EUROPEAN COMMISSION
HEALTH AND CONSUMERS DIRECTORATE-GENERAL

Directorate E – Safety of the food chain
Unit E.3 - Chemicals, contaminants, pesticides

SANCO/10553/2012 rev. 0

8 March 2012

Guidance document on the authorisation of plant protection products for seed treatment

1. Introduction

1.1 About this Guidance document

For whom is this guidance document intended?

This guidance document is intended for employees working on the evaluation of the dossier for plant protection products (PPP) for seed treatment under Regulation 1107/2009 at the Competent Authorities of their EU Member State. In addition, the information in this manual may also be useful for industry.

Legally binding

The guidance document as such is not legally binding. However, for a good working system of authorisation of PPP for the treatment of seed and the use of treated seed in all Member States, it is needed that all Member States use the same harmonised method.

Why has this guidance document been compiled?

Under Regulation 1107/2009 Europe is one zone concerning the authorisation of plant protection products (PPP) for seed treatment. When a PPP is authorised for seed treatment in an certain member state, the treated seed can be freely traded to, and used in all EU Member States. For both the treatment of seed and the sowing of the treated seed Member States are dependent on the assessment carried out by other Member States. This guidance document intends to harmonise the risk assessment and the criteria for evaluation of the application of a PPP for seed treatment and the use of treated seed.

Scope of this guidance document

This guidance document comprises the harmonisation of the evaluation and authorisation of PPP's for seed treatment. The evaluation involves the treatment process of seed and the sowing of the seed in the field. When the treated seed is intended to be exported outside the EU and not used in the EU, the evaluation for sowing the seed in the field can be omitted.

Definition of seed for the purpose of this guidance document: seed for sowing or intended for sowing and not for consumption or processing (grain) for any cultivation purpose, including pregerminated or primed seed.

Not included in the definition of seed in this guidance document are:

- Other types of propagating material such as seedlings, plantlets, bulbs, tubers, and any other part of plants used for the production of a new plant.
- Treated compost on which seed is placed prior to covering with compost in a module-based system.

Chapter 2 gives a short and comprehensive overview of the general principles of the authorisation process for PPP for the treatment of seed. In Chapters 3 – 9 the different aspects of evaluation and authorisation are elaborated in more detail and can be used as guidance by the evaluator responsible for those specific parts of the dossier evaluation.

Point for discussion:

1. The scope of this document should be discussed again and probably narrowed to take into account that seed treatment uses, as other uses, are currently assessed using the relevant existing guidance documents. Only specific considerations (e.g. dusts), which are not

currently included in the relevant guidance documents (i.e. honeybee and non-target arthropod risk assessment from dust drift) need to be included in the proposed guidance.

2. General principles of assessment of treatment of seed and the use of treated seed

2.1 Legal framework

This guidance document comprises the harmonization of the evaluation criteria to be considered within the evaluation process of applications of plant protection products for seed treatment. This guidance as such is not legally binding.

In case of seed treatment there are two different situations: the treatment of seed itself and the placing on the market of treated seed.

Treatment of seed

For the use of a plant protection product as a seed treatment in a Member State, a national authorization in that Member State is required. This is comparable to the situation with plant protection products used as a crop treatment. However, there is one important difference. In article 3 (Definitions) of the Regulation, the following definition for 'zone' is given (definition 17): 'zone means a group of Member States as defined in Annex I. For the purpose of use in greenhouses, as post-harvest treatment, for treatment of empty storage rooms and for seed treatment the zone means all zones defined in Annex I'. This means that the zonal evaluation can be done in any member state of the European Union which evaluates the application, taking account of all zones. After the authorization in one or more Member States has been obtained authorizations in other Member States can be obtained through the procedure for mutual recognition.

Placing on the market of treated seeds

Article 49 (Placing on the market of treated seeds) of the Regulation, lays down rules on the marketing of seeds treated with plant protection products. Strictly speaking, this is not about using a plant protection product, but about using seed treated with plant protection products for any cultivation purpose (agriculture, floriculture, horticulture, forestry…). It is forbidden to place seeds on the market or to sow seeds which are treated with a plant protection product that is not authorized in at least one of the EU Member States.

The regulation provides that a Member state may not impose any ban on the marketing or use of treated seed, if the seed has been treated with a plant protection product in a Member State that has authorized that plant protection product for the treatment of that seed.
Where there are substantial concerns that treated seeds are likely to constitute a serious risk to human or animal health or to the environment in another Member State and that such risk cannot be contained satisfactorily by means of measures taken by the Member States concerned, measures to restrict or prohibit the use and/or sale of such treated seeds shall be taken immediately in accordance with the regulatory procedure referred to in Article 79(3). Before taking such measures the Commission shall examine the evidence and may request an opinion from the Authority.

Article 49, fourth paragraph of the regulation further provides that the documents and the label accompanying the treated seeds (not on the official label for seed certification), shall include the name of the plant protection product with which the seeds were treated, the name(s) of the active substance(s) in that product, standard phrases for safety precautions as provided for in Directive 1999/45/EC and risk mitigation measures set out in the authorisation for that product where appropriate.

Treatment of seeds for export outside the EU

The application of a PPP in a Member State is subject to national authorization. There are no special EU rules for the export of the treated seeds outside the EU.

2.2 Procedural issues

This guidance document comprises the harmonisation of the evaluation and authorisation of PPP's for seed treatment. The evaluation and authorisation involves the treatment process of seed and the sowing of the seed in the field.

In the evaluation process of a plant protection product for seed treatment the following differentiations need to be considered:

1. evaluation and authorisation of the product intended for seed treatment;
2. evaluation of the treatment process of seed (covered by operator exposure studies and model calculation) .
3. evaluation of the sowing process in the field (new since dust issue occurrence during sowing or drilling process).

The procedure for the evaluation and authorization of the product intended for seed treatment is of the same as for other PPP. However, for seed treatment there is just one zonal Rappoteur Member State (zRMS) for the whole EU. Plant Protection Product for seed treatment need a national authorization to be used to treat seeds, then the marketing of treated seed with PPP should be free on the market within EU

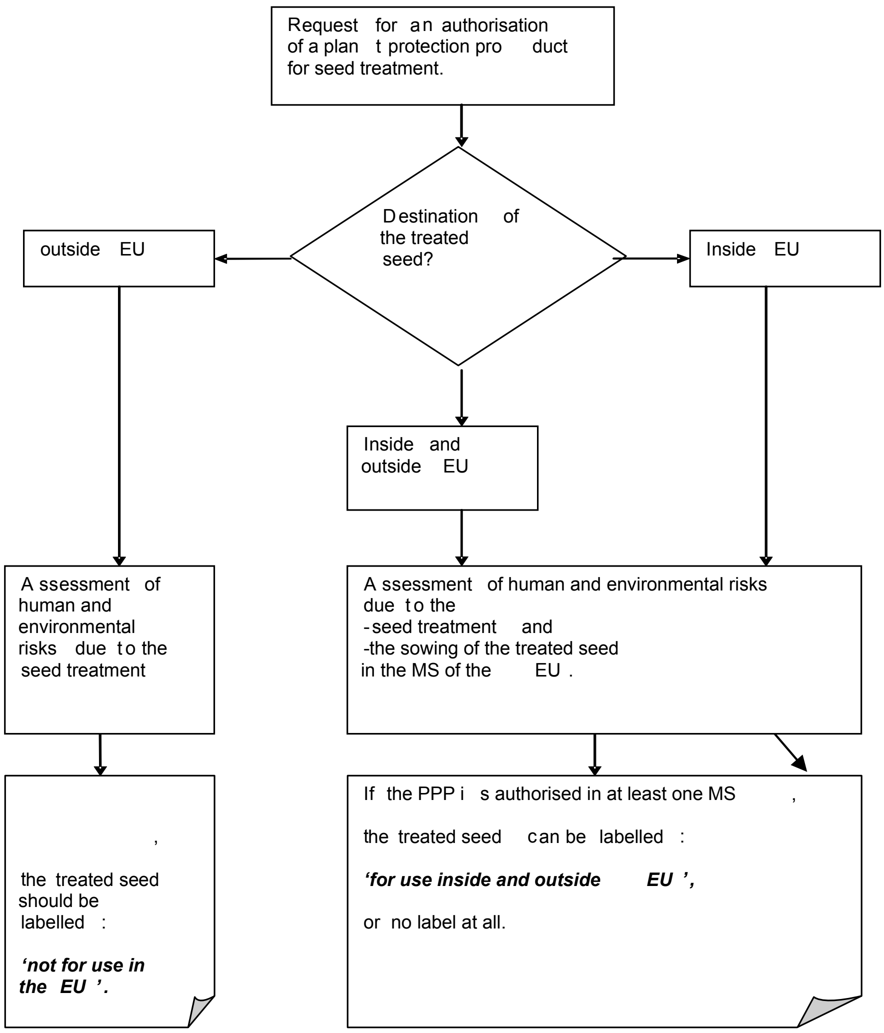
Member states shall not prohibit placing on the market and use of seeds treated with plant protection products authorised for that use in at least one member state of the EU [article 49]. This means that the zonal evaluation can be done in any Member State of the European Union which evaluates the application. The zonal Rapporteur Member State (zRMS) shall carry out the risk assessment according to the zonal evaluation and mutual recognition under Regulation (EC) No 1107/2009 (SANCO/13169/2010).

Article 28 of Regulation 1107/2009 states the following: 'A plant protection product shall not be placed on the market or used unless it has been authorised in the Member State concerned in accordance with this Regulation.' This means that for the treatment of seeds in the member states only an authorised plant protection product may be applied, even in the case of export of the treated seed outside the EU. It also means that an evaluation of risks of the sowing of treated seed is not needed when the treated seed is only used for export outside the EU (see Figure 1).

Point for discussion:

1. How to check the quality of the seed treatment process and the quality of the treated seed? Could we take the approach reported by ESA in their guidance document as a point to start

discussions? (This question could be discussed at level of Interzonal Steering Committee. Furthermore, this is already laid down in the legislation (art.36 (1) Regulation 1107/2009)


Request for an authorisation of a plant protection product for seed treatment.
Destination of the treated seed?
outside EU
Inside EU
Inside and outside EU
Assessment of human and environmental risks due to the seed treatment
Assessment of human and environmental risks due to the
-seed treatment and
-the sowing of the treated seed
in the MS of the EU.
,
the treated seed should be labelled :
'not for use in the EU'.
If the PPP is authorised in at least one MS ,
the treated seed can be labelled :
'for use inside and outside EU',
or no label at all.

3. Residues

3.1 Introduction

Although for the majority of uses after seed treatment no residues are expected in the harvested product, residues cannot be excluded on forehand. Depending on the active substance, its systemic properties and metabolic behaviour, the dose rate and the growth rate of the crop might determine whether residues are (still) present at the time of harvest. Therefore, in general a complete residue dossier should be provided for application via seed treatment for plants used for consumer and live stock products.

3.2 Risk Envelope approach

Since seed density determines the dose level in gram active substance per area it cannot be excluded that high seed densities result in higher residues. Therefore residue data should be generated according to the worst case seed density in Europe (‘risk envelope approach’).

3.3 Guidance Documents

Seed treatment is described in the current EU guidance for the assessment of residues: ‘Guidelines for the generation of data concerning residues as provided in Annex II part A, section 6 and Annex III, part A, section 8 of Directive 91/414/EEC concerning the placing of plant protection products on the market, Appendices A-I’.

For seed treatment, special data sets are needed for metabolism (i.e. application by seed treatment or soil treatment, appendix A of the EU guidance). Furthermore, a separate extrapolation table for supervised residue trials is applicable to seed treatment (table 5 of Appendix D).

3.4 Evaluation zone

For seed treatment, only one zone for evaluation is foreseen for Europe according to Article 3, (definitions) of 1107/2009. This means that residue trials performed according to worst critical EU-GAP in any member state cover the uses in the entire EU.

3.5 Others

For the other sub aspects (like storage stability, metabolism and feeding in livestock, MRL setting) the same procedures and guidance apply as to foliar applications.

4. Efficacy

For the assessment of the efficacy of plant protection products applied as a seed treatment no additional guidance is needed. The guidance is covered by EPPO standards that are regularly discussed and updated on expert level.

5. Physico-chemical properties

For the assessment of seed treatment no additional guidance is needed. Covered by current system (Manual on Development and Use of FAO and WHO Specifications for Pesticides, current edition and Croplife International: Technical Monograph No. 17). Furthermore, dust and abrasion tests (Heubach test) are introduced since 2008/2009 and a test methods are available. When this method becomes an European adopted method, this test may be included in this guidance document, since this is not (yet) covered by any other guidance documentation.

6. Analytical methods

For the assessment of treated seed no additional guidance is needed. This is covered by the current system (SANCO/3030/99 and SANCO/825/00).
When treated seed is used in MS other than the RMS, residue analytical methods need to be available for enforcement purposes (for both environment and consumer) for these MS. Therefore, residue analytical methods should be submitted and evaluated, by the RMS, even if the treated seed is used for trade to other EU Member States only.
If the treated seed is used only for export outside the EU, no residue analytical methodis needed.

7. Occupational health assessment

7.1 Exposure assessment

In 2010, the EFSA Panel on "Plant Protection products and their Residues" have prepared a draft scientific opinion on the preparation of a Guidance Document on pesticide exposure assessment for workers, operators, bystanders and residents. The finalisation of the Guidance Document is expected in the near future (December 2012). .

Since the above mentioned Guidance Document on pesticide exposure assessment is expected to become available soon, the information below should be regarded as helpful information for the risk assessment of human exposure during treatment of seeds and subsequent sowing.

For the human risk assessment, three distinct aspects should be considered:

a. risk assessment of people involved in the treatment (treating or coating) of seeds with plant protection products (PPPs);
b. risk assessment of people handling the treated seeds during the sowing activities, and
c. risk assessment of people located in the vicinity of the sowing site (the so-called 'bystander') or working or living in the vicinity of the sowing site (the so-called 'resident').

In general a first tier assessment for operator and worker exposure is based on models. Where no satisfactory model is available for an exposure scenario, or the initial risk assessment using a conservative model gives inadequate reassurance of safety, the notifier may generate higher tier exposure estimates through an ad hoc study specific to the circumstances in which the pesticide will be used (EFSA, 2010).

7.2 Treatment of seeds

Usually, highly specialist operators are treating the seeds with PPP in a (semi-) industrial environment. However, sometimes e.g. cereal or grass seed is treated by farmers using less automated equipment. There are SEEDTROPEX data, developed by industry, which estimates operator exposure during several activities of seed treatment, such as calibration, mixing/loading, cleaning, and bagging of seeds. These data cover static and mobile seed treatment units. The SEEDTROPEX data also includes monitoring data of forklift drivers to assess background exposure of subjects being not directly involved in the seed treatment process.
However, the data are owned by a Task Force and are not publicly available. Moreover, the data are applicable for certain types of seed and certain circumstance only. There appear to be different versions of a SEEDTROPEX model. The EFSA GD on pesticide exposure does not propose the use of a SEEDTROPEX model, and concludes that the SEEDTROPEX data should be used in the same way as other ad hoc data sets.

7.3 Sowing of treated seeds

During the process of sowing these treated seeds, workers (farmers) are potentially exposed to PPPs during loading the equipment with treated seeds and workers, bystanders and residents are potentially exposed during the actual sowing, and this exposure is therefore relevant for risk assessment.

7.3.1 Routes of exposure

During sowing activities of treated seed, the main routes of exposure are dermal adsorption and inhalation. Dermal exposure to PPPs can occur during contact with the treated seeds and through contact with contaminated equipment or through deposition on the skin. Inhalation exposure may occur as a result of drift from particles abraised from seeds and additionally, from solid or dried PPPs from the treated seeds that become airborne or from soil contaminated with residues from treated seeds. This secondary drift from contaminated soil is not considered relevant for the farmer exposure. Oral exposure may occur secondarily to dermal exposure, through hand to mouth transfer. This is especially relevant for infants or toddlers playing on contaminated surfaces. However, for farmers, maximum potential exposure by this route is generally assumed to be negligible in comparison with that via the skin and by inhalation.

7.3.2 Determinants of exposure

Dust drift from treated seeds during sowing is the main source of airborne exposure during sowing. The dust originates from the coated seeds. Studies performed by the Julius Kühn Institut (JKI) in Germany show that a considerable amount of fine dust (< 0.5 mm) may be present in bagged seeds. The pesticide residue has been determined in both fine and coarse dust present in the bags with seeds. In fine dust the residue content was in the order of 20-30%, while in coarse dust this was in the order of 10 to 15%. Amount of residue content might be variable (influenced e.g. by the content of the a.s. in the formulation and the application rate). Highest dust levels were measured in maize, while this was lower in rape seed, sugar beet, carrot and onion. Barley, wheat, triticale and rye also contained a relatively large amount of both fine and coarse dust in seed bags. Differences were seen between coating facilities and crop type (JKI info, from powerpoint presentations).
In a study on bee poisoning (Pistoris, 2009), it was concluded that the poisoning resulted from abrasion from treated maize seed which was released during the sowing process when using pneumatic sowing machines. In some seed batches, up to 40 grams of dust was found per 50,000 kernels of maize.

The seed treatment process is also of influence on the resulting dust in the end product (bags with seeds). Adequate application of processes for treatment of seed, have a positive impact on minimizing dust abrasion. For example, when during seed treatment only dust free seeds are used, any dust produced during the process is sucked off and dust is also sucked off before packing (preferably on dry seeds), or when additives (e.g. binders) are used this has a positive impact on the dust formation during the sowing activities. On the other hand, aging of the treated seeds can have a negative impact on the dust formation during the sowing.

The ESA has drawn up guidance for proper seed treatment facilities and adequate seed drilling equipment. Advice on safe use of treated seed is also given. The recommendations in the ESA guidance are targeted at minimizing the environmental risks linked to abraded dust from treated seeds (STISSC & ESA, 2010). However, no clear specifications on adequate equipment are given.

As indicated in appendix V, farmers should avoid exposure. Care should be taken not to shake the dusts off the bags or to load the dust in the bottom of bags into the driller. Hand contacts with the seeds in the hopper, for example with the aim to spread the seeds, should be avoided. During loading operations farmers must have appropriate individual protection. Clear water should be available on the tractor to rinse any dusts they could come in contact with and to rinse gloves after loading. Rinsed gloves should then be removed.

In case where a re-loading of the drilling machine is necessary, the turbine of the driller should be stopped. During sowing operations farmers must consider wind direction and wind speed to avoid contamination of surrounding areas.

The SEEDTROPEX data include data on worker exposure during sowing activities. However, the data are owned by a Task Force and are not publicly available. Moreover, the data are applicable for certain types of seed and certain circumstance only. There appear to be different versions of a SEEDTROPEX model. The EFSA GD on pesticide exposure does not propose the use of the SEEDTROPEX model, and concludes that the SEEDTROPEX data should be used in the same way as other ad hoc data sets.
For bystander and resident exposure during or after seed sowing operations no validated models are available. However, the attrition rate could be used as a first tier surrogate value for possible bystander and resident exposure via dust drift.

8. Environmental risk assessment

8.1 Treatment of seeds
For the risk assessment for the coating process of seeds a harmonised evaluation method is needed. *Has any of the member States a method (for PPP or biocides) that can be used?*

8.2 Sowing of treated seeds – in field exposure

8.2.1 Exposure parameters sowing in-field

a. exposure to surface water
The exposure to surface water due to run-off and drainage is covered by FOCUS SW[1]. In relation to FOCUSSW, exposure to surface water via dust was covered by a PPR Panel Opinion that has developed procedures to estimate dust drift deposition of NSAs (Non Spray Application) onto surface water and proposes another parameterization of the model input for the entries of various NSAs than the current parameterization of the FOCUSsw Guidance [2] (see 8.4.1).

Next to this an alternative method for calculating worst case concentration in surface water from dust drift exposure is presented in chapter 8.4.2.

b. ground water
The exposure calculation to groundwater for PPP applied via treated seeds will be equal to the calculation for field spray application. PECgw calculations are currently covered by FOCUS GW with a crop interception value of 0 combined with application made on the date of planting/sowing and incorporation into the soil over the top centimetre (cm).

c. exposure to soil arising from treated seeds
For an adequate risk assessment for soil organisms a refined approach may be needed.
For small seeds there is in fact no difference in PEC value if assuming equal spread over the top 5 cm. For large seeds with a low sowing density it may be more worst case in the direct surrounding of the seed kernel.
Therefore a division in small and large seeds is proposed (point for discussion).

Small seeds
For small seeds (diameter <0.5 cm) usually high sowing density is applied. Therefore there is in fact no difference in PEC value if assuming equal spread over the top 5 cm.

In the evaluation of spray formulations the homogeneous distribution of the active substance in the top 5 cm layer of the soil is considered. For the calculation of the PIEC, interception is taken into account but disappearance routes such as evaporation, photochemical transformation and microbial degradation are not. The volume of soil with a layer thickness of 5 cm of a hectare is 500 m^3, and the mass of the soil is $750*10^3$ kg (at a bulk density of 1500 kg/m^3). The

1 FOCUS (2001). "FOCUS Surface Water Scenarios in the EU Evaluation Process under 91/414/EEC". Report of the FOCUS Working Group on Surface Water Scenarios, EC Document Reference SANCO/4802/2001-rev.1. 221 pp

2 Opinion of the Scientific Panel on Plant Health, Plant Protection Products and their Residues on a request of EFSA related to FOCUS sw scenarios. *The EFSA Journal* (2004)145, 1-31.

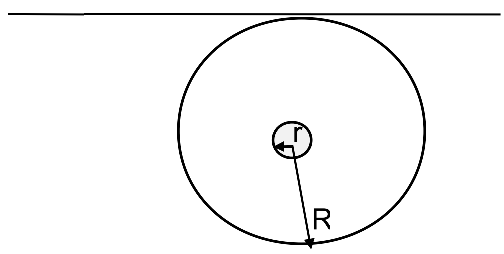
dose of active substance divided by the mass of the soil then yields a measure for the acute exposure of soil organisms (= PIEC).

