



Policy Recommendations



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NeoGiANT Policy Recommendations

The regulatory landscape surrounding agro-industrial by-products, such as grape marc, presents a complex interplay of challenges and opportunities across Europe. While some regions report minimal restrictions, the overarching EU regulatory framework imposes significant burdens, particularly regarding authorization procedures for feed additives. These stringent requirements affect not only the pace of innovation but also market accessibility and the economic feasibility of sustainable solutions. Stakeholders across various sectors highlight inconsistencies, inefficiencies, and the urgent need for reform to support the development of novel and environmentally friendly products.

Regulatory Barriers to Agro-Industrial By-Product Utilization

One of the foremost obstacles confronting the sector is the rigorous authorization process required for feed additives under EU regulations, including Regulation (EC) No 178/2002 on food and feed safety and Regulation (EC) No 1831/2003 on feed additives. These frameworks mandate extensive safety and efficacy trials, resulting in prohibitive financial and time costs that deter smaller companies from pursuing innovation. Freie Universität Berlin (FUB) has noted the immense difficulty in securing capital for large-scale authorization trials, a challenge exacerbated by an unpredictable European market. Similarly, LifeBioEncapsulation SL (LBE) emphasizes that the cost of authorization, often exceeding €1.1 million per application, coupled with prolonged approval timelines, places undue strain on companies striving to introduce sustainable alternatives.

Variability in national regulations further compounds the issue. In Hungary, Magyar Agrár- és Élettudományi Egyetem (MATE) reports that grape marc is not classified as hazardous waste, easing regulatory burdens yet presenting challenges in maintaining product consistency due to seasonal variations. Meanwhile, MAGAPOR

SL (MAGA) highlights a regulatory paradox in which plant extracts are controlled in porcine feed but remain unregulated in semen extenders, creating a landscape of uncertainty. Additional constraints arise in Belgium, where ANITOM (ATM) identifies extra compliance requirements, including stringent hygiene, traceability, and multilingual labeling standards. Nutrition Sciences N.V. (NUS) underscores the complications stemming from European legislation's "positive list" approach, which mandates European Food Safety Authority (EFSA) registration and delays the market entry of innovative products. Similarly, CZ Veterinaria SA (CZV) notes the added layer of regulatory oversight required for veterinary medicines, necessitating compliance with both national and European frameworks.

A critical concern is that current regulatory classifications for feed additives do not adequately accommodate novel products. While a dry grape extract from *Vitis vinifera* has been authorized as a sensory additive, other grape-derived feed additives have yet to receive approval under different categories. LBE proposes a shift in approach, advocating for a streamlined authorization process that allows existing scientific literature and in vitro studies to replace costly and time-consuming in vivo trials where safety concerns are minimal. This aligns with the principles of the 3Rs (Replacement, Reduction, and Refinement of animal testing). Additionally, the creation of new functional groups, such as an "other zootechnical additives" category, could facilitate the introduction of innovative feed additives that currently fall outside existing classifications.

Regulatory Challenges in Implementing Sustainable Animal Welfare Solutions

Beyond feed additives, regulatory barriers also hinder the development and adoption of sustainable animal welfare solutions. The process of bringing antibiotic-free treatments and innovative formulations to market is fraught with

delays and financial burdens. FUB highlights the disproportionate impact of lengthy approval timelines and high costs on smaller enterprises. A particularly contentious issue is the continued requirement for antibiotics in cryopreserved sperm doses under Commission Delegated Regulation (EU) 2020/686. Although MAGA acknowledges recent regulatory amendments that render antibiotic use optional, encouraging alternative solutions, full-scale implementation remains challenging.

Regulatory complexity in classifying animal health products creates additional roadblocks. In Hungary, MATE describes a fragmented legal landscape in which products may be classified as medicines, pharmaceuticals, or food supplements, each carrying distinct regulatory requirements. ATM identifies a further gap—the absence of a centralized system for recording animal welfare parameters—complicating efforts to establish regulatory claims for welfare improvements. Meanwhile, NUS points to EFSA's extensive dossier requirements as a deterrent to introducing natural and sustainable solutions. In the Czech Republic, VRI notes that a recent update to the Act on Medicinal Products (314/2022) now mandates at least 30 years of documented customary use for certain products to qualify for exemptions, further constraining market entry for innovative alternatives.

