

## **Better Regulation for Plant Protection Products**

### **The European seed industry's view on the revision of Directive 91/414/EC**

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**About ESA European Seed Association**

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. Its 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.

**I. Revision of Directive 91/414/EC**

The review of Directive 91/414/EC could become the long-overdue first step in establishing a harmonised European legislative framework for seeds. For many years, the European seed and seed treatment industry has been subject to a complex - and not always coherent - web of regulations on the authorisation, application, trade and use of plant protection products as seed treatments, in plant breeding and in seed production. At present, seed marketing Directives govern free movement of seed across the single market, while Directive 91/414/EC regulates the placing on the market of plant protection products.

In our view, the review offers an opportunity for EU legislation to provide a new approach, so that it supports - at last - both the authorisation and use of authorised plant protection products in plant breeding and as seed treatments. The benefits are there for the taking: for the environment, for public health, for safety of workers, and in particular for the users of the final product, the farmers and growers who use treated seed. It is a step which should be helped, and not hindered, by European legislation.

The seed industry calls on the Commission to assure that the new legislative framework providing a consistent and cost-efficient specific approach that will facilitate and encourage the development, authorisation and use of plant protection products as seed treatments. We therefore urge the Commission to consider all possibilities for amending its Working Document accordingly. Registering plant protection products for use as a seed treatment should be made easier, and registrations should be valid across the entire European Union.

Consequently, while the Commission's intention to propose a degree of harmonisation is welcome, ESA underlines that the seed industry's preferred option is for full harmonisation for plant protection products being used as seed treatments.

**II. ESA's Key Messages on a Better Regulation of Plant Protection Products used for Seed Treatment and Minor Uses**

European agricultural production should be environmentally friendly, safe for consumers, efficient, and productive, and should benefit from the technology and tools that can maintain and sustain a competitive position in the world

A coherent and integrated EU policy on seed treatment and minor uses will benefit farmers and the environment.

European decision-makers should therefore use seed treatments as a key tool for achieving the policy goals in the EU's "Thematic Strategy for the sustainable use of pesticides".

**ESA 's key messages on the planned revision of Directive 91/414/EC are:**

- The overall goal of the EU's policy should be to ensure that farmers and growers have access to a wide range of plant protection products - safe for the environment and consumers, effective, and at affordable prices - to combat all existing and potential crop-pest problems.
- A revision of Directive 91/414/EC should improve the authorisation process, making it faster, cheaper and more predictable, with strict timetables, fixed deadlines for each step, and a final decision-making procedure that precludes deadlocks.
- Legislation must take account not only of environmental safety and public health, but also of its impact on the competitiveness of European agriculture, the security of food and feed supply, and the consequences for related industries - including the seed industry and seed treatment companies.
- For the seed industry, any revision must finally take proper account of the specific use of plant protection products as seed treatments as well as of the issue of minor uses.
- Seed treatment applications and minor use authorisations are currently sidelined in the authorisation process. They are discouraged 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 fragmentation of the EU's internal market due to Member States' widely diverging implementation of legislation.

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- The lack of coherence and consistency in Member States' application of Directive 91/414/EC creates additional costs and great legal uncertainty, seriously damaging the EU seed industry's competitive position in a highly internationalised market.
- To encourage further research and development of plant protection products for use as seed treatments, and to ensure that a sufficient range of products will be available for minor uses in the future, the authorisation system must be greatly improved. The current system, based on Member State authorisations and without a functioning mutual recognition process, is inadequate. There is a need for an EU-wide authorisation system for seed treatments (or at least a "zonal approach" covering a large number of Member States), to encourage companies to file these specific small-scale applications.
- Either a centralised procedure or an automatic mutual recognition of national authorisations would be acceptable, since both approaches could help reduce application costs and uncertainties.
- Plant protection products that have been duly authorised should be allowed to remain on the market regardless of any subsequent authorisation of other products for the same or similar uses, even when assessed as potentially safer for the environment or public health. Compulsory substitution of authorised products with more recent competitors discourages investment by bringing additional uncertainties into recovery of development costs.
- Any substitution mechanism must take account of plant protection product authorisations as a seed treatment and for minor uses, which should in any case be kept, even where the authorisation of the respective product for conventional applications is revoked.

### III. An introduction to Seed Treatment

Seed is the starting point for all plant production. Throughout history, mankind has developed plant varieties that are ever more sophisticated, with higher potential for yield, resistance to pests and pathogens, and suitability for specific uses or areas of cultivation. Since the seed contains all the genetic information needed to realise the inherent potential of these efforts, its protection has always been crucial for plant breeders, seed producers, farmers and those involved in crop protection.

