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DIRECTOR-GENERAL

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# OPINION

## of the French Food Safety Agency (Afssa) concerning an application for marketing authorisation of the thiamethoxam-based CRUISER 350 insecticide submitted by the company Syngenta Agro SAS

The French Food Safety Agency (Afssa) acknowledged receipt of an application, submitted by the Syngenta Agro SAS company for marketing authorisation for Cruiser 350 insecticide. Afssa's assessment and Opinion on the health risks and efficacy of this product are required in accordance with Article L.253-4 of the French Rural Code,

This Opinion concerns an application for marketing authorisation for the thiamethoxam-based insecticide CRUISER 350, intended for the treatment of maize and sorghum seeds.

It is based on an evaluation of the application submitted for this insecticide, in compliance with the requirements of Directive 91/414/ECC[1].

After consulting the Scientific Panel responsible for "Plant protection products: chemical substances and preparations", which met on 25 and 26 November 2009, the French Food Safety Agency has reached the following conclusions.

### CONSIDERING THE IDENTITY OF THE FORMULATED PRODUCT

CRUISER 350 is an insecticide containing 350 g/L thiamethoxam (minimum purity of 98%), in the form of a flowable concentrate for treating seeds (FS). The claimed uses to which it may be put (crops and annual application rates) are cited in Annex 1.

Thiamethoxam[2] is an active substance included in Annex I of Directive 91/414/EEC.

### CONSIDERING THE PHYSICO-CHEMICAL PROPERTIES AND ANALYSIS METHODS

The specifications of the active substance in Cruiser 350 insecticide allow it to be characterised and comply with regulatory requirements.

The physical and chemical properties of Cruiser 350 insecticide have been described and the available data confirm that it is neither explosive, nor combustible, nor highly flammable, nor self-igniting at room temperature (self-ignition temperature = 410°C). The pH of the solution at 1% is 6.8. The insecticide is surface-active. Its relative density is 1.1699 g/cm$^3$.

Storage stability tests carried out for 7 days at 0°C, for 18 weeks at 30°C, for 6 months at 45°C and for 2 years at room temperature show that the insecticide remains stable in its packaging under these conditions. It would be advisable to mention that the insecticide should be stored at temperatures of less than 45°C.

Studies show that the insecticide foams within acceptable limits. Suspensibility is 100% at a concentration of 75% and 97% at 15%. Its technical properties guarantee that this insecticide is safe to use under the recommended conditions of use (ready-to-use or diluted to 37.5%). Studies

1 Council Directive 91/414/ECC of 15 July 1991 transposed into French law by the Order of 6 September 1994 promulgating Order 94/359 of 5 May 1994 on the control of plant protection products.

2 Commission Directive 2007/6/EC of 14 February 2007 amending Council Directive 91/414/EEC to include metrafenone, *Bacillus subtilis*, spinosad and thiamethoxam as active substances.

have also shown that the packaging (high-density polyethylene/varnished steel drum) were compatible with the insecticide.

The methods for analysing the active substance and the impurities in the technical active substance, as well as the method used to analyse the active substance in the insecticide comply with regulatory requirements.

The methods available for analysing the level of active substance residues in the different substrates and environments (plants, products of animal origin, soil, water, air) have been provided and are deemed to comply with regulations. Since the active substance is not classified as toxic or very toxic, no analytical method is required for biological fluids.

The limits of quantification (LOQ) of residues for thiamethoxam and its metabolite CGA 322704 (clothianidin) in the different environments are as follows:

| Matrices | Residues | LOQ |
|---|---|---|
| **Feedstuffs of plant origin** | Thiamethoxam and CGA 322704 | 0.02 mg/kg (cereals and dry goods) |
| **Feedstuffs of animal origin** | Thiamethoxam and CGA 322704 | 0.01 mg/kg (eggs, meat, liver and kidneys)<br>0.005 mg/kg (milk) |
| **Soil** | Thiamethoxam and CGA 322704 | 0.002 mg/kg |
| **Water** | Thiamethoxam and CGA 322704 | 0.05 µg/L (drinking water and groundwater)<br>0.5 µg/L (surface water) |
| **Air** | Thiamethoxam | 0.5 µg/m$^3$ |

**CONSIDERING THE TOXICOLOGICAL PROPERTIES**

The acceptable daily intake (ADI[3]) of thiamethoxam, set when listed in Annex I of Directive 91/414/EEC, is **0.026 mg/kg of b.w.[4]/day**. It was determined by applying a safety factor of 100 to the dose with no observed adverse effect obtained in an 18-month oral toxicity study in mice.

The acute reference dose (ARfD[5]) of thiamethoxam, set when listed in Annex I of Directive 91/414/EEC, is **0.5 mg/kg of b.w./day.** It was determined by applying a safety factor of 100 to the dose with no observed adverse effect, obtained in an oral toxicity study for development in rabbits.

Toxicity studies conducted with the insecticide produce the following results:
- $LD_{50}$[6] administered orally to rats over 3000 mg/kg of b.w.;
- $LD_{50}$ administered topically to rats over 4000 mg/kg of b.w.;
- Non eye irritant in rabbits;
- Non skin irritant in rabbits;
- Non skin sensitiser in Guinea pigs.

[3] The acceptable daily intake (ADI) of a chemical is an estimate of the amount of active substance in food or drinking water that can be ingested on a daily basis over a lifetime without appreciable health risk to the consumer, on the basis of all known facts at the time of evaluation. It is expressed in milligrams of chemical substance per kilogram of body weight (WHO, 1997).

[4] b.w.: body weight.

[5] ARfD: The acute reference dose (ARfD) is an estimate of the amount of substance in food or drinking water, expressed on a body weight basis, that can be ingested over a short period of time, usually during one meal or one day, without appreciable health risk to the consumer on the basis of all known facts at the time of evaluation. It is expressed in milligrams of chemical substance per kilogram of body weight (WHO, 1997).

[6] $LD_{50}$ (lethal dose) is a statistical value of a single oral dose of a substance/preparation required to kill 50% of a population of tested animals.

The classification of the insecticide, determined in view of these test results, of the classification of the active substance and of the formulants, as well as their content in the insecticide, is given at the end of the Opinion.

**CONSIDERING DATA ON OPERATOR, SOWER AND BYSTANDER EXPOSURE**

The acceptable operator exposure level (AOEL[7]) for thiamethoxam, set when listed in Annex I of Directive 91/414/EEC, **is 0.08 mg/kg of b.w./day**. It was determined by applying a safety factor of 100 to the dose with no observed adverse effect obtained in a 90-day oral toxicity study in dogs.

A skin absorption value of 0.5% for the non-diluted and diluted insecticide was used for the evaluation. This value is based on *in vivo* studies on rats and *in vitro* studies on human epidermis and rat epidermis conducted with Cruiser 350 insecticide.

Operator, worker (sower) and bystander exposure was estimated based on this skin absorption value.

***Estimate of operator exposure***

The systemic exposure of operators was assessed for thiamethoxam using the Seedtropex model, taking into consideration the following application conditions of Cruiser 350 insecticide :

| Use | Dose | Work time |
|---|---|---|
| Maize and Sorghum | 0.09 L f.p./U[8] (maize) and 0.9 L f.p./q (sorghum)<br>i.e. 315 g thiamethoxam/100 kg of seed | 7 hours/day for an operator weighing 70 kg |

The exposure estimated using this model, expressed as a percentage of the AOEL, is as follows:

| | **% of AOEL of thiamethoxam** |
|---|---|
| Without personal protective equipment (PPE) during all operations | 223% |
| Gloves worn during all operations except packing and breathing protection (minimum P2 level) worn during cleaning operations | **52%** |

These results show that operator exposure accounts for 52% of the AOEL for thiamethoxam when wearing gloves during all operations except packing, and breathing protection (minimum P2 level) during cleaning operations. Protective clothing is nevertheless recommended for all seed treatment operations.

The risks for the operator are considered to be acceptable under the above-defined protection conditions.

NB: personal protective equipment (PPE) must be adapted to the physico-chemical properties of the product used and to exposure conditions and, in order to guarantee efficacy, they must be used in conjunction with good hygiene practices (e.g. hand-washing, showering after treatment) and strict behaviour (e.g.: donning/doffing procedures). Cleaning and storage procedures for reusable PPE must comply with their user manual.

***Estimates of worker (sower) exposure***

The risk for workers (sowers) was assessed using the Seedtropex model, taking into consideration the amount of active substance absorbed by a man weighing 70 kg, sowing maize

[7] AOEL: (Acceptable Operator Exposure Level) is the maximum amount of active substance to which an operator can be exposed daily, with no dangerous effects on health.

[8] f.p./U: formulated product per unit of seed. In the case of maize: 1 U = 50,000 grains = 1 quintal based on a 1000-grain weight (TGW) of 200 g.

or sorghum seed for 10 hours per day without wearing personal protective equipment. The estimate for this exposure is 6.7% of the AOEL for thiamethoxam.

Moreover, the estimate of worker exposure to thiamethoxam was based on results obtained for maize seed treated with an imidacloprid-based insecticide. Total potential systemic exposures of sowers to thiamethoxam, at the 75$^{th}$ and 90$^{th}$ percentile, resulting from potential systemic contaminations by inhalation and through the skin, are estimated respectively at 12.6% of the AOEL and 21% of the AOEL.

Under the conditions of this study and taking into consideration that maize seed treated with Cruiser 350 insecticide generates a comparable amount of dust to seed treated with the imidacloprid-based insecticide (with similar seed-dressing qualities), worker exposure during the sowing of maize seed treated with thiamethoxam, extrapolated from data on imidacloprid, is considered to be acceptable.

The health risk for workers (sowers) is thus considered to be acceptable without them wearing personal protective equipment.

It should also be noted that in order to reduce dust emission during sowing and in accordance with the Ministerial Order of 13 January 2009[9], published in the Official Journal of 5 March 2009, a dust deflector must be fitted at the end of the seed drill nozzle for insecticide-treated maize seed.

***Estimate of bystander exposure***

Since operators are the only people authorised to enter the premises during seed treatment operations, the assessment of bystander exposure to Cruiser 350 insecticide during seed coating is not considered to be relevant.

**CONSIDERING DATA ON RESIDUES AND CONSUMER EXPOSURE**

The residue data presented for Cruiser 350 insecticide is based on maize data submitted for the inclusion of thiamethoxam in Annex I of Directive 91/414/EEC, supplemented by tests submitted with the application for the marketing authorisation of Cruiser 350 insecticide, as well as residue testing conducted in France.

**Definition of residue**

Metabolism studies in foliar treatment, soil treatment and seed treatment (particularly for maize), animal metabolism studies (dairy cows and laying hens), studies of plant product processing procedures and studies of residues in the following crops were carried out for the inclusion of thiamethoxam in Annex I.

These studies identified the residues such as thiamethoxam (sum of thiamethoxam and clothianidin expressed as thiamethoxam) in plants and in products of animal origin for monitoring, controlling and assessing risks for consumers.

