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OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

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**MEMORANDUM**

**SUBJECT**: **Fomesafen:** Ecological Risk Assessment for the Proposed IR-4 New Uses on Tuberous and Corm Vegetables Crop Subgroup 1C, Legume Vegetable Crop Group 6, and Low Growing Berry Crop Subgroup 13-07G (Except Cranberry)

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for Sujatha, Greg Orrick 2016.06.23 16:50:14 -04'00'

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**TO:** Lisa Pahel, Risk Manager Reviewer
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This memorandum summarizes the ecological risks associated with the proposed IR-4 new uses of fomesafen, an herbicide, for broad leaf postemergence weed control in tuberous and corm vegetables crop subgroup 1C, legume vegetable crop group 6, and low growing berry crop subgroup 13-07G (except cranberry). The proposed uses apply to the Reflex® label (Reg. # 100-993).

Preplant surface, preemergence and/or postemergence applications (aerial, ground, and irrigation applications through center pivot systems only are permitted) are proposed at a maximum application rate of 0.38 lb ai/A per year (only a single application per year). This maximum application rate may be further reduced according to the regional use map provided on the Reflex® Herbicide label or restricted to alternate year applications according to geographical region. These same application rate restrictions apply for all of the existing uses on this label, but is less than the maximum labeled annual application rate of 0.53 lb ai/A for use on pine seedlings (EPA Reg. No. 66222-242) (Table 1).

**Table 1. Fomesafen Application Rates for Proposed IR-4 New Uses**

| Crop (Subgroup) | Maximum Application Rate[1] (lb ai/A) | | Maximum Number of Applications Per Year | Minimum Interval (Days) | Method of Application |
|---|---|---|---|---|---|
| | Single | Annual | | | |
| **Proposed Fomesafen Application Patterns EPA Reg. No. 100-933** | | | | | |
| Annual Crop Members of Low Growing Berry Crop Subgroup 13-07G. Strawberry (annual and perennial) | 0.19-0.38 | 0.38 | 1 | NA | Broadcast Spray (aerial and ground) |
| Tuberous and Corm Vegetables Crop Group 1C Sweet Potato | 0.19-0.25 | 0.25[1] | 1 (season) | NA | Broadcast Spray (aerial and ground) |
| Legume Vegetable Crop Group 6 Dry Shelled Pea | 0.19-0.38 | 0.38 | 1 | NA | Broadcast Spray (aerial and ground) |
| **Currently Labeled Application Pattern of Maximum Exposure EPA Reg. No. 66222-242 and EPA Reg. No. 67760-93** | | | | | |
| Pine Seedlings | 0.52-0.53 | 0.53 | 1 | NA | Broadcast Spray (aerial and ground) |

[1]Based on the assumption of one crop season per year.

An abbreviated ecological risk assessment (ERA) is presented because it was determined that previous risk assessments could be relied upon to cover potential risk concerns for a substantial portion of the current assessment. This is in part because the application rates are equal to or less than, and the methods are the same as, those of previously assessed uses. In addition, to the extent that new information, approaches, guidance, and models are available they do not substantively impact the overall conclusions except as otherwise noted. Furthermore, the reported incident data[1] (discussed in a separate section) consists almost exclusively of terrestrial plant incidents, which is not unexpected since fomesafen is used as an herbicide. It is implied when past risk assessments are relied upon that the risk for the proposed uses is "covered" by previous assessments, meaning that risk for the proposed uses may be overestimated but is not expected to be greater than that of previously assessed uses.

However two recently-implemented guidance documents do need to be considered since no previous fomesafen risk assessments have incorporated this risk assessment guidance. The "Guidance on Light-Dependent Peroxidizing Herbicides" (LDPH) indicates chronic risk to fish in clear, well-lit, shallow bodies of water due to µV light-enhanced toxicity (see further discussion below). Previous assessments did not indicate risk to any non-listed aquatic species. The second guidance that needs to be considered is the pollinator guidance, which did not result in any change to risk conclusions.

## Ecological Risk Assessment

Risk conclusions for the proposed uses are covered by risk conclusions from past risk assessments (including the Registration Review Preliminary Risk Assessment (PRA) – USEPA 2008) except for risk to honey bees, which was previously considered but not with the most recent guidance (Table 2; also see USEPA 2008; DP 337939, USEPA 2010; DP 365204+, and

[1] The Ecological Incident Information System (EIIS), Avian Incident Monitoring System (AIMS), and the Incident Data System (IDS) were searched on June 2, 2016.

USEPA 2013; DP 411393 for greater detail). Risk conclusions for honey bees presented here supersede conclusions from past risk assessments. The overall ecological risk for honey bee exposure is uncertain due to data gaps and the herbicidal nature of the chemical, although a submitted study indicates low acute contact and dietary risk to adult honeybees from the proposed and existing uses.

