



Brussels, **XXX**
PLAN/2022/1649
[...] (2024) **XXX** draft

ANNEXES 1 to 6

ANNEXES

to the

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

amending Commission Regulation (EU) No 547/2011 of 8 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards labelling requirements for plant protection products

This draft has not been adopted or endorsed by the European Commission. Any views expressed are the preliminary views of the Commission services and may not in any circumstances be regarded as stating an official position of the Commission.

ANNEX I

INFORMATION ON THE PLANT PROTECTION PRODUCT IDENTIFICATION AND CONDITIONS OF USE

Information on plant protection product identification:

- (a) Trade name or product name.**
- (b) Authorisation number of the plant protection product.**
- (c) Permit number, for the label of a plant protection product for which a parallel trade permit has been granted.**
- (d) Authorisation holder and marketing company details:** name, address and telephone number of the authorisation holder and, if different, the name and address of the company responsible for the packaging and/or labelling.
- (e) Name and address of the permit holder, for the label of a plant protection product for which a parallel trade permit has been granted.**
- (f) Formulation type** (for example, wettable powder, emulsifiable concentrate).
- (g) Name and the concentration of active substance(s) that the plant protection product contains.**

The name of each active substance as common name and identification numbers of each active substance expressed as provided for in Annex VI of Regulation (EC) No 1272/2008 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 or 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 units per volume or weight of plant protection products.

- (h) 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).

(i) Formulation batch number and date of manufacture

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.

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”.

- (k) The **type of action** of the plant protection product (for example, insecticide, growth regulator, herbicide, fungicide). If available, the **mode of action** of the active substance(s).

This statement may use descriptive terms such as “kills”, “controls”, “repels”, “eradicates”, in accordance with the provisions of Article 2 of Regulation (EC) No 1107/2009.

- (l) **Crop(s)** including, where relevant growth stage(s), **or situations/land use(s)**¹ for which the plant protection product has been authorised.

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

- (n) **Dose rate including the minimum and maximum rate per application and the maximum number of applications** (for example, per year, season, growth stage) and the interval between each application.

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

“Efficacy has been established for the stated application rate and not for a reduced application rate. When using precision application equipment, reductions of the volume rate per treatment/ground area treated/canopy area treated are allowed while maintaining the authorised application rate. The maximum number of applications and other conditions of use shall be respected as authorised”.

- (o) Where relevant, **safety interval, re-entry periods, withholding periods** 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:

- interval between the last application and the harvest;
- re-entry period (in days) for livestock, to areas to be grazed;

¹ Refers to not agricultural areas: forests, public spaces, railways, etc.

- re-entry period (in hours or days) for humans to crops, buildings or spaces treated;
 - withholding period (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) For plant protection products that do not contain micro-organisms, **the expiry date** for normal conditions of storage.

For plant protection products containing micro-organisms, the label shall include the following:

- Use before (to complement depending on the efficacy/safety studies).

The expiry date shall be complemented with recommended **conditions of storage** of the product (for example, humidity, storage temperature, exposure to light of the package), **safe disposal of the product and the packaging** if they differ from the requirements for the standard phrases of Annex II.

ANNEX II

STANDARD PHRASES AND ATTRIBUTION CRITERIA FOR SAFE DISPOSAL OF THE PLANT PROTECTION PRODUCTS

1. STANDARD PHRASES FOR DISPOSAL OF THE PLANT PROTECTION PRODUCT AND ITS PACKAGING (SD) AND ATTRIBUTION CRITERIA

SD 1: Do not re-use container for any other purpose.

This phrase shall be assigned to all plant protection products unless the packaging has been specifically designed to allow re-use by the authorisation holder.

SD 2: To protect the aquatic environment, do not clean application equipment near surface water. Collect and purify the tank residues.

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

SD 3: Rinse container with water three times before disposal. Collect and purify the cleaning residues.

Where relevant, his phrase shall be assigned only to plant protection products that are supplied in a washable container unless a closed transfer system is used.

ANNEX III

STANDARD PHRASES AND ATTRIBUTION CRITERIA FOR HAZARD COMMUNICATION

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 a 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 being 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 standard² contact or oral acute LD50 endpoint on adult honeybees, bumble-bees or solitary bees is equal or below 11 µg formulation /bee. In case there are more than one datapoint for the formulation available, the one showing the lowest LD50 shall be considered.

Format of the hazard pictogram:

² OECD agreed test protocols.