**Residue testing**

Seventeen residue tests on maize were assessed for the inclusion of thiamethoxam in Annex I of Directive 91/414/EEC with the reference insecticide CRUISER 70WG (700 g/kg) in accordance with the intended good agricultural practices (GAP). These tests were supplemented by another 11 tests carried out with Cruiser 350 insecticide (seven in Northern Europe and four in Southern Europe) in accordance with the intended GAP. No withholding period was set on account of the method of seed treatment application.

The residue levels measured in these tests are always below the limit of quantification (LOQ) of 0.04 mg/kg (thiamethoxam equivalent) and confirm that the intended GAPs for maize are compatible with the European maximum residue level (MRL) of 0.05* mg/kg in force on 24 September 2009.

[9] Order of 13 January 2009 regarding conditions for seed coating and the use of seed treated with products cited in Article L. 253-1 of the French Rural Code with a view to limiting dust emission during plant processing.

The European guidelines entitled "*Comparability, extrapolation, group tolerances and data requirements*[10]" authorise the extrapolation of findings from maize to sorghum with regard to seed treatment. Consequently, the use on sorghum, following the same GAP to ensure compliance with the European MRL for sorghum of 0.05* mg/kg in force on 24 September 2009, is considered to be acceptable.

**Animal feeding studies**
Animal feeding studies led to defining MRLs in products of animal origin. The intended uses for Cruiser 350 insecticide do not change the theoretical maximum daily intake for farm animals. Consequently, no new animal feed studies are necessary.

**Crop rotations**
The results of crop rotation studies carried out for the inclusion of thiamethoxam in Annex I of Directive 91/414/EEC were used to define the residue, which includes metabolite CGA 322704. No additional studies are required.

**Effects of industrial processing and home preparations**
Due to the low level of residues in foods liable to be consumed by man, studies on the effects of industrial processing and home preparation on residue type and level are unnecessary.

**Assessment of risks for consumers**
Acute and chronic risks for consumers were assessed taking into consideration all of the MRLs in force on 24 September 2009. This assessment was made for thiamethoxam and metabolite CGA 322704.

The results of this assessment confirm that the acute and chronic risks for the consumer are acceptable.

**CONSIDERING DATA ON FATE AND BEHAVIOUR IN THE ENVIRONMENT**
In accordance with the requirements of Directive 91/414/EEC regarding Annex III, the data on fate and behaviour in the environment concern the active substance and its degradation products. With respect to thiamethoxam, the data below were generated as part of the European Community's assessment of this active substance. They correspond to the reference values used as input data for the models to estimate the expected exposure levels in the different compartments (soil, groundwater and surface water) following the use of Cruiser 350 insecticide for the intended purposes.

**Fate and behaviour in the soil**

***Degradation pathways in the soil***

Under aerobic controlled conditions, thiamethoxam degrades in the soil, generating mainly the metabolites CGA 322704 (36% of applied radioactivity (AR) after 90 days) and CGA 355190 (23% of AR after 180 days). After one year, 44% of AR is found as $CO_2$ and non-extractable residues account for 38% of AR.

Under anaerobic conditions, thiamethoxam mainly degrades to form the metabolites NOA 407475 (63% of AR after 180 days) and CGA 355190 (18% of AR after 90 days).

Photolysis has not been identified as a significant degradation pathway.

The metabolites NOA 459602 and SYN 501406 are not found in the studies on degradation in the soil, but are measured in lysimeter leachates. The risk of groundwater contamination thus needs to be assessed for these metabolites.

[10] Commission of the European Communities, Directorate General for Health and Consumer Protection, working document Doc. 7525/VI/95-rev.8.

***Dissipation rates and predicted environmental concentrations in the soil (PECsoil)***
Predicted environmental concentrations in the soil (PECsoil) were calculated according to recommendations made by the FOCUS group (1997)[11], based on the input parameters defined below.

- ***Thiamethoxam***
  The laboratory degradation rate of thiamethoxam in the soil ranges between 34 and 276 days ($DT_{50}$[12]lab). The field dissipation rate ranges between 7 and 172 days (median $DT_{50}$field of 36 days). The field dissipation studies carried out by spraying thiamethoxam and the studies conducted with treated seed show similar dissipation rates and kinetics for foliar application and seed treatment. All of the dissipation data were thus taken into account for the assessment, with no distinction made for the application method.

- ***Metabolite CGA 322704***
  The laboratory degradation rate of metabolite CGA 322704 ranges between 178 and 284 days. In terms of field dissipation, the $DT_{50}$ values used ranges between 22 and 228 days for five soils, with a standardised geometric mean of 95 days and a median of 112 days[13].

- ***Metabolites CGA 355190 and NOA 407475***
  The laboratory $DT_{50}$ considered to calculate the PECsoil for metabolites CGA 355190 and NOA 407475 are respectively 91.6 days (n=3) and 304 days (n=3).

The maximum PECsoil values calculated are as follows:
- Thiamethoxam : 0.092 $mg/kg_{soil}$
- Metabolite CGA 322704 : 0.028 $mg/kg_{soil}$
- Metabolite CGA 355190 : 0.018 $mg/kg_{soil}$
- metabolite NOA 407475 : 0.050 $mg/kg_{soil}$

***Persistence and risk of accumulation***
Field studies to assess accumulation and monitor the evolution of residues in the soil after the use of thiamethoxam were submitted. Thiamethoxam and metabolite CGA 322704 do not show any tendency to accumulate under good agricultural practice conditions that include ploughing.

**Transfer to groundwater**

***Adsorption and mobility***
Thiamethoxam and its metabolites CGA 322704, SYN 501406 and NOA 459602 are weakly adsorbed in the soil and are thus classified as highly to very highly mobile according to the McCall classification[14].

It should be noted that for thiamethoxam, the adsorption coefficients reported in the European conclusions are a mean of the Koc[15] and Kfoc[16]values. Since these parameters could not be averaged among themselves, only the Kfoc values combined with the corresponding 1/n[17] exponents were used to assess the risk of groundwater contamination.

***Predicted environmental concentrations in groundwater (PECgw)***
The risks of thiamethoxam and its metabolites transferring to groundwater were modelled for a set of agro-pedo-climatic scenarios representative of maize monoculture farming in France. These results had already been evaluated by Afssa in its Opinion of 13 June 2008[18].

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11 FOCUS (1997) Soil persistence models and EU registration, Doc. 7617/VI/96, 29.2.97.
12 $DT_{50}$: Time required for the degradation of 50% of the initial amount of the substance.
13 These two values are associated with kinetic formation fractions (ffM) ranging between 0.2 and 0.3.
14 McCall P.J., Laskowski D.A., Swann R.L., Dishburger H.J. (1981), Measurement of sorption coefficients of organic chemicals and their use in environmental fate analysis, In: Test protocols for environmental fate and movement of toxicants, Association of Official Analytical Chemists (AOAC), Arington, Va., USA.
15 Koc: organic carbon soil-solution distribution coefficient
16 Kfoc: organic carbon Freundlich distribution coefficient
17 1/n: exponent of the Freundlich equation
18 AFSSA Opinion on the conclusions of the assessment of the CRUISER insecticide concerning groundwater contamination risk, request no. 2007-SA-0393-4, of 13 June 2008.

The main representative regions of maize monoculture farming in France were identified[19]. Based on the 2001 AGRESTE survey[20], 90% of maize monoculture farming is concentrated in 10 regions. These ten regions are, by order of decreasing surface area, as follows: Aquitaine, Midi-Pyrénées, Rhône-Alpes, Pays de la Loire, Alsace, Brittany, Poitou-Charentes, Centre, Basse-Normandie and Burgundy.

For all these regions, adapted scenarios were used for modelling:
- For the Aquitaine, Midi-Pyrénées and Rhône-Alpes regions, existing maize monoculture farming scenarios were used.
- For the Brittany, Centre, Basse-Normandie and Burgundy regions, the scenarios that had led the authorities previously in charge of the assessment (June 2006)[21] to propose an SPe2[22] safety warning and which were used in the Afssa Opinion of November 2007[23], adapted for maize monoculture farming, were selected.
- For the Pays de la Loire and Poitou-Charentes regions, worst-case climate-soil scenarios for each region, adapted for maize monoculture farming, were used.
- For Alsace, different climate-soil combinations were used to create scenarios representative of maize monoculture farming.

Lastly, scenarios which had already been created for other regions, albeit not so representative of maize monoculture farming, were also proposed.

For each modelling exercise, the input parameters as set forth in the Afssa Opinion of 20 November 2007 were used. The values of these parameters are as follows:
- applied annual dose: 69.3 g a.s./ha (110 000 seeds/ha);-
- one application per year on 1 May, except for the Aquitaine region (on 20 April);
- for thiamethoxam: $DT_{50}$ = 36 days (20°C and pF2, median), Kfoc = 36.5 L/$kg_{oc}$ (median) and 1/n = 0.87;
- for metabolite CGA 322704: $DT_{50}$ = 126 days (20°C and pF2, average), Kfoc = 85 L/$kg_{oc}$, 1/n = 0.81 and ffM = 0.3;
- for metabolite NOA 459602: $DT_{50}$ = 19 days (20°C and pF2), Kfoc = 0 L/$kg_{oc}$, 1/n = 0.9 and ffM = 0.18;
- for metabolite SYN 501406: $DT_{50}$ = 24 days (20°C and pF2), Kfoc = 6 L/$kg_{oc}$, 1/n = 0.75 and ffM = 0.53 (from metabolite NOA 459602);

Simulations were performed using the PELMO model with scenarios adapted for the main maize monoculture farming regions in France.

Estimates of predicted environmental concentrations in groundwater do not exceed the 0.1 µg/L threshold for thiamethoxam. The highest value was obtained for the Brittany286 scenario, with 0.079 µg/L.

Estimated concentrations for metabolite CGA 322704 are below 0.1 µg/L, except for one result which exceeds the threshold. The value obtained, however, is only slightly over the threshold (0.1016 µg/L) and concerns the Haute-Normandie scenario. Maize monoculture farming in this region can be considered a minor practice accounting for less than 1% (14,894 ha) of maize monoculture farming in France (AGRESTE, 2001). Also worthy of note for this metabolite are the concentration values nearing 0.1 µg/L, more particularly for the Burgundy scenarios with 0.093 µg/L and Alsace298 with 0.075 µg/L.

For metabolite NOA 459602, predicted environmental concentrations in groundwater may exceed the 0.1 µg/L threshold, but nevertheless remain lower than 0.75 µg/L with a maximum

[19] Due to incomplete information on maize monoculture farming in France, the areas considered for this analysis were those for which two consecutive years of maize were recorded.

[20] AGRESTE, 2001 - La Statistique Agricole (SCEES) (French agricultural statistics) - Collection chiffres et données no.159 - Enquête sur les pratiques culturales en 2001 [Survey of crop practices in 2001].

[21] Report of the Toxicity Study Committee of Pesticide Products for Agricultural Use and Similar Products (CET ["Com Tox"]) – session of 14 June 2006.

[22] SPe2: To protect groundwater, do not apply this product on loamy soils with < 1.2% organic carbon in Aquitaine, Basse Normandie, Burgundy, Centre and Picardy.