To address these challenges, stakeholders call for greater harmonization of international standards to reduce compliance burdens and streamline approval pathways. Expedited regulatory procedures for proven natural solutions, such as antimicrobial compounds derived from food by-products like grape marc, would enable quicker market access while maintaining rigorous safety assessments. Clearer classification frameworks distinguishing "natural antimicrobials" from traditional antibiotics would further support this objective.

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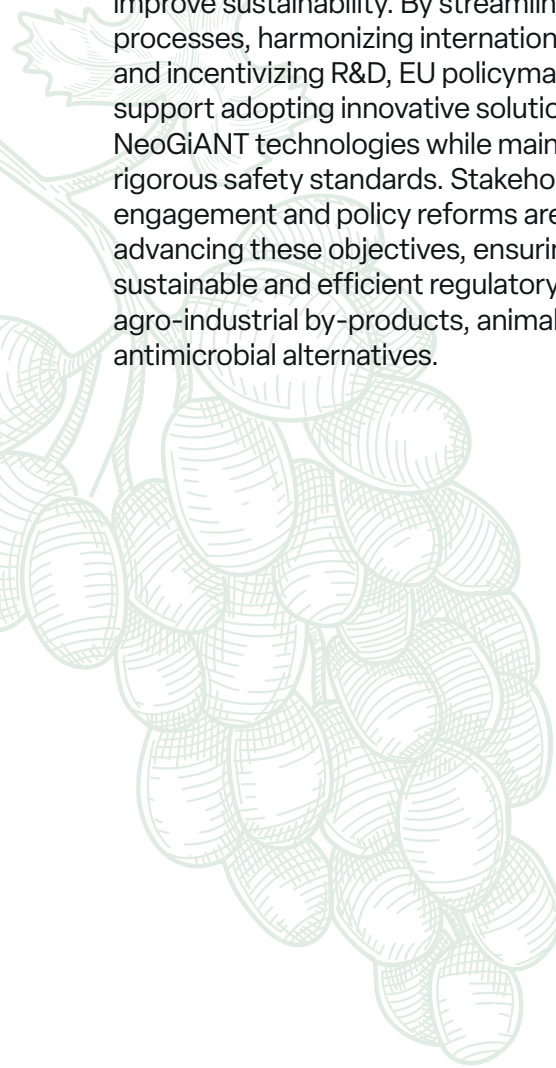
1. Streamline the authorization process: Accept existing scientific literature and in vitro studies to reduce reliance on costly in vivo trials.
2. Expand regulatory categories: Introduce new functional groups within the feed additive framework.
3. Improve market access for small-scale applications: Reduce authorization costs for niche markets (e.g., minor aquaculture species).
4. Facilitate antibiotic-free innovation: Align EU regulations with recent shifts allowing antibiotic-free sperm doses.
5. Create a centralized animal welfare measurement system: Standardize welfare parameters across Europe.
6. Simplify EFSA dossier process: Reduce documentation and expedite approval for proven natural additives.
7. Clarify classification frameworks: Define clear regulatory pathways for natural alternatives, particularly herbal medicines.
8. Create streamlined pathways for natural antimicrobials: Establish fast-track approvals for compounds with established safety profiles.
9. Harmonize global policies: Coordinate international standards to improve market access and enforcement.
10. Reduce regulatory burdens for antimicrobial alternatives: Differentiate natural antimicrobials from traditional antibiotics.
11. Provide economic incentives: Grants, tax credits, and public funding to support antimicrobial innovation.
12. Enhance regulatory harmonization: Establish consistent standards across EU member states.
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Conclusion and Next Steps

This policy document highlights key regulatory challenges and offers practical recommendations to enhance market access, foster innovation, and improve sustainability. By streamlining approval processes, harmonizing international standards, and incentivizing R&D, EU policymakers can better support adopting innovative solutions like NeoGiANT technologies while maintaining rigorous safety standards. Stakeholder engagement and policy reforms are critical to advancing these objectives, ensuring a more sustainable and efficient regulatory landscape for agro-industrial by-products, animal welfare, and antimicrobial alternatives.





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