- (a) The pictogram shall have the shape of an equilateral triangle;
- (b) The pictogram shall have a minimum dimension of 16x16 millimetres, corresponding to the height and width of the equilateral triangle. The frame of the triangle shall have a minimum width of 2 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.

ANNEX IV

STANDARD PHRASE FOR HAZARD COMMUNICATION OF PLANT PROTECTION PRODUCTS CONTAINING MICRO-ORGANISMS

1. STANDARD PHRASE FOR HAZARD COMMUNICATION (RSMo)

RSMo: Contains a micro-organism as active substance. It may have the potential to cause skin and/or respiratory sensitisation.

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

ANNEX V

STANDARD PHRASES AND ATTRIBUTION CRITERIA FOR RISK MITIGATION MEASURES

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

SRu 1: To protect (human health, environmental compartment, group of organisms or species to be specified), (do not) use/apply (temporal restrictions or restrictions to growth stages to be specified).

The phrase 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-breeding period for birds and mammals, non-consecutive years- every 2nd or 3rd year) or restrictions to particular growth stages (pre-emergency only, non-flowering period, before fruit setting, pre-harvest interval, etc.) 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, soil types or specific surfaces).

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, 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 (application equipment to be specified) when (task 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 technology (for example, closed transfer systems, closed cabins with an air conditioning and/or air filtration systems) is required to protect human health.

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 igniting the product, do not inhale the smoke 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 dry conditions.

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

SPo 6: Do not stay in the treated area if concentrations of the 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 1: To protect bystanders and residents, use drift reduction technology ensuring at least x% of exposure reduction.

The phrase shall be assigned to plant protection products for which the risk assessment according to the uniform principles concludes that drift reduction technology is required to protect bystanders and residents from an unacceptable level of exposure.

Further information on the technologies (for example, type of nozzles) may be included as specifications of the conditions of use

SPbr 2: To protect bystanders and residents keep an untreated buffer zone/vegetated field margin(s)/crop free zones of (width to be specified) between the field and the areas where bystanders and residents 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 margin(s) are required to protect bystanders and residents from an unacceptable level of exposure.

Further information on the vegetated field margins the type of vegetation may be included as specifications of the conditions of use..

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), use drift reduction technology ensuring at least x% of exposure reduction.

The phrase shall be assigned to plant protection products for which the environmental risk assessment according to the uniform principles concludes that drift reduction technology is 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) may be included as specifications of the conditions of use.

SPe 2: Do not apply 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.

SPe 3: To protect (environmental compartment, group of organisms or species to be specified) keep an untreated buffer zone/ vegetated field margin(s)/crop free zones of (width to be specified) to (for instance surface water, field margins).

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 margin(s) are required to protect certain environmental compartment and/or certain non-target species from an unacceptable level of exposure.

Further information on the vegetated field margins the type of vegetation may be included as specifications of the conditions of use.

SPe 4: 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 present solid formulations as granules or pellets to prevent exposure of birds and mammals at risk during their dispatch or sowing respectively.

SPe 5: 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.

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 beehives during application and for (state time) after treatment.

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

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, for one or more of the uses, risk mitigation measures are required to protect bees or other pollinator insects and their brood.

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

SPa: To prevent resistance do not apply this or any other product containing (identify active substance or class of substances, as appropriate) more than (number of applications or time period to be specified).

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

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 place them in refuse bins or on rubbish tips.

The phrase shall be assigned to all plant protection products that are rodenticides and that contain active substances that are anti-coagulant or may produce secondary poisoning to scavengers.

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 shall comply with the seed quality standards: (Heubach value x g dust /unit seed) (content of active substance in dust $x\%$) (Heubach a.s. = x g a.s. in dust/unit seed) (x g dust/100 kg seeds according to the Heubach method)

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

Sts 3: Dust should be removed from seeds before treatment using industrial 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 use or sowing of treated seeds (Sss)

Sss 1: To protect (environmental compartment, group of organisms or species to be specified), the packaging of treated seeds should not contain (more than x g dust per unit seed/100,000 seeds (according to the Heubach method)) / (more than x g active substance in abraded dust/unit seed (according to the heubach method)).

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

Sss 2: To protect (environmental compartment, group of organisms or species to be specified), treated seeds must be sown with an equipment that ensures at least $x\%$ of dust drift reduction).

The phrase shall be assigned to plant protection products for which the risk assessment according to the uniform principles concludes that dust drift reduction technology is required to protect a specific environmental compartment and/or non-target species from an unacceptable level of exposure to the treated seeds.

Further information on the technologies 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), treaded seeds must only be sown using a pneumatic seeding machine which operates with negative pressure (if this machine is registered (...)/ if this machine is equipped with deflectors/if this machine is equipped with ...).

