

Authorization of commercial PPPs and evaluation of human and environmental risks during 2015-2017



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Pesticide used in agricultural sector could potentially impacts in the ecosystem and consequently human and animal health. At European level, legislation such as Regulation (EU) N. 1107/2009 lays down the rules for the authorization of plant protection products in commercial form and for their placing on the market, use and control within the Community. This Regulation should also lay down harmonised rules for the placing on the market of plant protection products, including the rules on the mutual recognition of authorizations and on parallel trade.

The provisions governing authorization must ensure a high standard of protection. In particular, when granting authorizations of plant protection products, the objective of protecting human and animal health and the environment should take priority over the objective of improving plant production.

Therefore, before plant protection products placed on the market, that they present a clear benefit for plant production and do not have any harmful effect on human or animal health, including that of vulnerable groups, or any unacceptable effects on the environment. During 2015-2017, according to the collaboration between Italian Ministry of Health and National Institute of Health, the risk assessment performed for 173 plant protection products. According to the EU Regulation N. 1107/2009, the products evaluated for the chemical, environmental, human aspects (operator, worker, residential, bystander), consumers and efficacy aspects. For the authorization several procedure were follow according to the rule for First Authorization where Italy is Rapporteur Member State (RMS); Mutual Recognition; Re-Registration for that Italy is Rapporteur Member State (RMS); Authorization for that Italy is Concern Member State (Co-RMS); Authorization renewal art. 43 that Italy is zonal Rapporteur Member State (zRMS); Extension of Use; Extension of Use other Rapporteur Member State (RMS); Re-Registration with national procedure; Re-Registration with zonal procedure; Re-Registration with national procedure in voluntary work sharing.

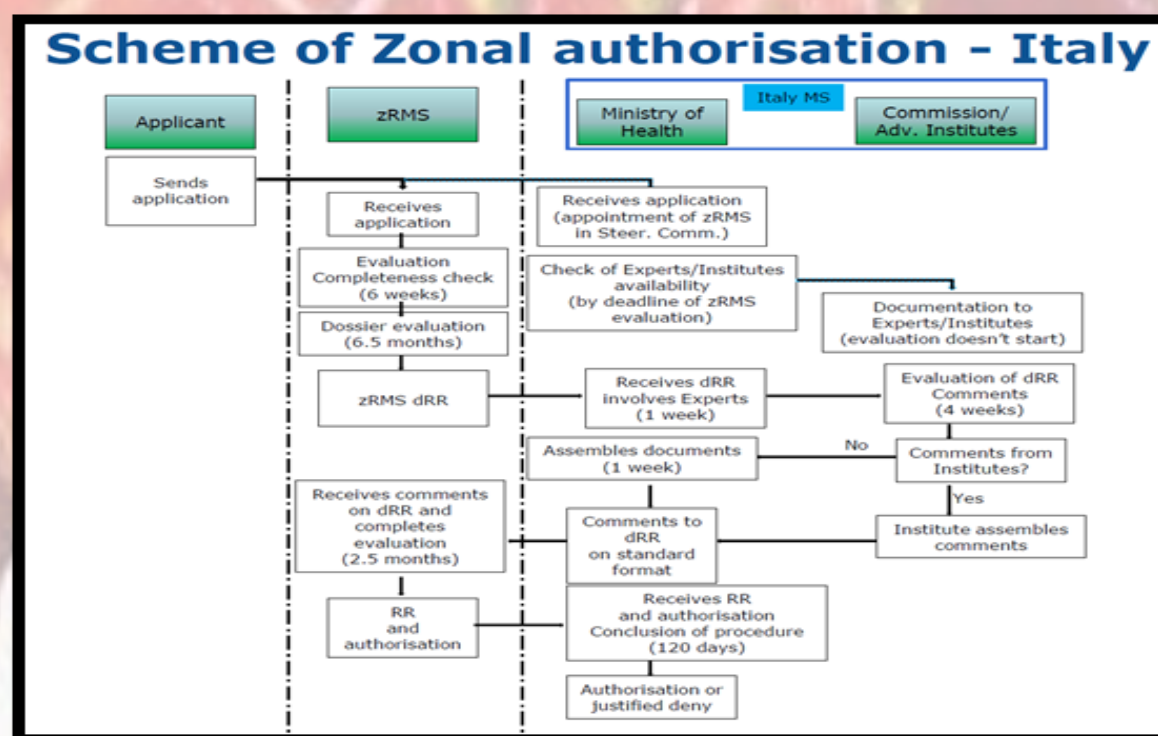
In the Table 1 are reported for each procedure, the number of plant protection products and the active substance.

