COMMISSION IMPLEMENTING REGULATION (EU) No 485/2013
of 24 May 2013
amending Implementing Regulation (EU) No 540/2011, as regards the conditions of approval of the active substances clothianidin, thiamethoxam and imidacloprid, and prohibiting the use and sale of seeds treated with plant protection products containing those active substances
(Text with EEA relevance)
(OJ L 139, 25.5.2013, p. 12)

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COMMISSION IMPLEMENTING REGULATION (EU) No 485/2013

of 24 May 2013

amending Implementing Regulation (EU) No 540/2011, as regards the conditions of approval of the active substances clothianidin, thiamethoxam and imidacloprid, and prohibiting the use and sale of seeds treated with plant protection products containing those active substances

(Text with EEA relevance)

Article 1

Amendment to Implementing Regulation (EU) No 540/2011

The Annex to Implementing Regulation (EU) No 540/2011 is amended in accordance with Annex I to this Regulation.

Article 3

Transitional measures

Member States shall in accordance with Regulation (EC) No 1107/2009, where necessary amend or withdraw existing authorisations for plant protection products containing clothianidin, thiamethoxam or imidacloprid as active substance by 30 September 2013.

Article 4

Period of grace

Any period of grace granted by Member States in accordance with Article 46 of Regulation (EC) No 1107/2009 shall be as short as possible and shall expire 30 November 2013 at the latest.

Article 5

Entry into force

This Regulation shall enter into force on and apply from the day following that of its publication in the Official Journal of the European Union.

However, Article 2 shall apply as of 1 December 2013.

This Regulation shall be binding in its entirety and directly applicable in all Member States.
ANNEX I

Amendments to the Annex to Implementing Regulation (EU) No 540/2011

1. The column ‘Specific provisions’ of row 121, Clothianidin, of Part A of the Annex to Implementing Regulation (EU) No 540/2011 is replaced by the following:

‘PART A

Only professional uses as insecticide may be authorised.

Uses as seed treatment or soil treatment shall not be authorised for the following cereals, when such cereals are sown from January to June:

barley, millet, oats, rice, rye, sorghum, triticale, wheat.

Foliar treatments shall not be authorised for the following cereals:

barley, millet, oats, rice, rye, sorghum, triticale, wheat.

Uses as seed treatment, soil treatment or foliar application shall not be authorised for the following crops with the exception of uses in greenhouses and with the exception of foliar treatments after flowering:

Alfalfa (Medicago sativa)

almonds (Prunus amygdalus; P. communis; Amygdalus communis)

anise (Pimpinella anisum); badian or star anise (Illicium verum); caraway (Carum carvi); coriander (Coriandrum sativum); cumin (Cuminum cyminum); fennel (Foeniculum vulgare); juniper berries (Juniperus communis)

apples (Malus pumila; M. sylvestris; M. communis; Pyrus malus)

apricots (Prunus armeniaca)

avocados (Persea americana)

bananas (Musa sapientum; M. cavendishii; M. nana);

beans (Phaseolus spp.)

blackberry (Rubus fruticosus)

blueberries, European blueberry, wild bilberry, whortleberry (Vaccinium myrtillus); American blueberry (V. corymbosum)

broad beans, horse beans (Vicia faba var. major; var. equina; var. Minor)

buckwheat (Fagopyrum esculentum)

carobs, carob-tree, locust bean (Ceratonia siliqua)

castor oil seed (Ricinus communis)

cherries (Prunus avium)

chestnuts (Castanea spp.)