For generations, farmers struggled to improve the performance of their seeds, and to protect them against pests and diseases. But the use of ash, oils, salts or manure did not amount to fully effective "treatments", and certainly did not break the cycles of infection and re-infection of seeds and plants.

Only at the end of the 19<sup>th</sup> century did increased understanding of chemistry and biology permit effective crop protection with the help of active substances. Since then, the direct treatment of the seed itself has become particularly effective in improving and controlling plant growth, in avoiding or limiting pests and diseases, in attaining consequently higher yields with low input of active substances. Over time, the central challenge has been met of maintaining the seed's capacity to germinate as desired while protecting it against pests and pathogens. Today, high-tech seed treatment is one of the keys to sustainable seed and crop protection and improvement in both commercial farming and plant breeding.

The technology of seed treatment offers a wide area of applications with very different solutions for a variety of equally different practical problems in seed and crop production. The many applications of seed treatment all share a common approach: using the minimum amount of active substance to promote natural processes safely and efficiently by putting the technology to work where it is most effective – directly on the seed.

#### i. Basic information on seed enhancement

The seed industry invests heavily in improving the genetics of its varieties, so they become more resistant to disease, and offer improved yields and a higher-quality final harvested product.

The seed industry also invests heavily in the physiological enhancement of seeds, to improve sowing or germination, or to protect the germinated seeds/plants against disease. The processes include:

- Breaking seed dormancies by pre-germination,
- Upgrading quality by removing seeds that germinate slowly or not at all
- Coating (by pelleting or film coating) to improve sowing
- Eliminating seed-borne diseases
- Additives that stimulate or enhance plant growth and
- Adding plant protection compounds directly onto the seed to protect it during germination, and/or to protect the plant itself during growth - what this paper terms "**Seed Treatment**".

These enhancement methods can be combined, but this paper concentrates on Seed Treatments with plant protection compounds.

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The seed and its development into a plant may be negatively affected by pests and diseases active in different environments. Classically, such diseases are differentiated as

- foliar diseases
- soil-borne diseases
- seed-borne diseases
- pests
- contaminants

The crop protection industry has developed a range of products targeting these health problems with highly specific chemical and/or biological substances and applications.

Seed treatment is more than simply applying chemicals to the seed rather than spraying the same chemical on the growing plants. Today, seed treatment often makes it possible to combine responses to several problems into one technical application which is simple and in any case irreplaceable in any crop production – the sowing of the seed. The technology exploits existing farming procedures, so it requires no additional use of specific machinery in the field, thus helping reduce the risks of soil erosion and compression, and assisting low-intensity farming practices such as ploughless sowing and reduced soil preparation.

The treatment of seed with plant protection products is the principal approach, even today, to overcoming the risks from pests and pathogens to seed and plant health, to crop development, crop quality, safety and yield,. And because only limited amounts of active substance are needed to achieve the desired result, seed treatment also offers the highest benefits, environmentally, in public health, and economically.

**ii. Explanation of regulatory framework and legal requirements**

**• Plant Protection Products**

The authorisation of plant protection products in the European Union is regulated by Directive 91/414/EC of 15.07.1991 on the placing on the market of plant protection products. Together with numerous accompanying Directives, it provides for the establishment of a positive Community list of active substances which are deemed acceptable for human or animal health and the environment. It establishes a system for Member States to authorise preparations containing active substances in the positive list, according to uniform principles. It also allows for the mutual recognition of authorisations among Member States where plant health, agricultural and environmental conditions are comparable - although this provision has been used only rarely

**• Seed Marketing**

The marketing of seed in the European Union is regulated by crop-specific Directives laying down detailed rules on quality and on testing obligations. All seed must be of a clearly defined plant variety (that is, it must be distinct, uniform and stable - or DUS, in the jargon). Testing and final authorisation is carried out by national competent authorities. When a new variety is authorised, it is included in a national catalogue of (agricultural or vegetable) plant varieties, and may be marketed in that Member State as long as the quality requirements of the seed marketing Directives are met. The total of these national marketing authorisations comprise the EU Common Catalogue of (agricultural or vegetable) plant varieties, which may be marketed freely throughout the EU - a process of automatic mutual recognition.