Procedure	Number Plant Protection Product	Active substance
First Authorization where Italy is RMS	n.33	Dimethomorph, Tri-benz Copper Sulfate, Cyazofamid, Imazamox, Metolachlor, Cymoxanil, Folpet, Fosetyl-Al, Acido ethephonico, Thiophanate-Methyl, Difencenzoazole, Mancozeb, Valifenalate, Iodosulfuron-Methyl Sodium, Measulfuron Methyl, NAD, Glomoxone, Meconitron, E-E-8-10-DODECADIEN-1-OL-OL, E-Z-7-9, DODECADIENYL ACETATO, Deltamethrin, Pyrethrin, Ethyl, Buprofezin, Ethepon 48% SL, Cipermetrin, Terbutylazine, Meconitron, Fluroxypyr, Thifensulfuron Methyl, Flusulfamid, Iodosulfuron-Methyl-Sodium, Thienocarbazono-Methyl, Mefenpir-Distile, Spiromesifen-Difencenzoazole, Bifenox 480 g/L, Tricloraz, Fenoxazole, ACPA, Deltamethrin, Difencenzoazole, Glyphosate, Mancozeb, Cymoxanil, Azoxystrobin, Folpet, Fosetyl-Aluminum-Folpet, Glyphosate, Fenpropidin, Fenoxazole, Malt oil, Clopyralid, pure Maltolene and 12-Benzotriazol-3-yl-1H-pyrazole, Zoxamide-Dimethomorph, Valifenalate, CU, Cyprodinil, Tebuconazole, Metiliclogopropene, Metolachlor, Spirotetramat, Metolachlor, Spirotetramat
Mutual Recognition	n.64	ACPA, Deltamethrin, Difencenzoazole, Glyphosate, Mancozeb, Cymoxanil, Azoxystrobin, Folpet, Fosetyl-Aluminum-Folpet, Glyphosate, Fenpropidin, Fenoxazole, Malt oil, Clopyralid, pure Maltolene and 12-Benzotriazol-3-yl-1H-pyrazole, Zoxamide-Dimethomorph, Valifenalate, CU, Cyprodinil, Tebuconazole, Metiliclogopropene, Metolachlor, Spirotetramat
Re-Registration for that Italy is Rapporteur Member State	n.2	Bifenoxazole, Fenpropidin, Fenoxazole, Malt oil, Clopyralid, pure Maltolene and 12-Benzotriazol-3-yl-1H-pyrazole, Zoxamide-Dimethomorph, Valifenalate, CU, Cyprodinil, Tebuconazole, Metiliclogopropene, Metolachlor, Spirotetramat
Authorization for that Italy is Concern Member State (Co-RMS)	n.18	Bifenoxazole, Fenpropidin, Fenoxazole, Malt oil, Clopyralid, pure Maltolene and 12-Benzotriazol-3-yl-1H-pyrazole, Zoxamide-Dimethomorph, Valifenalate, CU, Cyprodinil, Tebuconazole, Metiliclogopropene, Metolachlor, Spirotetramat
Authorization renewal art. 43 that Italy is zonal Rapporteur Member State (zRMS)	n.2	Bifenoxazole, Fenpropidin, Fenoxazole, Malt oil, Clopyralid, pure Maltolene and 12-Benzotriazol-3-yl-1H-pyrazole, Zoxamide-Dimethomorph, Valifenalate, CU, Cyprodinil, Tebuconazole, Metiliclogopropene, Metolachlor, Spirotetramat
Extension of use	n.7	Bifenoxazole, Fenpropidin, Fenoxazole, Malt oil, Clopyralid, pure Maltolene and 12-Benzotriazol-3-yl-1H-pyrazole, Zoxamide-Dimethomorph, Valifenalate, CU, Cyprodinil, Tebuconazole, Metiliclogopropene, Metolachlor, Spirotetramat
Extension of use other Rapporteur Member State (RMS)	n.2	Bifenoxazole, Fenpropidin, Fenoxazole, Malt oil, Clopyralid, pure Maltolene and 12-Benzotriazol-3-yl-1H-pyrazole, Zoxamide-Dimethomorph, Valifenalate, CU, Cyprodinil, Tebuconazole, Metiliclogopropene, Metolachlor, Spirotetramat
Re-Registration with national procedure	n.26	Bifenoxazole, Fenpropidin, Fenoxazole, Malt oil, Clopyralid, pure Maltolene and 12-Benzotriazol-3-yl-1H-pyrazole, Zoxamide-Dimethomorph, Valifenalate, CU, Cyprodinil, Tebuconazole, Metiliclogopropene, Metolachlor, Spirotetramat
Re-Registration with zonal procedure	n.3	Bifenoxazole, Fenpropidin, Fenoxazole, Malt oil, Clopyralid, pure Maltolene and 12-Benzotriazol-3-yl-1H-pyrazole, Zoxamide-Dimethomorph, Valifenalate, CU, Cyprodinil, Tebuconazole, Metiliclogopropene, Metolachlor, Spirotetramat
Re-Registration with national procedure in voluntary work sharing	n.16	Bifenoxazole, Fenpropidin, Fenoxazole, Malt oil, Clopyralid, pure Maltolene and 12-Benzotriazol-3-yl-1H-pyrazole, Zoxamide-Dimethomorph, Valifenalate, CU, Cyprodinil, Tebuconazole, Metiliclogopropene, Metolachlor, Spirotetramat