Large seeds
For seeds with a diameter larger than 0.5 cm the PECsoil may be more worst case in the direct surrounding of the seed kernel. This however, also will depend on the sowing density and the behaviour of the active substance of the coating.
Therefore on the fate side of the risk assessment besides the current homogeneous concentration in a soil layer of 5 cm an additional, sometimes more relevant PEC soil calculation is considered necessary.

Based on information of different seeds (e.g. radius, sowing density) and the amount of soil involved (sphere of influence of the seed) an alternative risk assessment based on a PEC sphere calculation methodology for the soil compartment will be proposed.

Seeds with a diameter > 0.5 cm sown at 5 cm or larger depth a scenario as presented below should be followed (figure 1).

Figure 1. Sphere of influence of seeds > 0.5 cm sown at 5 cm depth. Scenario B.



Depending on the soil organisms, the properties of the substance and the duration of the exposure this approach is sometimes more relevant.
The sphere of influence of seeds with a diameter > 0.5 cm, sown at 5 cm depth or below has the shape of a whole sphere (see figure 1). Since the size of the seed is not negligible, the volume of the seed must be subtracted from the volume of the sphere. The model parameters are described in Table 1.

The volume of a round seed is: v seed = 4/3 π r3

The volume of the sphere of influence of a seed is calculated as follows: v = 4/3 π (R3 - r3)

Whereby for R, the radius of the seed, the radius of the sphere of influence is added, hence R = r + 0.05

Subsequently, the volume and mass of the soil within the sphere of influence of seeds per m2 is calculated. The total volume of the sphere of influence on a hectare of soil is limited to a maximum of 500 m3/ha, and is calculated as follows: V = min[n·v, 500]

The total amount of soil on a hectare that is found within the sphere of influence of a seed is then: $M = \rho \cdot V$

The dose of the seed treatment product is then divided by the mass of the soil within the sphere of influence of the seeds, leading to the following calculation of the PIEC results in the PIEC: PIEC = 106 D / M

Table 1. Description of parameters.

Input		
R R N D ρ	radius of sphere of influence of the seed radius of the seed seed density Dose dry bulk density of the soil	M M ha^{-1} kg a.s.$\cdot$ ha^{-1} kg$\cdot$ m^{-3}
Intermediates		
V Vseed V M	volume of the sphere of influence of a seed volume of a seed total volume of soil within the sphere of influence of the seeds on a hectare of soil total mass of soil within the sphere of influence of the seeds on a hectare of soil	m^3 m^3 $m^3\cdot$ ha^{-1} kg$\cdot$ ha^{-1}
Output		
PIEC	Predicted Initial Environmental Concentration	mg a.s./ kg soil

8.2.2 Risk assessment treated seed in-field

General points of attention for the risk assessment for the EU as one zone:

- Sowing practice (e.g. density, depth, incorporation) differs between EU member states. For the environmental risk assessment this means that exposure concentrations will differ between EU member states.
- Risk mitigation measures may differ between member states.
- Dissipation/degradation data in soil, water, plant and invertebrate material differs between regions in EU.
- Soil PEC's may differ within EU when the eco-region concept (IRIS) is implemented in the revised guidance document on terrestrial ecotoxicology.

Ecotoxicology:
For the effect assessment on soil organisms no additional guidance is presented. It should be noted that it is not the intention of this guidance document to go into detail on the ecotox assessment, since new guidance is in development at EFSA with the revision of the Terrestrial guidance document (SANCO/10329/2002) (e.g. the new ecoregions concept). Until the revision of the Terrestrial guidance document is finished, the currently available guidance on soil organism risk assessment can be used. However: it should be noted that the higher tier risk assessment for the EU as one zone will have to differentiate between member states and/or EU-regions for several refinement options that may differ between member states. This is specifically the case for birds and mammals, but also for e.g. higher tier field testing with soil

arthropods and earthworms. In addition, general sowing practice (e.g. density, depth, incorporation), risk mitigation measures, and dissipation/degradation data in soil, water, plant and invertebrate material are general issues that differ between regions in EU.

Non target organisms that need to be adressed in the risk assessment for sowing of treated seeds:

Birds and mammals: Birds can be exposed to the active substance as a result from consumption of treated seeds, which is covered in the existing guidance for birds and mammals.

However: it should be noted that the higher tier risk assessment for the EU as one zone will have to differentiate between member states and/or EU-regions for several refinement options for birds and mammals that may differ between member states. This is the case for: focal species and accompanying refined PD and PT and residue decline data in soil, plant and invertebrate material.
In addition, soil PEC's may differ within the EU when the eco-region concept (IRIS) is implemented.

- Aquatic organisms: Aquatic organisms can be exposed to the active substance via the soil as a result from run off and drainage. This is covered with the existing methods (FOCUS SW). However: it should be noted that the higher tier risk assessment for the EU as one zone will have to differentiate between member states and/or EU-regions for several refinement options such as mesocosms and risk mitigation measures.

- Bees: Bees can be exposed to the active substance via the soil as a result from systemic uptake of the a.s. by the plant from the treated seed (via nectar, pollen and honeydew). This is covered by the recently revised EPPO standard PP3/10 (Environmental Risk Assessment Scheme for Plant Protection Products, Chapter 10: Honeybees). In addition, EFSA is working to produce a scientific opinion on the science behind the development of a Risk Assessment of Plant Protection Products on bees (Apis mellifera and Bombus spp.) (March 2012) and to prepare a Guidance Document on the Risk Assessment of Plant Protection Products on Bees (2012). However, should higher tier studies be used for risk assessment then care should be taken to ensure that these are relevant to each MS.

- Non-target arthropods: Soil dwelling non-target arthropods can be exposed to the active substance via the soil. Current test guidelines with soil arthropods are based on homogenous mixing of the test substance with the test soil. This can be tested against the current standard endpoints for soil arthropods. From a scientific point of view however, it is best to have matching types of exposure and effect concentrations in the risk assessment. Therefore, performing ecotoxicity tests (laboratory and/or field) with treated seeds could be a possible higher tier option for the risk assessment.

Further point of attention for the higher tier risk assessment, in addition to the general issues as mentioned above: when higher tier non-target arthropod field testing is performed, it should be assessed whether the tests can be used to adress the whole EU zone. When recovery is included in the endpoint, preferably field testing is performed in both North and South EU. In De Jong et al. (2010)[3], the following is stated on this issue:

[3] De Jong et al. (2010). Guidance for summarising and evaluating field studies with non-target arthropods. RIVM report 601712006.

'Furthermore Candolfi et al. (2000a) indicate that field studies cannot be extrapolated from Southern European countries to Northern European countries and the other way round. This is especially valid concerning recovery. Due to higher temperatures other species occur, a number of organisms have shorter life cycles in Southern Europe, or more generations per year as compared to Northern Europe. A study by Aldershof and Bakker (2010, Poster presented at ESCORT 3) however shows that the differences in the effects of insecticides might be limited. It is also indicated that more research is needed before a clear recommendation about the possibilities for extrapolation, and differences between crop types can be given. What the upcoming zonal registration means for the extrapolation of field study results remains to be studied. Concerning the NOER, or the rate at which the most sensitive endpoint starts to react, it might be possible to use a similar approach as for the use of aquatic mesocosms in risks assessment for aquatic aspects (cf. Brock et al., 2006) after proper scientific evaluation.'

- Earthworms: earthworms can be exposed to the active substance via the soil. In section 8.4 of this guidance document the estimation of the soil concentration resulting from treated seeds sown in the field is elaborated. If a relevant PECsphere has been calculated that is significantly higher than the homogenous PECsoil, the first should be used for risk assessment. Current test guidelines with earthworms are based on homogenous mixing of the test substance with the test soil. These can be tested against the current standard endpoints for soil arthropods. From a scientific point of view however, it is best to have matching types of exposure and effect concentrations in the risk assessment. Therefore, performing ecotoxicity tests (laboratory and/or field) with treated seeds could be a possible higher tier option for the risk assessment.

Further point of attention for the higher tier risk assessment, in addition to the general issues as mentioned above: when higher tier earthworm field testing is performed, it should be assessed whether the tests can be used to address the whole EU zone. When recovery is included in the endpoint, preferably field testing is performed in both North and South EU.

- Soil micro-organisms: Soil micro-organisms can be exposed to the active substance via the soil. For the risk assessment for soil micro-organisms it is referred to the existing and upcoming revised guidance (Terrestrial guidance document)

- Non-target terrestrial plants: For non target terrestrial plants no direct exposure via the soil as a result of treated seeds is expected. However, the dust drift route should be taken into account (see section on dust drift).

8.3 Sowing of treated seeds - Dust drift route

Aim of this chapter is to provide guidance on the assessment of the environmental risk for non-target organisms arising from dust deposition in non-target areas after sowing seeds treated with plant protection products. It is assumed that the risk assessment for birds and mammals via eating treated seeds (which is covered by existing guidance for bird and mammal risk assessment), will cover the potential exposure via dust drift. Further, since herbicides are not used for seed treatment a risk assessment for non-target plants via dust is currently not considered necessary, except when (screening) data indicate that the product may have adverse affects on plants.

The full, detailed version of the dust drift risk assessment guidance is included in Appendix VI. Below, a summary is included to facilitate a quick start with the risk assessment. It should be noted however, that Appendix VI includes several points for discussion/issues to be solved, which should be taken note of by the reader.

The assessment schemes and measures described below are of preliminary nature and follow precautionary principles. Further guidance will be given when a broader data base will be available.

8.3.1 Exposure parameters dust drift route

a. exposure to surface water
In relation to FOCUSSW, exposure to surface water via dust was covered by a PPR Panel Opinion that has developed procedures to estimate dust drift deposition of NSAs (Non Spray Application) onto surface water and proposes another parameterization of the model input for the entries of various NSAs than the current parameterization of the FOCUSsw Guidance [4].

Next to this an alternative method for calculating worst case concentration in surface water from dust drift exposure is presented in chapter 8.3.2.

b. exposure to ground water
The exposure calculation to groundwater for dust deposition from PPP applied via treated seeds is covered by the in-field assessment.

c. persistence in soil
The persistence in soil for dust deposition from PPP applied via treated seeds covered by the in-field assessment.

Off-field exposure.
The emission of seed dust during seeding is variable, depending upon the care taken during all the steps; from the preparation of seeds before treatment, up to the type of driller used. **Appendix V** describes Good practices and quality standards for the treatment of seeds and for the use of treated seeds. In this Appendix, four example crops are described in more detail (maize, OSR, sunflower, sugar beet)

Dust drift values used as a basis for risk assessment should not be generated with seed batches having outstandingly good treatment quality (i.e. relatively low Heubach-values and/or low concentrations of a.i. in the dust), since these are not representative for the quality of seed on the market. Therefore, the dust drift values presented in the second next table (please refer to Table 8-2) should only be used for regulatory risk assessments if the criteria of Table 8-1 below are fulfilled. They are meant for a general evaluation of all types of products. However, extrapolation between crops will need to be further substantiated.

Table 8-1: Quality values for four seeds/crops set as requirements for a worst case risk assessment of dust deposition in non-target areas.

4 Opinion of the Scientific Panel on Plant Health, Plant Protection Products and their Residues on a request of EFSA related to FOCUS sw scenarios. *The EFSA Journal* (2004)145, 1-31.

Crop	Maximum Heubach-value* (dust in g / ha or No. of seeds)	Maximum a.i. content in dust** (%)	Heubach-value recalculated to a.i. content (mg dust a.i./ ha or No. seeds)
Maize	0.75 g / 100.000 seeds	20 %	150 mg a.i./ 100.000 seeds
OSR	0.5 g / 700.000 seeds	10 %	40 mg a.i./ 700.000 seeds
Cereals	2 g / ha (ca. 150 – 250 kg/ha depending on the crop)	10 %	200 mg a.i./ha
Sugar beets	0.2 g / 100.000 seeds	10%	20 mg a.i./ 100.000 seeds

* See Chapter 2.1 in Appendix V

** See Chapter ????…

Standard 2-D ground deposition exposure assessment

Preliminary ground dust drift percentages at 1 m distance from field edge (defined as PECdust ground deposition) have been determined for four crops which can be used for a first tier risk assessment. The values were normalised for maximum Heubach values, drill width and a.i. % in dust (see Annex VI for details). Due to uncertainties in the underlying data, these values may be revised as soon as better data become available. It should always kept in mind, that the listed exposure values are valid only if pneumatic suction drillers are equipped with deflectors.

The 2-D dust drift values can also be used for the calculation of the PECsw, and for the off-field risk assessment for non-target arthropods (if no 3D-exposure values are available) (see below for further explanation).

Table 8-2: 90th percentile ground dust drift values and normalized 2-D-exposure data to be used in the risk assessment of contaminated dust in non-target areas (percentage of field rate of a.i. / ha in 1 m distance from field edge). (Valid only if pneumatic suction drillers are equipped with deflectors. See text Appendix VI for details).

Crop	Type of seeder	Experimental parameters covered	Experimental ground dust deposition (uncorrected value) (% a.i. field rate /ha)	Normalized Exposure 2-D (% a.i. field rate /ha)
Maize	pneumatic, vacuum technique	Drill width: 45 m Heubach: 0.45 a.i. in dust: 19.2 %	0.310	0.56
OSR	pneumatic	Drill width: 48 m Heubach: 0.38 a.i. in dust: 6.3 %	0.093	0.22
Cereals	pneumatic	Drill width: 100 m Heubach: 2.1 a.i. in dust: 8 %	0.266*	0.33

Sugar beets	all techniques	-	-	0.001

* 95th Percentile. See text for details

Table 8-2 presents the original ground deposition values from experiments (**see appendix V**) as well as the normalized values. Only the normalized ground deposition values should be used in the environmental risk assessment, since they correctly predict the 2-D exposure to dust drift in realistic worst case situations. If, in future, the standard quality of the seeds on the European market will improve clearly, adapted values for deposition in non-target areas may be derived.

Standard 3-D exposure assessment

Investigations after the bee incidents in Germany have shown that species living or foraging in 3-D structures like hedgerows, trees or other crops are exposed to higher deposition rates of contaminated dust than the species living on the ground. Therefore, an 2-D/3-D extrapolation factor was derived. Based on the experimental results from a worst case study in maize (see Appendix VI) where treated maize seeds were sawn, a factor of **12.4** has been determined for the extrapolation between residue levels of a.i. in petri dishes on the soil surface and the vertical projection area of gauze net. The proposed factor represents the median of all possible ratios of residues samples from experimental data. Since the extrapolated factor of 12.4 results from few experiments with variable experimental conditions, there is still a high degree of uncertainty to this factor.

A number of non-target organisms are however, potentially exposed from 3-D like structures. Measured or calculated 3-D dust drift values can be used for the off-field risk assessment for these organisms like e.g. honeybees and foliar-dwelling non-target arthropods.

Table 8-3: Predicted exposure in 3 dimensional structures in non target areas due to deposition of dust drift after sowing treated seeds. Values are given as percentage of max. field rate of a.i. / ha in 1 m distance from field edge, based on 2-D deposition values and considering an extrapolation factor from 2-D to 3 dimensional structures of 12.4. See text Appendix VI for details

Crop	**Type of seeder**	**Exposure 3-D** (% a.i. field rate /ha)
Maize	pneumatic, vacuum technique	7.0
OSR	pneumatic	2.7
Cereals	pneumatic	4.1
Sugar beets	all techniques	0.01

8.3.2 Risk assessment dust drift route

Aquatic organisms

For the risk assessment of aquatic organisms, TER can be calculated as follows:

$$TER = \frac{Tox\,(endpoint\ liquid\ formulation)}{\frac{PECground\ deposition\,(\frac{g}{ha}) * 100}{300\,(\frac{L}{m^2})}}$$

As long as no toxicological studies with dust in the aquatic environment are available and there is no evidence that dust might be more toxic in water then spray droplets, the endpoints from studies with the liquid formulations with the active substance can be used for the risk assessment.

Point for discussion: The risk for aquatic organisms from dust is likely to be different as compared to a risk assessment conducted for a spray application of the substance as big particles of dust may be floating on the water surface, when small ones may stay in suspension in the water column. In addition, it is unknown whether concentrations in water resulting from dust drift would be comparable to a concentration in water resulting from spray drift. No methodology is available to calculate the soluble fraction of the substance, which can be released in water. Neither are test guidelines for testing particle toxicity.

Honey bees
As a first approach in the risk assessment for honeybees, the

$$HQ_{(Product)} = max.\ application\ rate\ [g\ Product/ha]\ x\ LD_{50}\ [\mu g\ Product/bee]^{-1}$$

may be calculated for oral and contact toxicity, using the total amount used per ha.

If the HQ < 50, no unacceptable risk is anticipated for dust drift resulting from the sowing of treated seeds.

According to preliminary results (data from applicants and JKI, pers. comm.), honey bees seem to be more sensitive to dust drift compared to spray drift, especially to fine dust particles. However, from practical experiences, no effects on bees were ever observed with spray application of products with HQ < 50. Even though the toxicity effect may be underestimated by using the LD50 for liquid formulation, the exposure is highly overestimated (using the full in-field dose). Therefore, this approach is considered acceptable to determine for which products further refinement is necessary.

This first approach will be subject to further refinement in the future as more data will be available. Also the TER-approach considering 3-D structures may be used at a later stage. However, it needs to be defined which endpoints may be used and if extrapolation/safety factors are needed.

Proposal for refined off-field risk assessment: determine a NOEC or NOAEC from (semi-) field studies into dust toxicity and compare this with the PEC. However, at present we are not able yet to conclude on a reliable PEC that could be used and are not yet able to state the Trigger that should be used.

Non-target arthropods
For the route via dust drift, only foliar dwelling NTA have to be considered for risk assessment

(see Appendix VI).

It is considered that the realistic worst case exposure for terrestrial invertebrates – especially pollinators – will not be found on the ground but in 3 dimensional spatial structures (e.g. trees, hedges, adjacent crops). See Appendix VI for more details.

Thus, the predicted 3-D exposure data as listed in Table 8-3 will be employed in the assessment of the risk for foliar-dwelling NTA exposed to contaminated dust. As long as no generic factors are available for every crop, a worst case extrapolation factor of 12.4 will be use to derive 3-D exposure data from 2-D ground deposition data measured with petri dishes.

Because of the attractiveness of flowers to pollinators, a vegetation dilution factor is deemed to underestimate the risk for species e.g. foraging in the outer part of a flowering hedge. Moreover, pollinators like bees or butterflies will forage from one flower to the next and accumulate high amount of dust. Thus, no vegetation distribution factor should be used to assess the realistic environmental risk for NTAs exposed to contaminated dust deposited in 3-dimensional structures.

The very first studies on the effects of dust from treated seeds on non-target arthropods show that the standard beneficial test species are less sensitive to dust than to the liquid seed treatment formulation under the tested conditions. As long as no further data on the effects of dust on other non-target arthropods are available, it is proposed to use the standard endpoint from the liquid seed treatment formulation from the species which showed the highest sensitivity to the active substance. See Appendix VI for more details.

The TER-ratio can be calculated following the formula below:

$$TER = \frac{Tox\ (formulation\ as\ liquid\ or\ dust)}{PEC\ 3D\ Structure\ or\ PECground\ deposition * extrapolation\ factor}$$

A TER trigger value of 10 or 5 (Uniform principles; Regulation (EU) No 546/2011) is proposed. These triggers are in line with the ESCORT 2 safety factors of 10 or 5 in the off-field risk assessment based on resp. first tier and extended laboratory tests.

9. Classification, Labelling and Packaging

9.1 Introduction

The classification and labelling of the treated seed due to the use of the seed, may differ from the classification and labelling of the PPP used to coat the seed. This latter is foreseen in Directive 1999/45/EC, which remains in force until June 2015. After this date, Regulation (EC) No 1272/2008 will apply.

9.2 Specific information required by article 49 of Regulation (EC) 1107/2009

The labelling of seeds, the label and documents accompanying the treated seeds shall include (article 49 of Regulation (EC) 1107/2009):
- the name of the plant protection product with which the seeds were treated;
- the name(s) of the active substance(s) in that product;
- standard phrases for safety precautions as provided for in Directive 99/45/EC ;
- risk mitigation measures set out in the authorisation of that plant protection product where appropriate.

Thus, the label and documents accompanying the treated seeds shall include safety precaution and risk mitigation measures specific for the use of treated seed (sowing).

Risk mitigation measures could be harmonised at EU level.

Point for discussion:
Would it be feasible and useful to propose here harmonised risk mitigation measures to be used on the seed packages?

9.4 Conclusion

The labelling of treated seeds, the label and documents accompanying the treated seeds shall include (article 49 of Regulation (EC) 1107/2009):
- the name of the plant protection product with which the seeds were treated;
- the name(s) of the active substance(s) in that product;
- standard phrases for safety precautions as provided for in Directive 99/45/EC ;
- risk mitigation measures set out in the authorisation of that plant protection product where appropriate.

There are several remarks and discussion points:

1. ESA proposes a generic labelling for all seed treatment chemicals and crops, excluding active ingredient specific requirements. Specific safety phrases should be based on the occupational health assessment and environmental assessment and the intrinsic (eco)toxicological properties of the product. It seems therefore impossible to generate a generic labelling for all seed treatment chemicals.
2. The proposed pictograms of ESA are considered not suitable to draw the attention of the farmer on acute risks. It is strongly recommended to use GHS pictograms where possible and if necessary to create new ones that are appropriate to adequately draw attention to specific risks. We will check the actual situation at National level via SCoFCAH. Legislation does not foresee pictograms and theses pictograms could be not acceptable from a legal point of view.

In addition pictograms could be misleading. In Article 49(4), there is no requirement to place on the label the danger symbol listed in Directive 67/548/EEC or hazard pictograms listed in Regulation 1272/2008 on the classification, labelling packaging of substances and mixtures.

