely a call for a more nuanced and proportionate regulatory approach as well as better information (section 6).

#### 1. Legal factors contributing to a decline in authorized plant protection products

In recent years, there has been a significant decline in the number of authorized plant protection products in the EU. One of the main reasons for this decline are stricter authorization criteria regarding risks for the environment and human health. This has led to EU-wide bans of various active substances, for example neonicotinoids - including imidacloprid, thiamethoxam and clothianidin - due to their negative effects on bees and other pollinators.

Other important substance classes could follow: In March 2025, a German NGO initiated a complaint againt the authorization of Sulfurfluoryde (ProFume) for being a particularly harmful to the climate. In April 2025, a report by the European Pesticide Action Network Europe (PAN Europe) showed an exponential rise in the levels of trifluoroacetic acid (TFA) in European wine samples. It calls for an immediate ban of pesticides from per- and polyfluoroalkyl (PFAS) substances. These so-called « forever »pesticides have been used in wine production since the 1990s and have come under intense scrutiny for their environmental effects.

Another key factor contributing to the decline in authorizations may be recent case law of the European Court of Justice (ECJ). Landmark rulings concern an expanded access to justice for environmental NGOs, limited possibilities for nations emergency authorizations

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and the duty to consider new scientific findings in authorization procedures.

In a decision from November 8, 2022 (C-873/19), the ECJ ruled that environmental associations are entitled to take legal action against product authorizations under Article 9 (3) of the Aarhus Convention. The decision, which concerned authorizations of motor vehicles, enables environmental associations to take direct action against the approval of plant protection products and has already given rise to a number of such procedures in Germany.

In a decision from January 9, 2023 (C-162/21), the ECJ found that Member States may not grant temporary emergency authorizations for plant protection products that are banned at EU level.

Finally, the ECJ ruling of April 25, 2024 (C-308/22) clarified that authorization decisions must always take into account the most recent scientific evidence. This means that even plant protection products that have already been approved can be re-evaluated as soon as new scientific data reveals potential risks to the environment or health.

This ECJ case law will have a profound impact on the authorization and distribution of plant protection products within the EU. Scientific evidence will gain an even more important role, and legal developments will be more decentralized and dynamic. National and European regulatory authorities must regularly review existing authorizations and adjust them if necessary.

#### 2. Consequences in Agricultural Law: Sell-off and Use-up periods; Public Information

The non-renewal or revocation of active substance authorizations is enacted via Commission Implementing Regulations which may grant certain sell-off and use-up periods within the limits of Art. 20 Regulation (EC) 1107/2009. Sell-off periods may not exceed six months and an additional use-up period of twelve months can granted so that affected products may be used within a total of 18 months after the withdrawal of authorization. The periods are intended to give traders and farmers sufficient time to sell or use up existing stocks before the plant protection product in question finally disappears from the market. However, in cases where the authorization expires for environmental or health protection reasons, the periods can be adjusted or significantly shortened.

Indeed, recent developments show an increasing trend towards shorter transition periods. This means that affected companies have to adapt their strategies at short notice. This affects not only the purchase and storage of plant protection products, but also the planning and the use of alternative products. There is also an increased risk that farmers will unknowingly violate legal regulations if they use products whose use-by date has expired unnoticed.

Public information and advisory services may therefore play an increasingly important role. Farmers depend on reliable and timely information, especially when regulatory changes have a direct impact on the marketability of their products. In its current state, the European framework on public information and advisory services is rather fragmentary. In a ruling from January 27 2021, the Higher Regional Court of Northrine-Westphalia (OLG Hamm, 11 U 37/20) found that no information duties on revoked authorizations exist under European law. However certain duties regarding the provision of correct information may arise from national legislation on plant protection and advisory services

## 3. Consequences Food Law: Maximum Residue Limits, Marketability

Mind the Gap! The link between the non-renewal or revocation of the authorization of an active substance used in pesticides and food law is not automatic. It needs to be established through Maximum Residue Limits (MRLs).

MRLs for pesticides are a key element of EU food and consumer protection policy. As such they are governed by Regulation (EU) 396/2005. In line with the general risk analysis principle, they are based on scientific risk assessment by national risk assessment authorities and the European Food Safety Authority (EFSA). Risk assessment includes toxicological studies, acute and chronic exposure risks, carcinogenic and genotoxic potential and effects on vulnerable population groups.

A central basis for setting maximum residue levels is the so-called ALARA principle ("As Low As Reasonably Achievable"), which stipulates that residue levels should be reduced to the lowest possible level that can be achieved under realistic agricultural conditions. A sufficient safety margin is maintained between the maximum permitted level and a concentration that is actually hazardous to health. This safety margin serves to ensure consumer protection, even if the long-term or cumulative effects of certain residues are not fully known. In fact, most MRLs are calculated with very high safety factors, so that a slight exceedance does not have toxicological relevance.