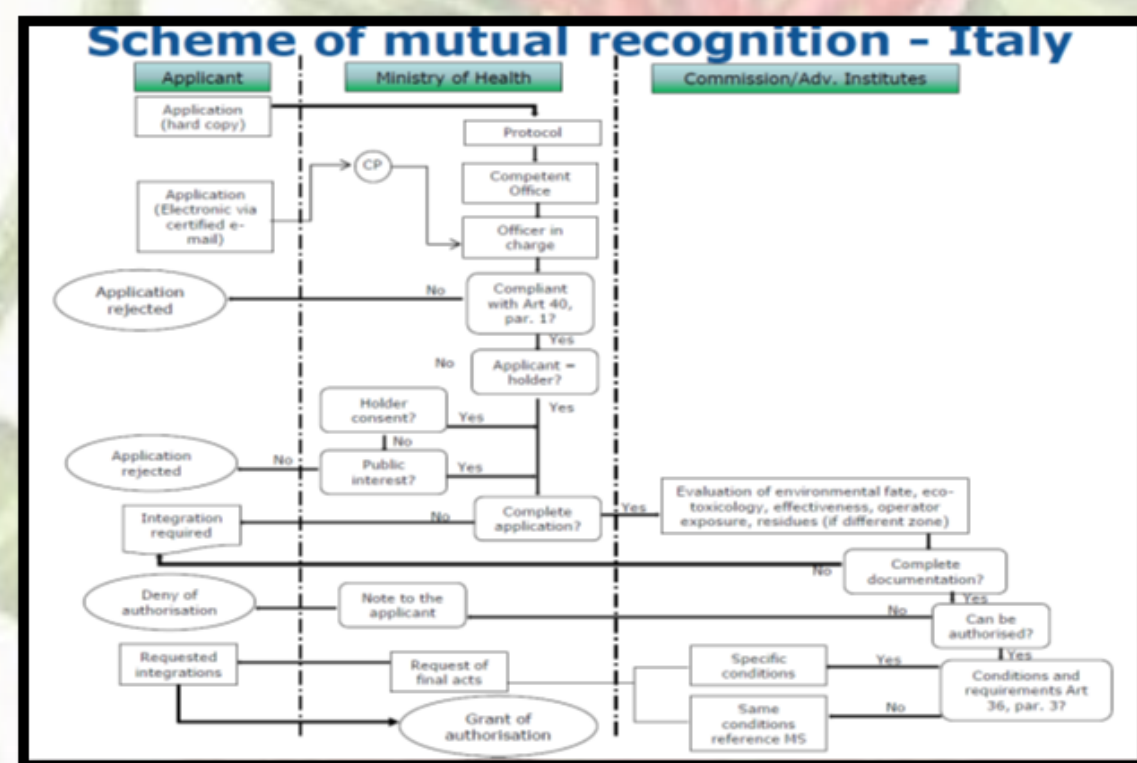
In the Table 2 are reported the number of plant protection products and for each the phytoiatric action and the crops.