3. The sentence: avoid transfer of dust from the seed bag into the sowing machine does not provide any instructions what to do with the dust remaining in the bags.
4. It is not sufficient to simply direct the air stream towards the soil; constructions need to be checked, whether these are suitable to reduce the emission into the environment.
5. There are no indication that sowing should not take place in strong winds, which should also be more specified.
6. The option for labelling small seed packages is not acceptable from a legal point of view. In the legislation (Regulation (EC) No1107/2009), no particular provision are laid down concerning reduced labelling obligations for packaging which are small.

Point for discussion:

1. Should the label and documents accompanying the treated seeds include safety precaution and risk mitigation measures specific for the use of treated seed (sowing) or should it include all risk and safety precaution of the product, independent of the use phase (treating the seeds or sowing the treated seeds).
2. Is it feasible to conclude in this Guidance Document on a consistent seed bag label, taking into account the ESA proposal?

References:

BROWSE (2011a) Bystanders, Residents, Operators and WorkerS Exposure models for plant protection products, Deliverable 1.1 Review of existing models and data
for Operator exposure. SEVENTH FRAMEWORK PROGRAMME

BROWSE (2011b) Bystanders, Residents, Operators and WorkerS Exposure models for plant protection products, Deliverable 2.1 Overview of currently used and emerging worker exposure models and data. SEVENTH FRAMEWORK PROGRAMME

EFSA (2010) Preparation of a Guidance Document on Pesticide Exposure Assessment for Workers, Operators, Bystanders and Residents. EFSA Journal 2010;8(2):1501 26

Hamey P, Byron N, Hanley L, Leslie W, Morgan N, Steurbaut W, de Backer E, Vergucht S. Project to assess current approaches and knowledge with a view to develop a Guidance Document for pesticide exposure assessment for workers, operators, bystanders and residents. Final report, version 1.02. EFSA, EFSA/PPR/2007/01, 2008.

Pistoris, J., Bischoff, G., Heimbach, J. (2009) Bienenvergiftung durch Wirkstoffabrieb von Saatgutbehandlungsmitteln während der Maissausaat in Frühjahr 2008. Journal für Kulturplanzen, 61(1). S. 9-14.

STISSC& ESA (2010) Seed Treatment Industry Stewardship Steering Committee Working Group and the European Seed Association. Professional seed treatment facilities, Adequate seed drilling equipment, treated seed safe use advise, April 2010.

10. Appendices

Appendix I Parameters associated with exposure as identified by stakeholders

Source:	Elements of sowing activities related to airborne exposure	Elements of sowing activities related to dermal exposure
UK	The exact physical form of the contamination is unknown but is expected to occur principally when the seed is added to the seed drill hopper. Dust containing active substance will be released into the air in the workers breathing zone, thereby contributing to their inhalation exposure.	Dermal exposure can occur from levelling (by hand) the seed in the seed hopper and also through contact with contaminated equipment surfaces.
France	dusty seeds or bad coated seeds, handling bags without caution	dusty seeds or bad coated seeds, handling bags without caution
	workers without mask (FFP2) when emptying the bags …..	Worker without gloves when loading
	when emptying the bags, loading and sowing with wind (>3 Beaufort)	worker touching seeds to help the loading….
	tractor without closed cabins when sowing	when emptying the bags, loading and sowing, wind (>3 Beaufort)
	pneumatic sewers(generate dust) without deflectors that drive dust into the earth	tractor without closed cabins when sowing
Germany	Residue content of dust from different types of coating processes can be very different. Residue content in dust of the seeds of the same crops and same coating type seems to be dose depending. Experiences in Germany: usually high residue content in dust of Maize seeds treated with neonicotinoids and methiocarb, usually low content in seeds of oil seed rape treated with neonicotinoids, usually low content detected in dust from cereal seeds, high content in dust from onions	
	filling of seed containers on the drilling machine either by emptying sacs or big packs or be using open transport media directly from a trailer to the container of the drilling machine	
	pneumatic sowing machines actively blow air and dust out which is especially a problem if the air outlet is not directed towards the soil	
	Wind during blowing will intensify the amount of dust leaving the field side	
	Turning areas at both sides of a field during the sowing because the driller is moved upwards and is more exposed to wind then	
	Poor abrasion quality of seeds as well as driller technology which has rough surfaces will increase amounts of dust	
	Rough handling of treated seeds before sowing (e.g. throwing of sacs etc.) will influence the amount of dust	
	Storage of treated seeds for a long time (e.g. several month) seems to change the quality regarding potential abrasion	

Appendix II Table with seed application characteristics

PM

Appendix III Standardised GAP seed treatment

For seed treatment the following GAP should be used.

Details of all national GAPs within each zone (to be sorted by crop) –

PPP (product name/code): Active substance(s) (name and content, g/L or g/kg): Formulation type: Field of use: Zone:

1	2	3	4	5	6	7	8	10	11	12	13	14
Use-No.	**Member state(s)**	**Crop and/ or situation**	**F G or I**	**Pests or Group of pests controlled**	**Application**			**Application rate per treatment**			**PHI** (days)	**Remarks:** a) TGWT (Thousand grain weight) b) Min/max sowing or planting density c) additional remarks
					Method / Kind	Timing / Growth stage of crop & season	min. Interval between sowing in greenhouse and transplating to the field	ml product / 100 kg seeds	maximum g as/ha	Maximum seedling rate (kg seeds/ha)		
1	NL		I or G or F treatment of seeds)			Seed treatment at BBCH 00.			N.a	n.a	n.a	
			G or F (sowing)			BBCH 00 + (mention months when sowing takes place)						
			G or F (transplanting)			BBCH + (mention months when transplanting place)						

Guidance for filling the GAP table

In the GAP it should be made clear where the seed is treated, where it is sown and if the young plants are transplanted.

General remarks/explanations:

All abbreviations in the GAP-Sheet used must be explained.
Make use of existing standards like EPPO and BBCH.

Formulation:

Type:

e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
see: GCPF Codes - GIFAP Technical Monograph No 2, 1989

Conc. of as:

g/kg or g/L
In case the plant protection product contains more than one active substance the amount applied for each active substance occurs in the same order as the substances are mentioned in the heading.

Explanations to the particular columns:

No.:
Numeration would be important when references are necessary e. g. to the dossier or to the authorisation certificate.

Member state(s):
For a better general view of the valid uses for the particular zones/MS it would be helpful to mention both (the zone as well as the MS) in the column. However, to keep the table clearly arranged it seems dispensable to cite the zone; each MS is distinctly allocated to one zone; moreover the zone(s) are cited in the head of the table.
Desirably MS are put in order accordant to the zone they belong.

Crop and/or situation:
The common name(s) of the crop and the EC (EPPO)-Codes or at least the scientific name(s) [EU and Codex classifications (both)] should be used; where relevant, the situation should be described (*e.g.* fumigation of a structure). In case of crop groups all single crops belonging to that group should be mentioned, (either in the respective table element or – in case of a very extensive crop group - at least in a footnote).
In case of crop groups all single crops belonging to that group should be mentioned, (either in the respective table element or – in case of a very extensive crop group - at least in a footnote). If it is not possible to mention all single crops belonging to a crop group (e.g. for horticulture), it should be referred to appropriate crop lists (e.g. EPPO, residue (codex). It would be desirable to have a “joint list” of crop groups for the zones.

Exceptions of specific crops/products/objects or groups of these and restrictions to certain uses (e.g. only for seed production, fodder) must be indicated.

This column should also include when indicated information concerning “crop destination or purpose of crop”.

Conditions / location of use:
Outdoor or field use (F), glasshouse application (G) or indoor application (I)
“Glasshouse” indicates that the respective trials are acceptable for all zones.

As results achieved in compartments without controlled conditions (temperature, light exposure), e.g. simple plastic tunnels [for those GAPs field trials have to be conducted in the respective zone the use is applied for], are not considered to be applicable for use in other zones the kind of glasshouse should be clearly indicated.
[Remark: Greenhouse definitions are at the moment under evaluation].

Conditions include also information concerning the substrate (natural soil, artificial substrate).

In this column it should also be indicated, whether the product is intended for professional or for non-professional use

Pests or Group of pests controlled:
Scientific names and EPPO-Codes of target pests/diseases/ weeds or when relevant the common names of the pest groups (e.g. biting and suckling insects, soil born insects, foliar fungi, weeds) and the developmental stages of the pests and pest groups at the moment of application must be named.
If necessary – in case of pest groups - exceptions (e.g. sucking insects excluding scale insects) should be indicated.
In some cases, the set of pests concerned for a given crop may vary in different parts of the EU region (where appropriate the pests should be specified individually).

If the product is used as growth regulator the target organism is the specific cop, whose development should be influenced; the aim could also be e.g. an empty room for treatment.

Application details:

Method / Kind:

Method: Seed treatment (in case of e.g. phytodrip is claimed this can also be mentioned here)
Kind: It would also be helpful to indicate whether seeds are surface broadcast or precision drilled together with depth of sowing

Timing of Application / Growth stage of crop & season:

Time(s), period, first and last treatment, e.g. autumn or spring, pre- or post-emergence, at sufficient pest density or begin of infection, including restrictions (e.g. not during flowering).
Growth stage of crop (BBCH-code, …) – period, first and last treatment.
Since the BBCH-codes are accomplished in the individual member states at different time periods the month(s) of application should be indicated in addition.

BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4

It seems sensible to constrain specifications in this column only to the crop, - information concerning the pest should be dealt in column “pest or group of Pests controlled”.

In certain circumstances it might be helpful to give information about the expected rate of interception related to the BBCH codes. In many minor crops no BBCH/interception rate scenarios have been specified so far. This could also simplify grouping for the envelope approach.

Min. Interval between sowing in greenhouse and transplating to the field

If it is relevant the number of days between sowing and transplanting to the field can be mentioned in this column

Application rate per treatment:

Application rate of the product per ha:

(Maximum) ml product rate per 100 kg seeds).

Maximum g, kg as/ha:

The dimension (g, kg) must be clearly specified by the applicant. The value in this column can be calculated if thousand grain weight and the seedling rate are known.

Maximum seedling rate (kg seeds /ha);

PHI (days) – minimum pre harvest interval
PHI - minimum pre-harvest interval

For some crop situations a specific PHI may not be relevant. If so an explanation (e. g. the PHI is covered by the time remaining between application and harvest.) should be given in the remarks column (e.g. crop harvest at maturity or specific growth stages).

Remarks:
Remarks may include: Extent of use/economic importance/restrictions
e.g. limiting the number of uses per crop and season, if several target pests/diseases are controlled with the same product.

d) TGWT (Thousand grain weight)
e) Min/max sowing or planting density

,
Additional recommendations:
For the description of uses of a PPP the following EPPO Standards should be considered:

- EPPO Standard PP 1/240 “Harmonized basic information for databases on plant protection products”
- EPPO Standard PP1/ 248 “Harmonized classification and coding of the uses of plant protection products“

Whereas EPPO Standard PP1/ 248 gives more general information on possible description of uses, EPPO Standard PP 1/240 especially gives an overview of all points necessary to fully understand a use.

For EPPO-Guidelines, see: http://archives.eppo.org/EPPOStandards/efficacy.htm

For EPPO extrapolation tables, see http://www.eppo.org/PPPRODUCTS/extrapolation/tables.htm

For EPPO Plant Protection Thesaurus, see: http://eppt.eppo.org/

Appendix IV Table for Procedural issues

Destination of the treated seed	**Evaluation of risks**	**Label of the treated seed [if plant protection product is authorised for seed treatment]**
Outside EU	Human and environmental risks during seed treatment, depending on the process [flow or batch; industrial, mobile or on-site treatment].	*“Not for use in the EU”* [see remark 2].
Inside EU [and outside EU]	1] Human and environmental risks during treatment, depending on the process [flow or batch; industrial, mobile or on-site treatment]. 2] Evaluation of human risks during sowing and environmental risks during and after sowing.	*“For use inside and outside EU”*

Remark 1: we need to establish EU-wide all kind of parameters and defaults dealing with industrial, mobile and on-site treatment of seed, what kind of process [batch or flow] etc.

Remark 2: treated seed labeled “*not for use in the EU*” : enforcement is highly appreciated to prevent U-turn imports in the EU.

Note :
the authorisation of a plant protection product is done according to article 28 par.1 of the Regulation.
For the authorisation of a seed treatment plant protection product the EU is one zone.
It is preferable that all MS are involved [with their national addenda] in the DAR process of the RMS.
Due to free trade of treated seed in the EU [art. 49 par. 1], the treated seed can be applied in every MS, not only in the RMS.
By participating early in the DAR process, MS will prevent restrictions according to article 49 par. 2 of the Regulation afterwards.

Appendix V

Good practices and quality standards for the treatment of seeds and for the use of treated seeds

Seed coating, i.e. the application of a plant protection product (PPP) directly onto the seed, is commonly considered as less dispersive than spraying the product in the field on bare soil or on early growth stages of the crop. In avoiding spray drift, the dispersion of active ingredient outside the field is considered low and the proportion of active ingredient soluble in the soil, being not bound to the seeds, and thus being subject to leaching, is considered very limited.
The use of coated seeds may however lead, in some circumstances, to some exposure at sowing due to dust dispersion. Coating quality and especially the presence of dusts on the seed during the coating process, are known to contribute to dust release during the handling of seeds and seed-bags. In addition, seeding drills might contribute to the generation of dusts.
The release of pesticides into adjacent areas via dust is influenced by following aspects:

- Drilling density of seeds per ha; width of drilling, application rate of active ingredient per ha
- Quantity of dust per seed unit after seed treatment and dust fraction size
- Resistance to abrasion of treated seeds in packages and in sowing machines
- Concentration of active substances in the dust
- Drilling technique
- Wind speed and direction
- Soil humidity conditions
- Stickiness and structure of neighboring plants.

This chapter is meant to give guidance mainly for the control of release of contaminated dust during drilling. The emission of seed dust during seeding is variable, depending upon the care taken during all the steps from the preparation of seeds before treatment to the type of driller used. In extreme cases, the amount of dusts has proven to be high enough to impact honey bees and has led to the poisonings reported in Germany and Italy in 2008, Austria and Slovenia in 2008 to 2011. These high amounts of dust were highly contaminated with insecticidal active substances (published data by JKI). While an aggravating factor for pollinators is the coincidental presence of flowering crops or weeds in the immediate vicinity of the fields sown, the emission of dusts towards aquatic systems or vegetated corridors may also affect aquatic and terrestrial life, even not mentioning the exposure of the farmer himself or of by-standers. Modalities of quantification of related exposure for the purpose of risk assessment will be discussed in later chapters (see chapter).

For these reasons, it is essential to ensure that the practice of seed protection is controlled so as to limit the quantity of dust generated and dispersed to the minimum. The same is valid for the concentration of active substances in the dust.
It is acknowledged that technologies will evolve in future so that the level of dust reduction being technologically reachable and the related recommendations will evolve accordingly. Thus the recommendations below are to be understood as reflecting the current state-of-the-art in the area and will be revised based on updated science.

Seed treatment process

Seed preparation is one of the most critical steps as cleaning is widely recognized as a means to reduce dust values. Indeed removing dusts before treatment improves the adherence of coating onto seeds. Cleaning may be automatically performed in industrial processes and devices exist that may allow seeds to be cleaned at the facility. Although cleaning is an effective means, the

step is not strictly controlled as the quantity removed depends on the seed type, aspiration method etc. The efficacy of the whole process is controlled through dust values measured at the end of the process on random seed batches.
Before the actual seed treatment can be applied the seed needs to be properly cleaned and for certain crops calibrated in a seed cleaning line.
The different cleaning steps are:

- pre-cleaning
  - by sorting out bigger particles etc.;
  - taking off dust by aspiration.
- cleaning
  - taking off under and over sized seeds;
  - calibration of the seeds depending on the species;
  - minimizing dust by further aspiration.

After these steps the seed is ready to be treated.
Treatment of seeds should follow recipes that are optimized for adherence and resistance to abrasion. The seed treatment is done by and in professional treating equipment:

- batch treaters for corn, oilseed rape, sunflower, sugar beet and vegetables;
- batch treaters as well as continuous treaters for cereals;
- during the treating process and when bagging, further aspiration needs to be done to absorb remaining contaminated dust as much as possible.

To avoid further stress for the bagged seeds, the bags are palletized and stretch wrapped with plastic foil for storing and distribution.
Each step should be carefully controlled and certification systems allow an appropriate supervision of all the steps in the process.
Additional to dust avoidance activities, only seed treatment recipes should be used which minimize the content of active substance in dust. Before new recipes are introduced for seed treatment, it needs to be checked if the content of a.i. in dust is not increased.
Examples of seed treatment process certification systems are the dust control program (Plan qualité poussière) in use in France, the certification for seed treatment plants in use in Germany and ESTA, the new European seed treatment and treated seed certification scheme developed by European Seed Association (ESA).
Process certification systems have found wide acceptance in the food and animal feed industry as they combine security aspects with process control. Process control implies that testing each and every batch of product is not necessary; monitoring adequate functioning of the processes secures reliability. Testing ad random samples is one of the tools to monitor the adequate functioning of the processes. Retaining a reference sample of each batch after treatment is done in order to always be able to respond to questions on the quality of the treated seed.
For facilities treating seed with plant protection products, the ESA is developing a quality management system (ESTA) that will lead to certification of seed treatment plants and of the treated seed coming from these plants. A general (i.e., not crop-specific) standard has been developed as the basis for ESTA.
In France and Germany certifications are in place already for maize and oil seed rape treatments, respectively. Extension to other crops is under way in both countries. Work is ongoing between these national initiatives and ESA to align the certifications, aiming at one EU-wide ESTA certification (and ESTA labelled seed) in future.
Treatments performed in non-certified processes are in principle possible and may be allowed if they reach the relevant quality criteria. General comment DE: This exemption in the paragraph before might lead to malpractice.
In some countries, the abrasion resistance of treated seeds is controlled and compared to a threshold or quality standard imposed by the legislation, as an example in France for maize seeds (JORF, 2010). The amount of dusts produced is commonly measured through a Heubach test (Figure 0-1).

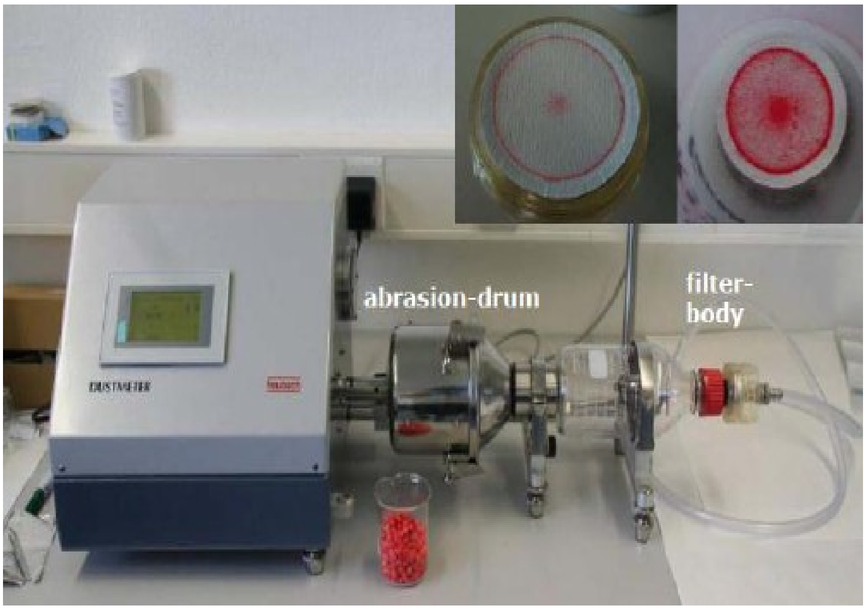


Figure 0-1: Measurement of dust on seed batch using the Heubach test (source Julius Kühn-Institute; DE).

Another test has been developed, known as CERES. This test relies on a different principle as seeds are not shaken in order to generate an abrasion but are placed in a device equipped with an aspiration that will collect air and dusts being present in the sample. The comparison of the amount of dusts quantified in both systems has been extensively described and indicates that values generated with the Heubach test, which is more abrasive, are more representative of a worst case. Thus the Heubach test has been selected for further development and a use as a reference test for abrasion dust control.

ESA and the European Seed Treatment Manufacturers have agreed one standard dust test protocol, available on the ESA website (http://www.euroseeds.org/codes/esta-european-seed-treatment-assurance/). The choice for Heubach equipment was made as this test actually 'abrades' the (treated) seed, in contrast to the 'milder' CERES test system.

In France for example, the Heubach test is currently performed on seed batches for maize. The threshold values used are 3 g/100kg seed to check that the seeds match with quality criteria. Any value comprised between 3 and 4 g/100kg seed a new control is performed and the treatment process is corrected. Any value higher than 4 g/100 kg seed leads to the interruption of the treatment process (JORF, 2009).

For the standardized Heubach dust test, a Cofrac-accredited reference laboratory exists in France. A certification system for independent, or seed company laboratories is operated by the Société Générale de Surveillance (SGS). The SGS certification scheme features yearly ring tested calibration comparisons between the laboratories to assure continuous data comparability, as well as random cross testing of commercial analyses performed by the labs to ensure quality of operations. Also management of deviations from the norms is comprised in the SGS certification scheme. SGS has trained auditors making the programme available for implementation across the whole of Europe.

Dust values generated from the tests are in general expressed as weight of dust reported to a weight of seed (g dust/100 kg seeds) or weight of dust reported to a quantity of seeds (e.g. g dust / 100,000 seeds). Because seeding density varies among countries and even locally, pending on the drilling equipment, dust values expressed as g dust/thousand grains allows an amount of dust /number of seeds to be defined for risk assessment purposes.

