

OPINION

of the French Food Safety Agency (Afssa) on the conclusions of the Cruiser assessment concerning the groundwater contamination risk.

On 13 December 2007, the Directorate General for Food (DGAI) requested the French Food Safety Agency (Afssa) to issue an Opinion relating to the conclusions of the Cruiser evaluation.

CONTEXT OF THE REQUEST

On 20 September 2007 Afssa received a marketing authorisation application for a thiamethoxam-based product, submitted by the company Syngenta Agro SAS as part of a mutual recognition procedure, on which it issued an Opinion on 20 November 2007. The Opinion concludes that: *“The assessment of predicted concentration levels in groundwater still contains uncertainties over the sensitivity of models to the input parameters [as elaborated upon above]. Because the calculated predicted concentration levels in groundwater are similar to the regulatory value of 0.1 µg/L for all these compounds, it is recommended, for the protection of groundwater, that this or any other product containing substances from the same family not be used to treat seeds on more than one in three crops in the rotation. A groundwater quality monitoring programme will also need to be put in place, particularly for groundwater that may be supplied from zones on which seeds have been treated with the insecticide Cruiser. This monitoring will consider thiamethoxam and the metabolites CGA 322704, NOA 459602 and SYN 501406.”*

A risk assessment of groundwater contamination based on 47 national scenarios developed and defined for the PELMO model had, in fact, been put forward by the applicant. However, these scenarios, which were mainly defined for crop rotations based on winter cereals, seemed to underestimate the frequency of maize in the rotation (1 crop in 5 to 1 crop in 9). Moreover, the Alsace region was not represented in these scenarios, even though maize cultivation is widespread there.

Following this Opinion, Afssa was asked to examine the additional data provided by Syngenta Agro SAS, concerning the assessment of the risk of groundwater contamination.

After consulting the Scientific Panel “Plant protection products: chemical substances and preparations”, which met on 15 and 16 April 2008, Afssa issues the following Opinion.

NATURE OF THE SUPPLEMENTARY INFORMATION

The extra information provided by the applicant presents the assessment results, by modelling, of the risk of thiamethoxam and its metabolites being transferred to groundwater for a series of representative agro-pedo-climatic scenarios of maize monoculture farming in France.

An argument is presented identifying the main representative regions of maize monoculture farming in France. This shows that 90% of it takes place in 10 regions (AGRESTE, 2001¹). In order of decreasing surface area, these 10 regions are: Aquitaine, Midi-Pyrénées, Rhône-Alpes, Pays de la Loire, Alsace, Brittany, Poitou-Charentes, Centre, Lower-Normandy and Burgundy.

¹ Agreste, 2001 - *La statistique agricole SCEES - Collection chiffres et données n°159 - Enquête sur les pratiques culturales en 2001.*

Adapted scenarios have been used for all of these regions for modelling:

- for Aquitaine, Midi-Pyrénées and Rhône-Alpes, the existing maize monoculture scenarios already in place;
- for Brittany, Centre, Lower-Normandy and Burgundy, the scenarios having prompted the assessment body previously in charge of these applications (June 2006) to propose an SPe2² phrase which was used in Afssa's Opinion of November 2007, adapted for maize monoculture;
- for Pays de la Loire and Poitou-Charentes, the worst-case climate-soil scenarios for each region, adapted for maize monoculture farming;
- for Alsace, different climate/soil combinations were created to make up scenarios representative of maize monoculture farming.

Lastly, scenarios that had already been created for other regions were also put forward, even though they were not very representative of maize monoculture farming.