Number Plant Protection Product	Phytoiatric action	Crops
63 plant protection product	Fungicide	Wine grapes, tomatoes, grapes, citrus fruits, apples, sugar beet, citrus fruits, eggplants, onions, shallots, garlic, celery, caponit, asparagus, lettuce, pears, olive, roses, ornamental crops, cucumbers, zucchini, water melon, melon, pepper, rape, barley, triticale, rice, oats, artichoke, peach, apricot, strawberry, cherries, corn, chestnut, wet almonds, spinach, beets, herbs, beans, broad bean, peas, chickpeas, carrots, fennel.
50 plant protection product	Herbicide	Corn, wheat, triticale, rice, potatoes, grapes, peaches, plums, cherries, kiwi, olive trees, lemons, artichokes, tomatoes, lemon, apricot, hazelnuts, walnuts, citrus fruits, rice, almond, apple tree, pears, sugar beet, oats, onion, cabbage, rape, alfalfa, soy, barley, asparagus, thistle, soft flower.
11 plant protection product	Insecticide	Corn, potatoes, grapes, corn, asparagus, wine grapes, grapes, citrus fruits, apple, pear, apricot, plum, peach, cherries, tomatoes, subergine, peppers, cucumber, zucchini, ornamentals, herbaceous, shrubby, cereals, brassicaceae, berries, fruit trees.
30 plant protection product	Plant Growth Regulator	Corn, citrus fruit, apple, peach, apricot, kiwi, avocado, plum, barley, wheat, ornamental crops, floral crops, potatoes, pear, castana, strawberry, subergine, peppers, water melon, melon, tomatoes, artichoke, celery, spinach, zucchini, cherries, wine grapes, grapes.
4 plant protection product	Pheromones	Grapes, peach, pome.
1 plant protection product	Disinfection of the soil in the absence of crops	///
1 plant protection product	Acaricide	///
9 plant protection product	Molluscicide	Potatoes, subergine, peppers, tomatoes, cabbage, lettuce, peach, cherries, ornamental crops, tomatoes, subergine, onion, cereals, rape, potatoes, strawberry, parsley, radishes, ornamental crops, grapes, corn, sugar beet, cabbage, asparagus, artichoke, celery, fennel, carrots, red chard, topinambur, floral crops.
4 plant protection product	Soil Fungicide	///

Graphics of authorization procedure and their phytoiatric action during 2015-2017.



Better training for safer food BTSF. Authorization of Plant Protection Products (course type 1) Agostino Santomauro, 20-24 may 2013 - Budapest, Hungary



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Conclusion

During the period 2015-2017, 173 plant protection products with different phytoiatric action were evaluated. As reported in the table 1 and 2 the products are evaluated for a large combination crops/substances.

The evaluation and finalization of the authorization was performed according to the conclusion of risk assessment for the environment, human health and agronomic efficacy.

References:
Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC.