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Evaluating the Importance of Fludioxonil in Europe: A Determination of Essential Uses as Seed Treatment in Key Crops

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Abstract

BACKGROUND: Broad-spectrum fungicides play a critical role in integrated pest management (IPM) and sustainable agriculture, particularly under intensifying pathogen pressures in Europe driven by climate variability, global trade, and evolving pathogen populations. Regulatory constraints, including the withdrawal of multiple active substances, have created gaps in disease control. Under Article 4(7) of No. 1107/2009, derogations for Essential Use of fungicides are permitted when there is a lack of effective chemical or non-chemical alternatives. Fludioxonil has been widely used for over 25 years for seed treatment and its importance in Europe was evaluated in this study. RESULTS: Across 23 EU Member States, 64 crop–pathogen combinations were identified where fludioxonil seed treatments are essential, particularly for cereals, potatoes, legumes, sunflowers and additionally in various minor crops. Two representative case studies illustrate its critical role: control of *Microdochium nivale* in cereals in France and of *Plenodomus lingam* in Brassicaceae in the Netherlands. In both cases, alternative fungicides are either unavailable or insufficiently effective, and non-chemical methods cannot reliably prevent disease. Resistance risk assessments indicate low to moderate potential for resistance development, supporting fludioxonil's long-term use.CONCLUSIONS: Fludioxonil meets the stringent criteria for Essential Use, providing the only reliable seed-applied protection for numerous European crops. Withdrawal would create significant gaps in plant protection, threaten crop establishment and yield, and disrupt seed production and supply chains. Maintaining access to fludioxonil under Essential Use provisions is critical to sustaining crop protection, supporting IPM, and ensuring food security across Europe and beyond.

Keywords: Seed treatment; essential use derogation; fungicide resistance; crop protection

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1. Introduction

Broad-spectrum fungicides that can protect against a range of diseases in multiple crop types are essential for integrated pest management (IPM) and sustainable food production. In Europe, the crop production sector faces intensifying pathogen pressures driven by climate variability, globalized trade, and rapidly evolving pathogen populations. At the same time, the regulatory environment has tightened, leading to the withdrawal of many active substances1 and leaving significant gaps in disease control strategies. Within the context of approval of active substances in the European Union under Regulation (EC) 1107/2009 [2], data can be submitted regarding the necessity to control a danger to plant health which cannot be contained by other available means, including non-chemical methods, in accordance with Article 4(7).

The European Food Safety Authority (EFSA) protocol [3] - for the evaluation of data supporting the necessity of the application of fungicide active substances to control a serious danger to plant health within the context of Article 4(7) of Regulation (EC) No. 1107/20092 - was developed following a mandate from the European Commission. The protocol provides a clear methodology for this kind of evaluation. The data are assessed on a case-by-case basis for specific country–crop–pathogen combinations, considering the availability of both chemical and non-chemical alternatives, the risk of the pathogen developing resistance, and the sustainability of proposed control strategies. Derogations can be granted only when fungicides are indispensable for the specific crop-pathogen combination, thereby aligning regulatory oversight with the principles of IPM and sustainable agriculture [3].

Fludioxonil, a synthetic phenylpyrrole fungicide derived from the naturally occurring antifungal metabolite pyrrolnitrin [4], has been registered for more than 25 years and is a cornerstone of crop protection [5]. It is active against a wide spectrum of fungal diseases belonging to the Ascomycete, Basidiomycete, and Deuteromycete taxonomic classes, and is particularly effective against economically important pathogens such as *Fusarium* spp., *Botrytis cinerea*, *Rhizoctonia* spp., *Alternaria* spp. and *Sclerotinia* spp. Globally, fludioxonil is approved for use on over 900 agricultural commodities and features in more than 30 commercial formulations [6]. In Europe, its registrations cover foliar, seed applied, and post-harvest treatments across cereals, fruits, vegetables, ornamentals, turf, and numerous other crops [5].

