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Delegations will find attached document D105864/06 annex.

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ANNEXES 1 to 5

ANNEXES

to the

COMMISSION REGULATION (EU) .../...

**laying down labelling requirements for plant protection products and repealing
Regulation (EU) No 547/2011**

ANNEX I

INFORMATION ON THE PLANT PROTECTION PRODUCT IDENTIFICATION AND CONDITIONS OF USE

1. INFORMATION ON PLANT PROTECTION PRODUCT IDENTIFICATION:

- (a) **Trade name or proposed trade name.**
- (b) **Authorisation number of the plant protection product.**
- (c) Name, address and telephone number of the **authorisation holder** and, if different, the name and address of the **company placing the product on the market.**
- (d) **Formulation type** (for example: wettable powder, emulsifiable concentrate).
- (e) **Name and the concentration of active substance(s) that the plant protection product contains.**

The name of each active substance as common name expressed as provided for in Regulation (EC) No 540/2011¹ with clear indication of the chemical form, or if not included therein its ISO common name. If the latter is not available, the active substance shall be designated by its chemical designation according to IUPAC rules.

In case the active substance is a micro-organism, the name of the approved strain as provided for in Regulation (EC) No 540/2011 and any other designation which may be relevant to identify the micro-organism (for example, isolate level, if relevant for viruses).

The concentration of each active substance expressed as follows:

- for chemical active substances in formulations which are solids, aerosols, volatile liquids (maximum boiling point 50 °C) or viscous liquids (lower limit 1 Pa s at 20 °C), as % w/w and g/kg.
- for chemical active substances in other liquids/gel formulations, as % w/w and g/l.
- for chemical active substances in formulations which are gases, as % v/v (at atmospheric pressure) and % w/w.
- for active substances that are micro-organisms:
 - the number of active units per volume or weight of plant protection product, for example, colony forming units or international units per volume or weight, or any other manner that is most relevant to the plant protection action
 - and the weight of active substance per volume or weight of plant protection products, if applicable.

¹ Commission Regulation (EU) No 540/2011 of 25 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances (OJ L 153, 11.06.2011, p. 1, ELI: http://data.europa.eu/eli/reg_impl/2011/540/oj).

(f) Name and the concentration of the safener(s) and synergist(s) that the plant protection product contains.

(g) Net quantity of plant protection product given in:

- g or kg for solid formulations
- ml or l for liquid formulations (at room temperature)
- g, kg, ml or l for gases (as measured at atmospheric pressure and room temperature).

(h) Formulation batch number and date of manufacture.

This information may be included only on the packaging of the plant protection product.

The digital label of the plant protection product shall include the following: "Refer to the formulation batch number and date of manufacture indicated on the physical label or on the packaging of the plant protection product."

(i) Information on first aid.

This information may be also included on the packaging of the plant protection product.

2. CONDITIONS OF USE OF THE PLANT PROTECTION PRODUCT:

(j) The categories of users allowed to use the plant protection product, where use is limited to certain categories.

(k) The type of action of the plant protection product (for example: insecticide, growth regulator, herbicide, fungicide) and where relevant the **pest(s) to be controlled**. If available and relevant, the **mode of action** of the active substance(s) in accordance with Resistance Committees Codes².

This statement may use descriptive terms such as “kills”, “controls”, “repels”, “eradicates”.

(l) Crop(s), where relevant, growth stage(s) of plants in accordance with the BBCH monograph³, **or situations/land use(s)**⁴ for which the plant protection product has been authorised.

(m) Conditions of use for which the plant protection product has been authorised. Where relevant, any other specification of the **method of application** required in the authorisation should be stated.

The label of plant protection products authorised for **professional users** shall include the following:

“To be used in accordance with the general principles of integrated pest management”.

(n) Dose rate including the maximum rate per application, where applicable, also the minimum rate per application, the maximum number of applications,

² Resistance Action Committee for herbicides (HRAC), insecticides (IRAC) and fungicides (FRAC).

³ Meier, Uwe, ed. Growth stages of mono- and dicotyledonous plants. BBCH Monograph. Quedlinburg 2018. Open Agrar Repositorium. doi: 10.5073/20180906-074619 ISBN: 978-3-95547-071-5.

⁴ Refers to not agricultural areas: forests, public spaces, railways, etc.

information on season at time of application and the interval between each application.

