

## **Better Regulation for Plant Protection Products for Seed Treatment and Minor Uses**

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

The impending revision of Directive 91/414/EC could become the long-overdue first step in establishing a harmonised European legislative framework for seeds - and for seed treatments.

The European Union now has the opportunity to create a system that will provide for effective, environmentally-friendly agriculture in Europe, and will simultaneously promote the competitiveness of Europe's vital seed treatment sector.

If the right choices are made, European consumers and farmers will benefit, and Europe's technological leadership will be strengthened. But if the wrong choices are made, Europe risks becoming dependent on imports of food and of technology - from countries that may not have the same high standards as the EU.

The European Seed Association has set out in this Executive Summary paper the key issues underlying this legislative revision. The paper

- explains the importance of seed treatment in modern agriculture,
- indicates how the European seed treatment sector is disadvantaged by the EU's current legislative framework, and
- sets out how a modified system could bring radical improvements for Europe.

#### **In brief:**

Seed treatment is a vital aspect of modern agriculture: it boosts yields and protects crops by applying minute quantities of plant protection product to the seed itself, prior to sowing. Seed treatments protect the seed during germination, and protect the plant itself during growth. It is more environmentally friendly (and safer for farmers) than spraying crops in the field, and better value for money. It is also a rapidly-developing high-tech area where companies in Europe excel - but where investment and research are essential to remaining competitive in the world-wide market place.

The seed treatment sector suffers from an incoherent EU regulatory framework which delays product authorisation, imposes uncertainty on producers, makes EU-wide product launch difficult, and discourages research and investment. It is trapped at the confluence of EU seed marketing rules and crop protection rules, which are inadequate to promote the sector's development or to foster European inputs to European agriculture.

Proper adaptation of Directive 91/414/EC would create new regulatory predictability for the sector, would speed authorisation processes at national and European level, and would lead to more sustainable and more productive agriculture in Europe. It would also enhance the prospects for one of Europe's high-tech sectors to contribute even more to the EU strategy of jobs and growth.

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.

### The importance of seed treatment in modern agriculture

*Seed treatment is a vital aspect of modern agriculture: it boosts yields and protects crops by applying small quantities of plant protection product to the seed itself, prior to sowing. It is more environmentally friendly (and safer for farmers and growers) than spraying crops in the field, and better value for money. It is also a rapidly-developing high-tech area where companies in Europe excel - but where investment and research are essential to remaining competitive in the world-wide market place.*

Today, high-tech seed treatment is one of the keys to sustainable seed and crop protection and to improvements in both commercial farming and plant breeding. Around 95% of all seed sown in Europe is treated with one or more seed treatment products - mainly fungicides and insecticides. But they usually require only minute quantities of plant protection product to provide for large cropping acreages.

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.

- In sugar beet, seed treatments have practically eradicated the common yellowing virus transmitted by aphids, which can cause yield losses of 50%. The damage to EU production if no treated seed was available could reach €2.44 billion a year. Furthermore, seed treatments have helped to boost sugar beet yields by some 10%.
- Lettuce seed treated with imidacloprid provides control of aphids until almost the end of the crop cycle. Without this treatment, the crop has to be sprayed every 4-5 days - needing at least an extra ten field sprays, driving production costs up significantly.
- Treating vegetable brassicas seed with chlorpyrifos insecticide requires only 4.8 grams/hectare of active ingredient - compared to 2,400 grams/hectare as a drench spray. This avoids the use of 240 tonnes of active ingredient per annum in the EU - a reduction of more than 99%.

There are many applications of seed treatments, offering customised solutions to challenges in seed and crop production. But they 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.

The use of seed treatment cannot be compared to the spraying and drenching systems regularly used in the field by growers and farmers. Using treated seed is a much more precise procedure. It makes it possible to combine responses to several problems into one technical application related to the irreplaceable phase of 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 actual process of seed treatment is highly industrialized, conducted by specialist professionals, with safety and environmental issues carefully managed throughout. Seed treatment facilities are designed to ensure containment, operating conditions and special equipment protect workers from accidental exposure to active ingredients, and all the plant protection products and processes used have been evaluated for safety and authorised for seed treatment.

### **Protecting the seed – the best start for any crop production**

*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 preventing 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.

About half the plant protection products used in seed treatment are fungicides: most commercial seeds are treated with at least one fungicide substance. Insecticides account for another 40% of the total (a lower volume than for fungicides, but high value, reflecting the higher cost of the technology). Mixtures of fungicides and insecticides account for the remaining 10% of the total business.

