UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON D.C., 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

**PC Code:** 109801
**DP Barcode:** 346417, 348818
**MRID**: 47244701
**Date:** January 31, 2008

**MEMORANDUM**

**SUBJECT:** Review of Bayer Crop Science's Iprodione Drinking Water Assessment (MRID 47244701).

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EFED has completed its review of the "Iprodione Drinking Water Assessment" (MRID 47244701) submitted by Bayer Crop Science in support of pending new uses and

existing uses of iprodione. A number of uncertainties still remain regarding the potential exposure of iprodione and it's degradation product, 3,5-DCA, to drinking water. In order to reduce the uncertainty, EFED recommends the following:

- Continue the surface water monitoring program for a minimum of three years, and provide the additional data needed to fully accept the submission:
  - The analytical method of analysis entitled "Method of analysis for the determination of residues of iprodione and its metabolites, isoiprodione and 3,5 –dichloroaniline plus vinclozolin" **and** an independent laboratory validation.
  - The analytical method modification to detect N-3,5-dichlorophenyl formamide (3,5 DCPF) **and** an independent laboratory validation.
  - A storage stability study.
  - Detailed usage information including how much iprodione was used, when and where, the percent of acres of golf courses (potential use sites) in the watersheds and the actual percent of sites treated.
- Continue the groundwater monitoring program for a minimum of three years, and provide additional data are needed to fully accept the submission:
  - Reporting of all trace levels of iprodione and 3,5-DCA (above method detection limit).
  - Analytical method description and levels of detection.
  - Detailed usage data (how much is used, when and where) in temporal and spatial relation to the sampling.
  - Include an update on monitoring sites originally submitted (MRID 472983-01).
- Submit another aerobic soil metabolism study of 3,5-DCA (162-1).
  - The study should use at least one very low organic matter soil representing an aquifer-soil system.
  - Prior to the definitive experiment, various extraction methods should be tested to ensure that a method that is most efficient at extracting aged 3,5-DCA residues is employed.
  - A sterile control should be included.
- Depending on the results of the above, a prospective groundwater study may be recommended.
  - A study protocol including site selection should be submitted and approved prior to the start of the study.

## 1 SUMMARY

EFED has completed its review of the "Iprodione Drinking Water Assessment" (MRID 47244701) submitted by Bayer Crop Science in support of pending new uses and existing uses of iprodione. The drinking water assessment consisted of a summary of the results of the surface water monitoring program, a refined surface water modeling assessment, results from the groundwater monitoring program conducted by Suffolk County, and a refined groundwater modeling assessment.

Results from Bayer's surface water monitoring program indicate that there have been some detections of iprodione at one of three sites, and there have been no detections

of 3,5-DCA at any of the sites. However, proprietary sales data, which is used as a surrogate for use on golf courses and nurseries, indicate that use intensity has reduced substantially since site selection, and thus actual usage data is needed to fully interpret the monitoring data.

Bayer's refined surface water modeling assessment consisted of refinements (such as bi-phasic degradation models, and reduction factors) that are not supportable by the currently submitted data or product labels. However, Bayer correctly states that a major difference in the modeling and monitoring data is due to assumptions regarding use intensity in the watersheds. This is probably because typical rates are much less than what is allowed on the label, and less than 100% of a given watershed is actually treated with iprodione.

The Suffolk County Department of Health Services drinking water monitoring database reported one detect of iprodione above the reporting limit at 5.75 ppb. Suffolk County indicated that this sample is actually from an irrigation well which does not serve as a drinking water source. There were no detections for 3,5-DCA above the reporting limits. The reporting limit of the Suffolk County database has varied from 0.2 to 5 ppb for iprodione and 0.3 to 1 ppb for 3,5-DCA over the years. Full interpretation of the monitoring results cannot be made until the registrant supplies actual usage data (how much is used, when and where) in temporal and spatial relation to the sampling. Additionally, a report of trace levels is also necessary to draw conclusions from the monitoring data.

