

# Chemical properties, toxicity and regulatory issues on neonicotinoids in Sweden and Europe

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# Properties

- Act on the central nervous system of insects (nicotine).
- Block a specific neuron pathway that is more abundant in insects than warm-blooded animals.
- Therefore, more toxic to insects than mammals.
- High water solubility, low potential to bioaccumulate ( $\log P_{ow} < 1$ ).
- Persistent in crop and soil (clothianidin  $DT_{50}$  143-1001 d)

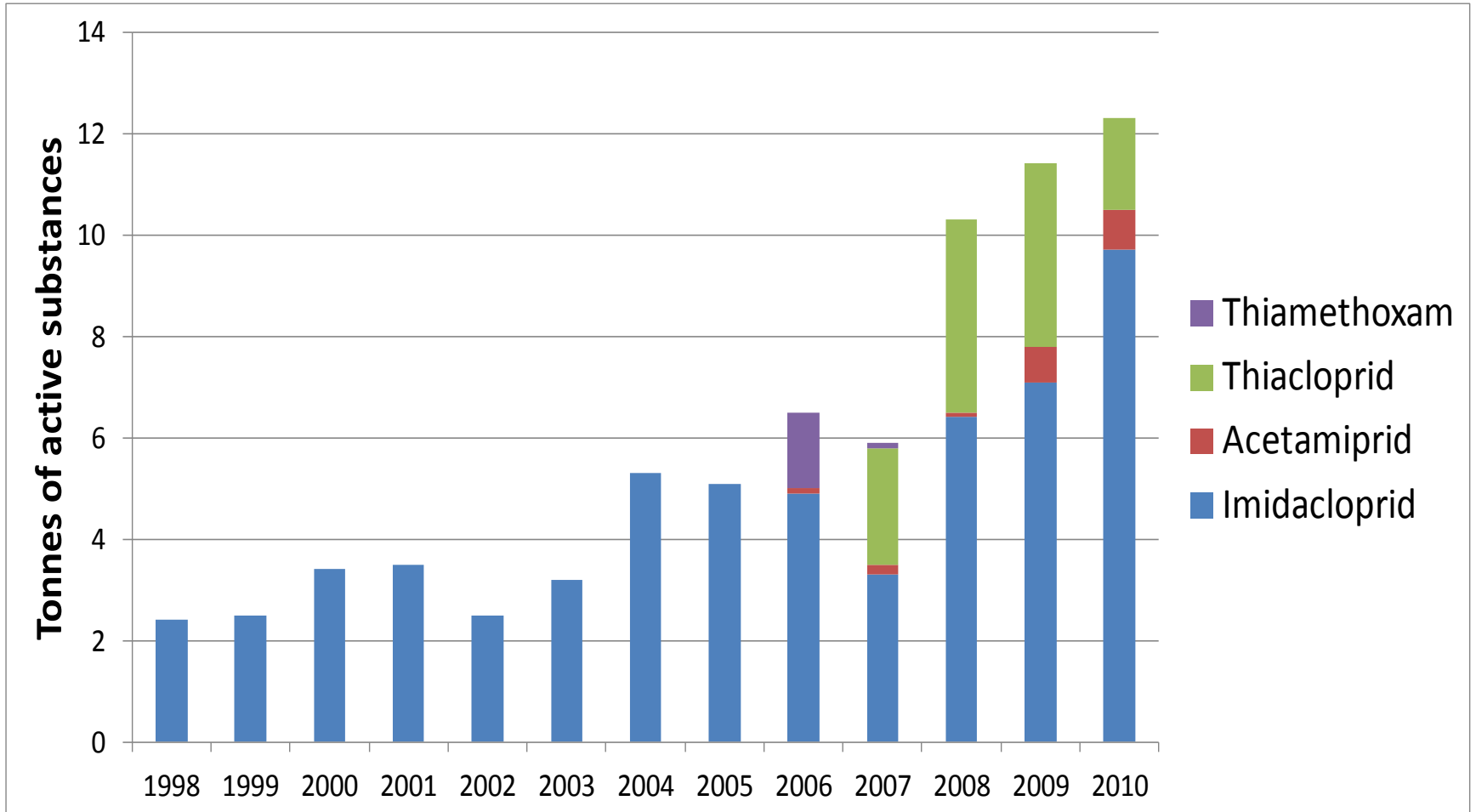
# Neonicotinoids approved in Europe

<b>Substance</b>	<b>Trade name</b>	<b>Acute oral bee toxicity (<math>\mu\text{g a.s./bee}</math>)</b>	<b>Authorised in Sweden</b>
(Fipronil)	Regent	0.004	
Clothianidin	Poncho, Elado	0.004	
Imidacloprid	Gaucho, Confidor	0.004	X
Thiamethoxam	Cruiser	0.005	X
Acetamiprid	Mospilan	14.5	X
Thiacloprid	Calypso, Biscaya	17.3	X