The setting of MRLs also has a political dimension. The European Commission may for example consider aspects of international trade policy. Despite the efforts to harmonize MRLs in the Codex Alimentarius, MRLs are not uniform in all countries. Differences can lead to trade conflicts and import restrictions.

For not (anymore) authorized pesticides, MRLs are typically reduced to the product-specific limit of determination which represents the lowest value that can be reliably detected analytically (usually 0.05  $\mu g/kg$ ). For active substances whose authorizations are not extended or revoked this often means a drastic reduction compared to the previously legal limit. If no MRL is defined, it is also no longer possible to use analytical dilution factors for the contamination of end products, which can cause severe economic consequences.

Unlike for sell-off and use-up periods, no legal limits apply too changing MRLs in the case of non-renewal or revocation of active substance authorizations. Still, recent practice by the Commission appears to show a shortening of the period between the withdrawal of an authorization and the adjustment of the respective MRLs.

This can create uncertainty, particularly with regard to final or intermediate products that have already been purchased or produced. As a general rule, courts have held that exceeding MRLs leads to a ban on the marketing of the food products (for example: Higher Regional Court of Munich on July 16, 2014 (20 U 4218/13). A proven health risk is not required for food to be considered "unsafe". In fact, exceeding a specified MRLs is generally not directly equivalent to a health risk because of the ALARA principle (see above). Nevertheless, compliance with MRLs is generally considered necessary to strengthen confidence in the safety and quality of food. Consumers expect products on the market to meet the highest safety standards.

Health considerations may play a role when deciding for administrative measures such as withdrawal, recall or specific treatments of products. In cases where there is evidence of human toxicity of residues, an order to destruct products can be proportionate. In cases where there is no proven health risk, authorities may resort to milder measures such as re-declaration, processing under stricter conditions or export to countries with different limits.

A notable current example is the MRL of *dimetopmorph*, an active ingredient contained in various fungicides against Peronospora in grape and hops production (eg. Orvego, Forum and Forum Gold). After repeated extensions, it was decided in Commission Implementing Regulation (EU) 2024/1207 of 29 April 2024 that the authorization would not be renewed and all affected approvals had to be revoked by November 20, 2024. The Commission is now in the process of setting an MRL and has consulted EFSA for a risk assessment. A decision is expected by the end of this year. An immediate reduction of the MRL, however, may lead to the non-marketability of hops pellets and derived products that could otherwise be used or consumed for several years. Stakeholders like the Brewers of Europe are therefore trying to intervene in the process with evidence that dimetomorph residues in beer do not cause risks for human health.

# 4. Consequences in Civil law – information duties and liability

Revocations and renewals can also lead to complex legal challenges in civil law. Whilst manufacturers and distributors are aware of the end of an authorization and their own activities in that respect (eg. submitting sufficient evidence for renewal), this is not the case for farmers and other customers, who bear the economic consequences of non-marketability. This raises the question, if manufacturers of plant protection products are obliged to inform about the (foreseeable) end of an authorization.

In EU Plant Protection Law, there is no explicit legal requirement to indicate the duration of the authorization on the packaging or in the description. In particular, such an obligation does not arise from Art. 66 of Regulation (EC) No. 1107/2009, which only obliges manufacturers and distributors to ensure that advertising for plant protection products is not misleading and does not contain inaccurate information about safety or efficacy. As a general rule, farmers or dealers must therefore inform themselves

independently about the authorization period, for example by consulting publicly accessible registers or by consulting the manufacturer or the competent authority.

Only in cases, where the seller of a product is aware of an imminent termination of the authorization but does not inform the buyer, liability may be based on general civil law principle of *culpa in contrahendo* or tort law.

Some further information obligations may however be derived from general civil law principles of « producer liability ». According to these principles, manufacturers bear a special responsibility for the safety and marketability of their products. This not only includes obligations regarding the careful development and manufacturing of a product, but also extends to the subsequent monitoring of risks that arise over time as a result of scientific findings or regulatory changes. The manufacturer has to ensure that its product not only complies with the applicable safety and legal standards when it is launched on the market, but also that possible new risks or legal changes affecting the usability of the product are taken into account throughout its service life. If a product that was originally legally approved may no longer be used, producer liability can require a timely and comprehensive warning to ensure that users can adapt to the new circumstances. In this sense, pesticide manufacturers could be obliged to inform customers about an (upcoming) reduction of MRLs.