The phrase shall be assigned to plant protection products authorised for seed treatment uses (except for the uses in permanent greenhouses) for which the risk assessment according to the

uniform principles concludes that risk mitigation measures are required to protect specific environmental compartment and/or non-target species from an unacceptable level of exposure to the treated seeds.

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

Sss 4: To protect (environmental compartment, group of organisms or species to be specified), the sowing equipment has to ensure a high level of soil coverage and the reduction to a minimum of airborne dust emission during sowing. Do not apply treated seeds using broadcast seeding.

Where appropriate, the phrase shall be assigned to plant protection products authorised for seed treatment uses, except for the uses in permanent greenhouses.

Sss 5: To protect birds/wild animals, treated seeds must be sown by using a seed drill equipment that leaves less than x, xx % of the treated seeds on the soil surface.

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

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

Sss 6: To protect (environmental compartment, group of organisms or species to be specified) do not sow treated seeds at wind speed of (more than m/s/wind speed of more than x Beaufort).

The phrase shall be assigned to plant protection products authorised for seed treatment uses (except for the uses in permanent greenhouses) for which the risk assessment according to the uniform principles concludes that risk mitigation measures are required to protect specific environmental compartment and/or non-target species at risk due to the exposure to the treated seeds.

Sss 8: 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, except for the uses in permanent greenhouses.

Sss 9: To protect (groundwater/aquatic organisms/soil organisms), leaching must be reduced by (drilling at minimum/maximum depth to be specified/ consolidating the soil bed).

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

Sss 10: Direct drilling/sowing/seeding should be disregarded in the cases where run-off is likely to be an issue.

The phrase shall be assigned to all plant protection products authorised for seed treatment, except for the uses in permanent greenhouses.

Sss 11: To protect (groundwater/aquatic organisms/soil organisms) do not sow on (soil type or situation to be specified) soils.

The phrase shall be assigned to plant protection products authorised for seed treatment, (except for the uses in permanent greenhouses) 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.

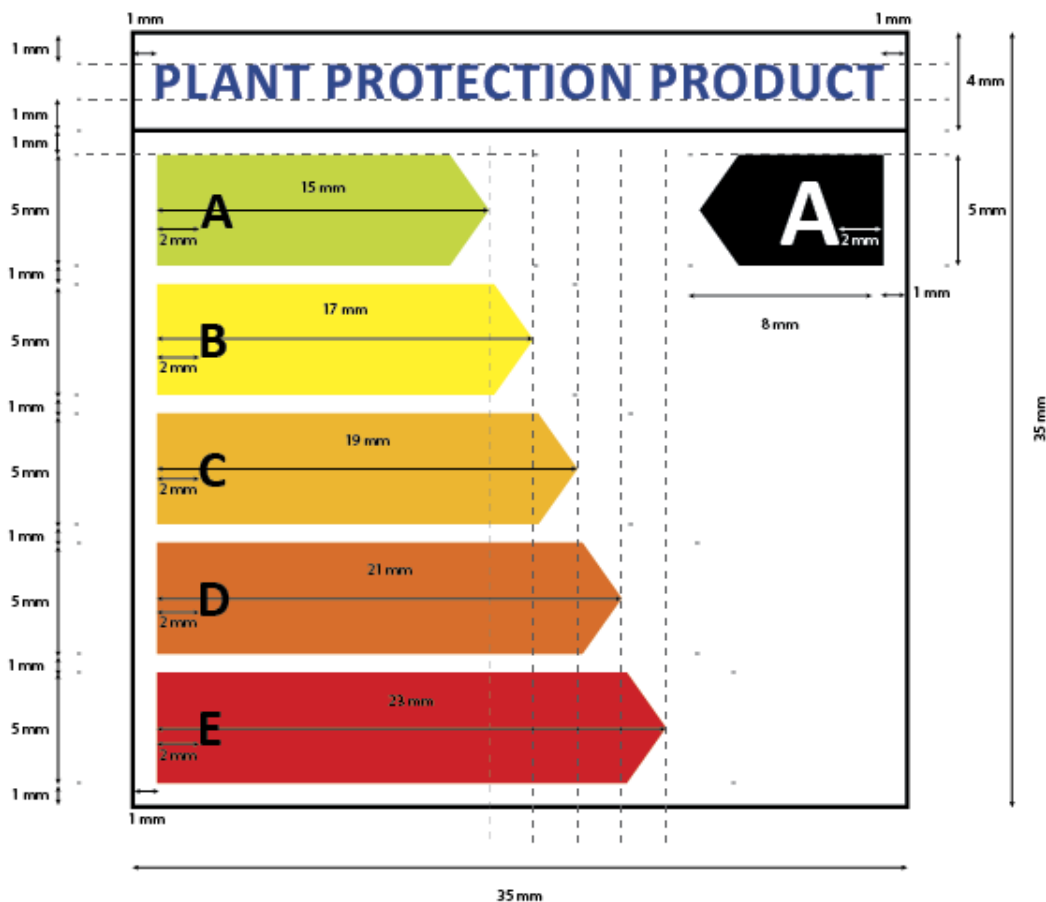
Sss 12: Do not contaminate water with the treated seeds, remains such as broken grains or dust, or the container.

