

**Proposals  
for an**

**improved legislation on Plant Protection Products  
used for seed treatments**

**in connection with the  
Revision of Directive 91/414/EC**

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Overall goal of the EU's policy on plant protection products must be to have a sufficiently wide range of environmentally and consumer safe but equally effective products available to farmers and growers at affordable prices to combat all known and potential crop-pest problems. ESA supports an environmentally friendly and consumer safe agricultural production that is efficient, productive and possesses the necessary technology and tools to maintain and sustain its competitive position in the world. We believe that a coherent and integrated EU policy on seed treatment and minor uses will equally benefit farmers, society and the environment.

Although only a small part of pesticide sales, Seed Treatments are widely used (95% of all seed sown is treated) and essential to growers for successful crop production. Seed treatments offer the advantage of applying much reduced amounts of active ingredients compared with alternative spray and other applications. For example, the use of chlorpyrifos insecticide as a seed treatment application on vegetable brassicas alone requires 4.8 grams/hectare active ingredient compared to 2400 grams/hectare as a drench spray resulting in a reduction of 240 tonnes of active ingredient use per annum within the EU. This is a reduction by more than 99%!

Seed treatments are

- Less harmful for the environment using less active ingredients in a targeted way,
- Less risky to the public as they are applied around the seed, often enclosed in a thin layer, avoiding risks from spray drift, etc.,
- Safe to workers as active ingredients are applied in factory controlled conditions, often handled in closed systems, and not handled by growers openly in the field or on the farm.

ESA urges European decision makers to use Seed Treatments as a key tool in achieving the policy goals formulated by the European Commission in its “Communication on the Thematic Strategy for the sustainable use of pesticides” and supplemented by the BiPRO study regarding its economic impacts.

However, as quantitatively seed treatments are a minor part of the total pesticide market, manufacturers have problems to actively carry out research, develop and market them under the current Directive designed for general pesticide applications. On the contrary - Seed Treatment developments are discouraged in particular for the small acreage crops in the different EU countries by relatively low volumes of active ingredients / products concerned, by the relatively high administrative and financial burden to applicants, by the uncertainty of decision making and the risk of revocation of authorisations and the factual fragmentation of the EU’s internal market due to largely different practice of implementation of the existing legislation in Member States.

Although the use of smaller quantities of active ingredients is generally beneficial,, this makes it for the manufacturer often impossible to bring seed treatments for many different crops to the market under sustainable economic conditions given the current administrative and regulatory burden. Based on these general observations ESA puts forward the following proposals in view of the planned revision of Directive 91/414/EC:

- A revision of the current Directive 91/414/EC should be used to improve the authorisation process with the aim to speed up procedures, decrease costs and make the outcome of applications more predictable. This should include stringent timetables (with fixed deadlines for each step) as well as a final decision making procedure that does not allow for any deadlocks. Mutual recognition between member states can be very beneficial to make the registration process more efficient and effective.
- For the seed industry, any revision must finally take proper account of the specific use of PPPs as seed treatments as well as of the issue of minor uses. With the EU seed industry being a highly internationalised business which today operates in a truly common market and under the EU’s seed marketing legislation and the EU’s plant variety protection legislation, the lack of coherence and consistency with the current directive 91/414/EC and its application by Member States seriously makes the use of seed treatments very difficult and makes the free flow of treated seeds within the EU very problematic.
- To encourage the further research into and development of PPPs for use as seed treatments and to assure that for minor uses a sufficient range of products will be available in the future, the current system based on individual authorisations at Member State level with a non-working mutual recognition provision must be greatly improved. ESA is of the opinion that seed treatment applications should be applied for and authorised EU-wide or at least for a large number of Member States (e.g. zonal approach) to encourage companies to file these specific small scale applications.

- This encouragement should be based on a centralised or standard procedure providing an automatic mutual recognition of national approvals. This is the procedure which operates successfully in the EU seed market. Member States would have the ability to veto products rather than give specific national approvals. This will reduce authorisation costs and uncertainties in decision making for applicants.
- PPPs that have been properly assessed and authorised for Seed Treatment should be allowed for marketing regardless of any products being authorised for the same or similar uses more recently and assessed as potentially better (e.g. possibly safer to the environment or public health). A compulsory substitution of authorised STs by more recent products will make investment even more risky and recuperation of development costs very uncertain. There would also be a significant impact on the potential market (share) of generics.

### Conclusion

**By reducing the amount of active ingredients used, Seed Treatments benefit the environment, the public, farmers and growers. To encourage research and developments of new seed treatment products and to facilitate their introduction to the market, the EU authorisation system should be simplified and made more cost effective. ESA proposes to include a standard EU wide Mutual Recognition scheme in the revision of Directive 91/414/EC to meet these objectives. With this, treated seed could move freely between Member States based on a very effective and efficient regulatory process**

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#### **ESA Mission Statement**

ESA is the voice of the European seed industry, representing the interests of those active in research, breeding, production and marketing of seeds of agricultural, horticultural and ornamental plant species.

Plants from seed are the origin of all food, provide innovative and environmentally friendly industrial products and beautify our landscape.

ESA's mission is to work for:

- ◆ effective protection of intellectual property rights relating to plants and seeds;
- ◆ fair and proportionate regulation of the European seed industry;
- ◆ freedom of choice for customers (farmers, growers, industry, consumers) in supplying seeds as a result of innovative, diverse technologies and production methods