Both the refined surface water and groundwater modeling assessments used a bi-phasic degradation model to describe microbial degrdatation of 3,5-DCA and discounted the substantial amount of unextracted material apparent in the laboratory study. The amount of unextracted and uncharacterized material prevents accurate estimation of degradation rates. This is a major source of uncertainty that has not been addressed in the current submission. Without additional data that affirmatively demonstrate the microbial degradation of 3,5-DCA, EFED has no means to refine this aspect of the drinking water assessment.

## 2 SURFACE WATER

### 2.1 Monitoring Study

Bayer Crop Science has commissioned a surface water monitoring study designed to determine the potential for iprodione residues to reach public water supplies following the use of iprodione on golf courses and plant nurseries. The surface water monitoring study was commissioned in response to a Data-Call-in (DCI) issued by EPA in February, 2001. Details regarding the study design and the results of the first year of monitoring data were reported in an interim study report (MRID 47170301) and reviewed by EFED (USEPA 2008, DP 291976).

Water from three community water treatment facilities located in Bradenton, FL, Aurora, IL and Rahway, NJ is being monitored for iprodione residues. Both raw and finished drinking water samples were collected at weekly intervals. Finished water samples were only analyzed when residues were detected in the corresponding pre-treatment samples. In the first year of sampling (2006), unacceptably low recoveries of

3,5-DCA in stored frozen samples collected from January to mid-August 2006 were reported. This resulted in an amendment of the protocol (See DP 291976 for more details). The current submission included results from March through mid-September of 2007.

Iprodione residues were not detected in raw water samples at the Bradenton, FL and Aurora IL sites at any sampling point during monitoring in 2007. No finished water samples were analyzed.

Iprodione was detected at the Rahway, NJ site above the method detection limit (MDL) on 12 sampling occasions (MDL = 0.025 ppb and LOQ = 0.05ppb for all analytes). . Iprodione was detected at a maximum concentration of 0.343 (raw) and 0.062 (finished) ppb on March 27, 2007. Isoiprodione was detected above the MDL on 11 sampling occasions with a maximum concentration of 0.309 ppb ppb in the raw water and was not detected in the finished sample on August 29, 2007. Vinclozolin was also detected above the MDL on 2 sampling occasions with a maximum concentration of 0.037 ppb (<LOQ) in the raw water and was not detected in the finished sample on July 5, 2007. 3,5-DCA was not detected above the MDL at any site at any sampling occasion. Samples with iprodione, isoiprodione or vinclozolin above the MDL are summarized in Table 1.

**Table 1. Results of samples at the Rahway, NJ site that had levels of iprodione, isoiprodione, 3,5-DCA or vinclozolin above MDL (0.025 ppb). LOQ = 0.05 ppb.**

| Sample Date | Water Type | Iprodione (ppb) | Isoiprodione (ppb) | Vinclozolin (ppb) |
|---|---|---|---|---|
| 03/05/07 | Finished | 0.159 | ND | ND |
| 03/12/07 | Raw | 0.077 | ND | ND |
| 03/20/07 | Raw | 0.258 | 0.028 (<LOQ) | ND |
| 03/20/07 | Finished | 0.044 (<LOQ) | ND | ND |
| 03/27/07 | Raw | 0.343 | 0.098 | ND |
| 03/27/07 | Finished | 0.062 | ND | ND |
| 04/03/07 | Raw | 0.064 | 0.03 (<LOQ) | ND |
| 04/11/07 | Raw | 0.106 | 0.054 | ND |
| 04/16/07 | Raw | 0.110 | 0.053 | ND |
| 04/16/07 | Finished | 0.026 (<LOQ) | ND | ND |
| 04/26/07 | Raw | 0.034 (<LOQ) | ND | ND |
| 05/01/07 | Raw | 0.027 (<LOQ) | ND | ND |
| 07/05/07 | Raw | ND | ND | 0.037 (<LOQ) |
| 07/17/07 | Raw | 0.080 | 0.058 | 0.034 (<LOQ) |
| 07/24/07 | Raw | 0.293 | 0.044 (<LOQ) | ND |
| 08/14/07 | Raw | 0.057 | 0.044 (<LOQ) | ND |
| 08/21/07 | Raw | ND | 0.072 | ND |
| 08/29/07 | Raw | ND | 0.309 | ND |
| 09/06/07 | Raw | ND | 0.127 | ND |

Note: If more than one sample was analyzed or processed for a sampling date, an average is shown
ND = non-detect. Method detection limit (MDL) = 0.025 ppb.
Limit of quantitation (LOQ) = 0.05 ppb.