Where relevant, the label of a plant protection product limited to **professional users** shall include the following:

“When using equipment that increases the precision and accuracy of the application compared to conventional application equipment, reductions of the applied plant protection product per hectare are allowed if the authorised application rate on the target surfaces is maintained.”

- (o) Where relevant, **safety interval, re-entry intervals, withholding intervals** necessary to minimise the presence of residues in or on crops, plants and plant products, or in treated areas or spaces, with a view to protecting humans, animals and the environment, shall be specified, such as:
- pre-harvest interval
 - re-entry interval (in days) for livestock, to areas to be grazed
 - re-entry interval (in hours or days) for humans to crops, buildings or spaces treated
 - withholding interval (in days) for animal feeding stuffs and for post-harvest uses
 - waiting period (in days) between application and handling treated products.
- (p) **Restrictions/specific farming practices** set by the competent authorities when authorising the plant protection product with consideration for specific local conditions.
- (q) Particulars of possible **phytotoxicity**, varietal susceptibility, and any other direct or indirect adverse side effects on plants or products of plant origin together with the intervals to be observed between application and sowing or planting of:
- the crop in question, or
 - succeeding and adjacent crops.
- (r) Appropriate **conditions of storage** (for example: humidity, storage temperature, exposure to light of the package) and **safe disposal of the plant protection product and of the packaging** according to the specific provisions set by Member States if these differ from the standard phrases of Annex II.
- (s) Where considered necessary, **the expiry date of the plant protection product**.
- This information may be included only on the packaging of the plant protection product.
- The digital label of the plant protection product shall include the following: “Refer to the expiry date indicated on the physical label or on the packaging of the plant protection product.”.

ANNEX II

STANDARD PHRASES FOR SAFE DISPOSAL OF THE PLANT PROTECTION PRODUCTS AND THEIR CONTAINER (SD) AND ATTRIBUTION CRITERIA

SD 1: Do not re-use the container.

This phrase shall be assigned to all plant protection products.

SD 2: To protect the aquatic environment including groundwater, do not clean application equipment near surface water.

Where relevant, this phrase shall be assigned to the plant protection product. Such phrase shall be assigned to plant protection products classified as hazardous to the aquatic environment according to Regulation (EC) No 1272/2008.

Where relevant, information according to the national provisions set by Member States on the disposal of products and its packaging could be added to the phrase.

SD 3: Rinse container with water three times before disposal.

Where relevant, this phrase shall be assigned only to plant protection products that are supplied in washable containers.

Where relevant, information according to the national provisions set by Member States on the disposal of products and its packaging could be added to the phrase.

ANNEX III

STANDARD PHRASES FOR HAZARD COMMUNICATION AND ATTRIBUTION CRITERIA

1. STANDARD PHRASES FOR HAZARDS TO HUMAN HEALTH (RSh) AND ATTRIBUTION CRITERIA

RSh 1: May cause photosensitisation.

The phrase shall be assigned where there is clear evidence from experimental systems or documented human exposure that the plant protection product show photosensitising effects. The phrase shall also be applied to plant protection products containing an active substance or formulation ingredient, which shows photosensitising effects in humans if the respective product contains this photosensitising component at a concentration of 1 % (w/w) or higher.

RSh 2: Contact with vapour causes skin burns and eyes damage and contact with liquid causes freezing.

The phrase shall be assigned to plant protection products formulated as liquefied gas, where appropriate, unless hazard statements H314 or H281 provided for in Regulation (EC) No 1272/2008 are assigned.

2. STANDARD PHRASE FOR HAZARDS TO BEES (RShb), PICTOGRAM AND ATTRIBUTION CRITERIA

RShb: Hazardous to bees.



The phrase and the pictogram shall be assigned to any plant protection product:

- for which a standard⁵ test for acute contact toxicity or for acute oral toxicity on adult honeybees, bumble-bees or solitary bees is required according to Commission Regulation (EU) No 284/2013⁶ and shows that the acute LD50 value is equal or below 11 µg formulation /bee. In case there is more than one LD 50 value for the formulation available, the one showing the lowest LD50 shall be considered, or

⁵ OECD agreed test protocols.

⁶ Commission Regulation (EU) No 284/2013 of 1 March 2013 setting out the data requirements for plant protection products, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market (OJ L 93, 3.4.2013, p. 85, ELI: <http://data.europa.eu/eli/reg/2013/284/oj>).