Seed treatments in particular highlight the importance of fludioxonil in modern agriculture. By protecting plants from infection at the earliest growth stages, seed-applied fungicides reduce the need for early-season foliar sprays and thereby lower the overall pesticide load in the environment. Fludioxonil's proven efficacy and compatibility with other seed treatment active substances make it a standard component in many integrated seed applied solutions, where it provides protection against both soil-borne and seed-borne pathogens.

Fludioxonil is unique within its Fungicide Resistance Action Committee (FRAC) classification as the only commercially available member of the phenylpyrrole group (FRAC group E2, code 12)7. Its non-systemic, contact activity makes it highly compatible with other seed treatments and an important resistance management tool. Fludioxonil disrupts fungal osmotic signal transduction through inhibition of group III histidine kinases in the high-osmolarity glycerol (HOG) pathway, leading to hyperaccumulation of glycerol, hyphal swelling, inhibition of spore germination and mycelial growth [5,8]. Resistance to fludioxonil, although documented, remains rare and is generally linked to point mutations in hybrid histidine kinase genes, such as *NikA* in *Botrytis cinerea* and *Alternaria* species [5,9]. This low resistance frequency reinforces its value as a long-term partner in IPM strategies. This paper examines the essential uses of fludioxonil as a seed treatment within the EFSA regulatory framework and presents two representative case studies that demonstrate its continuing relevance in safeguarding European agriculture against evolving pathogen threats.

2. Materials and Methods

2.1. Essential Use Evaluation Framework

This study applied the EFSA protocol[3] for assessing the necessity of fungicidal active substances in line with Article 4(7) of Regulation (EC) No. 1107/2009 [2]. Under this framework, a derogation for an essential use is only scientifically supported if:

1. no effective non-fungicidal alternatives (e.g., resistant varieties, biological control, or cultural practices) are available; and
2. no other active substance with the same mode of action (MoA) can adequately control the crop–pathogen combination under consideration.

The EFSA protocol is consistent with international standards from the European and Mediterranean Plant Protection Organisation (EPPO) [10] and has been reviewed by EU Member States including Austria, Belgium, Bulgaria, Croatia, Cyprus, Czechia, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain and Sweden.

2.2. Data Sources

Data sources consisted of literature, including peer-reviewed publications, regulatory dossiers, the Homologa database [11], EU Member State authorisation databases where available and Fungicide Resistance Action Committee (FRAC) guidelines [12].

2.3. Workflow for Essential Use Evaluation

The evaluation followed the EFSA Guidance Protocol for assessing the necessity of fungicide active substances[3], supported by FRAC resistance classification and registration data. The workflow comprised four main stages:

Stage 1: Selection of Crop–Pathogen Combinations

Registered uses of fludioxonil were reviewed to identify cases where no, or very few, alternative active ingredients, either chemical or biological, are available. For each case, the product name, target pathogen (including synonyms), crop(s) (with EPPO codes), and countries of registration were recorded. Pathogen life cycles were analysed to determine the infection stage targeted by fludioxonil, and potential impacts of withdrawal were considered for the EU.

Stage 2: Availability of Alternatives

Availability of seed applied alternatives was evaluated following EFSA's decision flow diagram. This included:

- **Chemical controls:** active ingredients with different Modes of Action (MoA), identified via the FRAC Code List 2024 [12].
- **Biological controls:** commercial biocontrol agents and "basic substances" registered against the relevant crop–pathogen combinations.
- **Non-chemical methods:** agronomic measures such as crop rotation, resistant varieties, seed disinfection (thermal, UV, steam treatment), and cultural practices.

Each alternative was scored on a scale of 0–3 for availability, effectiveness, adoption in practice, and feasibility, according to EFSA criteria.

Stage 3: Resistance Risk Assessment

Resistance risk was quantified for seed applied use, using the z/x ratio:

- z = resistance risk of pathogen (FRAC Pathogen List, 2019 [12]).

Interpretation: $z/x > 1.25$ indicated strong scientific support for derogation; $0.75 \leq z/x \leq 1.25$ indicated potential support. Where no alternative MoAs existed, the calculation was not applied.

