Report

Workshop Seed Treatment evaluation under Regulation (EC) 1107/ 2009

19 November 2020

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Preface

On Thursday 19 November 2020, Euroseeds and STISSC organized a workshop in view of the finalization of the guidance document for the authorization of plant protection products for seed treatments.

The workshop focused on the challenges the seed and crop protection industry is facing on the authorization and access of plant protection products for the treatment of seeds that are intended to be used within and outside the European Union (EU).

The workshop was well attended by representatives of the National Authorities of Austria, Denmark, Germany, Hungary, Ireland, Latvia, Lithuania, Netherlands, Poland, Spain, the European Commission (EC), academia and industry.

This report summarizes the content of the presentations as well as the discussion that followed.

Agenda

Virtual Workshop: Seed Treatment evaluation under Regulation (EC) No 1107/2009
Thursday 19 November 2020; 13.00-15.00 CET
Agenda

13.00-13.10	**Opening- Welcome**	***Amalia Kafka, Euroseeds***
	Sowing conditions	
13.10-13.30	**Sowing rates practices survey**	***Björn Neumann, Kynotec***
13.30-13.50	**The role of sowing rates in the evaluation and authorisation process**	***Anne Alix, Corteva***
13.50-14.10	**Q&A**	
14.10-14.40	**Access to PPPs for treatment of seeds that will be exported to 3rd countries**	***Michael Spellerberg, KWS*** ***Patrick Kabouw, BASF*** ***Steve Basel, Bayer***
14.40-14.55	**Q&A**	
14.55-15.00	**Conclusions- Closing**	***Klaus Schlünder, Euroseeds***

Sowing rate practices survey

Presented by Björn Neumann, Kynotec

The draft guidance document SANCO/10553/2012 May 2020_rev 19 for the authorization of plant protection products for seed treatment presents, in Appendix IV, an overview of maximum seed sowing rates for different crops. This overview is based on an EPPO publication Survey on dose expression and authorized dose, formally published in the EPPO Bulletin (2016) 46 (3), 618-624. In this paper, EPPO countries have been asked to provide information for a number of crops on maximum and minimum seed sowing rates as well as information on the most commonly used rate. The appendix IV of the guidance document retained the maximum commonly used rate for each crop as a basis for risk assessment.

The seed industry has some concerns about such methodology which does not reflect crop expertise. The seed industry has therefore commissioned a market survey on seeds for major crops, covering data collected over the last 30 years. The survey is designed to be representative of the market diversity. Farmers from all relevant countries for the target crop were interviewed each year with a standardized questionnaire. The number and distribution of interviewed farmers reflects the cropping area for the target crop in the country as well as national farm size class distribution according to national statistical offices. Such sampling method allows to weight data based on cropping area from respondent. In the survey, more than 12,000 farmers across 19 European countries were questioned every year for their maize seeds practices, for example.

The data analysis allowed to extract mean sowing rate or 90th percentile based on European cropping area. The results are presented below:

		EPPO, 2016		Kynetec, 2020 (2019 for WW)		
	Unit size	Max. rate	Max. common rate	Avge rate	Median rate	90th %ile
Maize	Thsd sd/ ha	150	110	82		
Grain use	Thsd sd/ ha			76	74	93
Silage use	Thsd sd/ ha			91	93	100
W-OSR	Thsd sd/ ha	1.600	900	501		
Hybrids	Thsd sd/ ha			468	480	600
Varietals	Thsd sd/ ha			668	495	750
Sunflower	Thsd sd/ ha	225	200	64	65	75
W-Wheat	kg/ ha	400	260	202		
Certified sd	kg/ ha			200	186	250
Farm saved sd	kg/ ha			207	190	277

Based on these results, the seed industry recommends to revise Appendix IV of the draft guidance document to reflect agricultural practices according to the following criteria: statistical analysis when seed survey data are available or on crop experts from the major growing countries where a survey isn't available. Indeed crops such as vegetables require more expert judgment as growers' practices and industrial production may be very different, so is their relative cropping area.