- to which any of the SPb 1, SPb 2, SPb 3, SPb 4 and SPb 5 phrases of Section 4.1 of Annex V has been assigned.

The phrase and the pictogram shall be displayed in the label together with the SPb phrases as set out in Section 4.1 of Annex V.

Format of the hazard pictogram:

- (a) The pictogram shall have the shape of an equilateral triangle.
- (b) The pictogram shall have a minimum dimension of 10x10 millimetres, corresponding to the height and width of the equilateral triangle. The frame of the triangle shall have a minimum width of 1,5 millimetres.
- (c) The colours of the pictogram shall be
 - i. CMYK – cyan, magenta, yellow and black, following this example: 0,70,100,0: 0 % cyan, 70 % magenta, 100 % yellow, 0 % black.
 - ii. The frame of the triangle red (0,100,100,0).
 - iii. The background of the triangle 100% white.
- (d) The pictogram shall include a black (0,0,0,100) and white symbol of a dead bee in the centre of the triangle. The symbol of the dead bee shall be the one in the figure shown in the present point.

ANNEX IV

STANDARD PHRASE FOR PLANT PROTECTION PRODUCTS CONTAINING MICRO-ORGANISMS (RSMo)

RSMo: Contains a micro-organism. It may have the potential to cause sensitising reactions.

The phrase shall always be assigned to all plant protection product containing micro-organisms as precautionary statement.

ANNEX V

STANDARD PHRASES FOR RISK MITIGATION MEASURES AND ATTRIBUTION CRITERIA

1. STANDARD PHRASES FOR RESTRICTIONS OF USE (SRU) AND ATTRIBUTION CRITERIA

SRu 1: (Contains (name of active substance (s) to be specified) / forms the metabolite(s) (name of the metabolite (s) to be specified)). To protect (human health, environmental compartment, group of organisms or species to be specified),

- **(do not) use/apply (this or any other product containing (name of active substance (s) to be specified)) (temporal restrictions, restrictions to growth stages or frequency of use to be specified), or**
- **respect a minimum interval (time to be specified) between applications (with (name of the plant protection product/products containing (active substance) to be specified)).**

SRu 1 shall be assigned to plant protection products for which the risk assessment according to the uniform principles concludes that temporal restrictions (for example: period of the year, day, re-entry period, non-consecutive years - every 2nd or 3rd year, more than twice per year) or restrictions to growth stages (pre-emergence only, non-flowering period, before fruit setting, etc.) or frequency of use are needed to protect human health and/or to prevent unacceptable effects on the environment.

SRu 2: To protect (human health, environmental compartment, group of organisms or species to be specified), do not use on (area to be specified, for example: specific surfaces, drained soils, soils with specific properties such as pH, carbon content, clay content, texture, ...).

SRu 3: To avoid run-off, do not apply on steep areas/areas which have an incline of more than x%/impermeable surfaces such as asphalt, concrete, cobblestones, railway tracks.

SRu 2 and/or SRu 3 shall be assigned to plant protection products for which the risk assessment according to the uniform principles concludes that restrictions on the location of use are needed to protect human health and/or to prevent unacceptable effects on the environment.

2. STANDARD PHRASES TO PROTECT OPERATORS AND WORKERS (SPO) AND ATTRIBUTION CRITERIA

SPO 1: Use (equipment to be specified) when (task/s to be specified).

The phrase shall be assigned to plant protection products for which the risk assessment according to the uniform principles concludes that specific personal protective equipment⁷ (for example: gloves, coveralls or goggles) and/or technology (for example: closed transfer systems, closed cabins with an air conditioning and/or air filtration systems) is required to protect human health when performing a specific task (for example: mixing, loading, handling the concentrated product or the treated seeds, applying or spraying the diluted product, cleaning of the application equipment).

⁷ Reference to certified personal protective equipment can be also included.

SPo 2: Ensure that during (operation to be specified) the temperature and humidity are within range of (range to be specified).

The phrase shall be assigned to plant protection products containing active substances which may react violently with water or damp air, or which may cause spontaneous combustion during storage, mixing/loading or application.

SPo 3: After applying the product, do not inhale the gases and leave the treated area immediately.

The phrase shall be assigned to all plant protection products of which the mode of action is to generate fumes or gases like fumigants.

SPo 4: The container must be opened outdoors and/or in controlled conditions following the manufacturer's specifications.

The phrase shall be assigned to plant protection products containing active substances which may react violently with water or damp air, or which may cause spontaneous combustion.