According to the product label for golf courses, applications up to 4 lbs ai/A are permitted and applications can be repeated up to 6 times per year, yielding a maximum yearly application rate of 24 lbs ai/A. For nurseries, applications up to 1.25 lbs ai/A are permitted and application can be repeated up to 4 times per year, yielding a maximum yearly application rate of 5 lbs ai/A. There are no seasonal restrictions on either use pattern, according to the labels. Actual usage data for the current monitoring period (2007) have not been submitted. For the first year of monitoring data (2006), usage was estimated based on iprodione sales information summarized at the zip code level. The estimated use information is for non-agricultural products only. The proprietary usage data (based on sales) suggests that use intensity (lbs ai of iprodione/ acre of total watershed) for 2006 decreased by 35, 41 and 50% for the FL, IL and NJ sites, respectively, compared to 2004, the year of data used to select the sites. Estimated use intensity for 2006 was over an order of magnitude greater for Rahway, NJ compared to the other two sites which were characterized by similar estimates of use intensity. Iprodione use is likely a function of fungal pressure which can vary from year to year.

Actual use information (how much was used, when and where), the percent of acres of golf courses (potential use sites) in the watersheds and the actual percent of sites treated have not been reported. This information would provide the necessary context

needed to interpret the monitoring results. Without this information, it is difficult to draw meaningful conclusions about the monitoring study, other than that iprodione has been detected. It would also allow meaningful comparison of monitoring results with modeled results.

## 2.2 Exposure Assessment

Bayer conducted a refined surface water modeling assessment for iprodione and 3,5-DCA using the EPA standard PRZM/EXAMS models. There are number of differences in this refined modeling exercise compared to the assessment conducted by EFED (USEPA 2007b, D285550). For the FL turf scenario, the refined modeling exercise yielded 30-year average concentrations of 0.31 and 1.10 ppb for iprodione and 3,5-DCA, respectively; whereas the EFED assessment yielded 30-year average concentrations of 6.0 and 24 ppb for the two compounds.

A major discrepancy in the two assessments stems from assumptions regarding the degradation of 3,5-DCA. In the Bayer assessment, 3,5-DCA was simulated according to a bi-phasic degradation model and did not include unextracted residues in the regression. The EFED assessment assumed that 3,5-DCA is stable to microbial degradation, as supported by submitted aerobic soil metabolism study (MRID#45239201). In that study, 3,5-DCA showed little evidence of degradation over a 9-month period at 25°C on two different soils. Unextracted and unidentified residues accounted for 66% and 81% of the applied in the two systems, and were indistinguishable from the parent. The only residues that were distinguishable from the parent amounted to only 4 to 5% of the applied $^{14}C$. Without evidence to the contrary, EFED made the conservative assumption that 3,5-DCA is stable to microbial degradation. This is a major source of uncertainty in both Bayer's and EFED's assessments. The amount of unextracted and uncharacterized material prevents accurate estimation of degradation rates, but do tend to suggest that 3,5-DCA may only degrade very slowly in the presence of soil. Without additional data that affirmatively demonstrate the microbial degradation of 3,5-DCA, EFED has no means to refine this aspect of the drinking water assessment.

