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DE SÉCURITÉ SANITAIRE
DES ALIMENTS

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DIRECTOR GENERAL

OPINION

of the French Food Safety Agency relative to the marketing authorisation monitoring programme on the Cruiser seed treatment product

The French Food Safety Agency (AFSSA) received a request on 17 March 2009 from the Directorate General for Food (DGAL) concerning the market authorisation monitoring programme on the Cruiser seed treatment product.

After consulting with the Scientific Panel on "Plant protection products: chemical substances and preparations", which met on 24 and 25 March 2009, and after having considered the reports of two appointed experts, the French Food Safety Agency is issuing the following opinion.

BACKGROUND OF THE REQUEST

The Cruiser preparation, thiamethoxam-based seed treatment, was the subject of an Opinion, issued on 14 November 2008, relative to the renewal of its marketing authorisation. AFSSA issued a favourable Opinion along with proposals of measures for managing the Cruiser seed treatment product.

At the request of the Minister of Agriculture, DGAL is pursuing its post-authorisation monitoring programme in 2009.

DGAL requests AFSSA to determine whether the monitoring zones and activities carried out in these zones satisfy the monitoring objectives, particularly concerning the risks of dust emission during seed drilling, risks of exposure for bees and for bee colonies in case of exposure to thiamethoxam under normal conditions of use.

DOCUMENT EXAMINED

The memorandum, internal reference number: 090311_PS-CRUISER_2009-vdef, sent by the Director General for Food to the Regional Directors for Food, Agriculture and Forests in the regions of Aquitaine, Midi-Pyrénées, Rhône-Alpes, Poitou-Charentes, Centre and Alsace, was examined. The subject of this memo was the national post-authorisation monitoring programme on the Cruiser seed treatment product.

GENERAL OBJECTIVES OF THE PROGRAMME

The declared objective of the programme is to verify the absence of unintended effects on pollinators, particularly honeybees, due to the marketing and use by farmers of seed dressed with the plant protection product Cruiser, containing thiamethoxam.

PRESENTATION OF THE PROTOCOL

A general protocol was described in the examined memorandum. Its structure is similar to that of the 2008 monitoring programme, but its implementation was extended to a total of six regions. The components comprising this protocol can be summarised as follows.

- **Identification of the "Cruiser-treated" sites and "non-Cruiser-treated" sites**. Each of the six regions must set up 16 sites (8 "Cruiser-treated" and 8 "non-Cruiser-treated"), being

equivalent to 48 sites for each type of treatment. The "Cruiser-treated" and "non-Cruiser-treated" sites must be located in small farming areas that have similar landscapes and environmental conditions. These sites are to consist of a 'focus zone' with a radius of 1 km, surrounded by a 'safety' zone with a radius of 3 km, within which certain land-use criteria must be satisfied and the characteristics of which must be recorded.

- **Collection of landscape and biological data** (on pollinators, butterflies and flora) for all monitored areas.

- **Experimental installation of apiaries at some of these sites ('pilot sites').** The purpose of these experimental installations is to compare two populations of bees: those whose hives are placed in 'Cruiser-treated' maize sites and those whose hives are placed in 'non-Cruiser-treated' sites. Four or six sites are designated 'pilot sites' in each of the six regions, with each site receiving an apiary of seven hives. This gives a total of 30 apiaries (15 at 'Cruiser-treated' sites and 15 at 'non-Cruiser-treated' sites), made up of 210 hives for observation. Twelve of these apiaries were already involved in the 2008 monitoring programme, and, for the second year running, will be placed in 2009 at sites following the same procedure as the previous year,

  In these pilot zones, the health of the bee populations will assessed together with toxicological monitoring of samples from the different compartments of the hive (bees, bee bread, honey and larvae). The hives will then be relocated together at a single site at the beginning of September for a health inspection before overwintering.

- **Collection of data on agricultural practices** in the 'focus zones' of the 30 'pilot sites', particularly including information on the use of insecticidal plant-protection products or seeds dressed with fungicides over the last two years.

- **A 'dust' test is to be carried out,** to analyse the quantity of active substance (thiamethoxam) in the dust emitted during seed-drilling operations at 'Cruiser-treated' pilot sites.

- **Sampling and analyses to be carried out**
  - On purchasing and installing hives
    Sampling live bees to be analysed for pathogenic agents, and analysis for thiamethoxam and clothianidin content;
  - On installing hives
    Sampling live bees to screen for pathogenic agents, and live bees and pollen to be analysed for thiamethoxam and clothianidin content;
  - During seed drilling
    - At pilot sites, sampling treated and untreated seed to quantify thiamethoxam and its major metabolite, clothianidin;
    - At pilot sites, collecting dust in Petri dishes placed at various distances from the seed drill, to be analysed for thiamethoxam and clothianidin, and also for imidacloprid. It is also planned to collect dust using a high-flow sampling device placed at the edge of the field at one 'Cruiser-treated' site and one 'non-Cruiser-treated' site, for analysis for the same active substances;
    - Sampling live bees and larvae to screen for pathogenic agents, and live bees, larvae and pollen to be analysed for thiamethoxam and clothianidin content;