# Authorised uses in Sweden

<b>Substance</b>	<b>Trade names</b>	<b>Main authorised uses in Sweden</b>
Imidacloprid	Gaucho, Chinook, Confidor	Seed dressing: Sugar beets and oilseed rape. Greenhouses: Ornamentals, tomatoes, cucumbers, peppers.
Thiamethoxam	Cruiser	Seed dressing: Sugar beets
Acetamiprid	Mospilan	Spray application: Oilseed rape, fruit, potatoes, ornamentals.
Thiacloprid	Calypso, Biscaya	Spray application: Oilseed rape, strawberries potatoes, ornamentals.

# Sold quantities in Sweden



# KemIs views on neonicotinoids

- Neonicotinoids can be transported to plant parts, pollen, nectar and guttation drops by their systemic action.
- Uncertainties still remains on the potential exposure to bees from treated seeds under different conditions.
- The magnitude of the different exposure routes and the impact on bees from long term exposure of low levels is yet to be investigated.
- Based on these uncertainties and reports from other member states on extensive bee mortality, KemI did withdraw all approvals of thiamethoxam and rejected new approvals of clothianidin in 2008.

# Concerns triggering EU actions

- Frequent reports on extensive honey bee mortality.
- Regulatory actions in individual member states.
- EFSA conclusions regarding pesticide risk assessments.
- Appeals and letters from NGOs – Environmental organisations and Beekeepers associations.
- EU Parliament resolution in 2008.
- EFSA project "Bee mortality and bee surveillance in Europe" in 2009.
- Communication from the Commission to the EU Parliament and the Council on honeybee health in 2010.

# Communication from the Commission

- As yet, no direct causal link between the increased bee mortalities and specific substances or agents has been established, it is still unclear what should be done to combat it effectively.

In the absence of data and results of monitoring action, it is impossible to understand what the real situation is. As a consequence, it is impossible to take appropriate actions on bee health. It is clear, however, that surveillance plays a major role in this exercise.

# Regulation of plant protection products in EU

## A two-step procedure

### 1. EU-level

Active substances are approved if **it may be expected**, that, taking into account the approval criteria, plant protection products containing that active substance meet the requirements.

**2. National level** Plant protection products shall **only** be authorised if they meet the requirements during national review.

# New specific provisions, 1(2).

For the protection of non-target organisms, in particular honey bees, for use as seed treatment:

- 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.

## New specific provisions, 2(2).

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

# Cut off criteria

*3.8.3. An active substance, safener or synergist shall be approved only if it is established following an appropriate risk assessment on the basis of Community or internationally agreed test guidelines, that the use under the proposed conditions of use of plant protection products containing this active substance, safener or synergist:*

- will result in a negligible exposure of honeybees, or*
- has no unacceptable acute or chronic effects on colony survival and development, taking into account effects on honeybee larvae and honeybee behaviour.*

# Next steps

- Monitoring programs are ongoing in several member states.
- Data requirements on bee toxicity are currently being revised.
- A mandate to EFSA to give its opinion on thiamethoxam and bee toxicity.

# Who is responsible?

- Those who put a product on the market has the prime responsibility for the impacts of that product.
- They shall submit all necessary data and they are invited to provide a relevant risk assessment.
- Competent authorities to check if the proposed uses comply with the legal requirements.

Recital 8 *“... this Regulation should ensure that industry demonstrates that substances or products produced or placed on the market do not have any harmful effect on human or animal health or any unacceptable effects on the environment.”*

# To conclude

- Neonicotinoids are presently approved in EU with strict approval provisions.
- They are highly toxic to honey bees and several reports on extensive bee mortality is associated with their use.
- Several member states including Sweden, have taken regulatory actions to completely ban or restrict some of the most toxic ones.
- The concerns expressed by interest groups has probably played a crucial role for the community actions taken.
- Extensive research and monitoring is ongoing in view of trying to find out their role in bee mortality.