Another major difference between Bayer's and EFED's assessment is the application of a reduction factor to account for attenuation of pesticide in mandated 25-ft buffers. The Bayer assessment assumed that 80% of iprodione residues would be discountable in runoff since a 25-ft (7.5 m) buffer strip between application area and surface water bodies is required by the label. The study authors cite a review publication (Reichenberger et al., 2007) that shows that the median expected buffer efficiency from an 8 to 10 m buffer for compounds with $K_{oc}$ < 1000 L/kg is about 80%. However, Reichenberger et al. (2007) states that the effectiveness of an edge-of-field buffer strip is highly variable and that the variability cannot be explained by strip width alone. For buffer strips 8 to10 m in width, the pesticide load reduction ranged from approximately 0% to 100% for compounds with $K_{oc}$ < 1000 L/kg. Additionally, the studies in the review were not long-term studies designed to evaluate slowly degrading compounds which could accumulate in a buffer strip and then be subsequently washed out upon saturation or failure of the buffer. The authors further state that it is clear [from the data] that it is difficult to derive recommended efficiency values for modeling purposes. The effectiveness of a buffer strip is highly dependent on the condition of the strip. For example, a well-established,

healthy vegetative setback can be a very effective means of reducing runoff and erosion from agricultural fields. Alternatively, a setback of poor vegetative quality or a setback that is channelized can be completely ineffective at reducing loadings. Until such time as a quantitative method to estimate the effect of buffer setbacks of various conditions on pesticide loadings becomes available, the aquatic exposure predictions are likely to overestimate exposure where healthy vegetative setbacks exist and underestimate exposure where poorly developed, channelized, or bare setbacks exist.

The Bayer assessment also employed a golf course adjustment factor of 0.34 to account for treatment of only tees, greens and fairways. However, the label does not specifically limit the area of a golf course that can be treated to these areas. EFED's assessment more accurately represents legal uses allowed by the current labels. Finally, in Bayer's assessment they assumed 0% spray drift since "generally golf course applications take place with low-boom sprayers that spray very coarse and high volume of spray". However, these are not restrictions that appear on the product label. In reality, it is impossible to eliminate spray drift from ground spray applications under all environmental conditions. EFED used the default spray drift value of 1% for ground boom applications.

Even though the Bayer assessment included refinements that are not supportable by the currently submitted data or existing product labels, the authors correctly point out that the principle factor in the differences between the surface water modeling and monitoring data result from assumptions regarding use intensity in the watershed. According to standard policy, EFED's drinking water assessment considers maximum application patters, a watershed that consists of 100% turf which is 100% treated. Bayer estimates that the actual highest intensity (lbs applied/ entire watershed area) observed at the Rahway, NJ site is over 58 times less than what was assumed in the drinking water assessments. This is because typical rates are much less than what is allowed on the label, and less than 100% of a given watershed is actually treated with iprodione. Bayer has previously reported that a "typical" application to turf is 2 applications of 1.375 lbs ai/A (2.78 lbs ai/year) (USEPA 2006a, DP 294254) compared to the maximum allowed on the label of 6 applications of 4 lbs ai/A (24 lbs ai/year). This is why actual use information (how much was used, when and where), the percent of acres of golf courses (potential use sites) in the watersheds and the actual percent of sites treated is being requested.

# 3 GROUNDWATER

## 3.1 Monitoring Study

### *3.1.1 Suffolk County Database of Drinking Water Sources*

In order to safeguard drinking water quality, Suffolk County Department of Health Services, has an extensive ground water source drinking water monitoring network consisting of private wells, non-community water systems and community water systems. Suffolk County provided a database including 9484 analyzes of iprodione and 734 analyses of 3,5-DCA from drinking water sources. The majority of samples represent private wells, non-community water systems and community water systems. A memo

from Suffolk County states that "the data from private wells is on either a complaint or survey basis, and while extensive, the data does not come close to representing every private well in the county". The database reports one detect of iprodione above the reporting limit at 5.75 ppb. Suffolk County indicated that this sample is actually from an irrigation well which does not serve as a drinking water source and should not have been captured in the database of groundwater drinking water sources. There were no detections for 3,5-DCA above the reporting limits.