Case law also sets high standards for the practical fulfillment of these warning obligations. It is not sufficient that legal changes are published in official publications. Rather, the manufacturer itself must ensure that all potentially affected users are informed of the new legal situation and can adapt their application practices.

These general principles of civil law may help to provide equitable solutions in individual cases. However, *de lege ferenda*, a statutory labelling obligation could be help to avoid uncertainty and proactively avoid incompliances. Digital labelling, for example, could be used to allow for up-to-date information on the authorization period and possible upcoming restrictions due to new scientific data, ongoing revocation or renewal procedures.

## 5. Legitimate expectations, precaution and proportionality

Given the far-reaching consequences of authorization revocations or non-renewals for the entire food chain, it seems important to also consider fundamental principles of European Law. These principles apply to legislation, administration and judicial enforcement in all legal areas. In particular, the protection of legitimate expectations, the precautionary princple and proportionality seem to be at stake and need to be reconciled.

The protection of legitimate expectations is derived from the overriding principle of legal certainty as a central element of the rule of law. It protects citizens and companies from unexpected legal changes and thus ensures a balanced consideration of individual and social interests and planning security. Of course, the principle of the protection of legitimate expectations is not absolute. The legislator can amend existing legal norms for objective reasons, in particular if a new regulation is necessary in the public interest. In these cases, the trust of those affected is weighed against the general interest. The stronger the trust of an individual in an existing regulation, the more weighty the reasons for a retroactive or short-term change to the legal situation must be. Consequences can be mitigated, for example via appropriate transitional periods.

The protection of legitimate expectations is particularly important in areas where legal requirements may change at short notice or official measures have a direct impact on the concerned stakeholders. In principle, this applies also to the agricultural and food sector.

Especially in food law, however, a tension exists with the precautionary principle that aims to prioritize the protection of human health and minimize potential risks as early as possible. The precautionary principle is a basis for following the ALARA principle in setting MRLs. It tends to favours a zero tolerance approach, as even the smallest quantities of an inadequately assessed active substance could pose an incalculable risk. The MRL regulation therefore does not foresee any transitional periods.

This strict approach can lead to practical consequences that seem incompatible with the principle of proportionality, for example when farmers and processors cannot market their products, even though no illegal substances where used in their production. Such situations also seem undesirable from an environmental point of view. They lead to a waste of food products without a clear benefit for public health. Food control authorities, however, can hardly correct such inequities in their individual decisions.

Given the increasing relevance of authorization nonrenewals and revocations, it may therefore be up to the European regulator to look at the entire process, distinguish between the various intendend and unintended consequences of individual acts and ensure proportionality in the interest of all stakeholders.

For example, some recent examples show that the European Commission reduced at the same time

- the time between a decision of not renewing an authorization and its entry into force
- the sell-off and use-up period for the concerned products
- the time between the end of the use-up period and the reduction of the respective MRL

even in cases where the non-renewal of an active substance authorization was based on insufficient data, and not a proven health risk.

Such a practice may create significant economic and administrative challenges for actors in the food chain as well as a high risk for non-compliance. At the same time, it may not yield any commensurate benefits for the environment or public health.

#### 6. Conclusions

Reducing toxic pesticides is an integral part of the transformation of agrifood systems. For better or worse, the European Commission has abolished the ambitious but contentious project of a Sustainable Use Regulation. Scientific and societal pressure, however, remains high.

Our analysis has shown, that recent ECJ decisions may lead to a more decentralised and bottom-up process. This may allow for a broader activation of knowledge and avoids certain political challenges. However, it also causes practical challenges that result from legal incongruencies. It can lead to arbitrary economic damages, unnecessary frictions and non-compliances.

Proportionality cannot easily be realized by individual administrators that operate within the existing legal framework. It has to be realized on the systems level. More generous transitional periods, especially for MRLs, could provide an easy solution that would not usually compromise environmental or public health goals. Additionally, more stringent information obligations for public and private actors could favor compliance. Digital labelling could enable practicable solutions. Such a « soft » approach would be in line with EU's new Vision for Agriculture and Food (COM(2025) 75 final), that emphasizes stable rules and economic opportunities for all actors in the food system

Overall, of course, the banning of individual active substances, will not be enough to protect ecosystems and humans. Scientists widely agree that a holistic approach is needed that combines different goals and reduces their trade-offs with food security and economic viability (Finger et al. 2024). It requires increased investment into R&D of effective and efficient alternatives to current pesticides, as well as suitable conditions for alternative plant protection and agroecological practices.

From a legal point of view, greater flexibility might be more important than stricter rules. For example, regulatory sandboxes could be introduced into the frameworks for plant protection, organic production and agricultural data. Despite its current challenges, the wine sector with its high-level of know-how and integration could offer an ideal laboratory for such approaches.