SPo 5: Before entering the treated area, ensure proper ventilation of the space until /spray has dried/gas has dissipated/ the concentration of gas is below (concentration to be specified).

The phrase shall be assigned to plant protection products authorised to be used in confined areas (for example: storage rooms, greenhouses).

SPo 6: Do not enter in the treated area if concentration of the gas/product is above (concentration to be specified).

The phrase shall be assigned to all fumigant plant protection products.

3. STANDARD PHRASES TO PROTECT BYSTANDERS AND RESIDENTS (SPBR) AND ATTRIBUTION CRITERIA

SPbr: To protect bystanders and residents,

- **keep an untreated buffer zone/vegetated field strip(s)/crop free zones of (width to be specified) between the (to be specified, for example: the end of the spray boom, the last row treated, etc.) and the areas where people may be present or**
- **use drift reduction technology (details to be specified) or**
- **use drift reduction technology (details to be specified) and keep an untreated buffer zone/vegetated field strip(s)/crop free zones of (width to be specified) between the (to be specified, for example: the end of the spray boom, the last row treated, etc.) and the areas where people may be present.**

The phrase shall be assigned to plant protection products for which the risk assessment according to the uniform principles concludes that untreated buffer zones or vegetated field strip(s), drift reduction technology or both are required to protect bystanders and residents from an unacceptable level of exposure.

Further information on the technologies (for example: type of nozzles) and on the type of vegetation of the field strips may be included as specifications of the conditions of use as set out in Annex I.

4. STANDARD PHRASES TO PROTECT THE ENVIRONMENT (SPE) AND ATTRIBUTION CRITERIA

SPe 1: To protect (environmental compartment, group of organisms or species to be specified),

- keep an untreated buffer zone/ vegetated field strip(s)/crop free zones of (width to be specified) to (for example: surface water, field strips) or
- use drift reduction technology (details to be specified) or
- keep an untreated buffer zone/ vegetated field strip(s)/crop free zones of (width to be specified) to (for example: surface water, field strips) and use drift reduction technology (details to be specified).

The phrase shall be assigned to plant protection products for which the environmental risk assessment according to the uniform principles concludes that untreated buffer zones or vegetated field strip(s), drift reduction technology or both are required to protect certain environmental compartment and/or certain non-target species from an unacceptable level of exposure.

Further information on the technologies (for example: type of nozzles) and on the type of vegetation of the field strips may be included as specifications of the conditions of use as set out in Annex I.

SPe 2: Do not apply/sow treated seeds if the wind speed is higher than (wind speed to be specified).

Where relevant, the phrase may be assigned to plant protection products containing volatile active substances or to plant protection products authorised for seed treatment uses.

SPe 3: To protect birds/wild mammals, the product must be entirely incorporated in the soil, including the end of rows. Remove spillages.

The phrase shall be assigned to plant protection products that are formulated as granules or pellets to prevent exposure of birds and mammals.

SPe 4: Ensure that the treated space is preventing release of the product into the environment. Ventilate the treated area thoroughly when gas/smoke has cleared.

The phrase shall be assigned to all plant protection products authorised to be used in confined areas (for example: storage rooms, greenhouses) which might affect human beings and/or non-target species inside and outside of the treated areas.

4.1. Standard phrases to protect bees and pollinators (SPb)

SPb 1: To protect bees, do not use when bees are actively foraging. Apply only after the daily bee flight (time to be specified, for example: in the evening, between X and X hour).

SPb 2: To protect bees and pollinating insects, do not apply when flowering weeds are present.

SPb 3: To protect bees and pollinating insects, do not apply to crop plants when in flower (except as directed on – specify crop as required).

SPb 4: To protect bees and pollinating insects, remove or cover bee colonies during application and for (time span to be specified) after treatment.

SPb 5: To protect bees and pollinating insects, remove weeds before flowering.

One, several or all the following phrases SPb 1, SPb 2, SPb 3, SPb 4 and SPb 5 shall be assigned to plant protection products for which the risk assessment according to the uniform principles concludes that risk mitigation measures are required to protect bees or other pollinator insects and their brood.

SPb standard phrases should be displayed on the label together with the RShb phrase and hazard pictogram as set out in Annex III.

5. STANDARD PHRASES TO AVOID RESISTANCE (SPA) AND ATTRIBUTION CRITERIA

SPa: To prevent the development of resistance, do not apply this or any other product containing (identify active substance) more than (number of applications per time interval to be specified).