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

Sss 13: Do not clean sowing equipment near surface water.

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

ANNEX VI
COLOURED SCHEME



The colour scheme shall indicate the following information:

- (a) the status of the most hazardous active substance that the plant protection product contains or consists of determined by its approval status under Regulation (EC) No 1107/2009;
- (b) if it is a micro-organism in accordance with the definition provided for Article 3(16) of Regulation (EC) No 1107/2009; and
- (c) whether the plant protection product has been authorised as low risk.

The format of the colour scheme shall be as follows:

- (a) the scheme shall have a square shape and be at least 35 mm wide and 35mm high. Where the scheme is printed in a larger format, its content shall nevertheless remain proportionate to the specifications below;
- (b) the background of the scheme shall be 100% white and the frame line 100% black;
- (c) the typefaces shall be Calibri Bold;
- (d) colours shall be CMYK – cyan, magenta, yellow and black, following this example: 0,70,100,0: 0 % cyan, 70 % magenta, 100 % yellow, 0 % black;

- (e) the scale, colours and position of the elements within the scheme shall be as follows:
- i. Term plant protection product:
 - a. Scale: Calibri Bold 10 pt.,
 - b. Colour: blue,
 - c. Position: centred in the square.
 - ii. Five coloured arrows:
 - a. Scale – rectangular right arrow shape. The light green arrow shall be 15 mm width x 5 mm of height. Each of the arrows shall have 2 mm longer of width than the previous one.
 - b. Colour:
 - A light green: (30,0,100,0);
 - B yellow: (0,0,100,0);
 - C light-orange: (0,30,100,0);
 - D dark-orange: (0,70,100,0);
 - E red: (0,100,100,0).
 - c. Position: centred on an axis at 1mm from the left side of the square.
 - iii. Letters within the coloured arrows:
 - a. Scale: Calibri Bold 7 pt.;
 - b. Colour: black;
 - c. Position: centred on an axis at 2 mm from the left side of the arrows.
 - iv. Black arrow:
 - a. Scale: rectangular left arrow shape of 8 mm width x 5 mm of height;
 - b. Colour: white;
 - c. Position: centred on an axis at 1 mm from the right side of the rectangle.
 - v. Letter within the black arrow:
 - a. Scale: Calibri Bold 7pt.,
 - b. Colour: black.

In the colour scheme of the plant protection product, the black arrow shall be placed following this rationale:

- i. **A- light green** indicates that the plant protection product has been authorised in the Member State as a low-risk plant protection product.
- ii. **B- yellow** indicates that the plant protection product:
 - contains or consists of only active substance(s) approved as low risk (listed in Part D of the Annex to Implementing Regulation (EU) No 540/2011) **and**
 - has not been authorised in the Member State as a low-risk plant protection product.

- iii. C- light orange** indicates that the plant protection product contains or consists of only active substance(s):
- which are micro-organisms (as defined by Article 3(15) of Regulation (EC) No 1107/2009) **and**
 - are approved and listed in Parts A or B of the Annex to Implementing Regulation (EU) No 540/2011.
- iv. D- dark orange** indicates that the plant protection product:
- does not contain any active substance approved as a candidate for substitution (listed in Part E of the Annex to Implementing Regulation (EU) No 540/2011) **and**
 - contains or consists of at least one active substance(s) other than micro-organisms (as defined by Article 3(15)) which is approved and listed in Parts A or B of the Annex to Implementing Regulation (EU) No 540/2011.
- v. E-red** indicates that the plant protection product contains or consists of at least one active substance:
- that is approved as a candidate for substitution (listed in Part E of the Annex to Implementing Regulation (EU) No 540/2011 **or** listed in Regulation (EU) 2015/408)³.

³ <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:02015R0408-20230731>.