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Position

on the

Draft Guidance Document

on the authorisation of plant protection products for seed treatment

ESA is the voice of the European seed industry, representing those active in research, breeding, production and marketing of seeds of agricultural and ornamental plant species. It represents more than 30 national seed associations (and with that more than 7000 seed businesses in the EU, most of them SMEs) and more than 60 direct company members.

ESA's mission is to work for fair and proportionate regulation of the European seed industry, freedom of choice for customers in supplying seeds as a result of innovative, diverse technologies and production methods and for effective protection of intellectual property rights relating to plants and seed.

Contact:

ESA

European Seed Association

Tel. 0032-2-7432860

secretariat@euroseeds.org

www.euroseeds.org

Introduction

ESA European Seed Association is representing the European plant breeding and seed industry which industry - by creating modern, innovative plant varieties and supplying high quality seed - is contributing significantly to one of the basic needs of society: producing enough healthy food at reasonable prices and in an efficient and environment-friendly way.

Here, integrated technology packages consisting of genetic progress delivered by plant breeding and supplied through high quality seed, modern crop protection products and state of the art application technologies for delivering these products (often in combination with targeted nutrients etc., help Europe's farmers and growers to combat ever new and growing plant health challenges, not least under new conditions of climate change and increasingly adverse growing conditions due to weather extremes.

ESA considers seed treatment to be the crop protection technology of the future: highly targeted, applied under professional conditions and effective at minimum dosages.

We are therefore convinced that the process of improving access to such technology which was started -not least based on ESA's respective input- with the revision of Directive 91/414/EC and resulted in specific provisions facilitating the common assessment and subsequent authorisation of seed treatment products and allowing for marketing and use of seed treated with such products throughout the European Union must be continued and may not be jeopardised by contradicting measures to be set out by the Guidance.

¹ Article 4(1)(a) and (b) of Directive 98/44/EC and Article 53(b) of the EPC.

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ESA's policy principles

I. EU-wide authorisation of PPPs for seed treatment

The 'one zone' approach for the authorisation of PPPs for seed treatment is a fundamental improvement of the new legislation on the authorisation of plant protection products (PPP).

It provides the much needed incentive for crop protection companies to put forward applications for this specific low volume use, even for so-called minor crops, acreages and markets.

ESA underlines that a future Guidance Document must further help to implement this principal provision of a single zone for seed treatment applications and must facilitate its practical use. It must in no way be (ab)used to add further burden on applicants or make such applications more cumbersome, costly or subject to new or additional requirements.

II. Joint evaluation of PPPs for seed treatment

ESA is of the opinion that the provisions of the new legislation allow for both, an efficient and effective evaluation of authorisation applications for seed treatment as well as the inclusion of specific comments and possible concerns from all EU Member States within this process.

Again, we wish to underline that such a process is regularly used for a number of products such as e.g. medical products, GMOs etc.. With this, scarce resources are used most effectively, account can be taken of specific information and/or regional concerns while the principles of the free movement of goods within the EU's common market are upheld, with the resulting benefits of reduced costs for products and wider choice for Europe's citizens.

ESA therefore requests that this approach must not be weakened but strengthened by the future Guidance.

III. Exemptions and/or specifications

The current legislation specifically allows room for differentiation or even denial of authorisations where there is sufficient evidence that such restrictions are required for the protection of the environment, plant or animal or public health. However, such exemptions are subject to a clear procedure and the prerequisite to supply respective scientific evidence to Commission and all Member States.

ESA considers this approach to be crucial for a future science based system of common scrutiny of applications and resulting joint decision making.

We therefore underline that no other approach may be promoted by the Guidance.

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IV. Free movement of treated seed in the common market

The well-established common market for seed is one of the main reasons for a continued improvement of agricultural productivity and the competitiveness of the European agri-food chain. Today, more than $\frac{3}{4}$ of these improvements are due to genetics or stem from technology platforms combining genetic progress with progress in crop protection, nutrition etc.: modern seed treatment and enhancement is thus one key driver of the progress needed to simultaneously address the challenges of food security, plant health and environmental safety.

Defending and safeguarding the common market for seed is one of the core missions for ESA. Consequently, ESA is strongly advocating the importance to assure that all European plant breeders, seed producers, farmers and growers enjoy the benefits of the current system of the European Catalogues of plant varieties that grant access to the widest possible choice and thus to the most suitable genetic material for a growing range of climatic conditions, plant health challenges and markets. Similarly, the widest range of targeted, modern plant protection solutions supplied with the seed is critical for Europe's seed and farming sector.

ESA will not accept any Guidance that results in a reduction of choice of PPPs for seed treatment and/or of treated seed for farmers and growers by rejecting the principles of the common seed market when it concerns the free movement and use of seed treated with a PPP authorised for this use in at least one EU Member State.

V. Evaluation and data requirements

n.b.: ESA does not comment on the specific parts of the guidance related to the evaluation and required data on individual active substances and/or PPPs. The seed industry considers these questions to be more appropriately addressed by the respective technology providers, either individually or via their common organisation, in their input to the Guidance.