### **The economics of Seed Treatment**

There is a significant economic dimension for Europe, too. The seed treatment sector is part of an industry which is important for Europe both as a support to its agriculture and as a component of its international trade. The overall EU market for seeds was worth more than €6 billion in 2005, while exports accounted for more than €2.75 billion - demonstrating the increasing globalisation of the plant breeding and seed production industry.

In 2005, the worldwide seed treatment market was worth some €1.1 billion. The EU is still the global leader: the farm gate value of seed treatments in the EU is estimated at €400 million - with cereals, followed by sugar beet and corn, as the largest crops for seed treatment. North America accounts for 22% of the world market, Latin America for 16%, and Asia for 3%.

Global growth of 5% per annum is predicted for seed treatments, particularly due to the increased use of insecticides instead of technologies such as soil-applied granules or early crop sprays. Further growth is likely as the introduction of newer technology displaces currently-used active ingredients.

### The economics of Seed Treatment – two examples

- **Seed treatment for sugar beet**

The EU25 market for sugar beet seed is worth an estimated €500-€550 million - 65% of the global market - and as a result of EU research into seed quality and genetics, EU sugar production from sugar beet is highly efficient.

EU seed, at some €145/ha, is 20% above the average global price, but brings annual increases in yield. Cutting-edge seed treatment technology alone accounts for 1% of this increase. New insecticide seed treatments are replacing granules and early crop sprays. In the UK in 1991, nearly two-thirds of the crop was treated with granules or soil-applied sprays, and the rest was 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. 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.

The increased use of insecticide has improved the efficiency of sugar beet cropping and has reduced the use of active ingredient. 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 their application technology, with consequent significant effects on the environment.

Seed Treatments are effectively saving around 800 tonnes of active ingredients in the EU25.

- **Seed treatment for outdoor vegetable crops**

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

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

For brassica, carrot, onion and lettuce alone, Seed Treatments effectively save nearly 2,000 tonnes of active ingredient in the EU 25.

### The current EU legislation disadvantages the European seed sector

*The European seed treatment industry is currently subject to a complex - and often incoherent - legislative web, some of which was designed to regulate seeds, and some to regulate plant protection products, but none of which makes specific provision for seed treatments. In consequence, the authorisation of seed treatments is complicated, expensive, and slow, requiring compliance with legislation both on seed marketing and on plant protection.*

It is difficult to maintain existing authorisations, and difficult to obtain new ones. Because the system depends largely on Member State authorisations, and there is no effective mutual recognition procedure, it is also unpredictable: the inconsistencies in Member States' application of the legislation amount to a *de facto* fragmentation of the EU's internal market.

The effect is to seriously damage the EU seed treatment industry - which has to operate in a highly internationalised and intensely competitive world market, but which is confronted by multiple regulatory barriers even within what should be its own home territory.

The difficulties are intensified by the fact that seed treatments employ relatively low volumes of active ingredients - making the already-high administrative and financial burden even more disproportionate, and discouraging applicants.

The result is that the growth expectations for the world seed treatment market do not apply to Europe. Mainly because of the unhelpful EU framework for seed treatments, further growth here is predicted to be limited, and well below the worldwide rate.

As a consequence, companies are reducing their investment in Europe, and European innovation is slowing. 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 in the future, the authorisation system must be greatly improved.

#### The current legal framework in brief

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

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.

**A modified system could bring radical improvements for Europe**

*EU legislation needs a new coherent and integrated 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 the safety of workers, for the farmers and growers who use treated seed, and for the economics of European crop production - with beneficial effects for final consumers too. It is a step which should be helped, and not hindered, by European legislation. The overall goal of the EU's policy must 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 consistent and cost-efficient specific approach will facilitate and encourage the development, authorisation and use of plant protection products as seed treatments. Registering plant protection products for use as a seed treatment should be made easier, and registrations should be valid across the EU. A Europe-wide authorisation system for seed treatments (or at least a "zonal approach" covering a large number of Member States) would 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, even after the authorisation of new competing products. Compulsory substitution of with more recent competitors discourages investment by adding uncertainty to recovery of development costs. Any substitution mechanism should allow the retention of product authorisations for seed treatment, even where the authorisation for the conventional application is no longer retained.

A revision of Directive 91/414/EC should make specific provision for seed treatments. It should make the authorisation process for them faster, cheaper and more predictable, with strict timetables, fixed deadlines for each step, and a final decision-making procedure that precludes deadlocks. The legislation should take account not only of environmental safety and public health, but also of the 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.

If these changes are made, Seed treatments will be one key tool in achieving the policy goals of the EU's Thematic Strategy for the sustainable use of pesticides" - European decision makers now have the opportunity to liberate that potential.

**The European Seed Association 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.**