The reporting limit of the Suffolk County database has varied from 0.2 to 5 ppb for iprodione and 0.3 to 1 ppb for 3,5-DCA over the years. Strangely, the reporting limits do not appear to be the same for a given sampling time-frame nor do they appear to improve (reduce) over time. In fact, higher reporting limits appear to be for more current samples. For example, for iprodione and vinclozolin all samples with reporting limits greater than or equal to 1 ppb were taken in 2007. The database does not report trace levels (above the method detection limit but below the reporting limit). A reporting limit as high as 1 ppb for 3,5 DCA adds considerably uncertainty to the interpretation of the data since the human health endpoint of concern is approximate to this value. Information on trace levels (whether or not trace levels have been detected and at what levels) would facilitate the interpretation of the drinking water source monitoring results from Suffolk County.

Bayer was able to geocode the majority of iprodione and 3,5-DCA sampling locations. Additionally, Bayer reported sales figures for all of Suffolk County for the years 2004-2006 along with maps of the sales data at the zip code level. Bayer did not submit the raw data that would enable EFED to examine the results thoroughly. Therefore, only a visual inspection is possible for comparing high sales area at the zip code level and sampling locations. From visual inspection, it appears that at least for certain zip codes in which sales have been reported in the last 3 years perhaps only one (or even zero) 3,5 DCA sample(s) exists. (Note that analysis of 3,5-DCA in Suffolk county only began in 2005, whereas sampling for iprodione began in 2001; thus there are many fewer analyses for 3,5-DCA than for iprodione.). Recently Bayer submitted information on golf course locations that had been treated with iprodione sold in 2004-2007 (MRID 47318201). The information consists of a map with point locations of the golf courses. No raw data have been submitted and no analysis of the proximity of the golf courses to the monitoring sites has been made.

Sales data at the zip code level may provide an indication of where iprodione is used, but it does not provide full characterization of the usage of iprodione relative to the sampling timing and locations. Actual usage data (how much is used, when and where) in temporal and spatial relation to the sampling is needed to interpret the monitoring results. Additionally, a report of trace levels is also necessary to draw conclusions from the monitoring data.

### *3.1.2 Suffolk County Monitoring Wells (non-Drinking Water Source)*

In a previous report entitled "Update on Suffolk County's Drinking Water Monitoring Data on Iprodione, Vinclozolin, and 3,5-DCA", Bayer CropScience reported on the results of other monitoring sites that are not included in the currently submitted database. EFED's review stated the following (USEPA, 2007a, DP 285550):

"...a cursory review of the reported results indicates that there were detections of iprodione and 3,5-DCA. All of the reported iprodione groundwater detections were at concentrations less than 1 ppb, except for one detection in an irrigation well that was 5.75 ppb (well depth not given but water table depth was stated to be 80 ft). Surface water detections of iprodione were higher with 3 detections greater than 1 ppb to 8.8 ppb at a golf course pond, 1.1 ppb at a golf course pond, and 2.6 ppb at unknown type of surface water (identified as a greenhouse). Lower and less frequent concentrations were reported for 3,5-DCA in groundwater, with the maximum concentration of 0.44 ppb in a golf course well. Surface water detections of iprodione include 4 ppb and 1.5 ppb in golf course ponds, along with three other golf course pond samples less than 1 ppb."

The EFED review was made in expectation that the registrant would make a more formal data submission including ancillary information (e.g., spatial context, well-depth). However, the registrant has not submitted any further information.

### 3.2 Exposure Assessment

Bayer conducted a refined groundwater modeling assessment for iprodione and 3,5-DCA using the physically based leaching simulation model, Pesticide Emission Assessment at Regional and Local scales (PEARL ver 2.2.2). EFED conducted a groundwater modeling assessment using the regression model SCIGROW (USEPA 2006b). The two approaches differ in model complexity and input parameter requirements. SCIGROW is based on the fate properties of the pesticide (i.e., the median $K_{oc}$ and mean aerobic soil metabolism half-life), the application rate, and monitored concentrations from small-scale ground water monitoring studies. PEARL is capable of considering site-specific information, bi-phasic degradation and variable sorption with time (with a commensurately larger input data requirement). SCIGROW estimated screening concentrations of 16 and 13 ppb for iprodione and 3,5-DCA, respectively. PEARL produced estimated 30-year mean concentrations at 1 m depth of 0.72 and 0.077 ppb for iprodione and 3,5-DCA, respectively.