For each of these modelling scenarios, the input parameters proposed by Afssa in the Opinion dated 20 November 2007 were used. The values of these parameters are as follows:

- total annual dose applied: 69.3 g a.s./ha (110 000 seeds/ha)
- one application a year, on 1 May except for Aquitaine, 20 April.
- for thiamethoxam: DT50 = 36 days (20°C and pF2, median), Kfoc = 36.5 L/kg (median) and 1/n = 0.87
- for CGA322704: DT50 = 126 days (20°C and pF2, median), Kfoc = 85 L/kg (median) and ffM = 0.3
- for NOA459602: DT50 = 19 days (20°C and pF2), Kfoc = 0 L/kg, 1/n = 0.9 and kinetic formation fraction = 0.18
- for SYN501406: DT50 = 24 days (20°C and pF2), Kfoc = 6 L/kg, 1/n = 0.75 and kinetic formation fraction = 0.53 (from NOA459602)

SUMMARY OF THE RESULTS PRESENTED

The main results of the simulations carried out with the PELMO model, using the scenarios adapted for the main maize monoculture farming regions in France, are presented in Annex 1.

The estimated predicted concentration levels in groundwater do not exceed the 0.1 µg/L limit for thiamethoxam. The highest value obtained is for the Brittany286 scenario, with 0.079 µg/L.

For the metabolite CGA322704, the estimated concentration levels are less than 0.1 µg/L, save for the Upper-Normandy scenario, for which the value slightly exceeds the limit with 0.1016 µg/L. Note the concentration values verging on 0.1 µg/L for this metabolite, particularly for the Burgundy scenarios with 0.093 µg/L and Alsace298 with 0.075 µg/L.

For the metabolite NOA459602, the predicted concentration levels in groundwater may exceed the 0.1 µg/L limit but remain in all cases below 0.75 µg/L, with a maximum value of 0.2272 µg/L for the Poitou-Charentes scenario. The toxicological and ecotoxicological relevance of this metabolite has been assessed on the basis of the guidance document Sanco/221/2000 – rev.10-Final³ which led to it being attributed a 0.75µg/L limit in groundwater.

For the metabolite SYN501406, the estimated concentration levels are below 0.1 µg/L, save for the Poitou-Charentes scenario, for which the value reached 0.1072 µg/L. Values around the 0.1 µg/L mark were also obtained, with 0.0876 µg/L for the Rhône-Alpes scenario, 0.08 µg/L for the Aquitaine scenario and 0.0802 µg/L for the Alsace257 scenario. Examination of the information

² SPe2: To protect groundwater, do not apply this product on fine silt, with organic carbon levels < 1.2% in Aquitaine, Lower Normandy, Burgundy, Centre and Picardy.

³ Guidance document on the assessment of the relevance of metabolites in groundwater of substances regulated under Council directive 91/414/EEC. Sanco/221/2000 –rev.10-Final 25 February 2003

available on this metabolite did not enable a conclusion to be drawn on its toxicological non-relevance⁴, and therefore the 0.1 µg/L limit has been attributed to it.

CONCLUSION

The risk of groundwater becoming contaminated by the insecticide Cruiser was assessed using national scenarios covering all of the most representative regions of maize monoculture farming.

For all of these scenarios, the simulation results show that the predicted concentration levels in groundwater do not exceed the 0.1 µg/L limit for thiamethoxam and metabolites CGA322704 and SYN501406, nor the 0.75 µg/L limit for the metabolite NOA459602.

Only two results exceed the 0.1 µg/L limit. For the metabolite CGA322704, the value obtained only slightly exceeds the limit (0.1016 µg/L) for the Upper-Normandy scenario. Maize monoculture farming in this region can be considered a minor practice, accounting for less than 1% (14 894 ha) of this type of farming in France. For the metabolite SYN501406, the value again only slightly exceeds the limit (0.01072 µg/L), but is obtained for the Poitou-Charentes scenario, where maize monoculture farming reportedly accounts for 9.6% (158,585 ha) of the total surface area of this type of farming in France (AGRESTE, 2001).

As a result, the French Food Safety Agency considers that a risk of groundwater becoming contaminated cannot be dismissed and that there should still be a usage recommendation, in order to protect groundwater from potentially exceeding the regulatory limit. In view of the new modelling data supplied, the recommendation not to use this product more than one in three years (Opinion of 20 November 2007) can be changed to **“do not use this product more frequently than one in two years”**. This recommendation should include the following precaution: “SPe1: To protect groundwater, do not use this or any other product containing thiamethoxam to treat seeds more frequently than one in two years in the rotation”.