chick peas (Cicer arietinum)

chillies (Capsicum frutescens; C. annuum); allspice, Jamaica pepper (Pimenta officinalis)
clovers (Trifolium spp.)
coffee (Coffea spp. arabica, robusta, liberica)
cotton (Gossypium spp.)
cowpeas, black eyed peas (Vigna unguiculata)
cranberries (Vaccinium macrocarpon); European cranberries (Vaccinium oxyccoccus)
cucumbers (Cucumis sativus)
currants black (Ribes nigrum); red and white (R. rubrum)
dates (Phoenix dactylifera)
elderberries (Sambucus nigra)
gooseberries (Ribes uva-crispa)
grapefruit (C. paradisi)
grapes (Vitis vinifera)
groundnuts/peanuts (Arachis hypogea)
hazelnut (Corylus avellana)
hemp (Cannabis sativa)
japanese rose (Rosa rugosa)
kiwi fruit (Actinidia chinensis)
leguminous: birdsfoot/trefoil (Lotus corniculatus); lespedeza (Lespedeza spp.); kudzu (Pueraria lobata); sesbania (Sesbania spp.); sainfoin, esparcette (Onobrychis sativa); sulla (Hedysarum coronarium)
lemons and limes Lemon (Citrus limon); sour lime (C. aurantiifolia); sweet lime (C. limetta)
lentils (Lens esculenta; Ervum lens)
linseed (Linum usitatissimum)
lupins (Lupinus spp.)
maize/corn (Zea mays)
melon seeds (Cucumis melo)
mustard seeds: white mustard (Brassica alba; B. hirta; Sinapis alba); black mustard (Brassica nigra; Sinapis nigra)
okra (Abelmoschus esculentus); gombo (Hibiscus esculentus)
olivest (Olea europaea)
oranges: sweet orange (Citrus sinensis); bitter orange (C. aurantium)
peaches and nectarines (Prunus persica; Amygdalus persica; Persica laevis)
pears (Pyrus communis)
peas garden pea (Pisum sativum); field pea (P. arvense)
peppermint (\textit{Mentha} spp.; \textit{M. piperita})

persimmons (\textit{Diospyros kaki}; \textit{D. virginiana})

pistachios (\textit{Pistacia vera})

plums and sloes greengage, mirabelle, damson (\textit{Prunus domestica}); sloe (\textit{P. spinosa})

poppy seed (\textit{Papaver somniferum})

pumpkins, squash, gourds and marrows (\textit{Cucurbita} spp.)

pyrethrum, (\textit{Chrysanthemum cinerariifolium})

quinces (\textit{Cyoquia oblonga}; \textit{C. vulgaris}; \textit{C. japonica})

rapeseed (\textit{Brassica napus} var. \textit{oleifera})

raspberries (\textit{Rubus idaeus})

safflower seed (\textit{Carthamus tinctorius})

serradella/birds foot (\textit{Ornithopus sativus})

sesame seed (\textit{Sesamum indicum})

soybeans (\textit{Glycine soja})

spices: bay leaves (\textit{Laurus nobilis}); dill seed (\textit{Anethum graveolens}); fenugreek seed (\textit{Trigonella foenumgraecum}); saffron (\textit{Crocus sativus}); thyme (\textit{Thymus vulgaris}); turmeric (\textit{Curcuma longa})

strawberries (\textit{Fragaria} spp.)

sunflower seed (\textit{Helianthus annuus})

tangerine (\textit{Citrus tangerina}); mandarin (\textit{Citrus reticulata}); clementine (\textit{C. unshiu});

turnips and turnip rapes (\textit{Brassica rapa} var. \textit{rapifera} and \textit{oleifera} spp.)

vetches Spring/common vetch (\textit{Vicia sativa})

viper’s Grass (\textit{Scorzonera hispanica})

walnuts (\textit{Jugland} spp.; \textit{J. regia})

watermelons (\textit{Citrullus vulgaris})

ornamentals flowering in year of treatment.

\textbf{PART B}

For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on clothianidin, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 27 January 2006 and the conclusions of the addendum of the review report on clothianidin as finalised in the Standing Committee on the Food Chain and Animal Health on 15 March 2013 shall be taken into account.

In this overall assessment Member States shall pay particular attention to:

— the protection of groundwater, when the active substance is applied in regions with vulnerable soil and/or climate conditions,
— the risk to granivorous birds and mammals when the substance is used as a seed dressing.