The role of sowing rates in the evaluation and authorisation process

Presented by Anne Alix, Corteva

The Seed Treatment guidance document (Sanco/10553/2012 rev 16) recommends the use of Maximum Commonly Used seed sowing rates for risk assessment purposes. The market survey conducted by Kynetec and presented during the workshop shows that for some crops, such as oilseed rape or sunflower, even the 90th percentile of the sowing rates recorded is significantly lower than the maximal common sowing rate reported in appendix of the guidance document.

The risk assessment of Plant Protection Products embeds a high level of conservatism, so that to ensure that a high level of safety is reached for all protection goals listed in (EC) Regulation No 1107/2009. In this context, it has become increasingly difficult to meet risk assessment criteria in the first-tiers of the risk assessment and high-tier risk assessments are triggered for a majority of products and uses.

Where refined risk assessments are triggered, a number of additional data is usually needed to refine entry parameters in models, such as groundwater and surface water models. Thus, where the sowing rate can actually be significantly lower than the recommended value, such as for winter oilseed rape for which the Kynetec survey indicated a 90th percentile of 600,000 seeds/ha, which is 2/3 of the Maximum Commonly Used Sowing Rate of 900,000 seeds/ha proposed by the guidance document (Sante, 2019), this can lead to a significant change in exposure estimates before to initiate additional studies.

In addition, where field studies are performed to complete a high-tier risk assessment, such as for soil organisms for example, or for non-target organisms exposed to dusts such as non-target arthropods or pollinators, the compliance with overestimated sowing rates is often not possible if they do not reflect the farmer's practice. Where a potential risk via dusts cannot be excluded, restrictions may apply regarding dust content that imply the use of stronger stickers, triggering possible problems of seed germination and interfering with current policy development regarding the use of polymers in formulations.

For workers, higher sowing rates will require longer seed loading time, and the size of area sown per day will be reduced as the sowing machine will have to dispatch more seeds. Although large farms have very fast sowing machines, the sowing rate is much lower. As for environmental compartments, the use of high sowing rate in conjunction with large areas sown per day is not realistic and can lead to unnecessary high-tier risk assessments, unjustified risk assessment conclusions and unnecessary use restrictions.

In conclusion, the ongoing work by the EU Commission and EFSA provide an opportunity to review the current proposed value for sowing rates to be used in the risk assessment, using the newly available data collected in the abovementioned survey. The use of realistic sowing rates would allow to avoid unnecessary studies, restrictions and refusals of authorizations, and would reconcile risk assessment to field conditions of use. It would also help towards the access to market of seed treatment solutions for minor uses and biological solutions developed as seed treatment, which are evaluated according to the same safety standards as Plant Protection Products.

Access to PPPs for treatment of seeds that will be exported to 3rd countries

Presented by Michael Spellerberg (KWS), Patrick Kabouw (BASF), and Steve Bäsel (Bayer)

Export of seeds is important for EU Member States and the seed industry. Such seed export has the unique feature that treatment for export takes place in high quality and certified facilities[1]. The EU Member States represent 62% of the worldwide seed trade, of which 90% are treated seeds. Thus, we need to ensure that the seed industry can use innovative seed treatments requested in the country of destination. We should use the favourable conditions of the EU and at the same time secure jobs and keep the EU as an attractive place for seed production.

Seeds which are exported from any EU-Member State (MS) into 3rd countries (meaning outside EU) are undergoing a clear and EU-wide harmonized ruling. A corresponding proof of export is given by the existing electronic customs procedure which is mandatory (Article 269 of the Union Customs Code - UCC) for any 3rd country export. With this procedure it is confirmed that an export of the goods has happened. A corresponding printout of the electronic export confirmation from the customs office of export on the border of the EU is available.
This export procedure is standard in any EU country and practiced since many years and applies to any type of seeds, so even those treated with a Plant Protection Product (PPP) not/no longer registered in EU.