Moreover, the results obtained by modelling are sometimes quite close to the regulatory limit for thiamethoxam and metabolites CGA322704 and SYN501406. As proposed by the applicant, the request for monitoring thiamethoxam and CGA322704, NOA459602 and SYN501406 metabolite levels in groundwater, for zones in which seeds treated with the insecticide Cruiser are used, should be maintained, according to a protocol to be defined with the competent authorities.

[signed by the Director-General]

Key words: Cruiser, thiamethoxam, FS, maize

⁴ Report of the *Commission d'Etude de la Toxicité des Produits Antiparasitaires à usage agricole et des Produits assimilés* (CET) – session of 14 June 2006.

Annex 1

Table 1: 80th percentile of predicted concentrations in groundwater (PEC_{gw}), modelled by PELMO, in µg/L

Scenario	Thiamethoxam	CGA322704	NOA459602	SYN501406	Comments
Rhône Alpes 329	0.023	0.024	0.1844	0.0876	With irrigation
Aquitaine 323	0.012	0.0242	0.062	0.08	With irrigation
Midi Pyrénées	0.012	0.0206	0.051	0.037	With irrigation
Brittany 286	0.079	0.0282	0.11	0.0306	Irrigation not appropriate for the region
Centre 336	0.013	0.0272	0.044	0.035	Use of 3 irrigated years out of 26
Centre 336	0.015	0.031	0.04	0.031	Irrigation taken into account ⁵
Lower Normandy 343	0.052	0.068	0.163	0.061	Irrigation not appropriate for the region
Burgundy 260	0.042	0.093	0.092	0.055	Irrigation not necessarily appropriate for the region, but use of 17 irrigated years out of 26
Poitou Charentes 276	0.0154	0.0462	0.2272	0.1072	Irrigation not taken into account
Poitou Charentes 276	0.0144	0.0442	0.2058	0.1072	Irrigation taken into account ⁶
Pays de la Loire 336	0.013	0.023	0.074	0.032	Irrigation not modelled as not representative of the region
Alsace 248	0.0324	0.045	0.153	0.0616	Irrigation taken into account ⁷ climate 1159155
Alsace 257	0.0472	0.0704	0.1578	0.0802	Irrigation taken into account ³ climate 1159155
Alsace 298	0.0474	0.075	0.1472	0.0758	Irrigation taken into account ³ climate 1159155
Picardy 343	0.071	0.072	0.12	0.07	Irrigation not appropriate for the region
Champagne Ardenne 327	0.005	0.003	0.06	0.032	Irrigation not appropriate for the region
Ile de France 260	0.019	0.04	0.058	0.04	Irrigation not appropriate for the region

⁵ According to AGRESTE (2001), 59% of the surface area where maize is cultivated in the Centre is irrigated with a mean irrigation dose of 102 mm over a mean number of passages of 3.7 (we shall assume 25 mm in 4 deposits). These deposits have been spread out theoretically between 15 June, 01 July, 15 July and 01 August for the years for which irrigation had not already been taken into account.

⁶ According to AGRESTE (2001), 49% of the surface area where maize is cultivated in Poitou-Charentes is irrigated with a mean irrigation dose of 152 mm over a mean number of passages of 5.4 (we shall assume 30 mm in 5 deposits). These deposits have been spread out theoretically between 15 June, 01 July, 15 July and 01 August

⁷ According to AGRESTE (2001), 31% of the surface area where maize is cultivated in Alsace is irrigated with a mean irrigation dose of 100 mm over a mean number of passages of 4.3 (we shall assume 25 mm in 4 deposits). These deposits have been spread out theoretically between 15 June, 01 July, 15 July and 01 August.

Afssa – request no. 2007-SA-0393-4
Associated file nos 2007-SA-0393 and 2007-3845 –
Cruiser

Lorraine 249	0.011	0.011	0.08	0.032	Irrigation not appropriate for the region
Nord Pas de Calais 343	0.025	0.036	0.098	0.044	Irrigation not appropriate for the region
Upper Normandy 343	0.05	0.1016	0.144	0.073	Irrigation not appropriate for the region