- x = resistance risk of active substance (FRAC classification [12] using weighted sum for multiple MoAs).

Stage 4: Data Compilation and Conclusion

For each crop–pathogen combination, two outputs were generated:

1. A narrative summary justifying the continued use of fludioxonil.
2. Structured dataset of registrations, resistance ratings, alternative products, and non-chemical control scores.

These outputs formed the evidence base for concluding on the necessity of fludioxonil in specific seed treatment uses under the EFSA protocol.

2.4. Case Studies

Two case studies were selected to demonstrate the Essential Use process and to exemplify the critical importance of fludioxonil in controlling key diseases in major European crops. The case studies selected were (i) control of *Microdochium nivale* in cereals in France, and (ii) control of *Plenodomus lingam* in brassica crops in the Netherlands. These examples provide contrasting diseases and crop types, both of significance in this region.

3. Results

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3.1. Crop–Pathogen–Country Combinations Reliant on Fludioxonil

A total of 64 crop–pathogen unique combinations were identified across 23 EU Member States where fludioxonil is currently registered as a seed treatment and was determined to represent an Essential Use (Table 1). These Essential Uses span major crops such as cereals, potatoes and legumes, as well as minor crops where no alternative fungicide options are currently available. Table 1 represents crop-pathogen combinations for which derogations are supported according to the EFSA protocol. The highest number of Essential Uses were observed in Italy (37 Essential Uses), France (31 Essential Uses), and the Netherlands (26 Essential Uses). In terms of crops, fludioxonil treatments are most frequently classed as Essential to cereals (142 Essential Uses), followed by potatoes and legumes (25 Essential Uses each), and sunflowers (24 Essential Uses). Among the 24 target pathogens, the greatest number of Essential Uses were identified for *Fusarium* spp. (67 Essential Uses), *Rhizoctonia* spp. (38 Essential Uses), and *Alternaria* spp. (25 Essential Uses).

3.2. Case Study: Essential use Of Fludioxonil for the Control of Microdochium Nivale in Cereals in France

This case study evaluated the necessity of fludioxonil in France for controlling pink snow mould across a range of cereal crops, including wheat, barley, oats, triticale and rye. CELEST NET (25 g/l fludioxonil), also known as CELEST 025FS or MAXIM 025FS in other countries, is a flowable suspension for seed treatment, authorized for use on many cereals and controlling early infection across a wide range of fungal seedling diseases.

Pink snow mould is caused by *Microdochium nivale* (synonyms *Fusarium nivale*, *Gerlachia nivalis*). *Microdochium nivale* designates the anamorph (asexual stage) of the organism formerly known as *Fusarium nivale* and *Gerlachia nivalis*. The teleomorph (sexual state) of *Microdochium nivale* is *Monographella nivalis* (synonyms *Calonectria nivalis and Micronectriella nivalis*).

Pink snow mould resulting from *M. nivale* infection is one of the most serious diseases of winter cereals in temperate and cold climatic zones [13]. It was previously thought to be a disease that affected cereals only in those regions where plants were affected by prolonged (>100 days) snow cover. However, today *Microdochium* species are seen as facultative snow mould pathogens that can also develop during the whole growing season of host plants [14] and produce symptoms of seedling blight, foot rot, leaf blight, and head blight.

The disease is common and problematic in northern European areas where prolonged periods of wet, cool weather occur from autumn to middle or late spring and early summer. Areas where the pathogen is frequently encountered typically comprise countries from Scandinavia, the Baltics, Poland, Czech Republic, Germany, Austria, and France. In other central European countries, it may occur but is less common. Wheat and some turf grasses are the main economic hosts, although these fungi have been reported on a wide range of cereals and grasses.

Snow moulds are most apparent in early spring when the snow first melts. Infested plants often have an extensive covering of white mycelium which spreads on overlapping leaves, causing a matting of leaf tissue. Later, as spores are produced on the mycelial mats, the affected patches assume a pink colouration. The fungus often infects the oldest leaves directly from the soil, but eventually the whole plant can be affected. Plants die-off in patches, but good growing conditions in the spring can allow crop recovery where plants have survived infection. In years with prolonged snow cover, the disease can be severe.