Member States shall ensure that:

— 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 conditions of the authorisation include, where appropriate, risk mitigation measures to protect bees,

— monitoring programmes are initiated to verify the real exposure of bees to clothianidin in areas extensively used by bees for foraging or by beekeepers, where and as appropriate.

Conditions of use shall include risk mitigation measures, where appropriate.

The notifier shall submit confirmatory information as regards:

(a) the risk to pollinators other than honey bees;

(b) the risk to honey bees foraging in nectar or pollen in succeeding crops;

(c) the potential uptake via roots to flowering weeds;

(d) the risk to honey bees foraging on insect honey dew;

(e) the potential guttation exposure and the acute and the long-term risk to colony survival and development, and the risk to bee brood resulting from such exposure;

(f) the potential exposure to dust drift following drill and the acute and the long-term risk to colony survival and development, and the risk to bee brood resulting from such exposure;

(g) the acute and long term risk to colony survival and development and the risk to bee brood for honeybees from ingestion of contaminated nectar and pollen.

The notifier shall submit that information to the Commission, the Member States and the Authority by 31 December 2014."

2. The column ‘Specific provisions’ of row 140, Thiamethoxam of Part A of the Annex to Implementing Regulation (EU) No 540/2011 is replaced by the following:

‘PART A

Only professional uses as insecticide may be authorised.

Uses as seed treatment or soil treatment shall not be authorised for the following cereals, when such cereals are sown from January to June:

barley, millet, oats, rice, rye, sorghum, triticale, wheat.'
Foliar treatments shall not be authorised for the following cereals:

- barley, millet, oats, rice, rye, sorghum, triticale, wheat.

Uses as seed treatment, soil treatment or foliar application shall not be authorised for the following crops with the exception of uses in greenhouses and with the exception of foliar treatment after flowering:

- Alfalfa (Medicago sativa)
- almonds (Prunus amygdalus; P. communis; Amygdalus communis)
- anise (Pimpinella anisum); badian or star anise (Illicium verum); caraway (Carum carvi); coriander (Coriandrum sativum); cumin (Cuminum cyminum); fennel (Foeniculum vulgare); juniper berries (Juniperus communis)
- apples (Malus pumila; M. sylvestris; M. communis; Pyrus malus)
- apricots (Prunus armeniaca)
- avocados (Persea americana)
- bananas (Musa sapientum; M. cavendishii; M. nana)
- beans (Phaseolus spp.)
- blackberry (Rubus fruticosus)
- blueberries, European blueberry, wild bilberry, whortleberry (Vaccinium myrtillus); American blueberry (V. corymbosum)
- broad beans, horse beans (Vicia faba var. major; var. equina; var. Minor)
- buckwheat (Fagopyrum esculentum)
- carobs, carob-tree, locust bean (Ceratonia siliqua)
- castor oil seed (Ricinus communis)
- cherries (Prunus avium)
- chestnuts (Castanea spp.)
- chick peas (Cicer arietinum)
- chillies (Capsicum frutescens; C. annuum); allspice, Jamaica pepper (Pimenta officinalis)
- clovers (Trifolium spp.)
- coffee (Coffea spp. arabica, robusta, liberica)
- cotton (Gossypium spp.)
- cowpeas, black eyed peas (Vigna unguiculata)
- cranberries (Vaccinium macrocarpon); European cranberries (Vaccinium oxycoccus)
- cucumbers (Cucumis sativus)
- currants black (Ribes nigrum); red and white (R. rubrum)
- dates (Phoenix dactylifera)
elderberries (Sambucus nigra)
gooseberries (Ribes uva-crispa)
grapefruit (C. paradisi)
grapes (Vitis vinifera)
groundnuts/peanuts (Arachis hypogea)
hazelnut (Corylus avellana)
hemp (Cannabis sativa)
japanese rose (Rosa rugosa)
kiwi fruit (Actinidia chinensis)
leguminous: birdsfoot/trefoil (Lotus corniculatus); lespedeza (Lespedeza spp.); kudzu (Pueraria lobata); sesbania (Sesbania spp.); sainfoin, esparcette (Onobrychis sativa); sulla (Hedysarum coronarium)
lemons and limes Lemon (Citrus limon); sour lime (C. aurantiifolia); sweet lime (C. limetta)
lentils (Lens esculenta; Ervam lens)
linseed (Linum usitatissimum)
lupins (Lupinus spp.)
maize/corn (Zea mays)
melon seeds (Cucumis melo)
mustard seeds: white mustard (Brassica alba; B. hirta; Sinapis alba); black mustard (Brassica nigra; Sinapis nigra)
okra (Abelmoschus esculentus); gombo (Hibiscus esculentus)
olives (Olea europaea)
oranges: sweet orange (Citrus sinensis); bitter orange (C. aurantium)
peaches and nectarines (Prunus persica; Amygdalus persica; Persica laevis)
pears (Pyrus communis)
peas garden pea (Pisum sativum); field pea (P. arvense)
peppermint (Mentha spp.; M. piperita)
persimmons (Diospyros kaki; D. virginiana)
pistachios (Pistacia vera)
plums and sloes greengage, mirabelle, damson (Prunus domestica); sloe (P. spinosa)
poppy seed (Papaver somniferum)
pumpkins, squash, gourds and marrows (Cucurbita spp.)
pyrethrum, (Chrysanthemum cinerariifolium)
quinces (Cydonia oblonga; C. vulgaris; C. japonica)
rapeseed (*Brassica napus* var. *oleifera*)
raspberries (*Rubus idaeus*)
safflower seed (*Carthamus tinctorius*)
serradella/birds foot (*Ornithopus sativus*)
sesame seed (*Sesamum indicum*)
soybeans (*Glycine soja*)
spices: bay leaves (*Laurus nobilis*); dill seed (*Anethum graveolens*); fenugreek seed (*Trigonella foenumgraecum*); saffron (*Crocus sativus*); thyme (*Thymus vulgaris*); turmeric (*Curcuma longa*)
strawberries (*Fragaria spp.*)
sunflower seed (*Helianthus annuus*)
tangerine (*Citrus tangerina*); mandarin (*Citrus reticulata*); clementine (*C. unshiu*)
turnips and turnip rapes (*Brassica rapa* var. *rapifera* and *oleifera* spp.)
vetches Spring/common vetch (*Vicia sativa*)
viper’s Grass (*Scorzonera hispanica*)
walnuts (*Jugland spp.: J. regia*)
watermelons (*Citrullus vulgaris*)

ornamentals flowering in year of treatment.

**PART B**

For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on thiamethoxam, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 14 July 2006 and the conclusions of the addendum of the review report on thiame-thoxam as finalised in the Standing Committee on the Food Chain and Animal Health on 15 March 2013 shall be taken into account.

In this overall assessment Member States must pay particular attention to:

— the potential for groundwater contamination, particularly of the active substance and its metabolites NOA 459602, SYN 501406 and CGA 322704, when the active substance is applied in regions with vulnerable soil and/or climatic conditions,

— the protection of aquatic organisms,

— the long-term risk to small herbivorous animals if the substance is used for seed treatment.

Member States shall ensure that:

— 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,
— monitoring programmes are initiated to verify the real exposure of bees to thiamethoxam in areas extensively used by bees for foraging or by beekeepers, where and as appropriate.

Conditions of use shall include risk mitigation measures, where appropriate.

The notifier shall submit confirmatory information as regards:

(a) the risk to pollinators other than honey bees;

(b) the risk to honey bees foraging in nectar or pollen in succeeding crops;

(c) the potential uptake via roots to flowering weeds;

(d) the risk to honey bees foraging on insect honey dew;

(e) the potential guttation exposure and the acute and the long-term risk to colony survival and development, and the risk to bee brood resulting from such exposure;

(f) the potential exposure to dust drift following drill and the acute and the long-term risk to colony survival and development, and the risk to bee brood resulting from such exposure;

(g) the acute and long term risk to colony survival and development and the risk to bee brood for honeybees from ingestion of contaminated nectar and pollen.