Maximum sowing rates per hectare used in Germany are reported in the following table: The table is meant as an example and should be considered as basis for a European table. Clearly there are differences in drilling practice within Europe and a product might pose no risk in a country with low seeding densities compared to another country. MS are invited to send in tables relevant for their countries. A future action might be to try to draft a table with these figures for all MS to determine a worst case per crop. This could be useful as an Annex to this guidance document

Table 0-4: Maximum seed loading in Germany (source: # Julius Kühn-Institute, DE; * BBA (2002)

Nachrichtenbl. Deut. Pflanzenschutzd. 54, p.247; § European Seed Association).

Crop	Maximum seed sowing rate (kg/ha)	Maximum seed sowing rate (no. seeds/ha)
Wheat#	250	
Maize, sugar beet#	25-35	100,000 seeds/ha
Oilseed rape#	3-6	700,000 seeds/ha
Sunflower#	ca 5.5	ca 75,000 seeds/ha
Barley#*	180	
Winter rye#	150	
Triticale	170	
Onion§	4	1,000,000 seeds/ha
Carrot§[5]	2.6	2,000,000 seeds/ha
Cabbage§	0.25	50,000 seeds/ha

It is acknowledged that drilling practice may differ among countries and for vegetable especially depending on harvest use patterns particularly with regard to the drilling density. Specificities will be easily accounted for through the expression of dust values per thousand grains.
Field experiments measuring dust dispersion outside plots indicated that Heubach-values have influence on dust deposition over all distances from the plot in the case of maize (Figure 0-2).
GENERAL COMMENT DE: Data from the review of Fent (2011) may be used if the study is accepted as valid, published or fully available to regulatory bodies – otherwise some of the figures have to be deleted. Industry claimes data protection for this study !

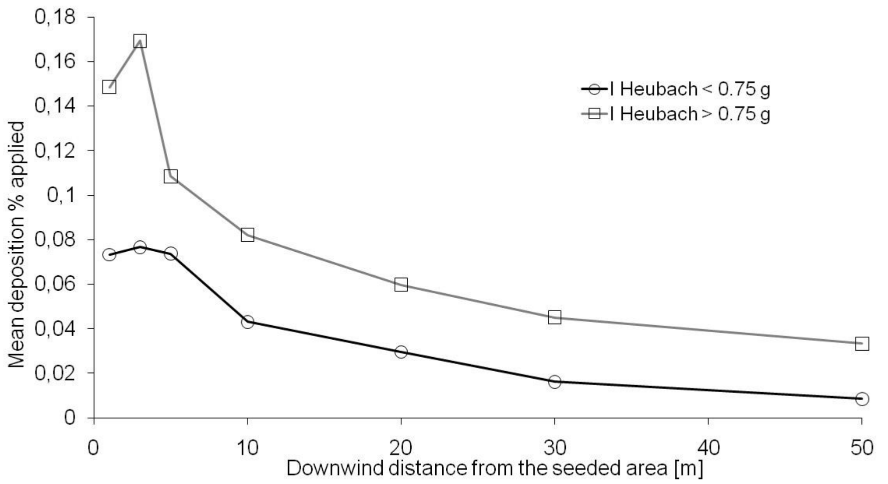


Figure 0-2: Relationship between Heubach-values on maize and ground dust deposition for maize, by way of example (from Fent, 2011).

Thus, even if dust values as provided by the Heubach test are not sufficient to estimate the overall dispersion level, they are a good indicator of the coating quality without which an appropriate reduction of dusts is not possible.

Maize

In maize, a certification of system/treating facilities is ongoing in France and Germany. Quality of treatment has been improved over the last years due to use of stickers, improved recipes and the use of best available technology.
The maximum level of 0.75 g dust/100,000 seeds before bagging is legally enforced in Germany (for methiocarb in maize) and in Austria. In France the level enforced at the regulatory level is similar, expressed as 3 g dust/100 kg seeds. These levels have been implemented in 2008 based on technical possibilities available at that time. In the Netherlands, a maximum level of 0.75 g dust/100,000 seeds is enforced for all insecticides used as maize seed treatment.

[5] For some carrot types like Nantes carrots, the big winter types have a much lower density

A compilation of dust measures in maize was performed by the Julius Kühn-Institute and is given in the following table:

Table 0-5: Dust measures in maize seeds in Germany, Heubach test. Results are expressed as g dust/ 100,000 seeds. (source: # Julius Kühn-Institute, DE; § Bayer Crop Science; * Landwirtschaftliches Technologiezentrums LTZ, DE,; **Agricultural Ministry France).

Year	No samples (source)	Mean dust measurement (g/ 100,000 seeds)	Max value (g/100,000 seeds)
2008	53 (§)	1.11	4.15
2009	41 (#)	0.30	0.56
2009	40 (*)	0.53	0.91
2009	42 (§)	0.38	0.96 (90% < 0.65)
2010	43 (*)	0.33	0.66
2010	1737 (**)	0.26	0.84 (90% < 0.45)
2010	52 (§)	0.29	0.78 (90% < 0.45)
2011	34 (*)	0.18	0.4
2011	37 (§)	0.22	0.78 (90% < 0.49)

These results show that since 2009 the quality standard of 0.75 g/100,000 seeds, at the time of bagging, which is legally used in Germany for one product, are respected in most cases. A few samples from Germany exceed the quality threshold value of 0.75 g/100,000 seeds, which is attributed to the fact that these samples were taken from the market after transport and storage and not at the time of bagging.
For 2009 and 2010, measurements on a total of 1,720 lots using the Heubach test indicate an average dust level of 0.42 g/100,000 seeds in 2009 and 0.31 g/100,000 seeds in 2010. The percentage of lots exceeding the maximum level was 11.30% in 2009 and 4.60 %, 2010. In both countries, the sales of lots exceeding the maximum level is not allowed.

Winter oilseed rape

For winter oilseed rape, a certification of treating facilities is ongoing in Germany. Quality of treatment has been improved over the last years for the same reasons as for maize.
Measurements on 180 batches (Heubach test), over 2009 and 2010 indicate dust amounts below 0.25 g/700,000 seeds. This value stands also for re-bagged seeds for which measurements indicate dust content below this value except for 10 out of the 100 batches for which dust content reached [0.25-0.50] g/700,000 over the two years.
Measurements performed in France on 650 batches indicate dust values below 0.5 g dust/700,000 seeds (UFS, 2011). These data correspond to the sum of data measured on a pool of market batches as well as on batches having been constituted for the purpose of the ring test.
Results obtained for 2007 and 2008 by the JKI indicate mean Heubach-values of < 4 and 0.119 g / 700000 seeds, respectively.
Based on the above mentioned results a maximum level of 0.5 g/700,000 seeds with an objective expectation level of 0.25 g/700,000 seeds is proposed by ESA for future developments. This level allows a clear commitment as a quality standard. It corresponds to approx.18 g dust/100 kg seeds.

Sunflower

For sunflower, measurements were performed over 700 batches and indicate a dust values below 5 g dust/100 kg seeds, which corresponds to 0.5 g/150,000 seeds (UFS, 2011). As for winter oilseed rape, these data correspond to the sum of data measured on market batches as well as on batches having been pooled for the purpose of the ring test.

Sugar beet

In sugar beet, the protection of seeds is ensured through a process of producing a pellet (Figure 0-3).

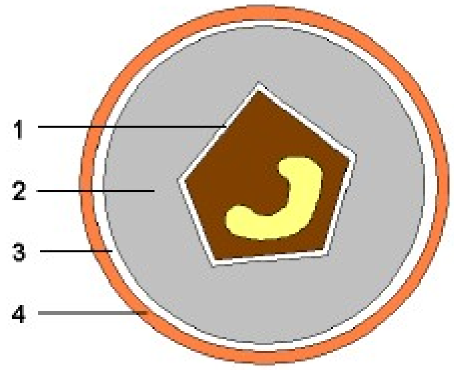


Figure 0-3: Sugar beet pellets (source: ESA)

Pellets are produced through the following successive steps:

- film coating to protect seed from seed borne fungi;
- pelleting aiming at giving shape for a round pellet, storage of fertilizer, giving a protection layer between seed and ppp and for control of soil borne pests and diseases. It is made of an inert material being a mixture of binder and solid substances;
- film coating for protection of seed for soil borne fungi and pests (fungicide and/or insecticide;
- film coating to protect from abrasion and for colouring.

This process leads to very smooth and resistant pellets and the level of dusts is almost negligible.

Other crops

Pending on the coating technology and the common driller used with them, dust values may have to be developed for other crops, as for example for green peas or cereals in some countries. Pelleting is quite common in vegetable seeds and the technologies used are comparable. While this process prevents abrasion and dust generation it is not suitable for all types of seeds as it can influence emergence in some species which are autumn sown due to drought. Especially coating of vegetable seed pellets typically is as shown in Figure 5 for sugar beet. Vegetable seed also can be coated (without pelleting). Market requirements are for the highest quality coated pellets and seeds because of precision sowing, which often takes place indoors at plant raisers facilities.

Handling steps

Several important steps preceding drilling itself may also contribute to the abrasion of seeds / dust emission if not considered with care. These steps include:

- Seed-bags or containers deliver and handling
- Seed-bags or containers stocking
- Loading of the driller
- Sowing
- After drilling, handling of the empty bags.

Seed-bags or container delivery and handling

Seed bags should be handled gently during the entire course of their use. This includes physical movements of the seed at the treatment site throughout the distribution chain, and on the farm. Abrasion through friction between individual seed kernels is a source of dust, and should be minimized. This can be done by:

- Always move individual seed bags with care. Never throw them.
- When transporting many seed bags – always do so on stretch wrapped pallets. By stretch wrapping the seed bags onto a pallet, the movement of seed inside the bag is restricted, as the bag cannot move, and thus also seed abrasion. Seed bags moved together on a pallet are also less susceptible to damage during loading/unloading, than if they would be managed individually.
- It could be recommended to print the sentence “Fragile - handle with care” on seed-bags or on stickers to be used on each pallet of seed.

The integrity of bags or containers should be checked by providers and also users at their delivery. Seeds from visibly damaged packaging or bags should not be used.
Seed treatment, seed companies and distributors have a responsibility to make sure that forwarders are made aware, and adhere to, the above recommendations.

Seed-bag or container storage

Seeds-bags or containers should be kept safely closed during the entire stocking period. They should be kept in safe and premises and out of sun, heat, humidity and kept out of access for children, livestock or wildlife. If possible premises should be locked. Repeated stacking of bags should be avoided.

Loading the seed drillers

Even with maximum caution, the complete absence of dusts in containers or bags might not be possible. Thus care should be taken in opening containers and loading the seed driller that the dusts will not disperse outside the sowing area. It may then be recommended to load the driller at a safe distance from water bodies, vegetated areas, flowering bushes, and bee hives. Also in choosing a place to stop the driller to proceed to loading, care should be taken in such a way to not load on the leeward side of sensitive areas.
Care should be taken to not shake the dusts off the bags or to load the dust in the bottom of bags into the driller. Hand contacts with the seeds in the hopper, for example with the aim to spread the seeds, should be avoided.
If for loading the driller any transport systems from the storage of seeds (e.g. wagon) to the driller are used, this should be closed systems with as little as possible mechanical abrasion.
During the whole loading stage farmers should wear individual protections like glasses and gloves and mask to avoid the contact with skin and mucous. Clear water should be available on the tractor to rinse any dusts they could come in contact with and to rinse gloves after loading. Rinsed gloves should then be removed.
In case where a re-loading is necessary, the turbine of the driller should be stopped.

Handling of the empty bags or containers after use

Bags and containers should not be left in the field without surveillance.
Bags and containers should be brought back after use. Preferably they should not be re- used but rather be recycled in a dedicated process or eliminated according to local legislation. They should be stocked in dry premises out of sun and heat. They should not be burnt or eliminated with household waste. Labelling of bags and containers having been used should be kept by for further possible control.

All relevant handling steps to be considered by the user before, during and after sowing in order to ensure minimization of dust exposure of the environment are summarized in the generic ESA Safe Use Bag Tags.

Drilling machines

Drilling machines need to separate the seeds to achieve an appropriate spacing of seeds in the seed furrow. There are three principal approaches used for this separation of seeds during the drilling process

Vacuum-pneumatic seed separation

To achieve a precise deposition of the seeds in the soil (precision seeding), seeds are fed from a seed reservoir to the driller head and held in place via vacuum (negative air pressure) on a perforated sowing disc (Figure 0-4). Seeds are separated by being held onto the holes on the sowing disc as long as the vacuum across the holes in the sowing disc is sustained (suction phase). During the rotation of the sowing disk, the seeds are individually released from the disk by releasing the vacuum in the corresponding holes, and the seeds then drop into the furrow created by the driller. During the suction phase, any abraded particles are pulled through the holes in the system and are transported with the exhaust air through the fan that generates the vacuum for the seed separation process. From the fan the air and any particles are either released with a high velocity from one single outlet 0.5 - 2 m above the ground (= un-modified vacuum-pneumatic driller) or from various outlets, that increase the total cross-section of the outlet area, close to the ground with a reduced velocity (= modified vacuum-pneumatic driller).

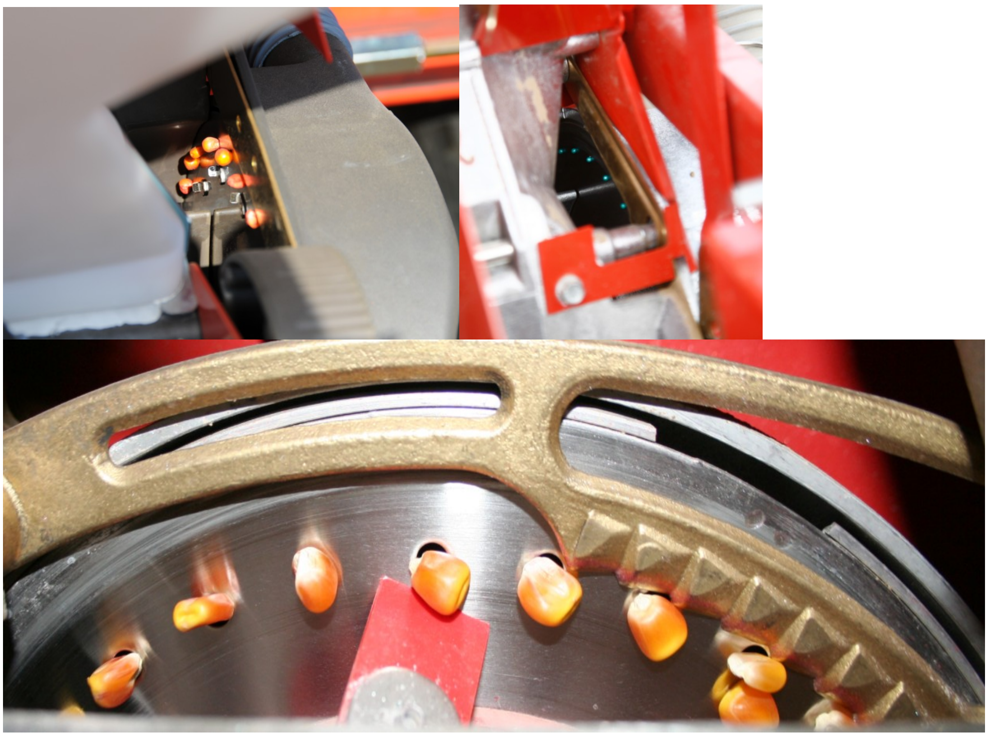


Figure 0-4: Seeds caught by the disc of a vacuum pneumatic seeder.

Pneumatic seed separation using air streams (compressed air)

Pneumatic drillers that work with compressed air can be separated into two types.
One type (precision seeding) separates the seeds with the help of funnel-shaped cells which are gravity filled with several seeds and excess seeds are blown-out of the funnel back into a seed reservoir by an air stream. The air and any dust particles are released, directed at the ground.
The alternative type separates seeds from a central seed container with a mechanical dosing unit into a riser tube. Inside the riser tube, an air stream transports the seeds to a seed dispersion unit.

Once the seeds have passed the dispersion unit, the air, the seeds, and any abraded dust are equally distributed via tubes down to all seed furrows and are released, directed into the ground.

Mechanical seed separation (without air assistance)

Mechanical drilling does not operate with any air assistance. In order to accomplish a seed separation, rotating disks with individual cells and other mechanical devices separate and transport seed from the seed reservoir to the seed outlet, where the seeds drop via gravity into the seed furrow. Abraded particles are therefore also released close to the ground, but not in any air stream created by the driller.

Representative machines used for each seed type

The majority of planters sold in Europe are pneumatic planters as they offer a bigger precision at drilling than mechanic planters.
The table below lists representative machines used to drill the mains crop cultivated in Europe. It is important to note however that a farmer may wish to use one driller for all his crops.

GENERAL COMMENT DE: The added value of images with machines can hamper the practical use of the GD (e.g. large files don’t pass firewalls). If images should be retained, they can be moved to an annex with cross-references.

Table 0-6: Representative machines used to drill the mains crop cultivated in Europe.

Machine	Crop
Mechanical seed drills	
	Wheat, Barley, Triticale, Oat
	Oilseed rape
	Alfalfa
	Soybean
	Peas
Pneumatic seed drills (compressed air)	
	Wheat, Barley, Triticale, Oat
	Oilseed rape
	Alfalfa
	Soybean
	Peas
Vacuum-pneumatic precision seed drill	
	Corn (maize)
	Sugar beet
	Rarely Oilseed rape
	Sorghum
	Sunflower
	Cotton
	Beans Peas Some vegetables
Mechanical precision seed drill	
	Sugarbeet
Pneumatic Miniseeds and vegetable machines	Vegetables

Data on dust generation available at the time this chapter was prepared indicate that dust dispersed from the seeded area are proven to be lower in the case of mechanical sowing techniques (Figure 0-5).

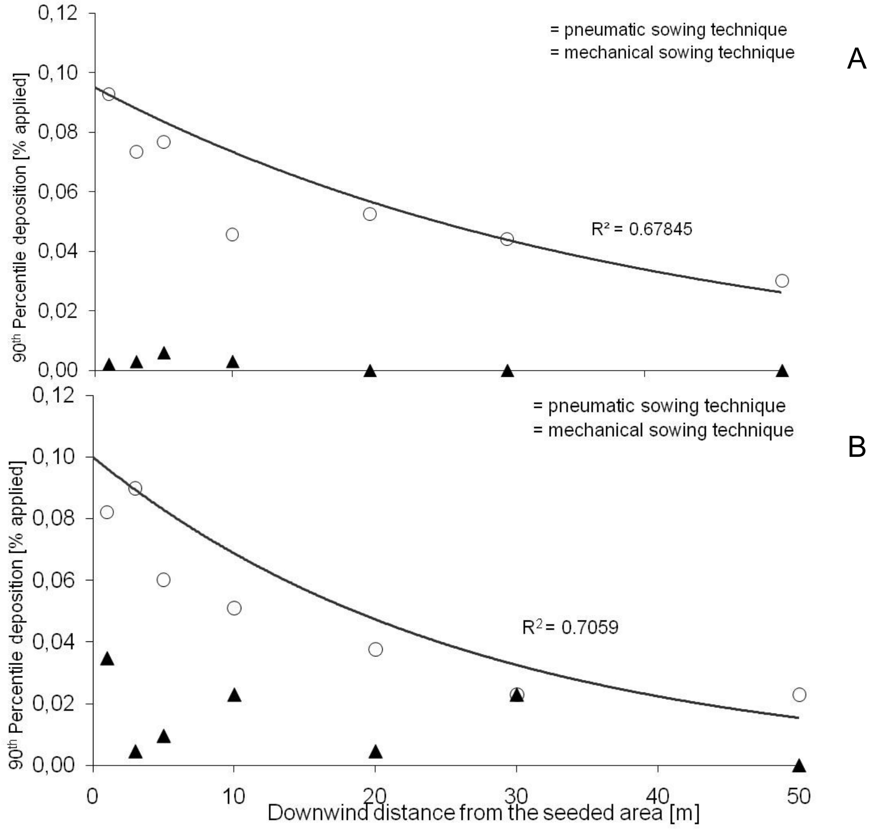


Figure 0-5: Dust deposition curves by way of example for cereals (A) and oilseed rape (B) using vacuum-pneumatic seed separation [circle[and mechanic seed drills (triangle; from Fent 2011).

As it can be observed with the data collected by applicants and analyzed by Fent (2011), there is a lower exposure to be expected in off-crop areas in the case of sowing with mechanical drillers.

Recommendations for the employment of pneumatic seed drillers

The following recommendations apply to pneumatic precision seed drillers, as they are identified as gathering seed and dust handling conditions that are favourable to dust production and dispersion.

Since abrasion of dust from seeds in the driller cannot be fully excluded, it is important that the dusts being produced are directed to the soil and not up or sidewards. Equipment of drillers with drift reducing devices, also called deflectors, have proven to be efficient in reducing the amount of dust being dispersed outside the area sown. The principle is to reduce the flow velocity of the outlet air stream, by dividing the air stream into several branch streams, and by diverting the outlet air stream directly to the soil (deflector technology). An example of dust reducing device is shown in Figure 0-6.

Figure 0-6: Example of dust reducing device on a driller

The aim is to reach a 90% reduction in dust dispersion on the ground. This 90% reduction is measured compared to a reference (i.e. standard machines used in the past), in redirecting air to the soil.

For an efficient redirection of air, it is generally recommended to fix the deflector pipes so that the outflow section is at 10- to 30-cm height above the soil. While currently deflector kits can be installed on the driller, equipment manufacturer are now developing drillers integrally fitted with deflectors at manufacture on all models sold in Europe.

Example of dust measurements is given in Figure 0-7.