[23] AFSSA Opinion on the marketing authorisation application for the thiamethoxam-based insecticide CRUISER, by Syngenta Agro SAS, as part of a mutual recognition procedure no. 2007-3845 of 20 November 2007.

value of 0.2272 µg/L for the Poitou-Charentes scenario. The relevance of this metabolite was assessed in line with the guidance document Sanco/221/2000[24], which led to it being given a 0.75 µg/L threshold in groundwater.

For metabolite SYN 501406, estimated concentrations only exceed the 0.1 µg/L threshold for the Poitou-Charentes scenario in which the value reached 0.1072 µg/L. They thus remain well below the 0.75 µg/L threshold. Within the framework of this request for an Opinion, the relevance of the metabolite was assessed in line with the guidance document Sanco/221/2000, which led to it being given a 0.75 µg/L threshold in groundwater.

Since the PECgw calculated for thiamethoxam and its metabolites were all below the regulatory values of 0.1 or 0.75 µg/L, the risks of groundwater contamination associated with the use of Cruiser 350 insecticide are considered to be acceptable for all of the intended uses.

However, since the modelling results obtained were sometimes rather close to the regulatory threshold for thiamethoxam and metabolite CGA 322704, monitoring of levels of thiamethoxam and metabolites CGA 322704, NOA 459602 and SYN 501406 in groundwater should continue for the areas in which seed has been treated with Cruiser 350 insecticide.

***Monitoring of thiamethoxam and its metabolites NOA459602, SYN501406 and CGA322704 in groundwater in France***

In response to the request for post-authorisation follow-up of the potential contamination of groundwater by thiamethoxam and its metabolites, the monitoring of wells was implemented by the applicant in 2008 and 2009.

The well selection method first identified maize-growing areas with a high likelihood of using seed treated with the CRUISER insecticide. The wells were then selected on the basis of operational (identification of the structure, verification of well use, sample-taking feasibility, etc.) and hydro geological (availability of studies, vulnerability, lack of exposure to surface water, etc.) criteria.

An initial 20 wells already being monitored as part of the post-authorisation follow-up of S-metolachlor were chosen. During the second phase another 15 were added for monitoring thiamethoxam. Samples were taken from these 35 wells from June to August and in October of 2008.

In 2009, the 15 wells were sampled, but of the wells monitored for S-metolachlor, only those for which the use of seed treated with the CRUISER insecticide had been recorded in 2008 were used (10 wells). A new well was included in the monitoring plan. Samples were thus taken from these 26 wells during four sampling programmes in 2009: at the end of January, mid-March, mid-June and the end of September.

Surveys of agricultural practices were conducted in 2008 and 2009 to determine the uses of seed treated with the CRUISER insecticide in each water catchment basin. The survey aimed to identify the maize fields in each catchment basin and, of these fields, those treated with the CRUISER insecticide in order to quantify the use of thiamethoxam within the basin.

The results of the two monitoring programmes conducted in 2008 and the three first programmes of 2009 are available. The results of the final campaign conducted in late September 2009 will be discussed in the final report to be published in November 2009.

- Treatment with CRUISER within proximity of a well was only confirmed for 20 of the 35 wells sampled in 2008.
- Treatment with CRUISER within proximity of a well was only confirmed for 19 of the 26 wells sampled in 2009.

Analysis results for the two monitoring programmes show that concentrations of thiamethoxam, as well as of its three metabolites NOA 459602, SYN 501406 and CGA

[24] Guidance document on the assessment of the relevance of metabolites in groundwater of substances regulated under Council Directive 91/414/EEC. Sanco/221/2000-rev4, 25 February 2003

322704, are below the limit of quantification for all of the analysed samples (limit of quantification of 0.05 µg/L for the four molecules).

The following is nevertheless worthy of note:

- the follow-up in 2009 of those wells monitored for S-metolachlor for which the use of seed treated with the CRUISER insecticide had not been recorded in 2008 should not have been ended. These wells in fact meet the monitoring selection criteria and there is no reason to exclude the possibility of the CRUISER insecticide being used in their catchment basin in 2009 and subsequent years;
- some selected wells have hydro geological characteristics that make them only slightly vulnerable. While this selection is generally representative of areas in which the CRUISER insecticide is used, the question nevertheless arises of its representativeness for assessing the risk of the most vulnerable areas. For example, the 66 m-deep well SMOC_57_01, in a confined aquifer, under a 30-m-thick surface layer of clay, is unlikely to be contaminated, at least in the short term (see Annex 2: summary table for a description of aquifers and their vulnerability);
- given the characteristics of thiamethoxam and its metabolites, in terms of persistence and mobility in the soil, it is in fact unlikely that the maximum potential contamination of groundwater will be observed so soon after the first uses of the product. It should also be noted that in the modelling, the maximum concentrations are only reached after several applications of the product. It is thus neither surprising nor contradictory, with respect to the results of the modelling, that no significant contamination of groundwater was observed during the initial programmes;
- in many situations, the treated surface areas accounted for a fairly low proportion of the catchment basin (Annex 3). In 2008, only three of the 35 wells sampled corresponded to a treated area accounting for more than 20% of the basin surface area (five wells were in areas accounting for more than 10%). In 2009, only one of the 26 wells sampled corresponds to a treated area representing more than 20% of the basin surface area (four wells were in areas accounting for more than 10%).

To conclude, these first measurement programmes appear as a first step in the follow-up of thiamethoxam use and its main metabolites in groundwater. More consolidated results are needed to draw definitive conclusions on this monitoring. The results currently available are not likely to cast doubt over the risk assessment's conclusions, namely the acceptable risk of using groundwater following applications of the maize seed-coating product.

**Fate and behaviour in surface water**

***Degradation pathways in water and/or water-sediment systems***

Thiamethoxam is stable in hydrolysis at pH 1.5 and 7. It hydrolyses at pH 9 ($DT_{50}$ = 7.3 at 15.6 days at 20°C, 4.2 at 8.4 days at 25°C and 0.75 days at 40°C) by forming three major metabolites: CGA 355190 (maximum 59.5% of AR after 30 days at 25°C), NOA 404617 (maximum 27.9% of AR after 30 days at 25°C) and CGA 309335 (9.1% of AR after 30 days at 25°C and 30% of AR at 40°C). Metabolite CGA 322704 is stable to hydrolysis.

Photolysis is a possible degradation pathway of thiamethoxam in water ($DT_{50}$ = 2.3 to 3.1 days in artificial light). The main metabolite observed is CGA 353042 (65.8% of AR after 30 days). In addition, volatile compounds, isocyanic acid and carbonyl sulphide (OCS) are formed (maximum 56.8% AR).

In water-sediment systems, thiamethoxam dissipates in water mainly by binding to sediment (maximum 36.6% of AR at 16 days). Metabolite NOA 407475 is observed at a maximum of 47.4% of AR after 42 days in sediment and remains at a high level. Mineralisation reaches 9.3% of AR at 100 days. Non-extractable residues account for up to 25.3% of AR in sediment.

Although it does not form in aquatic systems, the dissipation of metabolite CGA 322704 has also been studied in water-sediment systems. Metabolite CGA 322702 dissipates quickly in water and adsorbs on to sediment (maximum 36.6% of AR at 14 days). A major metabolite forms in sediment: CGA 421275 (maximum 47% of AR at 60 days). Non-extractable residues reach 49.6% of AR.

***Degradation/dissipation rates and predicted environmental concentrations in surface water (PECsw) and sediment (PECsed)***
Only the contamination of surface water by drainage is taken into account for a seed treatment product.

**Predicted environmental concentrations in surface water (PECsw)**
*PECsw calculated independently for thiamethoxam and metabolite CGA 322704:*
PECsw by drainage are calculated taking into consideration the following input parameters, and in particular:
- for thiamethoxam: $DT_{50}$water of 38.2 days (maximum for the water column in water-sediment systems, SFO kinetics)
- for metabolite CGA 322704: $DT_{50}$water of 5.4 days (maximum for the water column in water-sediment systems)
- drainage period beginning 1 December[25].

The maximum PECsw calculated are 0.401 µg/L for thiamethoxam and 0.038 µg/L for metabolite CGA 322704.

*PECsw calculated jointly for thiamethoxam and metabolite CGA 322704:*
The combined PECsw for thiamethoxam and metabolite CGA 322704 are also calculated using the following formulae:

PECsw (thiamethoxam + CGA 322704) = PECsw thiamethoxam + 7 x the PECsw of metabolite CGA 322704 (thiamethoxam equivalent)
PECsw (thiamethoxam + CGA 322704) = PECsw thiamethoxam + 7 x the PECsw of metabolite CGA 322704 (CGA 322704 equivalent)

The PECsw obtained are thus:
PECsw (thiamethoxam + CGA 322704) = 0.669 µg/L (thiamethoxam equivalent)
PECsw (thiamethoxam + CGA 322704) = 0.096 µg/L (CGA 322704 equivalent)

**Predicted environmental concentrations in sediments (PECsed)**
To calculate PECsed levels, the maximum percentages of thiamethoxam, CGA 322704 and their major metabolites found in the sediment were used:
- for thiamethoxam: 36.6% of the AR
- for the metabolite NOA 407475: 47.6% of the AR
- for the metabolite CGA 322704: 36.6% of the AR
- for the metabolite NOA 421275: 47.2% of the AR

The maximum PECsed levels calculated for drainage were 1.100 µg/kg for thiamethoxam, 0.105 µg/kg for the metabolite CGA 322704, 1.204 µg/kg for the metabolite NOA 407475 and 0.111 µg/kg for the metabolite NOA 421275.

**Behaviour in air**
There is no significant risk of thiamethoxam being transferred to the atmosphere.

**CONSIDERING THE ECOTOXICOLOGICAL DATA**
With treated seeds, exposure conditions for non-target organisms include exposure:
- to seeds (granivorous and omnivorous birds and mammals, soil organisms),
- to residues still found in the soil after harvest and during planting of the following crop (soil organisms),
- to residues that might be transferred to adjacent aquifers (aquatic organisms),
- to residues likely to migrate into the maize (herbivorous and omnivorous birds and mammals), in maize pollen, or in the various exudates of maize and following crops (bees),
- to seed dust, which may occur if this dust is dispersed on adjacent flowering crops or plants.

[25] Maize is sown by 15 May at the latest, or at least 200 days before the start of the drainage period.

The risk was assessed for the treatment of maize seed. The current application for marketing authorisation includes an extension of use for the treatment of sorghum seed. The use as a treatment for sorghum seed involves the same doses of active substance per quintal of seed and per hectare as for maize. The conclusions of the assessment of the product's use as a treatment for maize can be extrapolated for sorghum, with respect to direct exposure to seeds. However, neither the exposure of bees to residues in pollen, nor the exposure of non-target organisms to dust emissions during sowing depend on factors that can be extrapolated from one crop to the other.

The conclusions below therefore only relate to the use as a treatment for maize seed.

**Effects on birds**

***Acute, short-term and long term risks for granivorous and herbivorous birds***

The acute, short-term and long-term risks for granivorous and herbivorous birds were assessed according to the recommendations of the European Sanco/4145/2000 guidance document. To estimate these risks, the assessment was based on European-prescribed toxicological values for thiamethoxam use. These values are listed in the table below.