Development of the European Seed Treatment Assurance Standard (ESTA)

In order to address concerns on the quality of professional seed treatment applications and avoid any unintended effects on the environment and/or plant or animal health, ESA has committed itself and its membership to the development and implementation of an EU-wide quality assurance scheme for seed treatment applications.

This scheme has meanwhile been tested in practice, proven reliable and effective and has consequently now been finalised and formally adopted in recent meetings of the responsible ESA bodies.

The ESTA scheme is a voluntary, industry led quality assurance scheme, audited and certified by independent, accredited certification bodies. The respective quality standards, risk management procedures and mitigation measures etc. are all publicly available on a dedicated part of the ESA website (v. www.euroseeds.org). ESA supplies this information as integral part of its input.

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It is ESA's aim to reach a market penetration of >80% with this scheme within the first 18 months of its use in the crops maize, oilseed rape and beets (sugar and fodder beet).

ESA would like to underline that it has been agreed to continue the work on the ESTA scheme with the development of similar schemes for all other relevant crops (outdoor vegetables, cereals etc.) and for all PPPs applied as a seed treatment.

We would welcome if Commission and Member States in their further discussions on the Guidance Document would not only acknowledge the work already carried out by the sector and its self-commitment to the further extension of the scheme to all relevant crops and ST applications but would also make sure to take over the respective provisions in the future guidance to assure clarity and consistency.

Guidance for ESTA implementation by the Common Checklist

In order to facilitate the practical implementation of the ESTA Standard, ESA has also developed a common checklist which is made available to all interested and participating certifying bodies as well as the seed treatment companies / sites as a guidance how to perform audits, what issues and processes to address and how and what qualities to check.

The document is available on the public part of the ESA Website and may be used freely by all interested parties; it is supplied by ESA as additional input to this consultation.

n.b.: while certifying bodies are welcome to make use of the common checklist for guidance, they are of course independent and thus free to use any other suitable checklist to perform their proper controls and audit. Furthermore, the Common Checklist is a work in progress and is likely to be amended in the light of the results of the audits performed throughout the coming months. Further amendments are likely to result from detailed analysis of the findings of certifying bodies on a regular basis.

Accompanying measures: Safe Use Labelling Advice

An important aspect of assuring the safe use of treated seed under all conditions is the proper information of users with the seed supplied to them,

ESA is of the opinion that the current interpretation of the applicable EU legislation on the labelling of treated seed is impractical and not useful, neither for seed companies (seed suppliers) nor for the potential users of treated seed.

ESA therefore agrees to address this point within the Guidance Document with the aim of establishing a practical and harmonised approach to the labelling of treated seed that is in line with the principal objectives of the legislation: the free movement of seed treated with an authorised PPP and the proper information of users of such seed throughout the EU.

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In order to achieve this, ESA has developed a “Safe Use Labelling Advice” which is currently being widely used by the sector. It combines detailed recommendations for the use of treated seed (based on the S-phrases provided by respective EU legislation) in all EU languages with easy to read and grasp pictograms that may be attached even to smaller seed packages. Furthermore, ESA recommends to its membership to add any specific labelling provisions requested by individual Member States as an interim measure.

It should be noted that in the absence of an accepted EU Guidance how to develop a sustainable approach to the labelling requirements for treated seed that takes account of the practicalities of the seed sector (small vs. large seed bags; free movement of treated seed; clear and unambiguous information relevant for treated seed), ESA continues to advise its membership to make use of this ‘Safe Use Labelling Advice’.

At the same time, ESA has already indicated how such a further development of the labelling provisions could be achieved. We are of the opinion that the Guidance should establish what labelling provisions are relevant for treated seed (not necessarily identical with the PPP in question) and how this information may be supplied to farmers and growers in a manner that takes account of supply chains, market realities and practical conditions of use.

For information and as a base for further discussion, ESA also supplies an overview of the different labelling approaches currently applied and/or discussed,

Implementation of the ESTA scheme

ESA is convinced that the successful implementation of ESTA, its EU wide quality assurance scheme for seed treatment and treated seed, is crucial to safeguard and support the future development and use of modern PPPs as seed treatments throughout the EU, not least as one of the few means to achieve the various ambitious reduction goals for the overall use of PPPs as triggered by the EU's sustainable use Directive.

ESA continues to advocate seed treatment as the most modern, most targeted and most environmentally friendly crop protection tool available today.

In order to promote and speed up the ESTA implementation, ESA would like to inform the Commission that it is actively recruiting a dedicated ESTA Manager who will support interested companies in their implementation of the respective risk assessment and quality assurance processes and measures for their seed treatment sites.

ESA as well as its membership have already made major investments in the quality assurance of treated seed and will continue to do so over the months and years to come. The seed sector is confident that the work done up to today, the achievements so far and the continued investments prove the seriousness of the professional seed sector to drive and implement a strict quality assurance for all seed treated in the territory of the European Union.