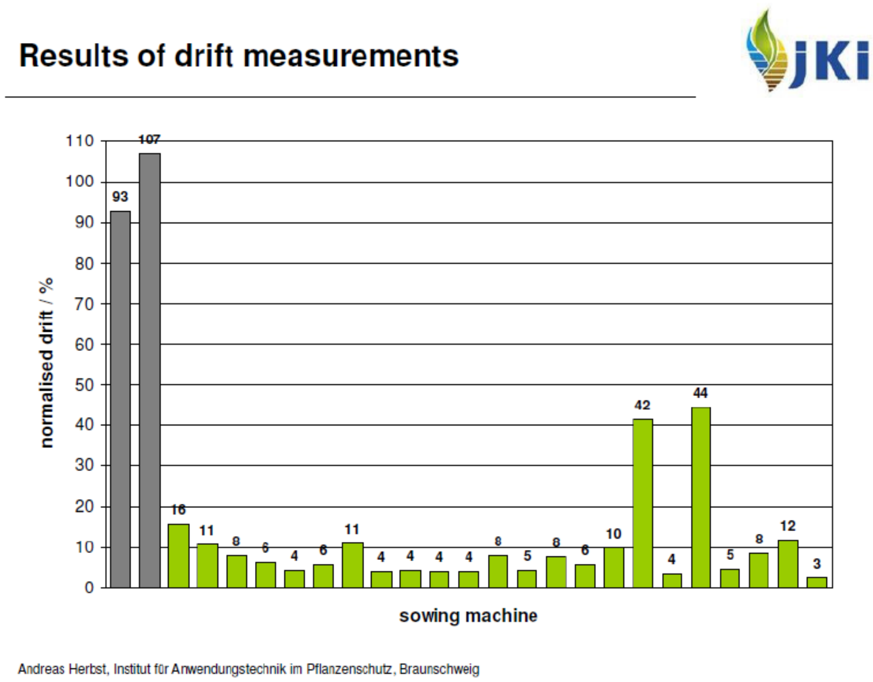


Figure 0-7: Example of dust measurement process (source JKI)

Survey of techniques to reduce dust output from machines

The efficacy of these kits, measured for the kit itself or as a couple kit + driller is commonly measured in Germany, France and the Netherlands and experiments have been initiated in Italy.

Germany

In Germany, a drift test has been developed by the Julius Kühn-Institute (JKI) together with manufacturers, where equipped sowing machines are tested against standard machines (Herbst et al., 2010). The drift is quantified from ground samples collected in petri dishes placed at 1, 3 and 5 metres from the sowing area. In this test the driller is filled with dust of small size, so that the measured drift represents a worst case.

In the approval process, JKI certifies the whole turbine + deflector combination so that not all seeders on the market need to be tested. To date, 223 turbine-deflector combinations from 16 manufacturers have been approved, the list of which may be found on their website (http://www.jki.bund.de/de/startseite/institute/anwendungstechnik/geraetelisten/abdriftmindernde-maissaegeraete.html). A label is put on the deflector, which allows checking of the origin of the deflector kit. The use of a deflector turbine combination requires the kit to be installed by a professional. A list of equipment under technical check is provided.

France

In France operators may choose the equipment via three different solutions:

– drift reducing techniques provided by seeder manufacturers
– deflector kit manufacturers (4 models available)
– deflectors manufactured by farmers themselves.

As for Germany, overall the goal is to reduce dust dispersion by 90% without affecting the effectiveness of seeding and to ensure the process does not degrade seeding quality. Specifications and guidance for deflector installation are provided for all systems. The system shall meet several characteristics:

– gathering air flow and which is to be directed to the ground
– the system shall be free of leaks and designed to avoid deposition of dust
– the sum of the area of output sections of the device shall be at least twice the area of the turbine outlet
– the height of output air flow shall not be more than 30 cm – 10 cm being optimal from the ground.

A recent survey has investigated drillers equipped with deflector from manufacturers (10 drillers), 3 deflectors kit manufacturers and 9 devices proposed by the farmers themselves. The seal was tested with flour (Grimbuhler et al., 2011). The results indicated that all drillers met the above mentioned specifications.

Italy

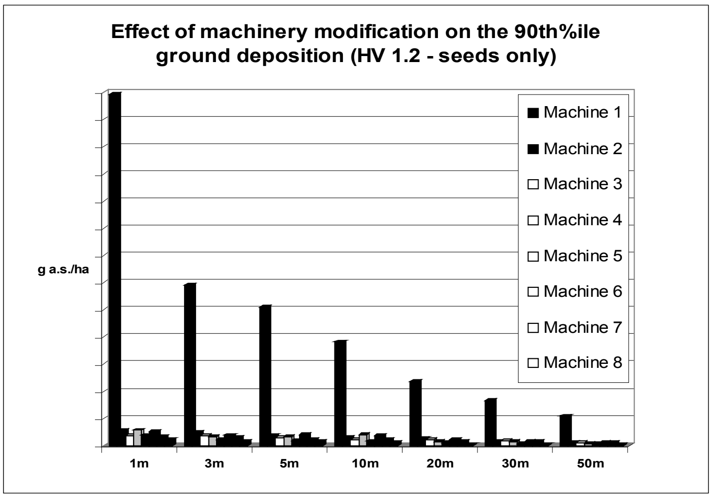
In Italy, some experiments have been undertaken by Balsari (2010) and more particularly in the research project Apenet. The aim was to measure dust drift at various distances from the sowing row and to compare driller equipments. Two reports are available, which indicate coinciding results compared to Germany and France. In 2009 some experiments displayed a limited efficacy of deflector devices, however the report does not state the effectiveness of the equipment used and dust deposition was very low, with or without deflector (maxima were ranging from 35 to 45 mg dust/ha). These results indicate that measuring dust reduction achieved with a deflector as a percentage from the reference without deflectors could tend to favor drillers that generate the highest level of dusts without deflectors. In other words, a dust reduction of 90% achieved on a low performance driller can easily be achieved whereas on a high performing driller a similar reduction rate is much more difficult to achieve. Consideration should be given to the level of dust that is actually generated once the drift reduction device is used.

The Netherlands

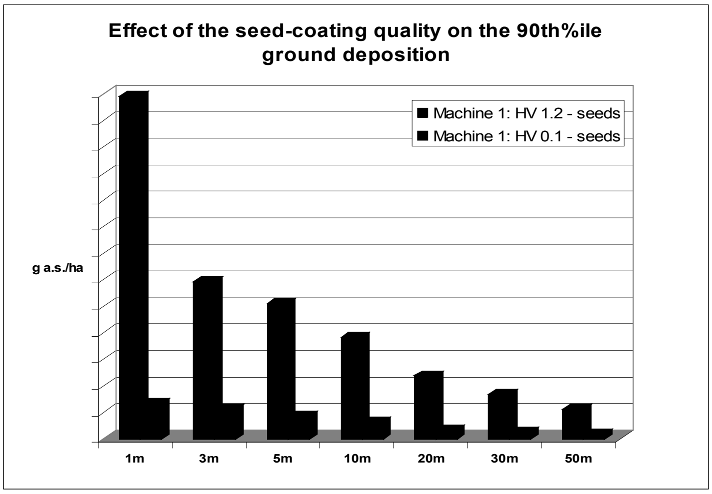
In the Netherlands, no specific experiments have been undertaken but deflectors are prescribed for insecticide-treated maize sowing machines since 2010, which, together with a low dust level on the seeds aims at 90% dust drift reduction.

State of the art and recommendations

The devices developed have been progressively implemented in Member states since 2008, date at which the first important accident allocated to seed dust dispersion was recorded. Since the implementation of driller equipment with deflectors has increased, even with home-made devices, sometimes because the availability of marketed devices was not wide enough to equip all the farmers demanding for, while the equipment had turned to be mandatory, as in France for example. However, both marketed and home-made devices can be effective (see 3.2.1.1 “Sowing techniques), as indicated by the limited number of accidents recorder over several years of use of coated seeds over Europe. Data available from the monitoring implemented in France alongside the use of maize seeds coated with Cruiser 350 indicate an important reduction of dust emission from the second year, date at which the use of drillers equipped with deflectors has been regulated (JORF, 2010, MAAPRAT 2010, see also Error: Reference source not found).



A



B

Figure 08: Effect of machinery modification on off-crop ground deposition (A). Machine 1 is an unmodified reference machine, machines 2-8 are all low-drift machinery (Nikolakis et. al., 2009). Effect of seed-treatment quality on off-crop ground deposition (B). Machine 1 is an unmodified reference machine (Nikolakis et. al., 2009).

As shown on the figure above, the efficacy of such devices may reach 90% and above drift reduction.
It is noteworthy that driller equipment with deflector devices is a preliminary step to the equipment of new drillers with re directing air devices, which is now the rule in manufacturing companies and thus should be fully implemented when the whole driller park will have been modernized.

Drilling conditions

In order to limit dust dispersion to a minimum and avoid conditions that favor dust re-suspension, drilling should be performed under wind conditions that should not lead to significant lateral transportation of dust particles.
In France for example, drilling conditions impose to respect a maximum wind speed of 19 km/h (3 on Beaufort scale[6]), as measured at the level of the soil (JORF, 2010).
A threshold of 5 m/s (18 km/h) wind velocity for wind speed has been suggested for German conditions. According to a literature study prepared at the University of Essen (Höke and Burghardt, 1997), drift of soilborne particles of different nature onto adjacent areas increased, if wind speed exceeded 5 m/s. Furthermore the size and shape of particles affect the potential of drift with respect to distance and duration. While particles of 1000 down to 70 microns creep, jump and roll over short distances of 1 to 1000 meters, particles of less than 70 microns may be subject to suspension and are spread over longer distances. The knowledge about the size and transport dynamics of dust particles from treated seeds is currently insufficient and therefore needs further consideration.
In Austria, an order dated March 2010 fixes wind conditions to 5 m/s (18 km/h) (Womastek, 2011).
In the Netherlands, wind conditions for spray applications are also fixed to 5 m/s (xxxreferentie}. This value is taken to apply also to sowing wind conditions.
To avoid the exposure of the farmer, the tractor cabin should be kept closed (no open window).
To avoid the exposure of granivorous birds and mammals to treated seeds, the presence of remaining seeds on the soil surface should be avoided. Seeds should be entirely incorporated into the soil and it should be ensured that the product is also fully incorporated at the end of rows. Spillages should be removed. This may easily be ensured by for example covering all remaining seeds with soil.

Raising Good Practice awareness throughout the value chain

Assuring the awareness, and furthermore adopted behaviour of what is good handling and use practice of treated seed, among all players in contact with the seed, is a challenging task, which merits significant thought to be successful. The Crop Protection industry has significant experience of stewardship activities directed to farm users and can be a good source for help in this task.
Key aspects to consider in the case of treated seed are:

- Simplicity – focus on the key messages will make retention and understanding easier, and then allow for interest for the rest of the message.
- Relevance – if the message is not relevant, it will be rejected e.g the set of safety phrases for Seed Treatment chemicals are only in exceptional cases relevant to the seed treated with those chemicals. If the sentences with safety advice for treated seed are out of proportion, they will be dismissed by the user – the farmer - as irrelevant, and not considered.
- Ease of access – The user must be able to appropriate the message without much effort. Pictograms are often more efficient than fine print text, and do not require to make the effort to put glasses on to be able to understand the message. The language needs to be understood by the target user.
- Consistency – the messages need to be consistent and repeated to be understood. The less confusion and the more enforcement of the message the easier to adopt good behaviour. Recognizing that seed is traded across Europe today, good practice messages have to be the same across all European countries. As the basic good treated use

[6] The Beaufort scale is reproduced in Annex II

practices also are the same irrespective of kind of seed treatment and crop, it is highly recommended to keep the message consistent also across the treatment types.

- Channels – In order to be effective, the same message should reach the user through different sources. Seed bag labelling is one, but information leaflets and farmer/industry/on-job trainings are other source for information.

Current standard set of S-phrases, may in part be relevant for treated seed, but these S-phrases for the seed treatment product (to be included in the labelling of the treated seed according to Article 49 (4) of Regulation (EC) No 1107/2009) do not necessarily provide an adequate picture of measures relevant to treated seed. Further, the standardized wording of S-phrases, needs support by alternative, easy-to-understand, ways of assuring understanding of the messages. ESA, together with the main seed treatment suppliers, have, based on the principles above, developed a voluntary EU-wide generic seed labelling initiative, which currently is being implemented. It is intended to support an effective communication of Good Practice messages for treated seed, irrespective of crop and seed treatment used. It is to be completed by crop/seed treatment specific requirements. More information can be found under www.euroseeds.org/esta .

Point for discussion (DE): According to Directive 2010/21, MEMBER STATES shall ensure that the label of the treated seed includes the indication that the seeds were treated with clothianidin and sets out the risk mitigation measures provided for in the authorisation. A voluntary EU-wide generic seed labelling by ESA is not requested and is deemed to conflict with the official labelling decided by the MEMBER STATES. ESA should be asked to discuss the initiative with the competent authorities of the MEMBER STATES prior to the implementation.

Point for discussion from NL: Should we propose the requirements for seed bag labels in this Guidance Document, so that it is harmonised by MS? It should also be highlighted that seed bag labels should contain, next to the general measures, also the product-specific mitigation measures (e.g. a waiting period for succeeding crops).

GB The protection of these seeds is performed according to an agreed industry quality standard. For your own safety and to protect the environment, the following precautions must be observed:

In general

Do not use treated seed for human or animal consumption or for processing. Keep out of reach of children, livestock and wildlife. Handle seed packages carefully. Avoid contact with skin and respiratory tract and wear suitable protective equipment during seed handling and equipment cleaning. Wash hands and exposed skin before meals and after work. Remove any seed spillages. Keep treated seeds away from surface water.

Before sowing

When opening seed bags and during, filling or emptying of the drilling machine, avoid dust exposure. Avoid transfer of dust from the seed bag into the sowing machine. Do not treat the previously treated seeds with additional products.

At sowing outdoors

When using a pneumatic drilling machine, dust from treated seeds should be directed to the soil surface or into the soil through deflectors. Sow at the recommended seeding rate. To protect birds and mammals, treated seeds must be covered by soil, also at row ends.

After sowing

Do not leave empty bags or left-over treated seed in the environment. Dispose of them according to local legislation. Ensure that left over treated seed is returned to their original bags and do not use empty seed bags for other purposes.

The ESA „European Seed Bag Labelling Initiative“ 11

Figure 0-8: Safety recommendations related to treated seed use (source ESTA).

Point of discussion (DE): The pictograms proposed by ESTA are considered as inadequate. The icons alone are not appropriate for an effective warning concerning risk to health of humans and animals or the environment, including honey bees. The same is true for the risk phrases. Example: The pictogram together with the phrase concerning the use of deflectors would not prevent the poisoning of honeybee colonies.

Conclusions and recommendations

The information gathered in this section is proposed as a support in evaluating the relevance of seed dusts at sowing as an exposure route for humans and the environment. PPP are evaluated for each specific use and as seed treatments, for the coating of specific seeds. Thus, for each type of seed, this chapter proposes the typical associated types of drillers (Table 0-6) from which it may be deduced if any dust production is expected or not.

Drilling equipment and deflectors

If the practice involves vacuum pneumatic drillers for a specific seed in a country, recommendations for risk management should be followed. These recommendations imply the equipment of drillers with deflectors and the respect of weather conditions at which a low dispersion of the dusts, if any, is expected. These recommendations may be either generic, as for example through orders published in the Official Journal as in France (JORF, 2010), or recommended through the labelling of the PPP.

Practical recommendations with regard to the specifications of deflectors are provided in section 1.3. In Germany and France, technical controls are performed and a list of devices having been tested is available. In future, it is expected that drillers will be generically designed to avoid dust release even in the case of precision drilling. Until then, it is proposed that a list of technically accepted devices is shared within Member States, for example through a website, in order to provide an access to updated information with regard to the effectiveness of drilling material to reduce seed dust at drilling. For this purpose COM can offer as a tool an "interest group" in circa to be used to share information between MS authorities.

Drilling conditions-weather

Practical recommendations with regard to drilling conditions are provided in section 1.4. Similarly these recommendations may be either generic (see for an example JORF, 2010), or recommended through the labeling of the PPP. Weather conditions and more particularly wind conditions differ between countries, and the relative contribution of this factor may thus not be considered in an harmonized way. Thus efforts to further reduce dust emission at source should be continued as they may represent the most effective way to limit exposure to negligible levels.

Coating quality and quality control

Coating quality as well as the presence of dusts on the seed during coating, may, if wrongly performed contribute to releasing dusts during the handling of seeds and seed-bags. Much effort is invested into the development of formulations being optimized for adherence and resistance to abrasion to very low levels.

The treatment itself is performed either in industrial facilities or at the farm by farmers themselves or by contractors.

When performed by seed producers, coated seeds may be certified. Certification systems have been developed in some countries, as for example in France and Germany, for maize and oil seed rape treatments, respectively. Certification aims at ensuring a high quality of coating through a high quality coating process.

The abrasion resistance of treated seeds may easily be controlled and compared to a threshold or quality standard imposed by the legislation, as an example in France for maize seeds (JORF, 2010). The amount of dusts produced is commonly measured through a Heubach test. This way, thanks to the work undertaken in developing certification systems it is possible to define the level of quality it may be expected to reach for each type of seed, as depicted in Table 0-5. This table will evolve with the update of science and the evolution of practice.

Seed quality criteria are as a priority needed for seed types that may involve vacuum pneumatic drillers that need a deflector equipment (as it means the air is pushed up and not down at the soil). It was the case for maize and oilseed rape which were the first seed types for which coating quality

criteria were developed. Extension to other crops is under way and work is ongoing between these national initiatives and ESA to align the certifications, aiming at one EU-wide harmonised certification (and ESTA labelled seed) in future.
Treatments performed in non-certified facilities are in principle possible and may be allowable if they reach the relevant quality criteria. Treatment performed in certified facilities can be considered as fulfilling the standard criteria. For treatment performed in non-certified facilities, some other evidences to demonstrate that the standard criteria are met have to be provided. Whatever the process used, a control of batches is recommended and batches should be sampled by the plant/farmer in order to be controlled and prove that they match quality criteria in terms of dust values.
In Member States, recommendations with regard to coating quality may be either regulatory or belong to a definition of Good Practice. If regulated, they may, as for driller equipment and weather conditions, be either generic, or recommended through the labeling of the PPP. The status of seed coating quality is a Member State issue, although the implementation of certified systems may contribute to a broader harmonization of practices and make seed exchanges between countries easier. Further discussions are needed at Authority level to agree on the best way to implement these measures.

Handling conditions

Additional recommendations with regard to the handling of seed bags are given in section 1.2. Although representing good sense and good practice, a broad communication about the importance of handling steps in ensuring that the benefit achieved during the previous step (seed coating quality) and later step (drilling) is not lost is essential. In France for example, a leaflet has been developed that lists all these steps for completeness and shows all up-to- date recommendations (http://www.cetiom.fr/fileadmin/cetiom/kiosque/PDF_fiches_TK/fiche_bonnes_pratiques_semences_traitees.pdf).

Appendix VI

Risk assessment, Regulatory decision making and need for further risk mitigation measures

Aim of this chapter is to provide guidance on the assessment of the environmental risk for non-target organisms (excluding birds and mammals) arising from dust deposition in non-target areas after sowing seeds treated with plant protection products (PPP). It is assumed that the risk assessment for birds and mammals via eating treated seeds (covered by existing guidance for bird and mammal risk assessment), will cover the potential exposure via dust drift.

Introduction

Exposure of the environment due to the treatment of seeds with PPP and subsequent seeding operations has long been regarded as negligible for regulatory purposes. However, investigations of incidences regarding honey bees and data from subsequently started research projects have shown that especially dust drift is an important exposure route, which may lead to severe effects for non-target life.

Although most studies especially investigated the effects of dust drift exposure on honey bees, it is likely that other pollinators and non-target arthropods dwelling in the canopy, in hedgerows and other vegetation are also at risk. Moreover, as in the recorded incidents poor coating quality of active substances belonging to the neonicotinoids led to severe poisonings of honey bees, also other compounds used for seed treatment might reach non-target areas in significant quantities. However, there is a clear focus on insecticides and fungicides, since herbicides are not used for seed treatment. Therefore, a risk assessment for non-target plants via dust is currently not considered necessary, except when (screening) data indicate that the product may have adverse affects on plants.

Amendments of the risk assessment schemes for non-target organisms are needed, in order to include the exposure to dust deposition into exposure and effect assessment. Please note that guidance to the evaluation of the risks for birds and mammals arising from the use of seeds treated with PPP is addressed in the relevant guidance document.

For the time being, regulatory exposure estimates for seeds treated with PPP described in this guidance are restricted to dust drift deposition, although guttation may play a role in the toxicity of highly systemic compounds. A clear cause and effect relationship between intake of guttation droplets and the effects on populations of non-target organisms under field conditions has not been established yet.

Article 49 of regulation (EC) No 1107/2009 allows for the implementation of risk mitigation measures where necessary and Article 4 (1) of the aforementioned regulation requires assessments in the light of current scientific and technical knowledge. In Directive 2010/21/EU specific risk mitigation measures for neonicotinoids and fipronil used for seed treatment are laid down. Besides seed coating in professional seed treatment facilities using best available techniques, especially adequate seed drilling equipment is addressed to ensure a high degree of incorporation in soil, minimisation of spillage and minimisation of dust emission.

Accordingly, the assessment scheme and risk mitigation measures outlined below are based on the assumption that a high quality of seed treatment and safe seeding operations are ensured by appropriate legislation under Regulation (EC) No 1107/2009, especially for those active substances to be used for seed treatment known to pose a high risk to non-target life.

Over the last 3 years, several studies have been conducted mainly to investigate not only the exposure of non-target areas due to dust from seeding operations but also the effects of contaminated dust on non target life. Unfortunately, even fundamental study results on dust drift behaviour and effects investigated by industry are not available to any or all regulatory bodies nor have been evaluated by them. Many details are still under discussion and additional experiments are planned.

Consequently, the assessment schemes and measures described below are of preliminary nature and follow precautionary principles. Further guidance will be given when a broader data base will be available.