    During flowering
    - In one field of 'Cruiser-treated' maize and one field of 'non-Cruiser-treated' maize at each site in each region, two sets of pollen samples are to be taken from 10 maize panicles, i.e. a total of 48 samples in duplicate for each type of crop (i.e. treated and untreated); the pollen from treated fields to be analysed for thiamethoxam and clothianidin while the pollen from untreated fields are to undergo multi-residue analyses;
    - Before and during flowering, sampling live bees to screen for pathogenic agents, and live bees, larvae, bee bread and pollen to be analysed for thiamethoxam and clothianidin;

- At the end of flowering, sampling live bees and larvae are to be analysed for pathogenic agents, and live bees, larvae, bee bread and pollen are to be analysed for thiamethoxam and clothianidin content;

- Before overwintering
  Sampling live bees are to be analysed for pathogenic agents and live bees and bee bread for multi-residue analyses.

The field monitoring will therefore last from Spring 2009 until the health inspection at the end of overwintering, in Spring 2010.

OPINION ON THE NATIONAL MONITORING PROGRAMME

General comments

The proposed monitoring system involves an increased number of sites and includes many components (detailed environmental description, detailed description of material used, floristic and faunistic monitoring, apiary installation in very contrasting environments). This programme should help better understand the potential impact of the use of treated seeds, taking into account all of these components, and identify any specific effect of use of the Cruiser product.

Methodological comments

Given the complexity of the protocol, the description of operations to be carried out deserves to be more detailed and sometimes illustrated with diagrams in order to limit variation in interpretation amongst the involved regions. The following items include comments on the methodological choices, questions raised by the lack of detail or absence of justification of the choices made, as well as proposals for clarification.

Definition and criteria for choice of sites

A diagram of the 'focus zone' and 'safety zone' should be used. The text suggests that the radius of the 'focus zone' cannot be less than 1 km, which seems to be a threshold size given the requirements (150 ha of Cruiser-treated maize, i.e., 80% of the maize fields, which must represent 50% of the fields in the zone).

Installation and operation of the apiaries

The relationship between the installation of the apiaries and the monitoring sites should be more clearly explained, particularly with regard to whether the apiaries will be placed in the 'focus zones' of these sites. Similarly, indications relative to the desired distribution of the hives within the apiaries will avoid creating bias related to the geographic dispersal of the hives amongst the different sites and/or different regions.

With regard to tending to the apiaries, if the beekeeper feeds the hive with pollen, this pollen may be a source of exposure of the bees and thereby introduce an experimental bias. When hives are fed, particular attention should be given to the quality of food provided, particularly if it contains pollen, and to keeping one or several samples for potential residue analysis.

Carrying out a 'dust' test

The description of the seed drill should include the angle of exhaust ventilation. This parameter could explain the differences in the observed dust emissions from one site to another. Photographs of the seed drills should be made available.

Similarly, it should be specified whether wind speed and direction will be continuously monitored. This would facilitate the interpretation of data relative to dust emissions. The environmental survey that is planned (surrounding landscape) should help in the interpretation of the obtained dust emissions, which could then be explained in the text.

Finally, the results of the dust tests that have been carried out on the batches of seeds used on the fields should be provided.

<u>Air sampling</u>

The protocol does not indicate the nature of the data that will be produced through the analysis of collected air samples. The interpretation of these data will probably be difficult due to the lack of toxicological reference values for inhalation in bees, or ecotoxicity data obtained by exposing the bees to an atmosphere containing seed dust, as well as the lack of historic data, which would enable the values obtained in the tests to be compared with values associated with a previously identified effect. The protocol should mention how the results of air extraction will be expressed and interpreted with regard to exposure of the bees.

In addition, the reasons for the following operational choices should be provided:
- for conducting the dust analysis in two of the six monitored regions;
- for sampling air for analysis one hour before seed drilling.

Details should also be provided with regard to the maximum distance that the air sampling devices should be set up from the edge of the fields.

Petri dishes

The Petri dish collection method is traditionally used to assess the dust or spray drift[1,2]. The data collected during sowing can be converted into the quantity of active substance or metabolite settling on the ground at a certain distance from the seed driller or on a certain field surface. However, the protocol should indicate how the results of the analyses of residues contained in the Petri dishes will be expressed and interpreted with regard to exposure of the bees.

Reasons should also be provided as to why the seed driller is to make five runs before the start of the testing.

The location of the control dishes should also be indicated.

In addition, it would be helpful to provide a reminder in the text that the E dishes correspond to rows perpendicular to the seed driller run, and to indicate the distance from the field where they must be placed. The diagram could show the nomenclature of the dishes.

It is recommended that the 10 Petri dishes be spaced at least 5 meters apart, and not 5 dishes distributed over 5 meters as indicated in the submitted proposed protocol In addition, these dishes should be placed downwind so that they are in the most optimal conditions for collecting dust. In this case, three lines of dishes spread over a length of 45 meters, parallel to and at a distance of 5 meters, 10 meters and 50 meters from the seed drilling line should be sufficient. The part of the seed driller (edge, middle) that is to be used for measuring the distance between the line of dishes and the seed driller should be indicated.