M. nivale usually survives as conidia or mycelium on living plants, and it can maintain itself as a crown and root rotting fungus. When *M. nivale* spores germinate, they invade plant tissue. Older leaves in contact with soil under snow are attacked first. Crowns may be invaded later. The fungi continue to develop under the snow and eventually produce conidia or sclerotia. The snow mould pathogens are most aggressive at low temperature that is, slightly above freezing. Early snowfall and deep, prolonged snow cover on unfrozen ground favour the disease. As *M. nivale* does not produce chlamydospores or sclerotia, soil-borne saprophytic mycelium on infested straw is central to the life cycle. Later in the growing season, air-borne inoculum (conidia or ascospores) can infect ears and results in ear blight and the development of seed-borne inoculum.

Seed-borne inoculum is the predominant source of *M. nivale* inoculum. Seed severely infested by *M. nivale* may be small and shrivelled and is associated with reduced germination and reduced emergence of seedlings. *M. nivale* can cause reduction in seedling emergence of up to 70%. In general, plant vigour may be markedly reduced, and in severe cases, the crowns are killed. Surviving plants recover slowly and are sensitive to additional stresses. Resulting yield reduction may reach 15 to 25%. The potential risk that *M. nivale* develops resistance towards fungicides is classified as low to medium by FRAC.

3.2.1. Evaluation of Alternatives

There is no practical/established and durable non-fungicide effective programme to manage *Microdochium nivale* seedling infection from seed or soil. Cultural control methods (such as crop rotation, intercropping, sowing / harvesting dates, fertilizers, soil tillage, biofumigation, raised beds, organic matter management) have no significant effect on the control of *M. nivale* in winter cereals and there are no winter cereals cultivars officially claimed to be resistant or tolerant. The biological agents *Pseudomonas chlororaphis* MA342 and *Bacillus amyloliquefaciens* subsp. *plantarum* D747 are available to be used on wheat, barley and rye, however their efficacy is not comparable to products containing fludioxonil and therefore could not be considered as suitable alternatives. Hot steam or radiation seed treatments were considered to have limited effectiveness and are therefore not suitable short or mid-term alternatives to a chemical seed treatment. Other physical methods and natural products were considered to not be relevant for the control of *M. nivale* and no effective resistance inducers are known.

Fludioxonil belongs to FRAC group E2, code 12. Fenpiclonil is the only other active substance belonging to this group. However, fenpiclonil is no longer registered in EU, and in practice was superseded by fludioxonil many years ago and is therefore not an alternative. Resistance in this mode of action group is found only sporadically, and therefore, the potential risk of resistance development is estimated as low to medium (FRAC Code list 2024 [12]. Pathogens reported having developed resistance to fludioxonil in isolates from the field are *Botrytis cinerea, Microdochium nivale*, *Penicillium* spp. and *Helminthosporium solani*. In France, five other MoA are registered for *Microdochium nivale* control on cereals, all of which have been taken into consideration for this calculation. These include Succinate dehydrogenase inhibitors (SDHIs; FRAC code C2/7), Quinine outside Inhibitors (QoIs; FRAC code C3/11), Thiophene-carboxamides (FRAC code C7/38), Anilino-Pyrimides (FRAC D1/9) and DeMethylation Inhibitors (DMIs ; FRAC code G1/3), all of which have been included in this calculation.