Environmental Risk Assessment

Products for seed treatment might exert clearly different effects on non-target life than the ones arising from the deposition of sprayed products. A tiered approach to identify potential risk is outlined below. The first step covers a realistic worst case and serves as a tool for identifying products leading to a low risk. For compounds which do not meet the requirements of Tier 1, it may be appropriate to conduct a higher tier risk assessment. Especially when passing to higher tiers, it should be considered if corresponding additional risk mitigation measures can be implemented.

Exposure

Basic requirements for risk assessment

Over the last years, a number of datasets on the emission and deposition of dust drift in the environment during sowing operations have been generated. Most studies were carried out on behalf of the Julius Kühn-Institute (JKI) or by industry on request and in close cooperation with regulatory bodies. Data are available for different crops (e.g. sugar beets, oil seed rape, maize and cereals).
In this chapter, generic requirements that are not related to the authorisation of specific single products are outlined. Since many of the studies were conducted with high quality seeds and sowing machinery, the outcome presented below can only be used for regulatory purposes if similar conditions will prevail during routine seeding operations in Europe.
Overall, dust deposition due to sowing operations is influenced by the dust amount emitted from the seeds, wind direction and speed during sowing, soil conditions and sowing machinery including sowing speed. For the exposure of non-target organisms, the concentration of the specific active ingredient (a.i.) in dust is relevant, but also the type of habitat where they live.
As a prerequisite for the validity of the exposure assessment, a set of acceptable ranges and technical implementations for seed and sowing quality parameters is described below.

Seed quality and coating

In chapter ., the process of seed treatment and measuring of potentially emitted dust via Heubach-values is described in detail. Here, some important additional items are discussed and recommendations are made.
Usually, the percentage of active ingredient (a.i.) in the dust released from treated seeds is influenced by the dose applied per seed unit, if the same coating process is used. However there are differences in the coating process between facilities and it has been shown e.g. for some fungicide content in cereal dust (JKI, pers. comm.), that the concentrations detected diverged, even if rate and coating process were similar. Unfortunately, several studies on dust deposition provided up to now –especially monitoring data – do not specify the concentration of a.i. in the dust.
When assessing results of exposure studies describing dust drift deposition in non-target areas, it is therefore important that the products, recipes and coating facilities are documented. Moreover, drift values used as a basis for risk assessment should not be generated with seed batches having outstandingly good treatment quality (i.e. comparably low Heubach-values and/or low concentrations of a.i. in the dust), since these are not representative for the quality of seed on the market.
As both parameters 'amount of dust' and 'a.i. in dust' directly influence the possible off-crop exposure, Heubach abrasion values might also be recalculated as 'dust a.i./ha', taking into account both maximum values for abrasion as well as content of a.i. in dust.
The values presented in Table 8-1 have proven to be achieved in seed treatment facilities and are taken as given for subsequent assessment. Regarding cereals, though, knowledge is still limited..

Thus, for risk assessment using drift experiments, a **maximum** Heubach value as well as a **maximum** content of a.s. in dust need to be ensured . (Earlier remarks on a **minimum** standard concerned the quality of the seed treatment, sowing techniques, and environmental conditions during sowing that have to be defined as legal basis).

Table 0-7: Quality values for four seeds/crops set as requirements for a worst case risk assessment of dust deposition in non-target areas.

Crop	Maximum Heubach-value* (dust in g / ha or No. of seeds)	Maximum a.i. content in dust** (%)	Heubach-value recalculated to a.i. content (mg dust a.i./ ha or No. seeds)
Maize	0.75 g / 100.000 seeds	20 %	150 mg a.i./ 100.000 seeds
OSR	0.5 g / 700.000 seeds	10 %	40 mg a.i./ 700.000 seeds
Cereals	2 g / ha (ca. 150 – 250 kg/ha depending on the crop)	10 %	200 mg a.i./ha
Sugar beets	0.2 g / 100.000 seeds	10%	20 mg a.i./ 100.000 seeds

* See Chapter 2.1
** See Chapter ?…

The dust drift values presented in the next chapter (please refer to Table 8-2) should only be used for regulatory risk assessments if the criteria of Table 8-1 are fulfilled. They are meant for a general evaluation of all types of products. However, extrapolation between crops will need to be further substantiated.
The regulation of highly toxic products might however require lower residue values in the dust or lower Heubach-values –especially if intended uses in maize and cereals cover high rates. Lower Heubach-values and lower content of a.i. in dust than given in Table 8-1 are frequently achieved in practice and might be implemented in a higher Tier approach.

Sowing techniques

Besides seed treatment, the quality of seeding machinery highly influences the amount of dust emitted (see Chapter , page 36). Mechanic seeders lead to less dust drift during sowing than pneumatic ones. Vacuum pneumatic machines must be equipped with devices ensuring dust deflection to soil. According to practical inspections conducted by JKI, the effectiveness of self-constructed adjustments by farmers is highly uncertain.
For the purpose of this guidance document, it is assumed that pneumatic machines are equipped with pertinent deflection devices. A list of acceptable equipment for pneumatic machines is given e.g. by JKI (http://www.jki.bund.de/no_cache/en/startseite/institute/anwendungstechnik/geraetelisten/abdriftmindernde-maissaegeraete.html).

Weather conditions

The field trials performed by JKI were conducted under those climatic conditions which are required in Germany under the principles for Good Agricultural Practice for the spraying of plant protection products. Especially high wind speed and dry weather conditions increase dust drift. Dry soil conditions generally seem to increase dust drift.

*** Issues to be solved / future actions:**
- It has to be discussed which data requirements have to be delivered for each application/dossier or whether it is feasible to use generic data one day (e.g. generic drift values correlated to Heubach values).

- The maximum Heubach values in table 3-1 are based on measurements before / at the time of bagging. These values can still be substantially lower than dust values after transport and storage. This may have implications for the exposure assessment. Whether there is an increase in dust values to be expected for seeds which were transported or not is depending on how the transportation was done and how the seeds were handled. But more knowledge in this field is needed.
- Knowledge on how Heubach values change over time is needed. First results on this show that there can be an increase in abrasiveness with time e.g. after 6 months. This is not as relevant for seeds of crops which regularly are taken back by seed companies (at least in Germany) as for oil seed rape, maize and sugar beet. This material will be tested before being sold again in the following year.

Product specific exposure assessment

Standard 2-D ground deposition exposure assessment

The prediction of dust drift deposition rates as laid down in Table 8-2 below are recommended to be used for a product/use specific exposure assessment of dust ground deposition (defined as PECdust ground deposition).
This so-called 'two dimensional (2-D)' exposure assessment of dust deposition is valid when assessing the risk for organisms living in habitats which are exposed in a way comparable to the employed sampling devices (petri dishes), e.g. soil organisms or aquatic organisms.

Experimental data base

Input data for regulatory risk assessment should be representative for the uses under practical farming conditions. Several of the currently available experimental data sets to assess the 2-D-exposure were provided by industry and evaluation of the results from these field studies was recently submitted to the regulatory authorities (Fent, 2011). During the review process in Germany, some main concerns were identified and reported to the author/study sponsor – especially regarding the insufficient description of experimental set ups, employed seeds and data treatment procedures. Due to the high uncertainties regarding the report of Fent (2011), it is currently not possible to assess how far the provided ground deposition values actually represent “realistic worst case” situations. Therefore, the study is considered as a preliminary version and not recommended for the general use in risk assessment procedures. However, the Fent study is partly useful; for some studies more details are available than for others. Only parts of the studies considered to be valid were used supplementary to JKI studies.
The following main uncertainties were identified for field studies in the review by Fent (2011):

- Some of the experiments were carried out with high quality seeds. The reported Heubach-values are far lower than the ones commonly achieved in practice and are therefore not representative for the quality of seeds on the European market.
- The concentration of active ingredients in dust is not specified.
- Further key parameters are not measured or reported in the study, e.g. drilling width (i.e. total field area where the treated seeds have been sown) or soil moisture.

By contrast, studies conducted by the Julius Kühn-Institute (JKI) with maize as well as oil seed rape (2011) and cereals (2008) represent worst case situations concerning key environmental conditions (e.g. dry soil and sufficient wind) and were assessed as sufficient conservative exposure endpoints for Tier 1. The results of the appropriate trials are summarized in more detail in III and IV. Since some experimental conditions regarding seed quality and sowing made normalization adjustments necessary, derivation of exposure data is described below:

Derivation of 2-D exposure data

- In case of maize and oil seed rape, experiments with no specific Heubach-values reported in the review of Fent (2011) were not selected for further evaluation.
- The Heubach-value of the seed lots used in the experiments should be adequate. By way of approximation, it is assumed that the Heubach-value directly correlates to the amount of deposited dust in the non treated area. If the reported Heubach-value in the study was clearly lower than the standard values set in Table 8-1, normalization to the crop standard value was performed (see III).
- If the residue content of active ingredient in the dust collected during the experiments was lower than the crop specific standard values in Table 8-1, the predicted a.i. exposure rates are normalized to the standard contents (e.g. 10 % a.i. in dust; see III).
- The drill width in the experiments correlates with the amount of dust deposited in the non-target areas. Typical drift curves in relation to the sowing width are presented. According to the derived scaling factors, a normalization to a standard field of 1 ha and a side length of 100 m is performed (see IV).

Table 8-2 presents the original ground deposition values as well as the normalized values. Values represent dust drift at 1 m distance from field edge. Only the normalized ground deposition values should be used in the environmental risk assessment, since they correctly predict the 2-D exposure to dust drift in realistic worst case situations. If, in future, the standard quality of the seeds on the European market will improve clearly, adapted values for deposition in non-target areas will be derived.

For sugar beet and cereals, the data set regarding the Heubach-values of the seeds and the residue content of a.i. in the dust is small.

For sugar beet, it can be assumed from the data in the review of Fent (2011) that the dust deposition arising from the sowing of pelleted seeds is less than 0.001 % a.i. field rate /ha (see Table 8-2). Since all Heubach-values for sugar beet from different treatment facilities showed a very low abrasion (JKI, pers. comm.), it is very likely that field experiments with sugar beets all had comparable good quality and thus represent a realistic exposure scenario.

For cereals, only one JKI study (from 2008) is available. The Heubach-value of the seeds was 2.1 g/ha, the Heubach filter residue content 8 % a.i. and the drilling width 100 m. Since the experimental results are based on 10 petri dishes replicates only, the values for cereals are considered as very preliminary and the 95th percentile is given. Please see III for details.

Since the application rate (amount of a.i. applied to seeds per ha) is not directly correlated to the concentration of a.i. in dust (emission is influenced by dust abrasion measured as Heubach-value), amount of seeds per ha and concentration of a.i. in dust (%) are additionally given in Table 8-2. For maize and OSR studies conducted by JKI and Fent were considered. For cereals only one appropriate JKI -trial was available.

It should be always kept in mind, though, that the listed exposure values are valid only if pneumatic suction drillers are equipped with deflectors. Without deflectors, the exposure in non-target areas might be more than 10 times higher than reported in the table below. As described in chapter , mechanical sowing will result in lower drift values compared to any type of pneumatic sowing. At the time being, only few data set are available and the extrapolation of deposition values was not feasible.

Table 0-8: 90th percentile ground dust drift values and normalized 2-D-exposure data to be used in the risk assessment of contaminated dust in non-target areas (percentage of field rate of a.i. / ha in 1 m distance from field edge). Valid only if pneumatic suction drillers are equipped with deflectors. See text for details.

Crop	Type of seeder	Experimental parameters covered	Experimental ground dust deposition (uncorrected value) (% a.i. field rate /ha)	Normalized Exposure 2-D (% a.i. field rate /ha)
Maize	pneumatic, vacuum technique	Drill width: 45 m Heubach: 0.45 a.i. in dust: 19.2 %	0.310	0.56
OSR	pneumatic	Drill width: 48 m Heubach: 0.38 a.i. in dust: 6.3 %	0.093	0.22
Cereals	pneumatic	Drill width: 100 m Heubach: 2.1 a.i. in dust: 8 %	0.266*	0.33
Sugar beets	all techniques	-	-	0.001

* 95th Percentile. See text for details

The assessment of dust deposition data for distances > 3 m was not considered relevant because in Germany the setting of buffer zones as risk mitigation measures for sowing operations is considered not feasible. However, other MS (e.g. NL) may have more experience with e.g. implementing crop free buffer zones. Thus, this could be an issue to be discussed by MS as risk management option.
Adequate dust drift data of representative field studies may allow a more detailed calculation of drift deposition in order to refine the realistic worst case values listed in Table 8-2. Despite the uncertainties in the Fent data, the data that were selected and used for the drift estimation above were considered as realistic worst case because of the harsh circumstances of the trials with very dry soil and sufficient wind. Especially for cereals, a content of 10 % of a.i. in dust may be too conservative.
A refinement of 2-D deposition according to specific crop values would correspond to a higher tier assessment.

Standard 3-D exposure assessment

Investigations after the bee incidents in Germany have shown that species living or foraging in 3-D structures like hedgerows, trees or other crops are exposed to higher deposition rates of contaminated dust than the species living on the ground.
Preliminary results of a limited amount of studies using gauze net sampling devices to simulate a 3-D structure show that a higher exposure has to be expected in the gauze compared with ground deposition as determined by petri dishes (Neumann & Jene, 2010; Heimbach et al. 2010, 2011a/b; see V for details). Gauze net technique has been selected after testing several dust collecting devices, because it produces standardised results comparable to nearly natural structures.
The high variability of environmental and technical conditions mirrored in the four available experimental studies led to different deposition rates and directly influences the quantifiable single 2-D/3-D extrapolation factors (see V). Because it is not yet possible to quantify the influence of important parameters based on the few available data sets, we derived an averaged 2-D/3-D extrapolation factor from the worst case study (which was in maize).
Based on the experimental results from the study of Neumann & Jene (2010, see V) where treated maize seeds were sawn, a factor of 12.4 has been determined for the extrapolation between residue levels of a.i. in petri dishes on the soil surface and the vertical projection area of gauze net (see Table 8-3). The proposed factor of 12.4 represents the median of all possible ratios of residues samples of 15 sections of the gauze net (50 cm x 50 cm, sampling height of 0.65 m) and 30 petri dishes with ground deposition (details of the Neumann & Jene study in V).
Since the extrapolated factor of 12.4 results from few experiments with variable experimental conditions, there is still a high degree of uncertainty.

Notifiers have announced to submit a study summarising all available data about the relationship between 2-D to 3-D deposition data. Unfortunately, the single studies and the review have not been made available to regulatory bodies yet.

Table 0-9: Predicted exposure in 3 dimensional structures in non target areas due to deposition of dust drift after sowing treated seeds. Values are given as percentage of max. field rate of a.i. / ha in 1 m distance from field edge, based on 2-D deposition values and considering an extrapolation factor from 2-D to 3 dimensional structures of 12.4. See text for details

Crop	**Type of seeder**	**Exposure 3-D** (% a.i. field rate /ha)
Maize	pneumatic, vacuum technique	7.0
OSR	pneumatic	2.7
Cereals	pneumatic	4.1
Sugar beets	all techniques	0.01

*** Issues to be solved / future actions:**
- Since the extrapolated factor of 12.4 results from few experiments with variable experimental conditions, there is still a high degree of uncertainty. At the moment the extrapolation factor is a conservative factor derivated in maize, however more experiments for different crops are considered necessary. It must be kept in mind that the choice of a median value can be considered arbitrary and might be a point of discussion.
- Particle size distribution varies between crops. E.g. barley and maize contain larger particle size. But as long as Heubach values are used to find out a correlation, only small particle sizes are important. So what is needed to know in future is, if Heubach values of different crops correlate differently with drift data in off crop. (But again particle size is not only influenced by crop type but also by cultivars , cleaning activity of seeds before treatment and type of sowing machines. So it is very variable and different factors may be found. And an even more relevant factor may be wind speed and direction and if there is air movement upwards.)

Refined exposure assessment

Where trigger values of Tier 1 assessment are not reached, a higher-tier risk assessment is necessary. For the refinement of the exposure estimation, it can be assumed that drift deposition values are related to the quality criteria parameters listed in the chapters above. If, in future, seed treatment quality parameters will improve (e.g. the percentage a.i. content in the dust is by a factor of 2 lower than the standard values in Table 8-1), a reduction of the respective drift values can be assumed.
Also when drilling machines with improved technical equipment will be developed and implemented, dust deposition in non-target areas will be reduced. The relationship between improved machineries and dust deposition should however be investigated in appropriate experiments.
The prerequisite for an exposure refinement in the authorisation procedure of seeds treated with PPP is that the required higher treatment and/or sowing quality is verifiable and enforceable under the current legislation.

*** Issues to be solved / future actions:**
This proposal is presented based on available data. It can be seen as starting point for a general discussion to decide which kind of data are still lacking.
This guidance document is meant to be general guidance. A need for more harmonised data is presented in this document several times. Some of the details about the type of exposure studies and which parameters should be derived can be found in the Annexes. For example in the documentation of the Neumann&Jene study in the Annex V it is described how to conduct a 3-study with gauze net study and why we currently consider this as worst case compared to the JKI studies.
In future these chapters can be discussed and reworked when more datasets with acceptable study design are available.

The proposal for refinement of exposure seems preliminary as the first tier assessment still has a lot of uncertainties in the chosen approach. Further refinement is for future consideration.

Ecotoxicological effects of contaminated dust

Experimental data

First trials have been made to compare the sensitivity of standard non-target arthropod species towards dust and spray exposure (Table 0-10). Preliminary results show that the sensitivity of standard non-target arthropods species (*Aphidius rhopalosiphi, Typhlodromus pyri and Chrysoperla carnea*) is comparable or lower when exposed to contaminated dust versus liquid formulation. However, according to preliminary results (data from applicants and JKI, pers. comm.), honey bees seem to be more sensitive to dust drift compared to spray drift, especially to fine dust particles.

These first results are to be validated and it is still questionable if the standard laboratory test species are representative for all arthropods regarding the sensitivity to contaminated dust (with special regards to pesticide uptake, e.g. activity and grooming behaviour) as they are currently considered for the risk assessment of spray formulations. It cannot be excluded that e.g. dust may stick longer at more hairy species -and thus these species may have a higher contact exposure. Non-Apis pollinator species are not expressly covered in the current valid Guidance Document on Terrestrial Ecotoxicology.

Another exposure route which has not being addressed up to now is the oral uptake of dust particles together with pollen. In flowers, high concentration of contaminated dust can be expected, which might constitute a high risk for pollinators (see below).

Table 0-10: Toxicity of active ingredients (a.i.) to arthropods, applied as spray formulations or as dust particles.

Species	Formulation toxicity $L(E)R_{50}$ (g a.i./ha)		Factor dust/ spray toxicity	Source
	liquid	dust		
A. rhopalosiphi	0.058	0.331	5.7	Stevens (2010)
	0.177	9.42	53.2	Jans (2010a,b)
T. pyri	133.3	> 800	> 6.0	Fallowfield (2010)
	197	> 256.1	> 1.3	Jans (2010c,d)
C. carnea	4.08	26.2	6.4	Spincer (2010)
	36.4	262.4	7.2	Jans (2010e,f)

Conclusions

The very first studies on the effects of dust from treated seeds on non-target arthropods show that the standard beneficial test species are less sensitive to dust than to the liquid seed treatment formulation under the tested conditions. By contrast, first results of tests with honey bees show that the standard species tested for liquid formulations may not be representative for species sensitive to the exposure toward contaminated dust. Wild bee species or butterflies might be more sensitive to the same compounds than the standard laboratory test species due to their body surface structure (e.g. hairs, scales).

Using effect studies with the liquid PPP formulation, which are not designed and validated for contaminated dust, has two deficiencies. On the one hand, the 2-dimensional sprayed glass plate test may lead to a conservative toxicity input value for risk assessment. On the other hand, the test design of a 3-dimensional (sprayed plant) extended laboratory test is not comparable to the exposure to dust filtered out and accumulated in 3-D structure (e.g. flowers, hedgerows) and therefore might underestimate the risk.

As long as no further data on the effects of dust on other non-target arthropods are available, it is proposed to use the standard endpoint from the liquid seed treatment formulation from the species which showed the highest sensitivity to the active substance. A problem may be that in dossiers for seed treatments usually no data for the standard arthropod indicator species are available (*Aphidius and Typhlodromus*), but only for in-soil/soil-surface dwelling species (tests conducted with a.s. mixed in sand/soil). If this is the case, it should be decided case-by-case if additional tests with the indicator species *A. rhopalosiphi* and *T. pyri* are required (for example depending on the margin of safety with the soil dwellers and aquatic invertebrates). Additional tests can be conducted more easily with the liquid seed treatment formulation than not yet harmonised and validated dust laboratory tests, and is therefore acceptable.

If the endpoint results from a glass plate or 2-dimensional study, no further considerations are necessary, since the endpoint and the exposure in the tests represent a worst case for field situations.
However, if the endpoint results from a 3-dimensional extended laboratory test, then regulatory decisions should be taken case by case. Further considerations should be given to the relationship between LR_{50} from test with glassplates and test with natural substrates. Especially when no standard endpoints from worst case exposure are available, results from 3-D test with liquid formulations should be evaluated with care (the test design of a 3-dimensional (sprayed plant) extended laboratory test is not comparable to the exposure to dust filtered out and accumulated in 3-D structure (e.g. flowers, hedgerows) and therefore might underestimate the risk.)
For honeybees, we propose to ask for a semi-field study which investigates the dust toxicity if the first tier risk assessment is not met (see below).

Refined assessment of ecotoxicological effects

As a higher tier approach, the standard species or other non target species like wild bees, bumble bees or butterflies can be field tested in the non-target area with the dust from the respective seed treatment formulation. As no agreed guidelines currently exist, it is recommended that the study protocols are discussed beforehand with the regulatory authority.