The notifier shall submit that information to the Commission, the Member States and the Authority by 31 December 2014.’

3. The column ‘Specific provisions’ of row 216, Imidacloprid, of Part A of the Annex to Implementing Regulation (EU) No 540/2011 is replaced by the following:

‘PART A

Only professional uses as insecticide may be authorised.

Uses as seed treatment or soil treatment shall not be authorised for the following cereals, when such cereals are sown from January to June:

barley, millet, oats, rice, rye, sorghum, triticale, wheat.

Foliar treatments shall not be authorised for the following cereals:

barley, millet, oats, rice, rye, sorghum, triticale, wheat.

Uses as seed treatment, soil treatment or foliar application shall not be authorised for the following crops with the exception of uses in greenhouses and with the exception of foliar treatment after flowering:

Alfalfa (Medicago sativa)

almonds (Prunus amygdalus; P. communis; Amygdalus communis)
anise (*Pimpinella anisum*); badian or star anise (*Illicium verum*); caraway (*Carum carvi*); coriander (*Coriandrum sativum*); cumin (*Cuminum cyminum*); fennel (*Foeniculum vulgare*); juniper berries (*Juniperus communis*)

apples (*Malus pumila; M. sylvestris; M. communis; Pyrus malus*)

apricots (*Prunus armeniaca*)

avocados (*Persea americana*)

bananas (*Musa sapientum; M. cavendishii; M. nana*)

beans (*Phaseolus spp.*)

blackberry (*Rubus fruticosus*)

blueberries, European blueberry, wild bilberry, whortleberry (*Vaccinium myrtillus*); American blueberry (*V. corymbosum*)

broad beans, horse beans (*Vicia faba var. major; var. equina; var. Minor*)

buckwheat (*Fagopyrum esculentum*)

carobs, carob-tree, locust bean (*Ceratonia siliqua*)

castor oil seed (*Ricinus communis*)

cherries (*Prunus avium*)

chestnuts (*Castanea spp.*)

chick peas (*Cicer arietinum*)

chillies (*Capsicum frutescens; C. annuum*); allspice, Jamaica pepper (*Pimenta officinalis*)

clovers (*Trifolium spp.*)

coffee (*Coffea spp. arabica, robusta, liberica*)

cotton (*Gossypium spp.*)

cowpeas, black eyed peas (*Vigna unguiculata*)

cranberries (*Vaccinium macrocarpon*); European cranberries (*Vaccinium oxyccocus*)

cucumbers (*Cucumis sativus*)

currants black (*Ribes nigrum*); red and white (*R. rubrum*)

dates (*Phoenix dactylifera*)

elderberries (*Sambucus nigra*)

gooseberries (*Ribes uva-crispa*)

grapefruit (*C. paradisi*)

grapes (*Vitis vinifera*)

groundnuts/peanuts (*Arachis hypogea*)

hazelnut (*Corylus avellana*)

hemp (*Cannabis sativa*)
japanese rose (*Rosa rugosa*)

kiwi fruit (*Actinidia chinensis*)

leguminous: birdsfoot/trefoil (*Lotus corniculatus*); lespedeza (*Lespedeza* spp.); kudzu (*Pueraria lobata*); sesbania (*Sesbania* spp.); sainfoin, espardette (*Onobrychis sativa*); sulla (*Hedysarum coronarium*)

lemons and limes Lemon (*Citrus limon*); sour lime (*C. aurantiifolia*); sweet lime (*C. limetta*)

lentils (*Lens esculenta; Ervum lens*)

linseed (*Linum usitatissimum*)

maize/corn (*Zea mays*)

melon seeds (*Cucumis melo*)

mustard seeds: white mustard (*Brassica alba; B. hirta; Sinapis alba*); black mustard (*Brassica nigra; Sinapis nigra*)