3.2.2. Resistance Risk Assessment

Table 2 shows registered alternative active substances for the control of *M. nivale*, their FRAC codes, resistance risk ratings, calculated x values (risk associated with alternatives), and calculated z/x ratios (pathogen resistance relative to available alternatives) for wheat, triticale, barley, oats, and rye. z/x values above 0.75 indicate potential support for fludioxonil essential use under the EFSA protocol. The table reflects the fact that alternative fungicides with different modes of action registered against wheat, triticale, barley, oats and rye are either only available in co-formulation with fludioxonil or have limited efficacy against *Microdochium nivale*. The x values were 1.75 for wheat, 1.25 for barley, 1.25 for oat and 1.75 for rye. FRAC classifies *Microdochium nivale* with a medium risk of developing resistance and the z value to be used was therefore 2. The calculated z/x values were 1.14 for wheat and triticale, 1.6 for barley and oat and 1.14 for rye. Since these z/x values exceed the 0.75 threshold, a derogation for the control of *Microdochium nivale* on cereals is supported, in accordance with the EFSA process.

3.3. Case Study: Essential Use of Fludioxonil for the control of Plenodomus Lingam in Brassicaceae Family, in the Netherlands

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This case study evaluates the necessity of fludioxonil in the Netherlands for controlling *Plenodomus lingam* (black leg/phoma leaf spot/phoma stem canker) across a range of crops belonging to the Brassicaceae family, including cabbage, brussels sprouts, cauliflower, broccoli, Chinese cabbage, kale, kohlrabi, swede, and radish. The fungicide MAXIM 480FS (480 g/l fludioxonil) is authorised for use on many vegetable crops as a seed treatment to control early infections caused by a broad-spectrum of fungal pathogens, including *P. lingam*.

Plenodomus lingam (synonyms *Leptosphaeria maculans*, *Phoma lingam* and *Pleospora maculans*) is an aggressive Ascomycete pathogen in a species complex with *P. biglobosa* [15,16]. The pathogen is primarily seed-borne, although airborne ascospores from oilseed rape debris can also be an important source of inoculum, particularly within 1 km of brassica production areas [17]. Studies have also suggested that inoculum can be soilborne [18]. The disease cycle begins with leaf infection through stomata or wounds, followed by the spread of the pathogen into stems, leading to cankers known as blackleg [19]. Infected seedlings often die or fail to mature, and crucially, even seed lots carrying less than 0.1% infection can initiate widespread outbreaks [20].

In vegetable brassicas, *P. lingam* can cause severe damage, particularly in cauliflower and swede, whereas crops such as Brussels sprouts and cabbages often show only minor leaf blemishes, though symptomless spread complicates disease management [21]. Leaf symptoms typically appear from the cotyledon stage onwards and may be devastating in young seedlings, sometimes killing plants within days. Typical leaf spots are pale brown to white with dark brown fruiting bodies (pycnidia) that produce diagnostic pink spore masses. The pathogen can move through leaf veins and petioles into the stem, often without visible external symptoms. Once established, it produces sunken stem cankers with blackened margins, internal tissue decay, and dry rot, which can weaken or kill the plant.

The severity and impact of the disease vary by crop type. In cauliflower, symptoms may remain undetected until plants wilt or collapse near maturity, resulting in sudden yield loss. In swede, root rot can markedly reduce marketable yield and storage potential, especially when wounding from cultivation or pests occurs. Leafier brassicas, such as Chinese cabbage, are highly susceptible to leaf spotting, which reduces market quality, while Brussels sprouts generally show limited leaf infection but may still experience hidden stem colonization. Beyond individual crop losses, the pathogen's persistence in residues and ability to spread via seed, water splash, and airborne spores make it a recurrent challenge in brassica-growing regions21.

Plenodomus lingam spreads both sexually (ascospores) and asexually (conidia), but it is considered by FRAC to be at low risk of fungicide resistance. Fludioxonil, the sole representative of FRAC group E2, code 12 (phenylpyrroles), is registered in the Netherlands for seed treatment against *P. lingam*. There are no other authorised substances either with the same mode or alternative mode of action.

3.3.1. Evaluation of Alternatives

Several alternative strategies exist for managing *Plenodomus lingam*, though their effectiveness is limited. Cultural control through the use of clean seed is critical, as even very low levels of infection (<0.1%) can trigger severe outbreaks. Crop rotation also helps by limiting soil-borne inoculum, although care must be taken to avoid planting vegetable brassica crops near to arable brassica crops such as oilseed rape and some cover crops. Weeds belonging to the Brassicaceae family can also be host plants. While resistant cultivars have not yet been developed, some crops show partial tolerance to leaf infection, providing limited host resistance [22]. Physical control measures such as hot water, hot air, or steam sterilisation are already used by seed companies to reduce seed-surface pathogens in vegetable seed lots, but these methods alone are not considered in practice to bring sufficient control. Seed companies typically combine a steam treatment together with fludioxonil seed treatment, to bring as close to 100% control as possible. Natural products and basic substances, such as *Urtica* spp. extract, is primarily effective against bacteria or oomycetes, and none currently provide effective control of *Plenodomus* species as a seed-applied solution. Overall, while these non-fungicidal

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methods can contribute to disease management, no alternative program can replace a chemical active substance in controlling *P. lingam*.

Fludioxonil is currently the only active ingredient registered in the Netherlands for use as a seed treatment for the control of *Plenodomus lingam* in Brassicaceae crops. Therefore, fludioxonil remains the only authorised active substance available for this purpose.

3.3.2. Resistance Risk Assessment

Table 3 shows registered alternative active substances, their FRAC codes, resistance risk ratings, calculated x values (risk associated with alternatives), and z/x ratios (pathogen resistance relative to available alternatives) for *Plenodomus lingam* on *Brassicaceae* crops. Values above 0.75 indicate potential support for fludioxonil essential use under the EFSA protocol. The table highlights that there are no alternative modes of action registered for seed-applied control of *Plenodomus lingam*, and non-fungicidal strategies alone cannot provide reliable protection. Consequently, the fungicide x value is 0 for all Brassica crops, and the x/z calculation cannot be performed. Despite the pathogens low risk of developing resistance (z=1), the absence of alternatives confirms that fludioxonil is the only effective seed treatment option and therefore a derogation is scientifically supported.

4. Discussion

The analysis of Essential Use cases highlights clear patterns of reliance on fludioxonil seed treatments across the European Union. Essential uses were most prevalent in Italy, followed by France and the Netherlands, reflecting both the intensity of production and local pathogen pressures in these regions. Various cereal crops, potatoes, legumes and sunflowers showed the greatest dependence on fludioxonil across EU states. Pathogens including *Fusarium* spp., *Rhizoctonia* spp. and *Alternaria* spp. were dominant among Essential Use cases, emphasising their status as persistent and economically damaging threats that continue to require control through the use of fungicide seed treatments. Overall, these findings indicate that reliance on fludioxonil seed treatments is not evenly distributed but rather clustered in specific crops, pathogens, and regions.

Importantly, the breadth of these Essential Uses demonstrates that the impact of fludioxonil withdrawal would extend across both large-scale commodity crops and more specialised systems, indicating the versatility and importance of fludioxonil for European food production. In addition to its role as a seed treatment fungicide, fludioxonil is also registered for foliar and post-harvest applications, with Essential Uses across many of these categories (data not shown). From a regulatory perspective, the EFSA Essential Use protocol provides an objective, science-based mechanism for evaluating necessity, and fludioxonil has been shown to meet these stringent criteria. In some cases, such as where no z/x calculation can be made because no alternatives exist, the case for derogation is particularly clear.

The case studies provide concrete examples of these dynamics. The evaluation of *Microdochium nivale* control in cereals in France illustrates the essential role of fludioxonil in safeguarding seedling health and preventing severe yield losses under northern European conditions. With limited alternative fungicide options and no effective cultural or biological controls, fludioxonil remains the backbone of seed treatment strategies against pink snow mould. Despite the availability of alternatives in this case, a derogation is still supported. Its continued use is therefore critical to securing crop establishment, preventing disease spread through seed and soil, and protecting cereal yields. Similarly, the case of *Plenodomus lingam* in brassicas in the Netherlands highlights a scenario where fludioxonil is the only registered and effective active substance available for seed treatment. Given that even very low infection levels can trigger widespread outbreaks, and that non-fungicidal treatments alone cannot guarantee control, fludioxonil is indispensable for preventing devastating epidemics in high-value vegetable crops.

The implications for the loss of fludioxonil as a seed treatment fungicide or active substance are particularly significant in the seed sector. In vegetable seed production, although seed multiplication occurs worldwide, seed processing is concentrated in a small number of highly specialised facilities,

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many of which are located in the EU. The Netherlands plays a pivotal role as a global hub for vegetable seed processing and export. For seed companies, protection of seed batches against seed-borne pathogens is paramount, not only to safeguard germination and establishment but also to meet international phytosanitary import requirements. The reliable broad-spectrum efficacy of fludioxonil makes it indispensable for vegetable production systems worldwide. Moreover, when applied as a seed treatment fungicide, it exhibits minimal uptake and lacks systemic movement, confining its antifungal activity to the seed surface and adjacent tissues, thereby reducing exposure to consumers and the environment.

In cereals, seed treatments play a similarly critical role in ensuring healthy crop establishment and productivity. Across Europe, treatments are applied on-farm, by mobile treaters, retailers, and breeders, providing protection against a wide range of seed- and soil-borne diseases. Given the unpredictability of field-level pathogen pressures and the scale of international seed trade, effective broad-spectrum fungicides such as fludioxonil are a necessity. Application rates are very low (measured in millilitres per 100 kilograms of seed), and modern sowing technologies help ensure precise delivery, thereby minimising environmental risks. Fludioxonil supports the successful multiplication of cereal seed from the breeder stage through successive multiplication steps to commercial production. By controlling key seed-borne pathogens such as *Microdochium nivale*, *Tilletia caries*, and other economically significant fungi, it prevents the spread of diseases across regions and secures consistent crop establishment. Protection during the emergence phase also shields seedlings from early infection by pathogens like *Fusarium* spp., ensuring healthy crop development. Today, fludioxonil remains a core active substance in cereal seed treatment products throughout Europe, reflecting its indispensable role in protecting yield potential and ensuring the production of safe, high-quality grain for food and feed.

Thus, while the present analysis focuses on the EU, the consequences of fludioxonil withdrawal would reverberate globally. Disruptions to EU-based seed treatment and export chains would have a ripple effect on international production systems, affecting growers beyond Europe. For young plant raisers and farmers worldwide, ensuring healthy seedling establishment is the foundation of productive crop cycles, and fludioxonil remains central to this goal.

Overall, these findings, reinforced by the case studies, strengthen the case for continued access to fludioxonil under Essential Use provisions. Fludioxonil withdrawal would not only threaten the resilience of European cropping systems but also jeopardise global seed supply chains.

5. Conclusions

This analysis demonstrates that fludioxonil meets the stringent scientific and regulatory criteria for Essential Use within the European Union. Across a wide range of crops and pathogens, it remains one of the few, and in some cases the only, reliable seed-applied fungicide available to secure early crop establishment and prevent serious yield and quality losses. The two case studies illustrate how the absence of viable alternatives makes fludioxonil indispensable to both broad-acre commodity crops and high-value vegetable systems. Derogations under Article 4(7) are temporary, yet the evidence shows that losing fludioxonil would create critical gaps in plant protection across the EU, especially for seed-applied treatments.

Importantly, the use of fludioxonil as a seed treatment fungicide aligns with the principles of integrated pest management by reducing the need for repeated foliar sprays, lowering the overall chemical load in the environment, and serving as a cornerstone for resistance management. Its unique mode of action, broad-spectrum efficacy, and favourable resistance profile reinforce its long-term value for sustainable crop protection strategies. Looking ahead, maintaining access to fludioxonil under essential ese provisions is not only critical for European growers but also for upholding the integrity of global seed supply chains. Continued regulatory recognition of its necessity will ensure that growers retain an effective, science-based tool to protect crops against persistent and evolving pathogen threats while supporting the broader objectives of sustainable agriculture.

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