Lastly, the funnel should be properly rinsed before reuse.

Sampling and analyses to be carried out

The planned sampling includes the seeds, the dust that may be emitted during sowing, the pollen from the maize during flowering, as well as the bees, larvae, pollen collected in the pollen traps and bee bread. The samples should help identify the causes of any incident affecting the colonies exposed to the maize fields on the pilot sites of the monitoring programme.

The protocol should specify whether the nature of the analyses can be adapted to the collected information with regard to the plant protection treatments carried out on the monitored sites. For this purpose, it would be useful to store at least one supplementary sample in order to be able to perform a complementary multi-residue analysis in the event of bee mortality.

- *Analysis of larvae*

[1] Ganzelmeier H, Rautmann D, Spangenberg R, Streloke M, Herrmann M, Wenzelburger H-J Walter H-F (1995): Studies on the spray drift of plant protection products. Mitt.Biol.Bundesanst.Land- Forstwirtsch. Berlin-Dahlem, Heft 305.

[2] Rautmann D, Streloke M, Winkler R (2001): New basic drift values in the authorisation procedure for plant protection products. In: Forster R, Streloke M (eds), Workshop on Risk Assessment and Risk Mitigation Measures in the Context of the Authorization of Plant Protection Products (WORMM). Mitt. Biol. Bundesanst. Land-Forstwirtsch Berlin-Dahlem, 383, 133-141

The toxicological analysis of the larvae is not feasible from a technical point of view considering the quality and the quantity of larvae contained in the samples sent to the laboratory (this matrix cannot be frozen). Furthermore, sampling some of the bee bread and some of the brood may disturb the colony. Although sampling and analysing larvae could provide information on the transfer of potential contamination from plant protection products to larvae, this procedure is not appropriate without a validated methodology.

- *Analysis of seeds*
  The volumes/weights of seeds to be sampled should be specified.

- *Analysis of pollen*
  While maize pollen was screened for as part of the previous year's monitoring, this screening was not included in the 2009 monitoring programme. Maize pollen should be screened for in the pellets collected from the pollen traps, as well as in the bee bread samples taken according to the calendar outlined in Annex 5B, in order to determine whether the bees gathered pollen from this floral species.

- *Screening for pathogens*
  From a general point of view, it does not seem to be scientifically or financially justifiable to systematically screen all the listed pathogens. On the other hand, the samples must be taken, as mentioned in Annex 5B, in order to be able to carry out the analyses in the event that disorders or mortalities are observed and documented in Annex 5A. If pathogen screening is carried out, the Israel acute paralysis virus (IAPV) should also be screened for if disorders occur. Finally, it is necessary to specify that the samplings must be carried out at the hive entrance.

Health monitoring

All of the observations noted on the inspection sheets are important. It is advisable however to specify the nature of the data to be entered on the sheets for each item (qualitative or quantitative information) according to the type of intended analysis.

Some of these data will probably be subjective (the size of the population, for example). It is therefore necessary to ensure that these observations are made by the same person at each site. Harmonisation rules should definitely be applied in order to reduce the variability between operators. These rules should also be applied to sampling methods, to thereby enable a comparison of the results from one region with those from another.

In every case, this inspection sheet should be accompanied by a document, as mentioned in the protocol, that very specifically presents the nature of each data item to be noted, as for example in the following cases:

- method of evaluating the population size
- eggs, royal jelly, mosaic distribution of broods, etc.: quantitative indicator or not

The following parameters may also be noted due to their composite character or their relevance as a quantitative parameter, which is therefore easier to compare statistically:

- overall weight of the hive (generic data and composite parameter)
- brood surface (quantitative parameter)
- honey production (quantitative and composite parameter).

Analysis and interpretation of data

As a general rule, the manner in which the results are to be expressed and then interpreted should appear in the protocol, in order to facilitate the discussion of results generated from the different sections of this monitoring programme.

It might also be useful to describe how the results obtained for the different monitored components (faunistic and floristic reports, for example) will be interpreted in relation to the environmental data. A similar preliminary study could be carried out for the particular monitoring results of honeybees, which will be interpreted in relation to the exposure data.

CONCLUSION

As a result, the French Food Safety Agency considers that:

- the characteristics and the number of monitoring sites involved, as well as the data collection planned in the national post-authorisation monitoring programme on the Cruiser seed treatment product should provide answers to the question regarding the potential impact of the use of treated seeds under normal conditions of use;
- the chosen methods are suitable for field monitoring and are relevant;
- the data that is intended to be collected as part of this ambitious programme should provide information on the exposure of bees during a period running from maize sowing to the end of the following overwintering under the recommended conditions of use for Cruiser; they should also reinforce or modify the results of the risk assessment done during the appraisal of the marketing authorisation dossier of the seed treatment product;
- details on the above-mentioned items should be included in the protocol to ensure the consistency of the collected data.

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