okra (*Abelmoschus esculentus*); gombo (*Hibiscus esculentus*)

olives (*Olea europaea*)

oranges: sweet orange (*Citrus sinensis*); bitter orange (*C. aurantium*)

peaches and nectarines (*Prunus persica; Amygdalus persica; Persica laevis*)

pears (*Pyrus communis*)

peas garden pea (*Pisum sativum*); field pea (*P. arvense*)

peppermint (*Mentha spp.; M. piperita*)

persimmons (*Diospyros kaki; D. virginiana*)

pistachios (*Pistacia vera*)

plums and sloes greengage, mirabelle, damson (*Prunus domestica*); sloe (*P. spinosa*)

poppy seed (*Papaver somniferum*)

pumpkins, squash, gourds and marrows (*Cucurbita* spp.)

pyrethrum, (*Chrysanthemum cinerariifolium*)

quinces (*Cydonia oblonga; C. vulgaris; C. japonica*)

rapeseed (*Brassica napus var. oleifera*)

raspberries (*Rubus idaeus*)

safflower seed (*Carthamus tinctorius*)

serradella/birds foot (*Ornithopus sativus*)

sesame seed (*Sesamum indicum*)

soybeans (*Glycine soja*)

spices: bay leaves (*Laurus nobilis*); dill seed (*Anethum graveolens*); fenugreek seed (*Trigonella foenum-graecum*); saffron (*Crocus sativus*); thyme (*Thymus vulgaris*); turmeric (*Curcuma longa*)
strawberries (*Fragaria* spp.)

sunflower seed (*Helianthus annuus*)

tangerine (*Citrus tangerina*); mandarin (*Citrus reticulata*) clementine (*C. unshiu*);

turnips and turnip rapes (*Brassica rapa* var. *rapifera* and *oleifera* spp.)

vetches Spring/common vetch (*Vicia sativa*)

viper’s Grass (*Scorzoneran hispanica*)

walnuts (*Jugland spp.: J. regia*)

watermelons (*Citrullus vulgaris*)

ornamentals flowering in year of treatment.

**PART B**

In assessing applications to authorise plant protection products containing imidacloprid, Member States shall pay particular attention to the criteria in Article 4(3) of Regulation (EC) No 1107/2009, and shall ensure that any necessary data and information is provided before such an authorisation is granted.

For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on imidacloprid, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 26 September 2008 and the conclusions of the addendum of the review report on imidacloprid as finalised in the Standing Committee on the Food Chain and Animal Health on 15 March 2013 shall be taken into account.

In this overall assessment Member States must pay particular attention to:

— the operator and worker safety and ensure that conditions of use prescribe the application of adequate personal protective equipment,

— the impact on aquatic organisms, non-target arthropods, earthworms, other soil macroorganisms and must ensure that the conditions of authorisation include, where appropriate, risk mitigation measures.

Member States shall ensure that:

— 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 conditions of the authorisation, include, where appropriate, risk mitigation measures to protect bees,
— monitoring programmes are initiated to verify the real exposure of bees to
imidacloprid in areas extensively used by bees for foraging or by
beekeepers, where and as appropriate.

Conditions of use shall include risk mitigation measures, where appropriate.

The notifier shall submit confirmatory information as regards:

(a) the risk to pollinators other than honey bees;
(b) the risk to honey bees foraging in nectar or pollen in succeeding crops;
(c) the potential uptake via roots to flowering weeds;
(d) the risk to honey bees foraging on insect honey dew;
(e) the potential guttation exposure and the acute and the long-term risk to
colony survival and development, and the risk to bee brood resulting from
such exposure;
(f) the potential exposure to dust drift following drill and the acute and the
long-term risk to colony survival and development, and the risk to bee
brood resulting from such exposure;
(g) the acute and long term risk to colony survival and development and the
risk to bee brood for honeybees from ingestion of contaminated nectar
and pollen.

The notifier shall submit that information to the Commission, the Member
States and the Authority by 31 December 2014.