Note that in maize plants, the metabolite CGA 322704 is measured at concentrations lower than those of thiamethoxam. Furthermore, the data relating to its toxicity indicate a level of toxicity equivalent to that of its parent compound. Both elements indicate that the risk assessment conducted with thiamethoxam covers the risks associated with exposure of birds to the metabolite CGA 322704.

The toxicity/exposure ratios (TER[26]) for the active substance were calculated in accordance with Directive 91/414/EEC and compared to the threshold values proposed by Annex VI of Directive 91/414/EEC, respectively 10 for acute and short-term risks and 5 for long-term risks, for the product application rate and uses requested by the applicant.

| | Birds | Toxicity |
|---|---|---|
| Acute exposure | Herbivores | $LD_{50}$ = 200 mg/kg b.w. (acute toxicity study in grey partridges). |
| | Granivores | |
| Short-term exposure | Herbivores | $LD_{50}$ > 1175 mg/kg b.w./d (dietary toxicity study in mallard ducks). |
| | Granivores | |
| Long-term exposure | Herbivores | NOEL[27] = 34.9 mg/kg b.w./d (reproductive toxicity study in mallard ducks). |
| | Granivores | |

- ***Granivorous birds***

  Long-term exposure of granivorous birds is not considered as relevant for a seed treatment. The acute and short-term risks following consumption of treated seeds were assessed for various species of granivorous birds (starling, pigeon, and pheasant). This assessment was based on consumption of treated seeds and on appetence studies.

  The number of seeds needed to reach the $LD_{50}$ is estimated to be 31 for a starling and 317 for a pheasant[28]. This amount corresponds to a search area of 2.8 $m^2$ for a starling and 29 $m^2$ for a pheasant, if the seeds remain on the surface. However, as few seeds actually remain visible on the surface following precision seed-drilling, the probability of rapid ingestion of an amount of seed which might threaten their survival is considered to be low.

  Moreover, the results from the two submitted appetence studies show, for birds placed in a situation of choice, a significant preference for untreated seeds. The consumption of treated

[26] The TER is the ratio between the toxicological value ($LD_{50}$, $LC_{50}$, NOEL, lowest effective dose) and the estimated exposure, expressed with the same unit. This ratio is compared to a threshold defined in Annex VI of Directive 91/414/EEC, below which the safety margin is not considered to be sufficient for an acceptable risk.

[27] NOEL: No observed effect level

[28] Calculations revised by AFSSA with a thousand grain weight (TGW) of 200 g (200 mg/seed) used to convert the sowing density into a dose per hectare, i.e. 0.63 mg a.s./seed.

seeds by birds placed in a situation of no choice leads to neither mortality nor clinical symptoms. Lastly, as the maize seeds germinate, the exposure of granivorous birds is limited over time.

Consequently, based on this assessment the acute and short-term risks for granivorous birds are considered to be acceptable.

Nevertheless, this assessment does not cover the accidental exposure of birds in the event of there being piles of seeds spilled on to the plots by the seed drill, particularly at the end of the furrows. Therefore, to protect wild birds it is necessary to ensure that the treated seeds have been incorporated correctly in the soil, particularly at the end of the furrow.

- ***Herbivorous birds***
  As thiamethoxam has systemic properties, it may be found in plants growing in soil containing residues, as well as following seed treatment. A risk assessment was carried out for various herbivorous species (larks, partridges, geese) which investigated the consumption of young shoots grown from treated seed, the gizzard or stomach volume of the modelled species, as well as residue levels measured in seedlings grown from treated maize seeds and their dissipation over time as observed during field trials.

  As the short-term and long-term TERs calculated were all higher than the threshold values ($TER_{ST}$ > 22 and $TER_{LT}$ = 5.5 to 9.7 depending on the birds), the short-term and long-term risks are therefore considered to be acceptable.

  Conversely, the acute TERs calculated were lower than the threshold value of 10 ($TER_a$ = 3.8 to 6.5). However, as this assessment was based on the fact that a bird had to eat the equivalent of 3.5 times its weight in contaminated food in just a few hours, this scenario was regarded as improbable. The short-term exposure is therefore considered to be more representative than the acute exposure.

The risks for birds associated with the use of Cruiser 350 insecticide are therefore considered to be acceptable. In order to protect wild birds, it is however necessary to bury the treated seeds in the soil and to ensure that they are fully incorporated at the end of the furrow.

**Effects on mammals**

The assessment of acute, short-term and long-term risks for granivorous and herbivorous mammals was carried out in accordance with the recommendations of the European Sanco/4145/2000 guidance document. To estimate the risks, the assessment was based on European-prescribed toxicological values for thiamethoxam. These values are listed in the table below.

The TERs for the active substance were calculated in accordance with Directive 91/414/EEC and compared to the threshold values proposed by Annex VI of Directive 91/414/EEC, respectively 10 for acute and short-term risks and 5 for long-term risk, for the product dose and uses recommended.

| | Mammals | Toxicity |
|---|---|---|
| Acute exposure | Herbivores | $LD_{50}$ = 783 mg/kg b.w. (acute toxicity study in mice) |
| | Granivores | |
| Short-term exposure | Herbivores | $LD_{50}$ > 711 mg/kg b.w./d (dietary toxicity study in rats) and $LD_{50}$ > 1163 mg/kg b.w./d (dietary toxicity study in mice)[29] |
| | Granivores | |
| Long-term exposure | Herbivores | NOEL = 115 mg/kg b.w./d and NOAEL[30] = 46 mg/kg b.w./d (chronic toxicity study in rats) |
| | Granivores | |

[29] These values are doses without mortality derived from short-term toxicity studies in rats and mice.
[30] NOAEL: No observed adverse effect level.

- ***Granivorous mammals***
  Long-term exposure of granivorous mammals is not considered relevant for a seed treatment. The acute and short-term risks following consumption of treated seeds were assessed for the wood mouse (granivorous mammals). This assessment was based on consumption of treated seeds.

  The number of seeds needed to reach the $LD_{50}$ is estimated to be 31, which corresponds to a search area of 2.8 $m^2$ if the seeds remain on the surface. However, as few seeds actually remain visible on the surface following precision seed-drilling, the probability of rapid ingestion of a quantity of seed which might threaten its survival is considered to be low.

  Based on this assessment the short-term risks for granivorous mammals are considered to be acceptable, since although the TERs are lower than the threshold value of 10 ($TER_{ST}$ = 4 to 6.5), they were calculated with respect to a NOEL on mortality and the safety margin is thus considered to be sufficient.

  Based on this assessment, the acute and short-term risks for granivorous mammals are acceptable.

  Nevertheless, this assessment does not cover the accidental exposure of mammals in the event of there being piles of seeds spilled onto the plots by the seed drill, particularly at the end of the furrows. Therefore, to protect mammals it is necessary to ensure that the treated seeds have been incorporated correctly in the soil, particularly at the end of the furrow.

- ***Herbivorous mammals***
  As thiamethoxam has systemic properties, it may be found in plants growing in soil containing residues, as well as following seed treatment. A risk assessment was carried out for various herbivorous species (voles and hares) which looked at the consumption of young shoots grown from treated seed, the alimentary bolus of the modelled species, as well as the residue levels measured in seedlings grown from treated maize seeds and their dissipation over time as observed during field trials.

  As the TERs calculated were all higher than the threshold values proposed by Annex VI of Directive 91/414/EEC ($TER_{ST}$ > 16 and $TER_{LT}$ = 10 to 50), the short-term and long-term risks are therefore considered to be acceptable.

  Conversely, the acute TERs calculated for voles were lower than the threshold value of 10 ($TER_a$ = 8.2). However, as this TER was calculated by taking into account the exclusive exposure of a small herbivorous mammal to the treated food, the safety margin is considered to be sufficient. Consequently, the acute risk is acceptable for herbivorous mammals.

The risks for mammals associated with the use of Cruiser 350 insecticide are considered to be acceptable. In order to protect mammals, it is however necessary to ensure that the treated seeds are fully incorporated in the soil, particularly at the end of the furrow.

**Effects on aquatic organisms**
The risk for aquatic organisms was assessed in accordance with the recommendations of the European Sanco/4145/2000 guidance document, based on the European data available on the active substance and its metabolites (CGA 322704, CGA 355190, NOA 407475, NOA 459602, SYN 501406, CGA 353042). These data were supplemented by a comparative study of the toxicity of thiamethoxam and the metabolite CGA 322704 to five aquatic invertebrates. In addition, the toxicity of Cruiser 350 insecticide was investigated in ecotoxicity studies for species representative of the three main trophic groups in aquatic ecosystems (trout, *Daphnia* and green algae). However, as these tests had not been carried out on the species that were most sensitive to thiamethoxam, they were not taken into account for the classification of the product.

Thiamethoxam is not toxic to fish ($LC_{50}$[31] > 100 mg/L), daphnia ($EC_{50}$[32] > 100 mg/L), algae or aquatic plants ($EC_{50}$ > 81.8 mg/L). It has a low bioaccumulation potential. As aquatic invertebrates are *a priori* the organisms which are the most sensitive to insecticides, data were provided for eight crustaceans, three molluscs, seven insects and six representatives of other groups. Thiamethoxam's toxicity to aquatic invertebrates varies according to the organism from 0.014 mg/L (*Cloeon dipterum*, insect) to more than 100 mg/L (*Daphnia magna*). Chronic toxicity is high in midge (*Chironomus riparius*), representative of sedimentary organisms (NOEC[33] = 0.010 mg/L or 0.10 mg/kg sediment according to two independent studies). The PNEC[34] for thiamethoxam of 1 µg/L was derived from the NOEC in midge, which are the most sensitive species, weighted by a safety factor of 10 for chronic toxicity, in accordance with Directive 91/414/EEC.

Data are available for the metabolite CGA 322704 and for representatives of the three main trophic groups. Like its parent compound, CGA 322704 has higher toxicity for aquatic invertebrates. Its acute toxicity varies from 0.007 mg/L (*Dysticidae*, insect) to more than 100 mg/L (*Daphnia magna*). Its toxicity for aquatic invertebrates is 3.7 to 6.7 times greater than that of the parent compound. Based on this, the metabolite CGA 322704 was considered during the risk assessment to be seven times more toxic than the parent compound. The most sensitive species was, as in the case of the parent compound, the midge (NOEC = 0.00067 mg/L or NOEC = 0.011 mg/kg sediment according to two independent studies). The PNEC for CGA 322704 of 0.066 µg/L was derived from the mean NOEC in midge for the metabolite CGA 322704 and clothianidin[35] weighted by a safety factor of 10 for chronic toxicity, as recommended by Directive 91/414/EEC.

Lastly, a cosm study is available. This study, which was carried out in England, aimed to assess the effects of an application of the Actara 25 WG[36] insecticide on aquatic systems at various concentrations. This study enabled an $NOEC_{community}$ of 0.030 mg of thiamethoxam/L to be calculated, based mainly on the significant effects observed on the emergence of insects in the *Chironomidae* family at a concentration of 0.1 mg thiamethoxam/L. This additional study, submitted as part of the application for inclusion of thiamethoxam in Annex I, did not undergo detailed assessment at the European level as it was not considered to be essential to the inclusion decision. Nevertheless, it enabled the effects of exposure of aquatic organisms to the active substance to be taken into account. It should be noted that it does not cover the effects of exposure to CGA 322704, due to the probable absence of the latter in cosms (as CGA 322704 was not expected to form from the parent compound by hydrolysis, photolysis or metabolisation). However, as the latter may be found in water following transfer by drainage, a dedicated risk assessment was carried out, based on the PNEC defined above.

The risk assessment was therefore based on the PNECs of the active substance and its metabolite (1 µg thiamethoxam/L and 0.066 µg CGA 322704/L) and according to the recommendations of the Sanco/3268/2001 document.

Due to the use of the product as a seed coating, the risk assessment for aquatic organisms took into account the transfer of thiamethoxam and the metabolite CGA 322704 to surface waters through drainage. Both compounds have very similar ecotoxicological profiles, their simultaneous presence in surface waters, following drainage from the soil, was also taken into account.

Comparing the PECsw for thiamethoxam and CGA 322704 with their respective PNECs leads to the conclusion that the risks related to drainage are acceptable for aquatic organisms. Consequently, the risks for aquatic organisms associated with the use of Cruiser 350 insecticide are considered to be acceptable.

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31 $LC_{50}$: concentration leading to a 50% mortality rate.
32 $EC_{50}$: concentration having 50% of effect (compared with control).
33 NOEC: No observed effect concentration.
34 PNEC: Predicted no effect concentration.
35 Identical compound supported by another notifier; a common PNEC was defined based on the two NOECs of chronic toxicity obtained under laboratory conditions.
36 250 g thiamethoxam/kg

**Effects on bees**

***Exposure conditions to thiamethoxam residues***

Thiamethoxam has systemic properties and can therefore migrate into plants and be found in pollen and/or nectar. In the plant it is hydrolysed to CGA 322704. The transfer of thiamethoxam and CGA 322704 to the hive cannot therefore be excluded and the risks for bees in the hive (particularly larvae, nurse bees, winter bees) were therefore assessed.

In addition, this metabolite may persist in the soil and be used by following crops. The risk assessment carried out therefore took into account the potential presence of melliferous and nectariferous crops in the rotation cycle.

The submitted application includes tests carried out on adult bees and larvae in the laboratory, tunnel tests and open field trials, which enabled the effects on bees of the substance and its residues to be assessed, as well as the expected exposure levels following use as a seed treatment in maize.

***Laboratory tests***

The laboratory data indicate that thiamethoxam and the metabolite CGA 322704 are highly toxic to adult bees (the $LD_{50}$ by oral route and by contact is respectively 0.005 and 0.024 µg/bee for thiamethoxam and 0.0168 and 0.0275 µg/bee for CGA 322704).

The toxicity of thiamethoxam and CGA 322704 by repeated administration for 10 days in adult bees was also determined. An NOEC of 10 µg/kg of food (i.e. an NOEL of 2 ng/bee for each substance) was determined for survival.

Two additional studies assessing the effects in the laboratory on the behaviour of foraging bees and hive bees led to NOECs of 100 µg/kg of food[37] for exchange of food (trophallaxis) and 25 µg/kg of food[38] for return to the hive being defined.

Lastly, thiamethoxam's toxicity for larval development was estimated using a laboratory test developed by INRA[39] which is currently being validated. The results of several repetitions were subjected to statistical analysis. The no observed effect concentration (NOEC) on larval development is estimated to be 12.5 µg thiamethoxam/kg of food.

***Quantification of exposure through tunnel tests***

The results of tunnel trials involving maize, sunflower and oilseed rape crops grown from treated seeds, are available. The tests were carried out to estimate the exposure of bees through the quantification of residues in matrices of interest for bees, as well as in hive products sampled from exposed colonies. The maximum concentrations of thiamethoxam measured in pollen from spring oilseed rape and sunflower (pollens sampled from foraging bees), and maize (pollens sampled from the plants) were respectively 3.6-4.2 µg/kg, 3.2 µg/kg and 3 µg/kg for seeds treated at the dose requested by the applicant. In this pollen, concentrations of the metabolite CGA 322704 were less than 1 µg/kg (LOQ) for oilseed rape and sunflower and 3 µg/kg for maize. Residue analyses of thiamethoxam and CGA 322704 in different samples (nectar, pollen, honey from the hive and nectar from the stomach of the foraging bees) collected during the trials showed levels lower or equal to the limit of quantification of 1 µg/kg.

Other tunnel trials have exposed colonies to crops grown from treated maize seeds drilled for two successive years on the same plots (85 to 90 g a.s./ha). Results of analyses indicate mean concentrations for thiamethoxam[40] of 4.81 µg/kg in 2005 (77 analyses) and 2.09 µg/kg in 2006 (53 analyses) in maize pollens gathered by bees. The mean concentrations for CGA 322704[41] were 2.65 µg/kg in 2005 (77 analyses) and 1.37 µg/kg in 2006 (53 analyses). The mean concentrations obtained from both years of 3.45 µg of thiamethoxam/kg and 2.01 µg of CGA

[37] corresponds to an NOEL of 5 ng thiamethoxam/bee; likewise for the CGA 322704 metabolite, the NOEC of 100 µg/kg corresponds to an NOEL of 2.8 ng CGA 322704/bee.

[38] corresponds to an NOEL of 3 ng thiamethoxam/bee; likewise for the CGA 322704 metabolite, the NOEC of 25 µg/kg corresponds to an NOEL of 0.8 ng CGA 322704/bee.

[39] The French national institute for agricultural research, www.inra.fr

[40] LOQ of 1 µg thiamethoxam/kg in pollen.

[41] LOQ of 1 µg CGA 322704/kg in pollen.

322704/kg (106 analyses for each substance) were used in the risk assessment for nurse bees and larvae[42].

In pollen sampled from the hive frames, concentrations of thiamethoxam and CGA 322704 were low, even lower than the limit of quantification (< 1 to 2 µg a.s./kg for the parent and < 1 to 3 µg/kg for the metabolite). The measured concentrations were no higher in 2006 than in 2005, i.e. following a second year of use of treated seeds on the same plots.

The results from trials using rotations of treated crops are also available (three studies, plus three studies without crop rotation to allow for comparison). Residues were analysed in different matrices sampled from winter rape and from exposed bees and colonies. Two crop scenarios were established (winter oilseed rape treated alone and treated spring barley followed by treated winter oilseed rape) at three sites. In the nectar sampled by the bees, thiamethoxam was measured at 1.85 µg/kg for the scenario with oilseed rape alone and 1.7 µg/kg for the barley/oilseed rape scenario[43], with the metabolite CGA 322704 remaining below the limit of quantification[44]. Thiamethoxam residue levels in pollen were similar or below the levels measured in nectar sampled by the bees. In nectar collected from the hives, thiamethoxam was higher than the limit of quantification at only one site (0.7 µg/kg for both crop scenarios) and the metabolite was always lower than the limit of quantification. Thiamethoxam and its metabolite were lower than the limit of quantification in honey and wax[45], and in royal jelly. Concentrations in the soil at the time of sowing winter oilseed rape following spring sowing of treated barley were measured at 0.0035 mg of thiamethoxam/kg in soil and 0.002 mg of CGA 322704/kg in soil[46]. These results showed that residues in pollen from treated winter oilseed rape following treated spring barley are low and less than the levels assessed with maize pollen.

***Risk assessment***

The Hazard Quotient (HQ), which compare the applied rate of product to $LD_{50}$ values measured during acute toxicity tests, were developed for products applied by spraying and are therefore not appropriate for products used to treat soil or seeds[47]. For products proposed as seed treatments, Directive 91/414/EEC stipulates that the risk assessment for bees should take into account concentrations measured in pollen and/or nectar, as measured during residue studies.

The above-mentioned data on residues measured in pollen were used to estimate the dose ingested by nurse bees, assuming consumption of 65 mg of pollen over 10 days, of which 80% was maize pollen[48]. The NOELs used came from toxicity studies carried out over 10 days and were 2 ng/bee for 10 days for thiamethoxam and its metabolite CGA 322704[49]. As these NOELs were measured over periods of 10 days, they were compared with exposure levels estimated from mean concentrations in pollen, to avoid overestimating exposure through the inclusion of occasional peaks. Since the mean estimated exposure levels (0.179 ng/bee for the parent and 0.105 ng/bee for the metabolite) were lower than the NOELs, the risk associated with exposure of nurse bees is considered to be acceptable. The risk for other categories of bees is also considered to be acceptable since they consume less pollen than nurse bees.

The risk for larvae was estimated by comparing mean concentrations found in pollens sampled from foraging bees (3.45 µg of thiamethoxam/kg and 2.01 µg of CGA 322704/kg) to the NOEC of 12.5 µg of thiamethoxam/kg. This comparison indicates an acceptable risk. It should be noted that lower concentrations in residues, even lower than the limit of quantification, were observed in pollen collected from hives, due to the bee pollens likely to contain residues being diluted in the stock of gathered pollen.

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42 The mean concentrations were used in the risk assessment for the nurse bees to avoid overestimating exposure through the inclusion of occasional peaks.

43 LOQ of 0.5 µg of thiamethoxam/kg in nectar, honey, royal jelly, wax.

44 LOQ of 1 µg of CGA 322704/kg in nectar, honey, royal jelly, wax.

45 Two detections in two tunnels and in a single sub-sample each time (mean 0.75 µg of thiamethoxam/kg)

46 Concentration in soil 0-30 cm thick.

47 Sanco/10329/2002 document, Rev 2 (Final), Chapter 4.

48 An approach in accordance with the proposals of the working group on “the assessment of systemic compounds used through soil/seed treatments” of the ICPBR (International Commission on Plant Bee Relationships).

49 The NOEL for clothianidin is 0.0029 µg/bee/10d.

***Assessment of effects via tunnel and field trials***
Tunnel and field trials complying with EPPO[50] guidelines and involving rape and sunflower crops grown from treated seeds are available. These tests did not indicate that exposure to these crops had any significant effect on bee survival, foraging activity, population development, larval development or behaviour.

As well as these tests, the applicant submitted open field studies with multi-year monitoring of hives exposed to maize pollen.

These trials, which were carried out in three French regions (Alsace, Lorraine, Aveyron), began in 2006. Conducted in order to assess the long-term effects of annual exposure to maize pollen from seeds treated with a product containing thiamethoxam, they have been extended to 2009-2010 and in this final year will enable hives to be exposed to extended flowering period through staggered sowing. The reports provided summarise the results obtained until spring 2009 thus covering three years of exposure during the maize flowering period (summers of 2006, 2007 and 2008) and three overwintering periods. The results of prolonged exposure to staggered flowerings, as well as the overwintering period following this exposure, will be provided in 2010.

In these trials, the same colonies were maintained on the same experimental plots during the maize flowering period for three successive years (exposure in 2006, 2007 and 2008). When the maize crop began flowering (BBCH 59-61), six colonies were installed next to each treated plot (one treated plot per site) and six others next to each control plot (one control plot per site). When the maize had finished flowering (BBCH 69), the colonies were relocated at a maintenance site selected to minimise additional exposure to other pesticides. With this experimental design, the short-term assessment of the impact of exposure was complemented by monitoring of colony health for the remainder of the foraging season, and the colonies' success at recovering from overwintering period can be assessed the following spring.

The health of the bee colonies (in terms of general health and disease) and the development of broods were recorded during exposure and at regular intervals afterwards. The observations focused on mortality, foraging activity, colony population (estimated number of adult worker bees), the presence of healthy eggs laid by the queen, verified by the presence of freshly laid eggs (less than one day old), estimated surface area containing eggs, larvae and capped cells (as a % of the total surface area), estimated area of pollen and nectar stores (as a % of the total surface area), weight of the colony and signs of bee diseases.

Samples from plants, pollen from plants, pollen gathered by bees and stomach nectar were obtained in order to analyse for thiamethoxam and CGA 322704. The pollen collected was subject to palynological analysis.

In the three open field trials, no effects on foraging activity on male maize flowers were observed. The palynological analyses indicated great variation in the proportion of maize pollen from one sample to another and from one hive to another (from 0 to 100%). These results indicate that even in the absence of flowering crops in the vicinity of the trials, the yield of maize pollen varies greatly.

Residue analyses indicated the presence of residues in samples of plants and pollen collected during the period the bees were exposed, with concentrations on the same scale as those measured in samples collected during residue trials in tunnels.

The available results indicate the absence of excess mortality or unexplained mortality, the absence of anomalies in bee behaviour, development in adult and larval populations and weight changes in hives consistent with good health, and good recovery in colony development in the spring. The specific observations made at each trial did not indicate any apparent link with exposure to maize pollen from treated seeds, but rather a more likely link with technical beekeeping activities, health or environmental factors. In particular, nosemosis (nosema), varroatosis and American foulbrood were found in several hives.

[50] EPPO: European and Mediterranean Plant Protection Organization.

To conclude, these field tests carried out in three different regions indicate that exposure of colonies during the maize flowering period (5 to 8 days) and three successive programmes carried out on the same plots did not have any significant effect on colony survival and development, with this impact being monitored over an observation period covering three overwintering periods.

The 5- to 8-day exposure periods of colonies – depending on campaign and region – were probably not representative of a extended flowering period in the event of phased sowing dates in the same region. These exposure periods are relevant for maize seed or silage sown before 15 May and for female strains of seed-plant maize regardless of the sowing date. Early sowing can indeed reduce variability in the duration of the flowering period and thence the duration of bee exposure to around a week (5 to 8 days).

Based on the available study results and conclusions relating to exposure durations, Afssa therefore recommends:
- keeping a distance of 3 km between hives and plots sown with maize treated with Cruiser 350 insecticide for male seed-plant maize, due to the absence of representative exposure data. This precaution is unnecessary for maize seed and silage and for female seed-plant maize if the sowing period is restricted according to the methods defined in the following point;
- restricting the sowing period for maize seed and silage and for female seed-plant maize treated with Cruiser 350 insecticide to a period ending on 15 May;
- prolonging and concluding the long-term trials already underway.

Afssa recommends that the following warning be added to the product label:
SPe8: Dangerous to bees. Do not introduce plants that may attract bees in the crop rotation, or **else** apply measures that may limit bee exposure (for example cutting before flowering)[51]. With the male seed-plant maize, during the flowering period, keep hives at a distance of more than 3 km from crops grown from treated seeds.

***Potential exposure to seed dust***
Seed dust deposits were measured at various distances from the seed row in field trials involving treated maize seed. One trial carried out in 2006 showed that the maximum exposure to thiamethoxam residues through seed dust (0.37 g a.s./ha, or 0.54% of the field rate, value deduced from the mean of maximum values measured at 5 metres from the sown plot) remained lower than the NOAEL of 1 g of thiamethoxam per hectare[52].

Two additional trials carried out in 2007 and 2008 were submitted and taken into account for this assessment, in addition to the test results already available. These trials were carried out with seeds treated with the product, with the addition of a coating agent. As previously, sowing was carried out under dry, low-wind conditions (forces 1 to 3 on the Beaufort scale) with a pneumatic drilling machine. The drilling machine either did or did not have a deflector installed.

These tests show that the maximum exposure to thiamethoxam residues via dust from seed-drillingseed-drilling operations, as calculated from the mean maximum values measured at a distance from the fields sown, is lower than the NOAEL of 1 g of thiamethoxam per hectare:
- exposure of up to 0.56 g a.s./ha, measured without deflector, in the first trial (0.81 % of the field rate)
- exposure of up to 0.74 g as/ha, measured without deflector, in the second trial (1.07 % of the field rate).

Installing a deflector on the drilling machine, to prevent dispersal of dust and send it back towards the line of drilling, reduces dust emissions by about 90 % compared to traditional drilling.

These trials therefore show that the level of exposure expected after possible emission of dust from seed at drilling is lower than the NOAEL for bees (1 g/thiamethoxam per hectare).

[51] For more information, see the AFSSA opinion in response to the request for an opinion on compliance with a management measure recommended for the CRUISER insecticide, dated 25 January 2008.
[52] NOAEL estimated for one application, on flowering phacelia, of a granular dispersible product containing thiamethoxam

Nonetheless, the tests show that the use of an additional coating agent (Secure™ was used in the case of these tests) has a significant influence on the quantities of dust emitted and dispersed.

Consequently, the risk for bees related to possible emission of dust from drill-sowing operations can be considered to be acceptable, but any changes to the nature or conditions of seed-coating could modify the degree of exposure and ought to be evaluated beforehand.

In compliance with Afssa's Opinion of 5 May 2009 (2009-SA-0116), we hereby repeat the two recommendations for ensuring that treated seed is used under safe conditions:
- that manufacturers carry out tests to verify the efficiency of anti-drift equipment designed to guide dust generated by the drill back towards the ground;
- that the efficiency of this type of equipment for guiding dust from seed back towards the ground be verified under windy conditions (between 20 and 30 km/h), or that supplementary precautions be implemented such as restricting seed-drilling to light wind conditions.

***Possible exposure to guttation droplets***

Lastly, a trial was carried out under field conditions in 2009 to evaluate risk related to the formation of guttation droplets on young plants of treated maize for bee colonies placed on the edge of fields (at 5 to 10 metres). During the period when guttation droplets can form, about 37 days[53], very few bees were observed flying over the fields and no bees were seen collecting transpiration droplets. No significant mortality was observed in the hives nor any difference in the strength of the colonies and the surface area occupied by reserves and larval stages of brood. An analysis of the probable contribution of these guttation droplets to the exposure of the bees was dealt with in an Afssa Opinion issued on 30 April 2009 (No. 2009-SA-0656-exudate from maize).

***Results of the 2008 and 2009[54] monitoring campaign***

The purpose of the monitoring campaign implemented in 2008 and 2009 was to evaluate the unintended effects of thiamethoxam on pollinators, particularly honey bees, related to the use of Cruiser, which is thiamethoxam-based, when applied as a seed treatment. It was deployed for three regions in 2008 and was extended to six in 2009, so as to make it more representative of national conditions. The inclusion of observations of fauna and flora in addition to monitoring the effects on apiaries gives the campaign the status of a surveillance plan to determine how growing/agronomic practices for particular crops have been affected.

The results currently available led to the following observations:
- the available data suggest that precautions concerning weather conditions on seed-drilling days and installing equipment to reduce dust dispersal can significantly reduce the exposure of bees during seed-drilling operations;
- results are currently available for two of the six regions involved in the 2009 monitoring campaign, the Aquitaine region and the Centre region, and cover the seed-drilling phase. Bearing in mind the conditions under which the monitoring was implemented, described above, the data concerning the health status of the bee colonies does not reveal any losses of colonies attributable to seed-drilling of maize crops using seed treated with the CRUISER insecticide.

These conclusions are based on the preliminary reports supplied and will need to be consolidated in the light of all the monitoring data once they become available.

From the data received so far, Afssa considers that the conclusions and recommendations issued in the previous Opinion[55] need not be called in question.

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53 This time window corresponds to the period during which it was possible to observe drops as they were exuded, and not the time during which drops were present on the plants

54 AFSSA issued an Opinion on the analysis of these results dated 1st December 2009 (Opinion No. 2009-0253 relative to the results of the monitoring campaign for the marketing authorisation for Cruiser).

55 Opinion of 20 December 2007 on the conclusions of the assessment of Cruiser concerning the long-term risk for bee colonies.

**Effects on arthropods other than bees**

The risks to arthropods other than bees were assessed in accordance with the recommendations of the Sanco/10329/2002 guidance document; based on: toxicity data from standard laboratory studies for the indicator species *Aphidius rhopalosiphi*, *Typhlodromus pyri*, *Poecilus cupreus* and *Aleochara bilineata*; toxicity data from studies of *Poecilus cupreus* on natural substrate; data from semi-field tests on *Poecilus cupreus* and *Aleochara bilineata*; and data from field studies, carried out with Cruiser 350 insecticide or substances considered to be similar for this evaluation.

***Standard risk assessment***

The results of the laboratory tests carried out on standard species show that thiamethoxam is highly toxic for non-target arthropods. Indeed, a 90 to 100 % mortality was observed for *Typhlodromus pyri* and *Aphidius rhopalosiphi* (by spraying) and for two arthropods living in the soil (*Poecilus cupreus* and *Aleochara bilineata*) when exposed to treated seed. In enclosures placed in fields sown with treated wheat, there was also a significant reduction in parasitism by *Aleochara bilineata*, whereas the impact on the survival and predatory capacities of *Poecilus cupreus* was considered to be acceptable.

***Refined risk assessment***

Four field studies were carried out concerning the effects on non-target arthropods of coating barley, wheat, rape or maize seed with different formulations containing thiamethoxam. The four studies gave concordant results even though they involved four different formulations used on four distinct crops.

Treating seed with thiamethoxam leads to a reduction in the abundance of plant-eating species and certain non-target arthropods. Few auxiliary species are affected and, in most cases, the effects are transitory and the populations return to comparable levels to those of control areas before the end of the experiments (in about 110 days). Taxonomic diversity was not affected in the course of these studies. Multivariable analysis of the results of the four studies shows that changes within arthropod communities is mostly controlled by changes in the abundance of the Sminthurides family (Collembola). Taxonomic identification of several samples of this family showed that *Bourtellia* and *Sminthurus*, the members found most commonly in these tests, are in fact plant-eating species that can therefore be considered as crop pests. The disappearance of these insects from the fields studied could therefore have led indirectly to a reduction in the abundance of certain secondary consumer arthropods (predators such as syrphids and ladybirds) because of the decrease in available prey.

The results obtained from one of the field tests indicate that the populations of collembola were still significantly low 102 days after treatment with thiamethoxam (treated barley seed), meaning that the populations would have only partially recovered from the effects of the treatment at the onset of normal seasonal decline.

For this reason, because of the action of thiamethoxam and its metabolite CGA 322704, the considerable sensitivity of collembola (see the section on macro-organisms in the soil) and of the only partial restoration of population levels by the end of the crop cycle, and in order to allow sensitive populations of useful macro-organisms to recover from the effects of treatment with Cruiser 350 insecticide, Afssa recommends that no treatment should be applied with any other product containing thiamethoxam or clothianidin within a year after applying Cruiser 350.

The risks for arthropods other than bees, related to the use of Cruiser 350 insecticide, are therefore considered to be acceptable, on condition that no other product containing thiamethoxam or clothianidin be used less than a year after the application of Cruiser 350 insecticide.

**Effects on earthworms and other non-target soil macro-organisms**

The risk to soil macro-organisms from the use of Cruiser 350 insecticide was assessed based on the data from the European records on thiamethoxam and in accordance with the recommendations in the Sanco/10320/2002 guidance document. Supplementary studies are available that describe the acute toxicity of the metabolite NOA 459602 for *Eisenia foetida*, the toxicity of the metabolite CGA 322704, the effects of barley seed treated with Cruiser 350

insecticide on the reproduction of *Eisenia foetida*, the toxicity of thiamethoxam and the metabolite CGA 322704 on the reproduction of *Folsomia candida* and, lastly, the effects of thiamethoxam and the metabolite CGA 322704 on the decomposition of organic matter.

The acute toxicity of thiamethoxam and the metabolites NOA 407475, CGA 355190 and NOA 459602 is low for earthworms. In contrast, the chronic toxicity of thiamethoxam is high for earthworms and collembola. The metabolite CGA 322704 has both acute and chronic toxicity greater than that of its parent compound for earthworms and chronic toxicity greater than that of its parent compound for collembola.

A comparison of these data with the estimated concentrations of residues in the soil leads to the conclusion that acute risks are acceptable for earthworms exposed to thiamethoxam and its metabolites and that chronic risks resulting from exposure to thiamethoxam are also acceptable. In contrast, a long-term risk has been identified for collembola and earthworms exposed to the metabolite CGA 322704 (TER < 5).

The risk for collembola in the field has been examined in studies carried out to evaluate the effects of thiamethoxam from treated seed on populations of non-target arthropods (see the corresponding section).

The effects on earthworm populations of spraying with thiamethoxam or the metabolite CGA 322704 were followed up in two field studies. The studies did not reveal any significant effects after an application of thiamethoxam in a recently-cut hay field (200 g a.s./ha), or after multiple applications of CGA 322704 on bare soil (3 x 37.5 g/ha after 1 months, 3 x 150 g/ha after 5 months).

Thiamethoxam and the metabolite CGA 322704 do not have a negative effect on the decomposition of organic matter in the soil at application rates greater than those applied through the use of Cruiser 350 as a seed treatment.

Consequently, the risks for earthworms and other non-target soil-borne macro-organisms related to the use of Cruiser 350 insecticide are considered to be acceptable.

**Effects on non-target soil micro-organisms**
Four toxicity tests, carried out with thiamethoxam, the Actara 25 WG insecticide, the metabolite CGA 322704 and the metabolite CGA 355190 on soil respiration and the mineralisation of nitrogen were submitted with this application. The results of these tests show that no adverse effect greater than 25 % on the transformation of nitrogen and carbon in the soil is expected for concentrations which exceed the maximum PECsoil for thiamethoxam, the metabolite CGA 322704 and the metabolite CGA 355190.

The risks for non-target soil micro-organisms related to the use of Cruiser 350 insecticide are therefore considered to be acceptable.

**Effects on plants and other non-target organisms (flora and fauna)**
The risk for land plants and other non-target organisms is considered to be negligible.

**Effects on biological methods for sewage treatment**
The risk for biological methods of treating waste water is considered to be negligible.

**CONSIDERING THE BIOLOGICAL DATA**
Thiamethoxam belongs to the neonicotinoid family and acts as an antagonist on the nicotinic acetylcholine receptors. The active substance is absorbed by the leaves and roots and has a systemic action. Thiamethoxam acts on a wide range of insect pests by contact and by ingestion.

**Preliminary tests**
Nineteen preliminary tests were carried out in France, under full field conditions, between 1994 and 1997, to determine the optimum dose of thiamethoxam for combating the principal maize

pests (wireworms, leafhoppers, aphids and frit flies). The results of these tests show that a dose of 315 g of thiamethoxam/100 kg of seed can be used as a common dose for these four pests.

It should be noted that this application rate was calculated for maize with a Thousand Grain Weight (TGW) of 200 g, equivalent to a dose of the insecticide of 0.9 L/100 kg of seed (i.e. 315 g of a.s./100 kg of seed, or 31.5 g of a.s./U, or 0.63 mg of a.s./grain). However, TGW can vary widely in maize, ranging between 200 g and 400 g. It is therefore wiser to calculate the quantity of active substance per grain rather than per 100 kg of seed. The intended dose is consequently 0.63 mg of a.s./grain, or 31.5 g/50 000 grains, i.e. 31.5 g/Unit or, finally, 0.09 L of formulated product per Unit.

In the case of sorghum, TGWs are much lower and seem much less variable. The dose has therefore been calculated only in terms of hundred kilograms of seed, or 0.9 L of insecticide per 100 kg of seed.

**Efficacy**
Thirty-three tests were carried out between 1997 and 2000. Twenty-four of these tests took place in the presence of infestations and attacks (depending on the insects) of a degree which justified their use: 8 tests concerned frit flies, 11 concerned wireworms and 13 concerned leafhoppers (including 2 selectivity tests). No specific tests were carried out with Cruiser 350 concerning aphids on maize; only five preliminary tests have been submitted with this application, comparing the insecticide CRUISER NC (WS70) (containing 70 % of thiamethoxam) with an insecticide based on imidacloprid.

All of these efficacy tests show that Cruiser 350 insecticide has a level of efficacy comparable to those of the reference insecticide based on imidacloprid when used on maize to treat seed in the fight against wireworms, leafhoppers and frit flies, at the intended dose of 0.09 L formulated product per unit of seed. By biological extrapolation, the same conclusion can be drawn for use of the insecticide as a seed treatment against wireworm on sorghum.

Concerning the treatment of seed to control against aphids on maize, although it has been demonstrated that the CRUISER NC (WS70) used with the same rate of thiamethoxam as Cruiser 350 was effective against early attacks of aphids, it would be preferable to have the results of experiments conducted specifically with Cruiser 350, to verify its efficacy against later attacks of aphids.

**Phytotoxicity**
Thirty specific phytotoxicity tests using Cruiser 350 insecticide, mostly on maize, but also on sorghum, were submitted with this application. These tests show that, irrespective of the variety of maize, no particular phytotoxic effect was observed, whether for crop density, vigour, yield, or symptoms of colouring or discolouring. The same results were found for sorghum.

Cruiser 350 insecticide is therefore selective of the crops treated.

**Incidence of treatment on yield and/or quality of plants or plant products**
The phytotoxicity tests included yield measurements. The results show no particular negative effect on yield after the use of this insecticide to treat seed for the intended purpose. Although no specific study was submitted concerning the quality of the plants or plant produce grown from treated maize seed, no particular negative effect is expected on the quality of plants or plant products after the use of Cruiser 350 insecticide to treat seed.

**Observations concerning adverse or unintended secondary effects**
No information concerning adverse or unintended secondary effects has been submitted with this application. The applicant suggests that the risk of adverse effects resulting from the use of Cruiser 350 insecticide on follow-on crops is weak, considering the manner in which the insecticide is applied (as a seed treatment ). This argument is acceptable.

No tests concerning the effect on the germination of seed grown from treated seed-bearing maize have been supplied. Post-authorisation germination tests should be carried out on a few representative strains of seed-bearing maize.

**Resistance**
The risk that insects might develop resistance to thiamethoxam is deemed to be equivalent to the risk for other neonicotinoids. The risk is deemed to be weaker for ground-living pests (wireworms and frit flies) than for airborne pests (aphids and Colorado beetles). The most worrying risk of resistance concerns aphids, which are likely to be exposed to neonicotinoids because of the treatments applied to other host plants. A monitoring programme should be set up to verify that the insecticide remains effective against ground-based pests over time.

There is only a slight risk of cross-resistance developing between thiamethoxam and pyrethroids, carbamates or organo-phosphorous compounds, because of the different ways in which these molecules act. However, the risk of cross-resistance developing should not be excluded as regards the other neonicotinoids.

Resistance risk management is recommended for all neonicotinoids. In this context, the applicant lists a number of recommendations, including that neonicotinoids should not be used for the foliar treatment of crops grown from seed treated with these active substances. This recommendation is thought to be wise and sufficient to manage the risk of the development of cross-resistance.

The French Food Safety Agency considers that:

**A** The physical and chemical properties of Cruiser 350 insecticide have been described adequately. These properties are sufficient to ensure that it can be used safely under the recommended conditions of use. The methods used for analysis are acceptable.

Risks to operators, people present and workers (seed-drilling operators) related to the use of Cruiser 350 insecticide are considered to be acceptable under the conditions of use defined below.

The risks to consumers from acute and chronic exposure to the use of Cruiser 350 insecticide are considered to be acceptable.

The risks to the environment from the use of Cruiser 350 insecticide re considered to be acceptable under the conditions of use laid out below. However, any water tables that could be supplied from areas in which seed is treated with the CRUISER should be monitored for levels of thiamethoxam and the metabolites CGA 322704, NOA 459602 and SYN 501406, using a protocol drawn up beforehand with the competent authorities.

The risks for living organisms in the environment, particularly birds, mammals, non-target soil-borne organisms and aquatic organisms, related to the use of Cruiser 350 insecticide, are considered to be acceptable under the conditions of use specified below.

For bees, on the basis of the results of the studies available and of considerations relative to the exposure times used in the studies, it is recommended that:
- a minimum distance of 3 km should be kept between hives and fields sown with maize treated with Cruiser 350 insecticide for male seed-bearing maize, because of the absence of representative data on exposure. This precaution is not necessary for maize grown for grain or silage or for female seed-bearing maize if the seed-drilling period is restricted according to the instructions defined in the following section;
- the sowing period for maize grown for grain or silage and female seed-bearing maize treated with Cruiser 350 insecticide should be restricted to a period ending on 15 May;
- the long-term tests currently in place should be continued and completed.

The risk to bees from possible emissions of dust during seed-drilling can be considered to be acceptable. However, this conclusion is based on the estimated exposure from experimental data obtained under specifically-defined conditions of seed-coating (absence of coating agent or use of the coating agent Secure$^{TM}$) and in the absence of further information cannot be extrapolated for other conditions.

Furthermore, the following technical measures should be taken in order to reduce the emission and dispersal of dust during seed-drilling operations:
- fitting drills with anti-drift equipment whose efficacy for deflecting dust back towards the ground has been established by manufacturer's tests;
- verifying the effectiveness of this type of equipment for directing dust from seeds back towards the ground under windy conditions (between 20 and 30 km/h, i.e. 3 to 4-5 on the Beaufort scale) or taking supplementary precautions such as limiting seed-drilling to days with light wind conditions.

In the absence of data on sorghum from which to evaluate the risks to bees, this usage is not considered to be acceptable.

**B** The degree of efficacy of Cruiser 350 insecticide when used for treating maize seed in the fight against wireworm, frit fly, early attacks of aphid and leafhoppers, at the intended dose of 0.09 L of formulated product per unit of seed and for treating sorghum seed to control wireworm, at the intended dose of 0.9 L of formulated product per 100 kg is considered to be satisfactory. Cruiser 350 insecticide is also selective for the intended crops.

The following measures should be taken, however:
- post-authorisation germination tests on a few representative strains of seed-bearing maize, to study the incidence of treated seed on the germination of seeds from treated maize;
- post-authorisation tests to confirm the efficacy of Cruiser 350 insecticide used as a treatment on maize seed in combating later attacks by aphids,
- a follow-up process to verify the efficacy of protection provided against soil-borne pests over time.

Finally, Afssa recommends that insecticides of the neonicotinoid family not be used for foliar treatment of crops grown from seed treated with thiamethoxam, in order to avoid the development of cross-resistance.

**Classification of thiamethoxam: Xn, R22; N, R50/53** (EC regulation No.1272/2008[56])

**Classification[57] of Cruiser 350 insecticide, risk phrases and safety phrases: N, R50/53 S60 S61**

N : Dangerous for the environment
R50/53 : Very toxic to aquatic organisms, and may cause long-term adverse effects in the aquatic environment

S60 : This material and its container must be disposed of as hazardous waste
S61 : Avoid release to the environment. Refer to special instructions/safety data sheet

**Conditions of use:**
- Wear gloves and protective clothing during all operations for treating the seed, and respiratory protection (level P2, minimum) during the cleaning phase.
- SP1: Do not contaminate water with the product or its container. (Do not clean application equipment near surface water/Avoid contamination via drains from farmyards and roads).
- SPe1: To protect soil organisms do not apply this or any other product containing thiamethoxam or clothianidin less than a year after applying a thiamethoxam-based product.
- SPe5: To protect birds/wild mammals, treated seed must be entirely incorporated in the soil; ensure also that the treated seed is fully incorporated at the end of rows.

[56] Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006

[57] Directive 1999/45/EC of the European Parliament and of the Council of 31 May 1999 concerning the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations.

- SPe8: Dangerous to bees. Do not introduce in the crop rotation cycle plants that could become attractive to bees, or, alternatively, apply measures to limit exposure of bees (e.g. by cutting before the crop flowers). For male seed-bearing maize, during the flowering period keep a minimum distance of 3 km between hives and crops grown from treated seed.
- Maximum seed rate: 110 000 grains/ha.
- Re-entry interval: not applicable for a seed treatment.
- Maximum residue level (MRL): see European MRLs[58]
- Pre-harvest interval: no pre-harvest interval has been set, as the insecticide is applied as a seed treatment.
- Store at a temperature lower than 45°C.

**Comments on the agronomical recommendations on the label**
The Table of Use must be amended to indicate:
- that the product is for treating seed;
- that the recommended usage dose is to be understood in terms of "formulated product";
- that the insecticide has only been shown to be efficacious against early attacks of aphids.

Consequently, in view of all the information available, the French Food Safety Agency hereby issues a **favourable** Opinion (Annex 1) for a marketing authorisation for Cruiser 350 insecticide for use on maize under the labelling and usage conditions specified above.

The risk to bees associated with the emission of dust from seed is considered to be acceptable under seed-coating conditions used in the tests submitted with the application (absence of coating agent or use of the coating agent Secure$^{TM}$) but in the absence of further data this conclusion cannot be extrapolated for other conditions.

Furthermore, the technical measures defined above should be applied to reduce the emission and dispersal of dust during seed-drilling operations.

In the absence of data on which to base an evaluation of the risk on bees, the French Food Safety Agency hereby issues an **unfavourable** Opinion for its use with sorghum.

**Marc MORTUREUX**

**Key-words:** CRUISER 350, thiamethoxam, insecticide, maize, sorghum, FS, MA

[58] Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005, on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC (OJEC of 16/03/2005) and regulations modifying its Annexes II, III and IV relative to the maximum applicable limits for residues of products listed in its Annex I.

**Annex 1**

**List of uses intended and proposed for a marketing authorisation for Cruiser 350 insecticide**

| Ingredient | Composition of the insecticide | Dose (application rate) of active substance |
|---|---|---|
| Thiamethoxam | 350 g/L | 69.3 g a.s./ha |

| Uses | Usage dose | Maximum rate of active substance | Maximum number of applications | Proposed Opinion |
|---|---|---|---|---|
| 15551101 – Maize * seed treatment * frit fly (*Oscinella* sp.) | 0.09 L f.p./U* | 69.3 g a.s./ha** | 1 per crop | Favourable |
| 15551103 – Maize * seed treatment * wireworm (*Agriotes lineatus*) | | | | Favourable |
| 15551104 – Maize * seed treatment * aphids (corn or cereal aphid, *Rhopalosiphum maidis*) | | | | Favourable Only for early attacks |
| 15551105 – Maize * seed treatment * leafhoppers (*Peregrinus maidis*) | | | | Favourable |
| 15561102 – Sorghum * seed treatment * wireworm | 0.9 L f.p./100 kg | | | **Unfavourable** |

** f.p./U: formulated product per unit of seed. 1 unit = 50 000 grains*

*** on the basis of a maximum seed rate of 2.2 U/ha for maize (i.e. 110 000 grains/ha) and 22 kg of seed/ha for sorghum*

## Annex 2

### Table summarising the characteristics of the wells sampled

| Identification | Aquifer | Depth of the well (in metres) | Intrinsic vulnerability of the well | Total area of catchment basin | Sampling | |
|---|---|---|---|---|---|---|
| | | | | | 2008 | 2009 |
| **Ain** | | | | | | |
| SMOC-57-01 | Alluvia (sandy layer located at a depth between 39 and 66 m. Surface layer of clay (30 m thick) | 66 | Locally low | 80 ha | **X** | **X** |
| SMOC-394-01 | Glacio-fluvial alluvial complex | Collector drain | High | 125 ha | **X** | |
| SMOC-439-01 | Dombes[59] gravel bed | Collector drain | Considerable | 134 ha | **X** | |
| **Haute-Garonne** | | | | | | |
| SMOC-1000-31 | Intermediate alluvial terrace | 6 | High | 139 ha | **X** | |
| **Gers** | | | | | | |
| SMOC-70-32 | *Sables fauves* (Miocene)[60] | 30.3 | High | 168 ha | **X** | **X** |
| SMOC-97-32 | *Sables fauves* (Miocene) | source | High | 197 ha | **X** | |
| SMOC-126-32 | *Sables fauves* (Miocene) | source | Medium | 157 ha | **X** | **X** |
| SMOC-338-32 | Old lower alluvial terrace | 2 | High | 314 ha | **X** | **X** |
| TMX-9-32 | *Sables fauves* (Miocene) | source | High | 314 ha | **X** | **X** |
| TMX-13-32 | *Sables fauves* (Miocene) | source | High | 158 ha | **X** | **X** |
| TMX-18-32 | *Sables fauves* (Miocene) | source | High | 201 ha | **X** | **X** |
| TMX-20-32 | *Sables fauves* (Miocene) | 15 | High | 125 ha | **X** | **X** |
| TMX-24-32 | Alluvia from terraces of the Adour | 8 | High | 121.6 ha | **X** | **X** |
| **Landes** | | | | | | |
| SMOC-62-40 | Eocene sands (Infra-Molassic) | 27 | Low to medium | 185.87 ha | **X** | **X** |
| SMOC-75-40 | Surface aquifer: sandy layer. Deeper aquifer: cracks in limestone rock | 100 | High for the surface level and medium for the underlying level | 314 ha | **X** | **X** |
| SMOC-413-40 | Eocene limestone | 100 | Low (3 m layer of impermeable clay) | 314 ha | **X** | **X** |
| SMOC-1002-40 | Sandy surface layer (5 m thick). Underlying limestone layer | 6 | High | 314 ha | **X** | **X** |
| TMX-39-40 | Sandstone/limestone (Helvetian) | 4.6 | Medium | 152.97 ha | **X** | **X** |
| **Pyrénées-Atlantiques** | | | | | | |
| SMOC-65-64 | Alluvial with gravel/stones | 10 | Medium | 141.79 ha | **X** | **X** |
| SMOC-1002-64 | Alluvia from the *Gave de Pau*[61] | 5 | Very considerable | 218.21 ha | **X** | **X** |
| TMX-3-64 | Urgonian limestone | source | High | 135.58 ha | **X** | **X** |
| TMX-34-64 | 'Sub-molassic' layer | 100.5 | Medium | 123.95 ha | **X** | **X** |
| TMX-47-64 | Urgonian limestone | source | High | 183.89 ha | **X** | **X** |
| TMX-49-64 | Alluvial terrace of the Vert River[62] | source | High | 178 ha | **X** | **X** |

[59] Eastern France; similar latitude to Switzerland
[60] Middle-Miocene sandy deposits in the Aquitaine basin
[61] Western Pyrenees
[62] Western Pyrenees

| Identification | Aquifer | Depth of the well (in metres) | Intrinsic vulnerability of the well | Total area of catchment basin | Sampling | |
|---|---|---|---|---|---|---|
| | | | | | 2008 | 2009 |
| **Hautes-Pyrénées** | | | | | | |
| TMX-1-65 | Alluvia (Würm glaciations) | 31.2 | High | 128 ha | **X** | **X** |
| TMX-3-65 | Alluvia (Rissian) | 33 | High | 135 ha | **X** | **X** |
| TMX-7-65 | Recent alluvia | 13.4 | High | 261 ha | | **X** |
| TMX-19-65 | Alluvia | ? | High | 155 ha | **X** | **X** |
| TMX-22-65 | Alluvial terrace | source | High | 153.2 ha | **X** | **X** |
| TMX-37-65 | Alluvia | 7.5 | High | 157.3 ha | **X** | **X** |
| **Haut-Rhin** | | | | | | |
| SMOC-2-68 | Alluvia of the plain of Alsace | 19.2 | Medium | 314 ha | **X** | |
| SMOC-8-68 | Typical Sundgau aquifer, layer of limestone + marl | 4.5 | High | 314 ha | **X** | |
| SMOC-200-68 | Alluvia from the plain of Alsace | 9 | Medium to high | 314 ha | **X** | |
| **Vienne** | | | | | | |
| SMOC-182-86 | Limestone aquifer (“Niort layer") | 78 | ? | 314 ha | **X** | |
| SMOC-211-86 | Free surface layer – deep captive layer | source | High for the surface layer, low for the deep captive layer | 225 ha | **X** | |
| SMOC-326-86 | Alluvial layer (Vienne[63]) | 9.2 | High | 164 ha | **X** | |

[63] *Département* of western France

**Annex 3**
**Proportion of area treated with the insecticide CRUISER relative to total area of catchment basins for all wells sampled in 2008-2009**