The phrase shall be assigned when such a restriction appears necessary to limit the risk of development of resistance.

Where relevant, information on the resistance code of the active substance(s) contained in the plant protection product as explained under point k) of Annex I could be added to the phrase.

6. STANDARD PHRASES FOR RODENTICIDES (SPR) AND ATTRIBUTION CRITERIA

SPr 1: Baits must be securely deposited to minimise the risk of consumption by other animals. Secure baits in tamper proof boxes.

The phrase shall be assigned to plant protection products that are rodenticides baits.

SPr 2: Dead rodents must be removed from the treatment area each day during the application of the product. Do not dispose them neither in bins nor in landfills.

The phrase shall be assigned to all plant protection products that are rodenticides and may produce secondary poisoning to scavengers or other animals.

Where relevant, information on the handling of dead rodents according to the national provisions set by Member States could be added to the phrase.

7. STANDARD PHRASES FOR SEED TREATMENT USES AND ATTRIBUTION CRITERIA

7.1. Standard phrases relevant to the treatment of seeds with plant protection products (Sts)

Sts 1: The seed treatment shall only be performed in professional seed treatment facilities (which are registered in .../which comply with ...).

Where relevant, the phrase shall be assigned to plant protection products authorised for seed treatment uses.

Sts 2: The treatment process must ensure that the treated seeds comply with the seed quality standards: (Heubach value X grams of dust/unit seed) (X grams of dust/100 kilogram of seeds according to the Heubach method).

Where relevant, the phrase shall be assigned to plant protection products authorised for seed treatment uses.

Sts 3: To protect (environmental compartment, group of organisms or species to be specified), the packaging of treated seeds should not contain (more than X gram of dust per unit seed or per 100 kilogram of seeds (according to the Heubach method)) / (more

than X gram of active substance in dust per unit seed or per 100 kilogram of seeds (according to the Heubach method)).

Where relevant, the phrase shall be assigned to plant protection products authorised for seed treatment uses.

Sts 4: Dust should be removed from seeds before treatment using appropriate cleaning processes.

Where relevant, the phrase shall be assigned to plant protection products authorised for seed treatment uses.

7.2. Standard phrases relevant to the sowing of treated seeds (Sss)

Sss 1: To protect (environmental compartment, group of organisms or species to be specified), treated seeds must be sown with equipment ensuring a high level of soil coverage and reducing airborne dust emission. Do not apply treated seeds using broadcast seeding.

Where relevant, the phrase shall be assigned to plant protection products authorised for seed treatment uses.

Further information on the sowing equipment including the percentage of dust reduction to the achieved may be included as specifications of the conditions of use as set out in Annex I.

Sss 2: To protect birds/wild animals, treated seeds must be sown in a way to minimize the number of the treated seeds remaining on the soil surface.

Where relevant, the phrase shall be assigned to plant protection products authorised for seed treatment uses.

Further information on the equipment may be included as specifications of the conditions of use as set out in Annex I.

Sss 3: To protect (environmental compartment, group of organisms or species to be specified), treated seeds and dust must be effectively incorporated in the soil and at the end of rows. Remove spillages.

Where relevant, the phrase shall be assigned to all plant protection products authorised for seed treatment.

Sss 4: To protect (groundwater/aquatic organisms/soil organisms), leaching must be reduced by (drilling/sowing treated seeds at minimum/maximum depth to be specified/ consolidating the soil bed/ limiting the sowing rate/density to xx g seeds/ha or xx seed unit/ha).

Where relevant, the phrase shall be assigned to plant protection products authorised for seed treatment.

Sss 5: To protect (groundwater/aquatic organisms/soil organisms), do not sow/drill treated seeds on (soil with specific properties or situation to be specified).

Where relevant, the phrase shall be assigned to plant protection products authorised for seed treatment for which the risk assessment according to the uniform principles concludes that restrictions on the location of use are needed to prevent unacceptable effects on the groundwater, aquatic organisms and/or soil organisms.

Sss 6: Do not contaminate water with treated seeds, remnants such as broken grains or dust, or a container.

The phrase shall be assigned to all plant protection products authorised for seed treatment uses.

Sss 7: Do not clean sowing equipment near surface water.

The phrase shall be assigned to all plant protection products authorised for seed treatment uses.