**iii. Specific safety requirements and application practice for treated seed**

Seed treatments usually require only minute quantities of plant protection product to provide for large cropping acreages. The exposure to the active substance is therefore very limited, and in practice it is restricted to trained specialists in the closed industrial systems of seed treatment companies. The treated seeds are subsequently subject to further testing for physical quality, germination potential etc..

Seed treatment cannot be compared to the application systems regularly used in the field by growers and farmers; it is a highly-industrialized process in which safety and environmental issues are carefully managed throughout:

- Products must be safety evaluated and authorised for seed treatment

Only products have been specifically evaluated and approved for use as seed treatments may be used - to protect operators as well as consumers.

- Treatment takes places under professional industrial conditions

Treatment is always a tightly-controlled industrial process in closed premises ,conducted by trained specialists. Specific equipment and installation requirements - including air exhaust and closed systems – reduce worker exposure, and improvement and enforcement of clean working practices is a constant feature of the industry. Plant protection products are stored in a clean environment and are used in closed transfer systems. This guarantees clean handling and limits direct contact with the products. Use of appropriate personal protective equipment are standard in seed treatment plants.

- Workers' protection and operator safety are part of the registration process

Worker protection is regulated by EU as well as national legislation and operator safety assessment is part of the product registration process - which identifies potential hazards inherent to products, and conducts a risk-assessment for all plant protection product applications.

- Industry guidelines complement safety legislation

Guidelines such as “Seed Treatment Operator Safety Guidelines” and “Seed Treatment – User Safety” complement legislation, increasing awareness and establishing best practices.

Managers of the European seed treatment industry are committed to supporting the highest standards of operation and production safety, including continuous operator safety training, maintenance of high operating standards and promoting awareness of best working practice.

**IV. The economic importance of seed treatments for the seed industry**

**The EU is still the global leader in seed treatments!**

In 2005, the worldwide seed treatment sector was worth some €1.1 billion, and the farm gate value of seed treatments in the EU is estimated at €400 million. Western Europe represents about 36% of the world total, with North America accounting for 22%, Latin America for 16%, and Asia for 3%.

Seed treatment plant protection products fall into three main categories:

- Fungicides, accounting for 50% of the total: most commercial seeds are treated with at least one fungicide substance.
- Insecticides, representing 40% of the total: the volume of seeds treated is lower than for fungicides, but the high value reflects the higher cost of the technology.
- Mixtures of fungicides and insecticides represent the remaining 10% of the total business.

Global growth is predicted to at 5% per annum, particularly due to the increased use of insecticides instead of technologies such as soil-applied granules or early crop sprays.

Europe is, however, expected to show only limited further growth, well below the worldwide rate, mainly because of the unhelpful legislative framework, which lacks appropriate provisions for seed treatments, makes it difficult to maintain existing authorisations and to obtain new ones. As a consequence, companies are reducing their investment, and innovation is slowing.

**i. Key economic data of the EU seed industry**

The EU commercial seed market was worth some €6.1 billion in 2005<sup>1</sup>, while exports accounted for more than €2.75 billion - demonstrating the increasing globalisation of plant breeding and seed production, which in turn shortens innovation cycles and raises efficiency, presenting additional opportunities to the EU farming sector in its race for competitiveness.

Around 95% of all seed sown in Europe is treated with one or more seed treatment products. The continuous growth up to today proves the sustainability and effectiveness of the technology; the potential growth in the future will therefore be related mainly to increased quality and performance rather than to an increased market share.

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<sup>1</sup> The figure does NOT include farm-saved seed which for some crops reaches substantial volumes. As farm-saved seed often does not reach the quality standards of regular certified or professional seed, seed treatment is a key technology for farmers making use of farm-saved seed.

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ii. Example sugar beet

The global value of sugar beet seed is estimated at €500-€550 million, with the EU25 accounting for 65%. The rest is split between North America (12%), Eastern Europe (9%), the Middle East and North Africa (8%), Asia (5%) and South America (1%)

In the EU, strenuous efforts have led to improved seed quality and genetics, which explains the efficiency of EU sugar production from sugar beet. It also explains the high cost of seed (some €145/ha - 20% above the global average) - which has to be seen in the context of an average annual increase in yield, with cutting-edge seed treatment technology alone accounting for 1% of this increase.

In parallel, seed treatment technology has evolved, exploiting the most advanced seed treatment processes and chemistry<sup>2</sup>. The value of plant protection products used in sugar beet is estimated at €90 million (at farmer level) - corresponding to 22% of the total seed treatment market in the EU25. Sugar beet is the second largest crop for seed treatment in EU (after cereals, and at the same level as corn). All seeds marketed in Europe are treated with a fungicide to prevent diseases that are mainly soil-borne, but nearly 90% of the value of sugar beet seed treatment is accounted for by insecticides..