[1] Based on data that was presented at last year's workshop, ESTA has improved treated seed quality with a high decrease of the level of dust.

A return of seeds treated with a non-registered PPP back into the EU would be possible only with an import permit, which will not be granted due to the non-registered PPP.

There is currently no harmonized approach to treatment of seeds produced in the EU that are destined for export outside the EU. Some Member States have put in place specific procedures to allow the treatment of seeds for their export in a country where the product is authorized, without requiring registration of the seed treatment under Regulation (EC) No 1107/2009; some Member States require to follow the complete registration process under the same Regulation. The draft seed treatment guidance document (GD) stipulates that a registration is needed and out-lines a potential scheme that can be used. Euroseeds & STISSC propose a middle ground approach: a permit for national treatment. This middle ground proposal considers the important characteristics like no environmental exposure and that treatment takes place in closed high-quality systems. The proposal as is currently stipulated in seed treatment guidance document is currently not complete as it is no specified which physical-chemical / toxicological /ecotoxicological studies are required. Also, a gap for the seed industry is the use of active ingredients (a.i.) that are not approved in the EU but for which there is a registered and safe use in countries outside of the EU, and that are potentially required by law in regions outside of the EU.

Our suggested workflow would consider the risk assessment for the operator, independently of the status of the a.i. in the EU. The risk assessment would be done according to EU models in force at the time of application, considering available endpoint. If an a.i. is not renewed in the EU, endpoint considered in the renewal process could be used. If the a.i. has never been approved / reviewed in the EU, an endpoint could be derived based on studies performed for non-EU countries. These two scenarios are illustrated with the example of a Bacillus a.i. that has never been approved in the EU, with an existing toxicological data package, and an insecticide that has been non re-approved, with an endpoint updated during the renewal process. In both cases, treatment for export to 3rd countries should be allowed according to our proposed workflow.

To summarize this topic:

- It is essential that the seed treatments remain accessible for treatment in the EU for seeds exported to non-EU farmers.
- There is high quality system in place that ensures that seeds intended for export to 3rd countries are traceable for export only.
- There currently are differencing views on how products intended for treated seeds for export should be considered.
- We suggested a balanced approach with national permits for treatment.
- The current guidance is not complete to address export only registration and if needed should be improved.

Discussion:

- Differences in sowing density has a significant influence on the risk assessment for all compartments (soil, surface and groundwater), workers, and in case of exposure via dusts. In the case of in-field non-targeted species such as birds and mammals feeding out of seeds and seedlings, or arthropods and pollinators feeding on nectar or collecting pollen, sowing density differences has less consequences since the number of individuals is largely outnumbered by the seed/plant density per hectare.
- Treated seeds intended to be exported to 3rd countries cannot be re-imported to the EU. For such activity, an import permit is required. This import permit however cannot be issued in this case since the seeds are treated with non-approved a.i./products.
- Operator exposure assessment (RA) may be proposed by the company and may be evaluated by the MS authorities where the treatment takes place. MSs shall align amongst them regarding the RA requirements.
- Treatment can take place in all facilities located in the MS under a "national permit"
- The operator's RA shall be performed as it would have been performed under Regulation (EC) No 1107/2009 applications.
- ESTA certification may be used as prerequisite for treatments for exports to 3rd countries.
- AOEL for active substances that have never been approved in the EU can be derived from studies that are generated in the country of destination, or any other country where the a.i. is authorized.

Conclusions

- Currently the authorisation of new seed treatment products is often refused due to the use of exaggerated sowing rates. A realistic scientific based approach was presented. The National Authorities representatives were invited to make use of this data.
- The seed industry operates under highly professional requirements and thus it needs to maintain its business for export while treating within the EU, even with non-approved active ingredients according to Regulation (EC) No 1107/2009.