*** Issues to be solved / future actions:**
- It is not known if the standard laboratory test species as currently considered for the risk assessment of spray formulations are representative for all arthropods regarding the sensitivity to contaminated dust (with special regards to pesticide uptake, e.g. activity and grooming behaviour).
- Oral uptake of dust particles together with pollen is an exposure route that has not been adressed up to now.
- Considering the uncertainties involved with field studies (i.e. do they detect and cover all risks caused by contaminated dust? - this has to be validated), it should be evaluated which set of data can cover all ecotoxicological and ecological sensitivities of non target species.

Risk assessment - Toxicity to Exposure Ratio (HQ- and TER-values)

In the current risk assessment schemes, different approaches to determine the Exposure to Toxicity Ratio are available (HQ resp. TER). It has to be kept in mind, though, that neither the trigger values of the HQ approach nor the TER approach used in the EU risk assessment for bees and non target arthropods have been validated for the exposure to dust particles.

Risk assessment resulting from 2-D exposure - Aquatic organisms

As mentioned above, the risk assessment for aquatic organisms should be based on the soil deposition data (see chapter , page 58). Whilst no FOCUSsurfacewater scenario for dust drift has been developed yet, the TER approach is recommended in the risk assessment for aquatic organisms. The PECground deposition of dust deposited in the non-target area (in g a.i./ha) has to be converted into a so called PECsw (µg/L), corresponding to a standard water body (1 m width, 1 m length, 0.3 m depth containing 300 L of water/ m² surface area). As long as no toxicological studies with dust in the aquatic environment are available and there is no evidence that dust might be more toxic in water then spray droplets, the endpoints from studies with the liquid formulations with the active substance can be used for the risk assessment.

$$TER = \frac{Tox\,(endpoint\ liquid\ formulation)}{\frac{PECground\ deposition\,(\frac{g}{ha}) * 100}{300\,(\frac{L}{m^2})}}$$

The respective TER trigger value 100 resp. 10 (Uniform principles; Regulation (EU) No 546/2011) should be used.

Issues to be solved / future actions:

The exposure via dust is not incorporated in FOCUS, but the PPR Panel Opinion has developed procedures to estimate dust drift deposition of NSAs (Non Spray Application) onto surface water and proposes another parameterization of the model input for the entries of various NSAs than the current parameterization of the FOCUSsw Guidance. (The exact citation is: Opinion of the Scientific Panel on Plant Health, Plant Protection Products and their Residues on a request of EFSA related to FOCUS sw scenarios. *The EFSA Journal* (2004)145, 1-31.) This PPR-opinion was not taken into account for this guidance document.

Assessment of risk for honey bees

An in-field risk assessment is not necessary, as there will be no bees present in-field during sowing. However, bees may be exposed off-field (in flowering margins or neighbouring crops).

As a first approach in the risk assessment for honeybees, the $HQ_{(Product)}$ = max. application rate [g Product/ha] x LD_{50} [µg Product/bee] $^{-1}$ may be calculated for oral and contact toxicity, using the total amount used per ha.
If the HQ < 50, no unacceptable risk is anticipated for dust drift resulting from the sowing of treated seeds. From practical experiences, no effects on bees were ever observed with spray application of products with HQ < 50. Even though the toxicity effect may be underestimated by using the LD50 for liquid formulation, the exposure is highly overestimated (using the full in-field dose). Therefore, this approach is considered acceptable to determine for which products further refinement is necessary.
This first approach will be subject to further refinement in the future as more data will be available. Also the TER-approach considering 3-D structures may be used at a later stage. However, it needs to be defined which endpoints may be used and if extrapolation/safety factors are needed.
Proposal for refined off-field risk assessment: determine a NOEC or NOAEC from (semi-) field studies into dust toxicity and compare this with the PEC. However, at present we are not able yet to conclude on a reliable PEC that could be used and are not yet able to state the Trigger that should be used.

*** Issues to be solved / future actions:**
- Further refinement of first tier approach.
- Which PEC and which trigger to be used for the higher tier off-field risk assessment.

Assessment of risk for non-target arthropods

An in-field risk assessment for the route via dust for foliar NTA is not necessary, as there will be no foliage present in-field during sowing. Risk assessment for soil surface dwelling NTA in-field via dust drift is considered to be covered by the in-field risk assessment for in-soil dwelling NTA (via PECsoil). However, foliar dwelling NTA may be exposed off-field (in flowering margins or neighbouring crops). The off-field risk for soil surface dwelling NTA is considered to be covered by the risk assessment for the foliar dwellers, as explained below.

After the bee incidents in Germany, high residue levels have been found especially in 3-D structures that had filtered the dust arising from treated seed sowing out of the air (e.g. flowers of common dandelion, orchard trees, rape). Due to different particle size, shape and weight, dust particles have a completely different environmental behaviour than spray drift droplets. Furthermore, portions of the dust could be relocated after being deposited during dry weather conditions. **The realistic worst case exposure for terrestrial invertebrates – especially pollinators – will therefore not be found on the ground but in 3 dimensional spatial structures (e.g. trees, hedges, adjacent crops).**

Thus, the predicted 3-D exposure data as listed in Table 8-3 will be employed in the assessment of the risk for foliar-dwelling NTA exposed to contaminated dust. As long as no generic factors are available for every crop, a worst case extrapolation factor of 12.4 will be use to derive 3-D exposure data from 2-D ground deposition data measured with petri dishes (see chapter , Exposure).

Because of the attractiveness of flowers to pollinators, a vegetation dilution factor is deemed to underestimate the risk for species e.g. foraging in the outer part of a flowering hedge. Moreover, pollinators like bees or butterflies will forage from one flower to the next and accumulate high amount of dust. Thus, no vegetation distribution factor should be used to assess the realistic environmental risk for NTAs exposed to contaminated dust deposited in 3-dimensional structures.

For the time being, the options for the appropriate toxicity endpoint for the risk assessment of NTA are described in chapter .

The TER-ratio can be calculated following the formula below:

$$TER = \frac{Tox\ (formulation\ as\ liquid\ or\ dust)}{PEC\ 3D\ Structure\ or\ PEC ground\ deposition * extrapolation\ factor}$$

A TER trigger value of 10 or 5 (Uniform principles; Regulation (EU) No 546/2011) is proposed. These triggers are in line with the ESCORT 2 safety factors of 10 or 5 in the off-field risk assessment based on resp. first tier and extended laboratory tests.

*** Issues to be solved / future actions:**

- Agree on trigger to be used for the off-field risk assessment for NTA.

Risk mitigation measures

According to Article 49 (4) of Regulation (EC) No 1107/2009, treated seeds have to be labelled with, amongst others, standard phrases for safety precautions (as provided for in Directive 1999/45/EC) for the seed treatment product and risk mitigation measures set out in the authorisation of that product. Besides generic risk mitigation measures to be set for all seed treatments and seeding operations with treated seed through appropriate legislation, additional product and use specific ones might be set. According to Regulation (EU) No 547/2011, appropriate S-phrases are to be set by member states when authorising such products. Directive 2010/21/EU amending specific provisions relating to clothianidin, thiametoxam, fipronil and imidacloprid provides for the following provisions:

- the seed coating shall only be performed in professional seed treatment facilities. Those facilities must apply the best available techniques in order to ensure that the release of dust during application to the seed, storage, and transport can be minimised,
- adequate seed drilling equipment shall be used to ensure a high degree of incorporation in soil, minimisation of spillage and minimisation of dust emission,
- the label of the treated seed includes the indication that the seeds were treated with the specific active and sets out the risk mitigation measures provided for in the authorisation,
- the conditions of the authorisation, include, where appropriate, risk mitigation measures to protect honey bees.

It is acknowledged that both drilling equipment and weather conditions may vary from a country to another, and evolved in a country within time. Thus it is important that knowledge is updated constantly and shared within Member States, so that they may adapt their specific recommendations based on the state of the art and on the most harmonized way.
The decision to emit the corresponding recommendations, through generic regulatory texts or the labelling, is a Member State issue, although it does not preclude from agreeing on a common tool box for risk management measures. Since seeds may be used in the whole EU, a harmonized EU approach would be better (e.g. legislation). It is thus recommended that a website is developed, which would contain all the necessary information and scientific resources on risk management tools that are ready for implementation in Member States and under development.

Appropriate S-Phrases

Article 49 provide for "standard phrases for safety precautions as provided for in directive 99/45/EC" and the interpretation of this wording should be read as referring to "Safety advice (S phrases)" referred to in Article 10 paragraph 2.6 of Directive 99/45/EEC. Those can be found in Directive 67/548/EEC. The safety phrases will be the ones applicable to the plant protection product applied on the seed. Therefore the list of phrases have to be amended accordingly.

The sentences below are an example now in use for German registration.

SPe11:

To protect (aquatic organisms/groundwater/non-target plants/non-target arthropods) (this product/seed treated with this product) may only be (applied/drilled) with equipment classified as drift reducing by at least (50%/75%/90%) (cf. Register of risk mitigating application conditions ...).

NH6831

The following label must be printed on the seed package: "Treated seeds may only be sown by using a pneumatic seeding machine which operates with negative pressure, if this machine is registered in the "List of drift reducing sowing equipment" of the Julius Kühn-Institute (this can be seen on the Julius Kühn-Institute's website at <http://www.jki.bund.de/geraete)/>)."

SPe12:

To protect (groundwater/aquatic organisms/non-target plants/non-target arthropods/insects/birds/wild mammals) it is to be assured with an appropriate treatment process, which includes the use of an appropriate adhesive agent, that the treated seed is dust-free and abrasion-resistant, unless similarly efficient measures are taken or conditions are fulfilled (cf. Guideline for the proper compliance with use conditions ....).

NT6991

The seed treatment shall only be performed in professional seed treatment facilities, which are registered in the index of "Seed Treatment Facilities with Quality Assurance Systems to Minimise Dust" of the Julius Kühn-Institute (visit the homepage of the Julius Kühn-Institute <http://www.jki.bund.de)/>).

NH681

On packaging containing dressed seeds, the following label is necessary: "Do not sow treated seeds at wind speeds of more than 5 m/s".

NH682

On packaging containing dressed seeds, the following label is necessary: "The treated seeds, including any dust they contain, or dust which is produced during the sowing process, has to be incorporated completely into the soil".

NB6632

The following label must be printed on the seed package: The farm manager is obligated to notify the area designated for the sowing of the treated seeds to beekeepers, whose bee hives are located within a radius of 60 m to the sowing area, at least 48 hours prior to sowing.

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2 Annexes to Appendix VI

Annex I (Annex to Appendix VI) : Representative coating practice and conditions of use of coated seeds within the EU

Table A 1: Representative coating practice and conditions of use of coated seeds

crop	Direct sowing or transplanting	If direct sowing outdoors, type of driller [1]	Seed treatment technology [2]
arable crops			
cereals - spring	Direct sowing	mostly mechanical and pneumatic seed drill equipment, pneumatic with vacuum principle upcoming	seed treatment facilities (fixed or mobile) and on farm treatment basic seed treatment / basic coating
cereals - winter	Direct sowing	mostly mechanical and pneumatic seed drill equipment, pneumatic with vacuum principle upcoming	seed treatment facilities (fixed or mobile) and on farm treatment basic seed treatment / basic coating stickers more recently introduced more widely
maize, sweet corn, sorghum	Direct sowing	Yes, 90% vacuum principle	Professional treatment basic seed treatment direct on the seed (active ingredient can be present on the outside surface of the seed)
oilseed rape	Direct sowing	mechanical and pneumatic seed drill equipment, pneumatic with vacuum principle upcoming	Professional treatment basic seed treatment / basic coating finishing powder to ensure flowability of seeds
sunflower	Direct sowing	both mechanical and pneumatic with and without vacuum technique are possible	Professional treatment basic seed treatment / basic coating finishing powder to ensure flowability of seeds
beet (sugar and fodder)	Direct sowing	Pneumatic or mechanical precision drilling equipment	Professional treatment pelleting, with active ingredient not on the outside of the seed but closed in by an inert layer; new development: filmcoating on top of the pellet
beans, peas	Direct sowing	Pneumatic (mainly vacuum technique) or mechanical precision drilling equipment	Professional treatment basic seed treatment / basic coating

crop	Direct sowing or transplanting	If direct sowing outdoors, type of driller [1]	Seed treatment technology [2]
cotton	Direct sowing	Vacuum pneumatic drilling equipment	Professional treatment basic seed treatment / basic coating delinting process
flax, poppy seed	Direct sowing	mostly mechanical seed drill equipment, pneumatic with vacuum principle upcoming	basic seed treatment / basic coating
grasses, grasseed	Direct sowing	both mechanical and pneumatic (vacuum) are possible	basic seed treatment / basic coating
alfalfa, caraway, green manure crops	Direct sowing	both mechanical and pneumatic (vacuum) are possible	no seed treatments
outdoor vegetables			
onion, carrot, radish	Direct sowing	Pneumatic precision drilling equipment	Film coating/rotostat;
leek	Most sowing in seed beds and transplanting later, approximately 10% direct sowing. Mostly sowing outdoors, some sowing indoors in trays.	Pneumatic precision drilling equipment	filmcoating/rotostat;
asparagus	Sowing in seed beds, later transplanted.	yes	filmcoating/rotostat
chicory, endive, lamb's lettuce	Direct sowing	mainly coated seed, pneumatic ; also pelleted seeds, sown mechanically	filmcoating/rotostat
spinach	Direct sowing	mainly mechanically drilled, pneumatic equipment upcoming (both vacuum and gauge pressure principle)	basic coating, partly filmcoating, and sometimes toplayer
beetroot	Direct sowing	Pneumatic precision drilling equipment	basic coating
greenhouse vegetables			

crop	Direct sowing or transplanting	If direct sowing outdoors, type of driller [1]	Seed treatment technology [2]
lettuce, including lettuce-like (radichio rosso, endive, etcetera)	All these crops are only sown and raised to young plants indoors; later transplanted indoors or outdoors.	not applicable	pelleting, with active ingredient not on the outside of the seed but closed in by an inert layer
brassica, including head cabbages, Brussels sprouts, cauliflower, broccoli, Chinese cabbage, kale	All these crops are only sown and raised to young plants indoors; later transplanted indoors or outdoors.	not applicable	filmcoating/rotostat, and sometimes top layer
fruiting vegetables (tomatoes, cucumber, weet pepper, eggplant, etcetera)	Plant raising only indoors, later transplanted indoors or outdoors. In case of outdoor sowing (e.g. cucumber in Germany) vacuum systems are used.	Pneumatic precision drilling equipment	sometimes fungicide treatments,
celeriac	Sown indoors, later transplanted outdoors.	not applicable	
ornamentals			
several ornamental crops from seed	Cultivation both indoors and outdoors; many crops through plant raising indoors; limited crops directly sown outdoors.		filmcoating (high value seeds)

1) Mechanical seed drill equipment does not work with air and therefore can not release air flows. With pneumatic seed drill equipment there are two principles: using the vacuum principle and using the gauge pressure principle. When using the gauge pressure principle there is no more air replacement (with potential dust) than with mechanical seed drill equipment. When using the vacuum principle seeds are put in the sowing row by vacuum and the excess air will come free. At conventional corn sowing machines, this exhaust air was directed upwards. Meanwhile, these machines (mostly) are modified: they have deflectors directing the exhaust air downwards to the

soil. For vegetable vacuum seed drilling machines (unfortunately not true!) the airflows already always were directed towards the soil.

2) There is no complete one-on-one relationship crop - seed treatment: which method is used also depends on eg the type of pesticide used, the composition of that pesticide and whether multiple pesticides are used, seed type (smooth, rough, etc.), to a certain extent for which market the seed is treated, etc. Also, various terms are used. This table presents an indication. In general, the more valuable the seed is, the higher quality (and more expensive) seed treatment technology can be used. Furthermore: coating means stickers are used; in basic coating the pesticide can irregularly be distributed over the seed, in film coating a regular layer is spread over the seed (used for somewhat higher valuable seeds); a part of the market has on top of that a top layer (without active ingredient).

Annex II (Annex to Appendix VI): Beaufort scales for wind

Table A 2: Beaufort scales for wind

Beaufort*	Avg Miles per Hour	Knots	Surroundings
0 calm		0-1	Smoke rises vertically and the sea is mirror smooth
1 light air	1.2 - 3.0	1 - 3	Smoke moves slightly with breeze and shows direction of wind
2 light breeze	3.7 - 7.5	4 - 6	You can feel the breeze on your face and hear the leaves start to rustle
3 gentle breeze	8.0 - 12.5	7 - 10	Smoke will move horizontally and small branches start to sway. Wind extends a light flag
4 moderate	13.0 - 18.6	11 - 16	Loose dust or sand on the ground will move and larger branches will sway, loose paper blows
5 fresh breeze	19.3 - 25.0	17 - 21	Surface waves form of water and small trees sway
6 strong breeze	25.5 - 31.0	22 - 27	Trees begin to bend with the force of the wind and causes whistling in telephone wires. Some spray on the sea surface
7 moderate gale	32.0 - 38.0	28 - 33	Large trees sway. Moderate sea spray
8 fresh gale	39.0 - 46.0	34 - 40	Twigs break from trees, and long streaks of foam appear on the ocean
9 strong gale	47.0 - 55.0	41 - 47	Branches break from trees
10 whole gale	56.0 - 64.0	48 - 55	Trees are uprooted and the sea takes on a white appearance
11 storm	65.0 - 74.0	56 - 63	Widespread damage
12 hurricane	75+	64 +	Structural damage on land, and storm waves at sea

Table A 3: Scales for wind (miles and km per hour are given)

BEAUFORT SCALE

NUMBER	NAME	WIND SPEED		DESCRIPTION
		MPH	KPH	
0	calm	<1	<1	calm; smokes rises vertically
1	light air	1-3	1-5	direction of wind shown by smoke but not by wind vanes
2	light breeze	4-7	6-11	wind felt on face; leaves rustle; wind vane moves
3	gentle breeze	8-12	12-19	leaves and small twigs in constant motion; wind extends light flag
4	moderate breeze	13-18	20-28	wind raises dust and loose paper; small branches move
5	fresh breeze	19-24	29-38	small-leaved trees begin to sway; crested wavelets form on inland waters
6	strong breeze	25-31	39-49	large branches move; overhead wires whistle; umbrellas difficult to control
7	moderate gale *or* near gale	32-38	50-61	whole trees sway; walking against wind is difficult
8	fresh gale *or* gale	39-46	62-74	twigs break off trees; moving cars veer
9	strong gale	47-54	75-88	slight structural damage occurs; shingles may blow away
10	whole gale *or* storm	55-63	89-102	trees uprooted; considerable structural damage occurs
11	storm *or* violent storm	64-72	103-117	widespread damage occurs
12	hurricane	>72	>117	widespread damage occurs

Annex III (Annex to Appendix VI) : Summary of results from dust ground deposition experiments in maize, oil seed rape, sugar beet and cereals

In Table 8-2, the following dust drift values (relative to the applied amount of a.i.) were recommended for exposure assessment of ground deposition (2-D exposure) onto non-target soil surface. Crop specific assumptions were considered in order to address experimental uncertainties (see chapter "Experimental data base"). Therefore, study parameters (Heubach-value, concentration a.i. in dust, drill width) were corrected to allow comparable test conditions to the standard quality criteria in Table 8-1. The crop specific correction approach is presented below.

Maize

For maize, dust deposition was calculated using experimental data as reviewed by Fent (2011) and data from studies performed by the Julius Kühn-Institute (JKI) in 2011.

The Heubach-values of the seeds employed in the experiments reviewed by Fent (2011) were distributed between 0.29 and 0.75. Experiments with no specific Heubach-value reported were not selected for further evaluation. Eight experiments were further considered that were performed with seeds having a Heubach-value between 0.29 and 0.45 g / 100.000 seed (mean Heubach-value 0.36 g / 100.000 seed).The JKI study conducted in 2011represents worst case situations regarding environmental conditions (dry soil and sufficient wind).

Table A 4: Summary statistics of ground dust drift values (uncorrected experimental raw data) in percentage of max. field rate of a.i./ha in 1 m distance after seeding maize

Crop / Seeder	Reference	Number of experiments	Number of petri dishes	Arithmetic mean [% a.i./ha]	Median [% a.i./ha]	90. Percentile [% a.i./ha]	Standard deviation
Maize / pneumatic, vacuum technique	JKI (2011)	1	12	0.41	0.38	0.46	0.15
	Fent (2011)	7	70	0.07	0.06	0.12	0.05
	Overall	8	82	0.12	0.07	**0.31**	0.15

Table A 5: 90th percentile ground dust drift values and normalized 2-D-exposure data (percentage of field rate of a.i. / ha in 1 m distance) to be used in the risk assessment of contaminated dust in non-target areas. See text for details.

Crop	Type of seeder	Parameters covered by correction	experimental ground dust deposition (uncorrected value) (% a.i. field rate /ha)	Normalized Exposure 2-D (% a.i. field rate /ha)
Maize	pneumatic, vacuum technique	Drill width: 45 m Heubach: 0.45 a.i. in dust: 19.2 %	0.310	0.56

Correction approach of study parameters:

- → *Heubach-value*: To make the experimental Heubach-value of 0.45 g/100.000 seeds representative for a batch of seed having a standard Heubach-value of 0.75 g/100.000, a linear correlation between Heubach-values and deposition values was assumed.
- → *Drill width*: The drift curve of this experiment was corrected for the limited experimental sowing width of 45 m for a sowing width of a norm field of 100 m width (IV for details).
- → *Concentration a.i. in dust*: Residue content in dust was covered by the trigger value (20 %) in Table 8-1. Therefore, no further correction was required.

Oil seed rape (OSR)

For oil seed rape, only one study was reviewed by Fent (2011). The seed lot had a Heubach-value of 0.33 g / 700.000 seeds. One additional study was conducted by JKI (2011) with seeds having a Heubach-value of 0.38 g / 700.000 seeds, which is close to the standard value of 0.5 g / 700.000 seeds (Table 8-1).