Insecticides have been increasingly used as seed treatment over the last ten years because they are highly effective in prevent severe damage from soil pests and from virus transmission by insect vectors (notably beet-yellowing viruses transmitted by aphids). Nowadays, nearly 90% of the seeds planted in Europe are protected with an insecticide seed treatment, although the intensity of use differs from one country to another, mainly depending on local pest pressure.

Example of insecticide seed treatment intensity in the EU (in % of seeds sold in the country):

- 100% ST: Austria, Czech Rep, Germany, Poland, Slovakia, Sweden, Finland, France
- 85% ST: Belgium
- 70-80% ST: Italy, Denmark, The Netherlands, UK
- 60% ST: Spain, Greece

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<sup>2</sup> History of seed treatment use in Europe for sugar beet:

- 1980: Standard fungicide treatment was either thiram or ethyl mercury phosphate. Some carbamate insecticide treatments such as carbofuran or methiocarb were used.
- 1985: Tachigaren used as standard fungicide treatment against soil-borne diseases.
- 1990: New insecticide "Force" (tefluthrin) introduced and started to replace either older insecticides (carbamates) or soil applied granules.
- 1991: Launch of a new family of insecticide seed treatment (neonicotinoids): Gaucho (imidacloprid) accelerated the rate of replacement of granules and early crop sprays with insecticides.  
[Replacement of insecticide granules or soil-applied sprays by seed treatments - example UK:  
In 1991 a total of 64% of the crop was treated with granules (62%) or soil-applied sprays (2%), with the remainder untreated, largely due to factors associated with inconvenience of application. By 2004 only 9% of the crop received a granular treatment while 78% was sown with a seed treatment.]
- 2001 to 2005: Increased used of insecticide seed treatment: Introduction of combination of active ingredients (neonicotinoids + Force) in order to widen the spectrum of activity. Launch of new active ingredients such as Cruiser (thiamethoxam) and Poncho (clothianidin)

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The increased use of insecticide has improved the efficiency of sugar beet cropping and has reduced the use of active ingredient, as shown in the following table:

- **Effect of seed treatments on the environment in EU sugar beet production**

Without seed treatments, farmers would have to combat major pests/diseases with products such as pyrethroid sprays or carbamate granules - which require higher dosage due to their application technology, with consequent significant effects on the environment:

Crop	Target pest/disease	Seed treatment	Alternative	Difference of active ingredient load to the environment
Sugar beet	Soil insects + early foliar pests	70-100g/ha active ingredient (depending on active substance and seedling rate)	Soil granules such as carbamate: 600g/ha	Minimum 500g/ha less active ingredient
<b>Total environmental benefit for EU25:</b>				In active chemical substance: <b>- 760 tons</b> <b>- 880 tons</b>
- assumption: 1.9Mio ha sugar beet, 80% treated - assumption 2.2Mio ha sugar beet, 80% treated				

Further alternatives may emerge as a result of constant seed industry improvements to disease or pest resistance of conventional sugar beet varieties - although chemical plant protection products are still needed in order to ensure adequate performance. Even greater hope lies in the creation of new varieties, in particular genetically modified varieties.

**The effect of seed treatment on the economics of EU sugar beet production**

1.9 million ha production	to	2.2 million ha
55 tonnes harvest / ha		51 tonnes / ha
€36/tonne sales price		€43.63 /tonne
= €3.76 billion sales		= €4.88 billion sales

Crop	Area sown	Value of seed	Value of seed treatments	Value of crop
Sugar beet	2.200.000	240 – 330.000.000 <sup>3</sup>	165.000.000	4.880.000.000
		(= €110-150/ha)	(= €75/ha)	(= €2.225/ha)

Seed treatments have practically eradicated the common yellowing virus transmitted by aphids, which can cause yield losses of 50%. Furthermore, seed treatments have helped to boost sugar beet yields by some 10%.

The damage to EU sugar beet production if no treated seed was available could reach €2.44 billion per year (loss of yield and cost for higher intensity of application of PPPs).

<sup>3</sup> Due to the different resistances incorporated, the value of varieties ranges widely. Value might be even higher or lower respectively than the numbers used in this example.

iii. Examples of Vegetable Crops

- Outdoor Vegetable Crops

For outdoor vegetable crops, over 95% of the seed is sold as treated - mainly with fungicides for the control of soil-borne and against seed-borne diseases. But increasingly, growers demand insecticide seed treatments so as to combat widespread pests such as cabbage-root fly and aphids.