Similar to the surface water modeling, the major difference in the modeling approach is the assumption regarding the degradation of 3,5-DCA. Again, Bayer assumed a bi-phasic two-compartment model to describe the microbial degradation of 3,5-DCA and neglected the unextracted and uncharacterized residues which were indistinguishable from 3,5-DCA. As previously discussed, there is considerable uncertainty regarding the degradation of 3,5-DCA because of the large amount of unextracted uncharacterized residues in the aerobic soil metabolism. Using a higher tier leaching model and bi-phasic degradation model does not address this uncertainty. Without evidence to the contrary, EFED made the conservative assumption that 3,5-DCA is stable. Additional degradation data that affirmatively demonstrate the microbial degradation of 3,5-DCA is needed to consider a higher tiered groundwater modeling assessment.

## 4 CONCLUSIONS

Results from Bayer's surface water monitoring program indicate that there have been some detections of iprodione at one of three sites, and there have been no detections of 3,5-DCA at any of the sites. However, use intensity has reduced substantially since site selection, and thus actual usage data is needed to fully interpret the monitoring data.

The Suffolk County Department of Health Services drinking water monitoring database reported one detect of iprodione above the reporting limit at 5.75 ppb from an irrigation well which does not serve as a drinking water source. There were no detections for 3,5-DCA above the reporting limits. The reporting limit of the Suffolk County database has varied from 0.2 to 5 ppb for iprodione and 0.3 to 1 ppb for 3,5-DCA over the years. Full interpretation of the monitoring results cannot be made until the registrant supplies actual usage data (how much is used, when and where) in temporal and spatial relation to the sampling. Additionally, a report of trace levels is necessary to draw conclusions from the monitoring data.

Bayer's refined surface water modeling assessment consisted of refinements (such as bi-phasic degradation models, and reduction factors) that are not supportable by the currently submitted data or product labels. However, Bayer correctly states that a major difference in the modeling and monitoring data is due to assumptions regarding use intensity in the watersheds. This is because typical rates are much less than what is allowed on the label, and less than 100% of a given watershed is actually treated with iprodione.

Both the refined surface water and groundwater modeling assessments used a bi-phasic degradation model to describe microbial degrdatation of 3,5-DCA and discounted the substantial amount of unextracted material apparent in the laboratory study. The amount of unextracted and uncharacterized material prevents accurate estimation of degradation rates. This is a major source of uncertainty that has not been addressed in the current submission. Without additional data that affirmatively demonstrate the microbial degradation of 3,5-DCA, EFED has no means to refine this aspect of the drinking water assessment.

**REFERENCES**

Reichenberger, S., Bach, M., Skitschak, A., Frede, H-G. 2007. Mitigation strategies to reduce pesticide inputs into ground- and surface water and their effectiveness; A review. Science of the Total Environment 384: 1-35.

USEPA. 2006a. Iprodione Monitoring Site Selection. DP 294254.

USEPA. 2006b. Water Models. U.S. Environmental Protection Agency, Pesticides: Science and Policy. Last updated: May 4, 2007. Online at: http://www.epa.gov/oppefed1/models/water/

USEPA. 2007a. Iprodione Preliminary Drinking Water Monitoring. DP 285550.

USEPA. 2007b. Iprodione drinking water assessment, including proposed new use on pistachio (IR4) and labelrevisions affecting rates for strawberries, stone fruits, and grapes. DP 288850.

USEPA. 2008. Review of Surface Water Monitoring for Residues of Iprodione in High Use Areas in the United States: Interim Report (MRID 47170301). DP 291976, 343734.