Table A 6: Summary statistics of ground dust drift values (uncorrected experimental raw data) in percentage of max. field rate of a.i./ha in 1 m distance after seeding oil seed rape

Crop / Type of seeder	Reference	Number of experiments	Number of petri dishes	Arithmetic mean [% a.i./ha]	Median [% a.i./ ha]	90. Percentile [% a.i./ha]	Standard deviation
OSR / pneumatic	JKI (2011)	1	12	0.075	0.067	0.097	0.02
	Fent (2011)	1	30	0.059	0.059	0.089	0.02
	Overall	2	42	0.068	0.062	**0.093**	0.02

Table A 7: 90th percentile ground dust drift values and normalized 2-D-exposure data (percentage of field rate of a.i. / ha in 1 m distance) to be used in the risk assessment of contaminated dust in non-target areas. See text for details.

Crop	Type of seeder	Parameters covered by correction	experimental ground dust deposition (uncorrected value) (% a.i. field rate /ha)	Normalized Exposure 2-D (% a.i. field rate /ha)
OSR	pneumatic	Drill width: 48 m Heubach: 0.38 a.i. in dust: 6.3 %	0.093	0.22

Correction approach of study parameters:

→ *Heubach-value*: Correction of the deposition values for the experimental Heubach-value of 0.38 g/700.000 seeds to the standard value of 0.5 g/700.000 seeds.

→ *Drill wide*: The deposition values were corrected for the narrow sowing width of 48 m according to its very flat drift curve (see IV for details)

→ *Concentration a.i. in dust*: Correction for the low a.i. content in the dust (6.3 % vs. standard value 10%)

Cereals

For cereals, only one JKI study from 2008 is available. Heubach-value of the seed lot was 2.1 g/ha, the Heubach filter residue content 8 % a.i. and the drilling width 100 m. The experimental results are based on 10 petri dishes replicates only, and therefore the values for cereals are considered as very preliminary and the 95% percentile is given.

Table A 8: Summary statistics of ground dust drift values (uncorrected experimental raw data) in percentage of max. field rate of a.i./ha in 1 m distance after seeding cereals.

Crop / Type of seeder	Reference	Number of experiments	Number of petri dishes	Arithmetic mean [% a.i./ha]	Median [% a.i./ ha]	95. Percentile [% a.i./ha]	Standard deviation
cereals/ pneumatic	JKI (2008)	1	10	0.078	0.040	**0.266**	0.13

Table A 9: 95th percentile ground dust drift values and normalized 2-D-exposure data (percentage of field rate of a.i. / ha in 1 m distance) to be used in the risk assessment of contaminated dust in non-target areas. See text for details.

Crop	Type of seeder	Parameters covered by correction	Experimental ground dust deposition (uncorrected value) (% a.i. field rate /ha)	Normalized exposure 2-D (% a.i. field rate /ha)
Cereals	pneumatic	Drill width: 100 m Heubach: 2.1 a.i. in dust: 8 %	0.266*	0.33

* 95. Percentile. See text for details.

Correction approach of study parameters:

→ *Heubach-value*: No further correction was required.

→ *Drill wide*: No further correction was required.

→ *Concentration a.i. in dust*: correction for 8.0 % for a.i. in dust vs. 10 % standard value for cereals.

Sugar beet

For sugar beet, not sufficient data presenting Heubach-values and residue content of a.i. in dust were available. From the 19 experiments reviewed by Fent (2011), it can be assumend that the depostion for pelleted seeds is less than 0.001 % a.i. field rate /ha. Since all Heubach-values for sugar beet from different treatment facilities showed a very low abrasion (JKI), it is very likely that field experiments with sugar beets all had comparable good quality and thus represent a realistic exposure scenario.

Table A 10: 90th percentile ground dust drift values and normalized 2-D-exposure data (percentage of field rate of a.i. / ha in 1 m distance) to be used in the risk assessment of contaminated dust in non-target areas. See text for details.

Crop	Type of seeder	Parameters covered by correction	Experimental ground dust deposition (uncorrected value) (% a.i. field rate /ha)	Normalized exposure 2-D (% a.i. field rate /ha)
Sugar beets	all techniques	-	-	0.001

Annex IV (Annex to Appendix VI): Adjustement of dust ground deposition for the sowing width of the treated field.

The aggregated data presented in the Figure A 1below were derived from field studies from the Julius Kühn-Institute and have been evaluated by Schmidt (Landwirtschaftliches Technologiezentrum LTZ Augustenberg, Germany). The parameter of the curves used to correct the width of the drilled area in the dust drift experiments up to 100 m width: "Maize 2011" (equation: 0,165*e^-0,06x) and "OSR 2011" (equation: 0,021*e^-0,04x) were used to calculate the respective correction factor.

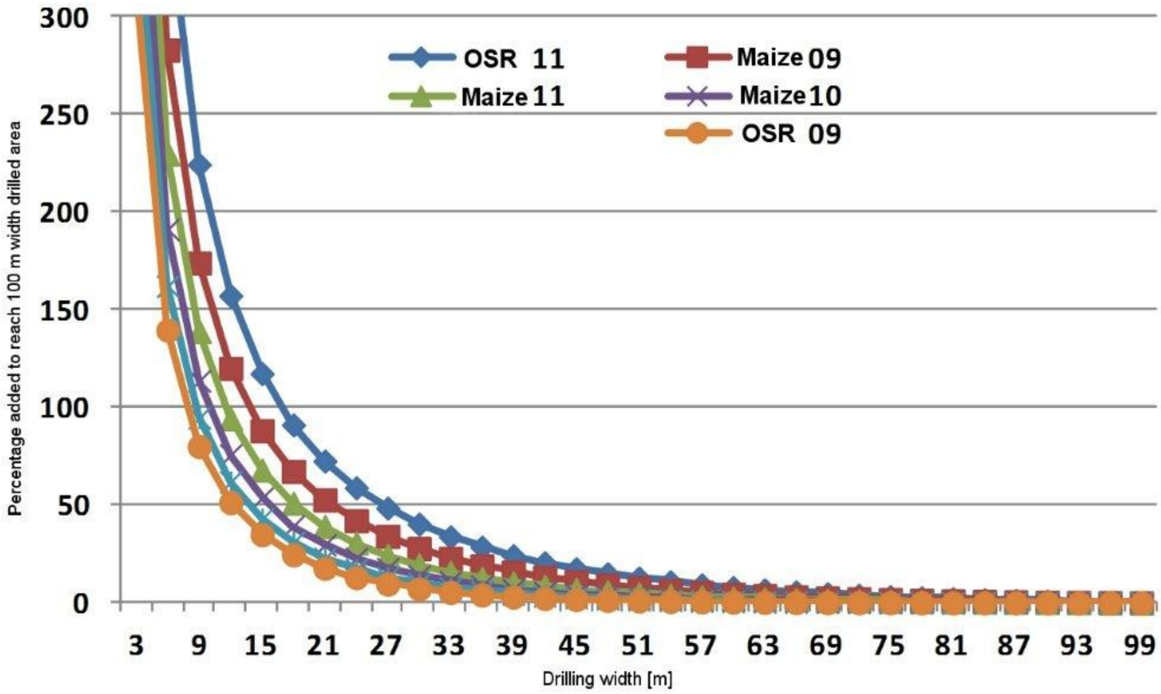


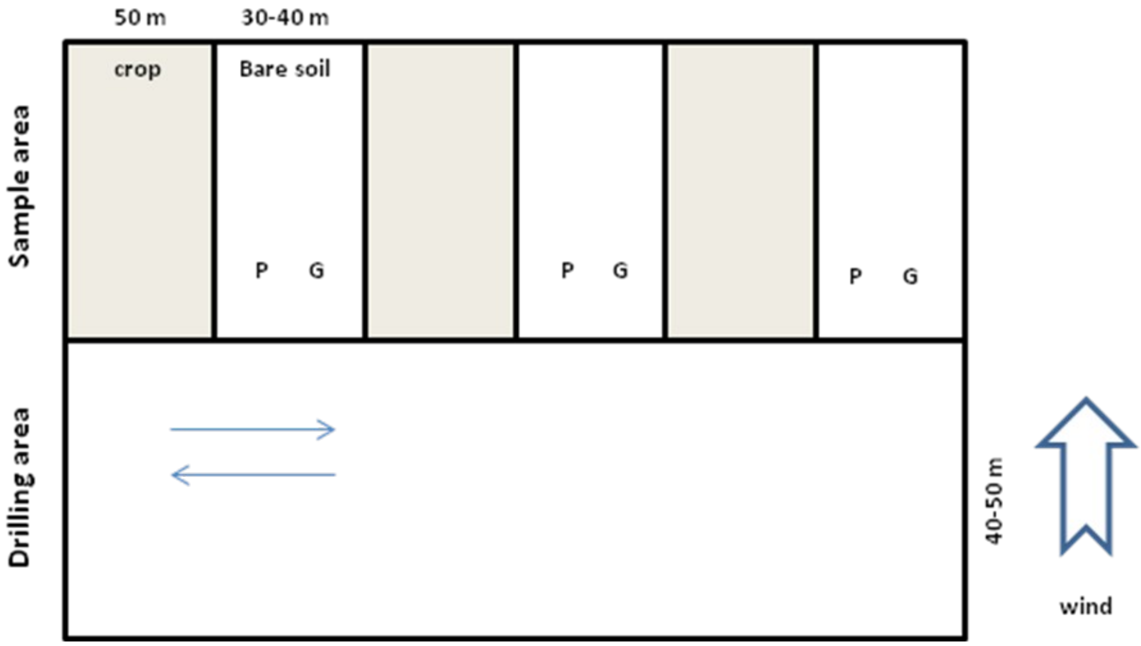
Figure A 1: percentages of dust drift to be added to measured drift when drilling a field with less than 100 m width

Annex V (Annex to Appendix VI): Summary of the estimation of an extrapolation factor from 2-D- to 3-D-deposition of contaminated dust

Investigations after the bee incidents in Germany (2008) have shown that species living or foraging in 3-D structures like hedgerows, trees or other crops will be exposed to higher deposition rates of contaminated dust than the species living on the ground.
For the time being, a generic extrapolation 2-D/3-D factor between residue levels of active ingredients in petri dishes on the soil surface and the vertical projection area of gauze net was determined based on the experimental results of four studies (Heimbach et al. 2010, 2011a/b, Neumann & Jene 2010). In all four studies, the same gauze net sampling devices were used to simulate 3-D structures. More details about the study of Neumann & Jene (2010) and the three studies of Heimbach et al. (2010, 2011a/b) are given below. A comparison between main technical and environmental conditions during measurements is presented in Table A 11 for all available studies.

Studies by Heimbach et al., Julius Kühn-Institute (DE) 2010, 2011 a/b

The figure below illustrates the experimental set up of the three studies perfomed by the Julius Kühn-Institue (JKI; Heimbach et al. 2010, 2011 a/b). Petri dishes and gauze net were placed in plots without crops next to the drilling area. The crops planted in the sample area next to the drilling area were mustard or rape.



P 4-5 petri dishes placed in 1, 3, 5, 10 m distance
G 1 gauze net (2 m height, 3.5 m length) in 3 m distance,
3-5 subsamples of 0.25 m² were taken at 0.65 m height

Figure A 2: Experimental layout of the three studies from Heimbach et al. (2010, 2011a/b), Julius Kühn-Institute, DE

Study Neumann & Jene (2010); Industrieverband Agrar (IVA, german association of plant protection products producers)

Summary

Report: Neumann, P. & Jene, B. (2010): Comparison of measurement methods to assess off-crop drift deposition patterns of seed treatment

	particles abraded from dressed maize seeds, emitted during sowing with a deflector modified pneumatic machine. Source: Bayer CropScience AG unpublished Report No.: IVADUST1 Date: January 13th, 2010
Guidelines:	Special designed study protocol, considering recommendations of the BBA Drift Guideline Part VII, 2-1.1, 1992
GLP:	All parts of the study were not performed under GLP.
Start and end of field activities:	May 29, 2009 – June 26, 2009
Start and end of analytical activities:	June 02, 2009 – July 06, 2009

Material and methods

The aim of the study by Neumann & Jene (2010) was to gain experience with technical options to quantify aerial dust drift and deposition from the sowing of treated seeds in future drift trials. Therefore, the capture efficiency of several types of artificial, vertically oriented sampling devices and a semi-natural hedge were compared for the assessment of aerial dust drift occurring during sowing maize seeds (Heubach-value at time of drilling: 1.23 g/100000 seeds) with a JKI (Julius Kühn-Institute, Germany) approved modified pneumatic drilling machine. Samplers were located downwind from the drilled area at different heights above the ground.

All sampling systems were installed prior to the drilling procedure at distinct locations along the downwind long edge of the drilling area (base line) and at different heights. The distance to the first row of maize seeds (zero-line) was 3 m. petri dishes were placed in metal placeholders on the soil surface and filled with an acetonitrile-water mixture (2/8, v/v). The following types of passive dust samplers were installed at 0.65 and 1.65 m height: Pipe cleaners, polypropylene scourer pads, and BSNE wind aspirated dust sampler. Gauze netting, and artificial hedge (made from cherry laurel branches) screens (5 m wide and 2 m high) were also used. Additional polypropylene scourer pads were installed on a pylon at 1 m, 2 m, 3 m, 4 m, 5 m and 6 m above the soil surface. With exception of the pipe cleaners and the BSNE samplers, all passive samplers were wetted with a glycerol/water mixture (1/1, v/v) to enhance dust retention. The only active dust samplers were HVAS (high volume air sampler), which were also installed at 0.65 and 1.65 m height.

Sowing started at the zero-line. After the drilling of 8 rows in alternate directions was completed, there was an additional waiting period of 30 minutes before the collection of samplers, to allow those dust particles which had not yet been deposited to settle on the sampling area ("primary drift").

Sampling system and layout

Petri dishes

At three discrete sampling locations (A, B, C; see Figure A 3), 10 polystyrene petri dishes (Ø 13.7 cm, height 1.7 cm, 147.41 cm²) were placed in metal placeholders on the field ground with a distance of 1 meter between the dishes and with a sampling distance of 3 m relative to the planter "zero-line" (first seed row). Hence, a total of 30 samples were taken.

Gauze Net

At three further discrete locations (G, H, I; see Figure A 3) along the downwind long edge of the drilled plot, at 3 m distance from the planter 'zero-line', an array of passive dust-drift samplers made of gauze net were fixed to a construction fence. The netting (5 m x 2 m) was attached by cable ties, so that it did not become displaced by wind. In order to enhance dust adhesion, the netting was evenly wetted for 60 s with a glycerol/water mixture (1/1, v/v). Starting 30 minutes after completion sowing, ten sections of material (50 cm x 50 cm) were cut from the netting. Five sections were taken such that their centre was at 0.65 m height from soil surface and five sections with their centre at 1.65 m. In total, 30 netting samples were collected, sampling height (0.65 m or 1.65 m).

Sampling layout

The orientation of the field plot and setup with the three discrete sampling locations for the petri dishes and the gauze net is shown in Figure A 3.

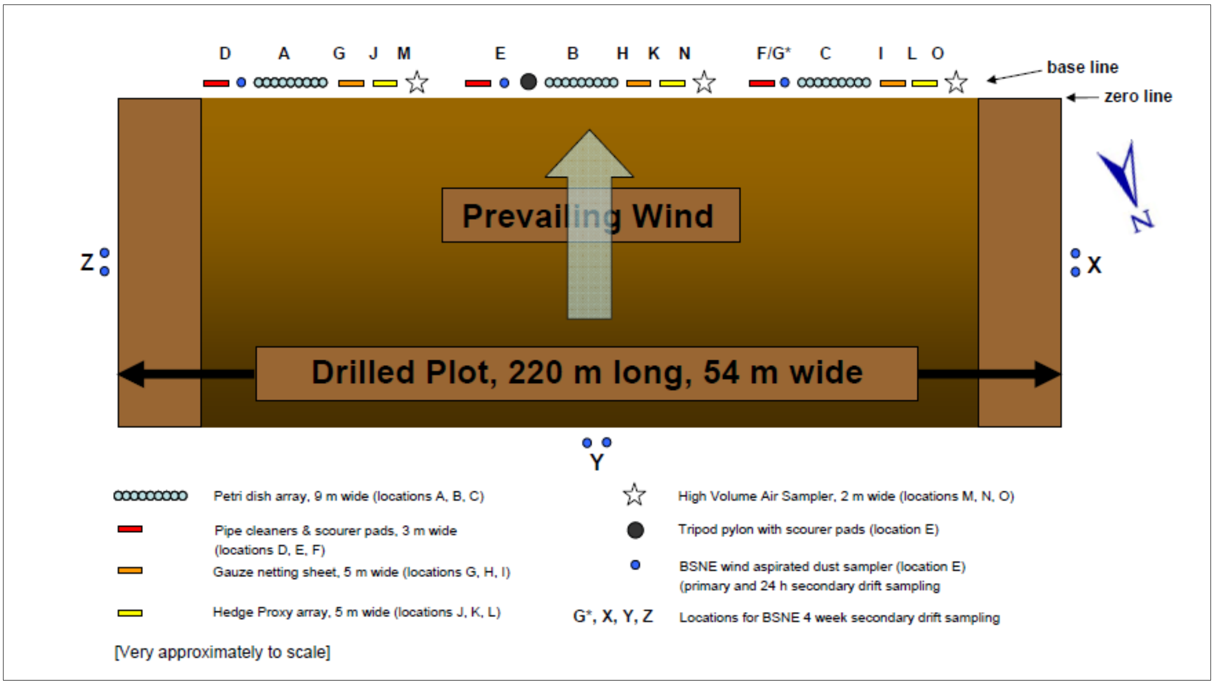


Figure A 3: Overview of the plot layout (Neumann & Jene, 2010)

Results

Due to the data protection claimed, the publishing of the individual residue values of the experiment in this annex is not possible.

We propose to derive a factor of 12.4 as the median of all 450 possible ratios of the residues samples of 15 gauze net sections (50 cm x 50 cm, sampling height of 0.65 m) and 30 petri dishes with ground deposition. This factor represents the difference between residue levels of a.i. in petri dishes on the soil surface related to the vertical projection area of gauze net.

This approach was chosen under the assumption that all three replicates of this experiment represent one main unit of all individual sampling points. Furthermore, since this result is based on a single experiment with a little data base it is proposed to consider all sampling points of all three plots together.

Derivation of an 2-D/ 3-D extrapolation factor from the available studies

In the table below, the available studies addressing the deposition of dust from treated seeds in non-target 2-D and 3-D structures are compared and the parameters that are deemed to influence the deposition of dust from treated seed in non-target areas are listed.

Table A 11: Comparison of the study design and the calculated 2-D/3-D factors of the studies of Heimbach et al. (2010, 2011a/b) and the study by Neumann & Jene (2010).

Study owner	**IVA[a)]**	**JKI[b)]**	**JKI [b)]**	**JKI [b)]**
Author	**Neumann & Jene**	**Heimbach et al.**	**Heimbach et al.**	**Heimbach et al.**
Year	2010	2010	2011a	2011b
Crop	Maize	Maize	Maize	Rape seed
Machine type	pneumatic suction, with deflector	pneumatic suction, with	pneumatic suction, with	pneumatic pressure

		deflector	deflector	
Wind [m/s]	approx. 4	approx. 2.3	approx. 2.3	approx. 2.1
Soil humidity	6.8 % water content	Dry soil	Slightly wet soil	Dry soil
Heubach-value of the seed lot [g/100.00]	1.23	0.86	0.45	0.38
Content a.i. in the dust [%]	--	10.6	19.1	6.33
Field rate [g a.i./ha]	104.63	125	50	36
2-D/3-D Factor	**12.4**	8.2	3.3	6.9

a) Industrieverband Agrar, German association of plant protection products producers.
b) Julius Kühn-Institute

Environmental circumstances (e.g. wind speed, soil humidity) as well as technical conditions (machine type, quality and type of the treated seeds, a.i. content in the dust) were different in the four available studies (Table A 11). The varying experimental conditions led to diverging deposition rates of a.i. in petri dishes on the soil surface and in the vertical projection area of gauze net and, finally, to diverging 2-D/3-D factors. As long as it is not possible to quantify the influence of important parameters based on the few available data sets, the extrapolation of a generic 2-D/3-D factor should follow precautionary principles and be conservative. Therefore, it is recommended to use the median value of the realistic worst case study results from Neumann & Jene (2010) to derive a 2-D/3-D factor for dust deposition in non-target areas.
In each of the experimental studies, three plots were set up showing more or less diverging values for dust deposition, with higher variances in the measured concentrations on the soil surface than in the deposition values vertical gauze nets. In the studies of Heimbach et al. (2010, 2011a/b), the differences between the experimental field plots are reasonable and are explained by wider spaced replicated field plots. Being all single plots adjacent to each other, the variance in the measured ground depositions in the study of Neumann & Jene (2010) is lower. In conclusion, it is proposed to derive a 2-D/3-D extrapolation factor as the median of all possible ratios between the 15 gauze net samples in 0.65 m height and the petri dish samples on the soil surface from the study of Neumann & Jene (2010). The determined median factor is 12.4.

Due to the remaining high uncertainties, and in order to estimate the impact of spatial variability and experimental set up on the deposition of dust from treated seeds in 2 and 3 dimensional structures in non-target areas, further investigations with joint measurements should be conducted.

Annex VI (Annex to Appendix VI)

Table A 12: List of currently drift reducing devices approved or under testing in Germany and France

	Germany: 223 turbine-deflector combinations from 16 manufacturers (JKI)	France	
		Deflector manufacturers	Merlettt + Advanta + Creatis
Gaspardo	14 combinations	Deflector tested	
Amazone	53		
Kverneland	12		
Kuhn	15		
Monosem	22		
Link	8		
Wintersteiger	11		
Schmotzer	22		
Rabe	12		
Baurel	3		
Mascar	3		
Ludwig and Hauer	3		
Matermacc	24		
John Deere	17	Current test	
Samco	3		
Inotec GmbH	1		
Sola	-	Current test	
Vico Rau	-		
Lely	-		
Semeato	-		
Sfoggia	-		