The EU Seeds Regulation specifies the use of 'sufficiently healthy seeds'. In most outdoor vegetable crops this is possible only with the aid of seed treatments.

Nowadays, seed treatments are indispensable in preventing major crop losses. For the EU, by preventing major losses they also prevent the related risk of imports from non-EU countries with less stringent legislation on plant protection products - as well as reducing transport.

**Effect of seed treatment on the economics of selected EU outdoor vegetable production**

Crop	Area sown (hectares)	Value of the seeds (€ million)	Production value (€)
Brassica	100,000	65	1.48 billion
Carrot	75,000	40	310 million
Onion	100,000	30	250 million
Lettuce <sup>4</sup>	100,000	50	1.12 billion
<b>Total</b>		<b>185 million</b>	<b>3.06 billion</b>

<sup>4</sup> Example lettuce: prepared lettuce remains one of the fastest-growing sectors within the fresh produce industry. Mixed lettuce packs account for around 70% of the processed vegetable market. Aphid control is vital because aphids will quickly establish colonies in the heart of plants. Aphids rapidly cause direct feeding damage and reduce produce quality. Lettuce growers need to produce crops free from visible damage in order to meet the requirements of the supermarkets and of the consumer. Seed treated with Gaucho (imidacloprid) provides control of aphids until almost the end of the crop cycle.. Without this seed treatment, the crop has to be sprayed every 4-5 days ,and will thus need at least an extra ten field sprays, driving production costs up significantly. 2002/2003 saw an upsurge in Europe in the price per tonne and in the value per planted hectare. The hot summer stimulated demand and high temperatures caused many crop problems, including aphids. The lettuce price reached €1,200 per tonne with an average value per planted hectare of €20,500. Assuming an average marketable yield of 20 tonnes per hectare and a value of €600 per tonne, in a good year the total crop value is around €1.1 billion.

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- **Examples of seed treatment effects in selected outdoor vegetable crops:**

If seed treatments were not available, pesticide input volumes would substantially increase

Crop	Target pest/disease	Seed treatment	Alternative	Difference of ST application as regards active substance load to environment
Brassica	Cabbage root fly	Chlorpyrifos Application rate 4.8 grams / hectare	Chlopyrifos drench Sprayed at 2400 grams / hectare	- 240 tonnes
Carrot	Pythium species	Metalaxyl-M Application rate 1 gram / hectare	No real alternative Try soil application at 12,000grams / hectare	- 900 tonnes
Onion	Botrytis spp (neck rot)	Carbendazim or thiabendazole Application rate 1gram / hectare	Field spray 1 to 7 times at 1,000 – 7,000g /hectare	-200 tonnes to - 700 tonnes (assuming 2 sprays min.)
Lettuce <sup>5</sup>	Aphids	Imidacloprid	Field spray	- 15 to
<b>Total environmental benefit to EU 25:</b> (100K ha brassica, 75K ha carrot, 100K ha onion, 100K ha lettuce)				Active substance: <b>- 1355 to (min)</b> <b>- 1855 to (max)</b>

<sup>5</sup> The figure refers to the application on only around 8,000 ha in the UK, the Netherlands and Germany, where this seed treatment is currently authorised. Given the overall production of 100,000 ha in the EU25, the potential difference could amount to a maximum of around 180 tonnes!

aphicide coating: countries involved UK, NL, DE	Before introduction of aphicide coating in 2000	After introduction of aphicide coating in 2000	Remark
Acreage in ha	8,000	8,000	Mainly on Iceberg lettuce. UK + NL 75 % of the acreage, Germany about 15 %.
Total crop value in € million	317	317	
% crop loss because of aphids	20%	4%	In UK enormous loss because of root aphid. In other countries mainly leaf aphids (Nasonovia).
Total crop loss in € million	63.4	12.68	
Difference for the growers in € million on 8.000ha	<b>50.32</b>		
Average number of aphicide applications	10	2	Before 2000 up to 18 applications at 100 gram pirimicarb in summer crops. After 2000: 1 time coated seeds + 1 field application. No field applic. for early crops.
Total input of active ingredient in kg per ha	2.65	0.7	0.6 l pirimicarb + 0.1 g imadachloprid
Total input of active ingredient in kg on 8,000 ha	21200	5600	
Difference in kg for the environment on 8000 ha in kg or liter	<b>15.600</b>		