**Table 2. Ecological risk conclusions for each assessed taxon.**

| Effect | Taxonomic Group | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | **Birds** | **Mammals** | **Terr. Plants** | **FW Fish** | **E/M Fish** | **Aquatic Invert.** | **Aquatic Plants** | **Terr. Inverts.** |
| Direct Effect | **?** | √[1] | √[2] | √[3] | √[3] | -- | -- | **?**[4] |
| Indirect Effect | √ | √ | √ | √ | √ | √ | √ | √ |

[1] Chronic exceedances only for small herbivorous mammals at the highest application rates (both listed and non-listed species).
[2] Terrestrial and semi-aquatic plants, especially dicots.
[3] Chronic risk due specifically to µV light-enhanced toxicity.
[4] Additional toxicity data is needed to rule out possible risk concerns for honeybees.

## Terrestrial Organisms

The terrestrial organisms most at risk from fomesafen are terrestrial plants, especially dicots (risk quotients (RQs) of 1 to 67). Other terrestrial organisms had lower risk concerns.

### *Birds and Mammals*

For birds (and by extension, reptiles and amphibians), the chronic endpoint was non-definitive, but this non-definitive endpoint is not high enough that risk to birds is not of concern (*i.e.*, potentially, LOCs could be exceeded at all but the lowest fomesafen application rates). Chronic LOCs were also exceeded for mammals, but only for small herbivorous mammals at the highest application rate (RQ of 1.04).

### *Honey bees*

Although risk to bees was previously considered (USEPA 2008 and 2010), tier 1 EECs were calculated for honey bees using the recently approved guidance (USEPA 2014). Foliar applications may result in contact and dietary exposure.

The acute contact EEC for the highest proposed single application rate is calculated as follows:

Acute contact EEC (adult) = 0.53 lb ai/A * 2.7 µg ai/bee per lb ai/A = 1.4 µg ai/bee

The acute dietary EEC for the highest proposed single application rate is calculated as follows:

Acute dietary EEC (adult) = 0.53 lb ai/A * 110 µg ai/g per lb ai/A * 0.292 g/day = 17.12 µg ai/bee

The assessed single application rate (0.533 lb ai/A) is the highest application rate for all existing (0.533 lb ai/A) and proposed uses (0.375 lb ai/A); therefore, these EECs cover the proposed uses as well as all currently registered uses.

There is not an acute contact or dietary risk concern for adult bees from the proposed or existing uses based on available data (acute contact, >100 µg ai/bee, and acute oral, >50 µg ai/bee, toxicity to adult honeybees; MRID 00135651). Acute contact- and acute dietary-based RQs were not calculated because the available toxicity studies resulted in non-definitive endpoints ($LD_{50}$). However, a conservative comparison can be made between EECs and the highest concentration

tested in the applicable toxicity studies. The acute contact and dietary EECs are less than 1/2.5 (i.e., LOC = 0.4) of the non-definitive $LD_{50}$s (reported in USEPA 2008) for adult acute contact and dietary (oral) toxicity, respectively.

Considering that fomesafen is an herbicide and no risk was identified from the acute contact and acute oral studies, pollinator risks are not anticipated. However, there is uncertainty about chronic dietary risk to adult honeybees and acute and chronic dietary risk to bee larvae due to a lack of toxicity studies. Therefore, these risks cannot be precluded.

Aquatic Organisms

Previous assessments did not identify risks for any aquatic taxa even at an application rate of 0.53 lb ai/A. However, based on the new "Guidance on Light-Dependent Peroxidizing Herbicides" (LDPH), chronic risk is indicated for fish in clear, well-lit, shallow bodies of water due to µV light-enhanced toxicity. Based on the LDPH guidance, fomesafen's enhanced µV molar threshold NOAEC is 0.88 µg/L. The highest aquatic EEC for fomesafen is 14.49 µg/L (USEPA 2010), which produces an RQ of 16.5. No other risks to aquatic taxa are expected at the proposed application rates.

Ecological Incidents

Reviews were conducted of the Ecological Incident Information System (EIIS, version 2.1.1), the Agency's Aggregated Incidents Reports database, and the Avian Incident Monitoring System (AIMS) on 6/2/2016. Incidents associated with fomesafen were reported in two of the three databases (no fomesafen incidents in AIMS).

Of the 78 fomesafen incidents in EIIS (this number includes all incidents including those previously summarized in the PRA), 77 are for terrestrial plants. Of the 77 terrestrial plant incidents, the legality of those applications were classified as misuse or misuse (accidental) for seven incidents, 24 were classified as registered use, and for the remaining 47, the legality of the use was classified as undetermined. Given that fomesafen is an herbicide, it is not surprising that the vast majority of reported incidents were to plants (mostly corn, soybean, or not reported in terms of the use site). The only non-plant incident was an aquatic incident involving a fish kill of 200 fish in 1998. However, this aquatic incident was classified as unlikely to be related to the fomesafen application.

There are 344 minor incidents reported in the Aggregated Incidents Reports database; one was classified as a minor fish and wildlife incident, 339 were minor plant incidents, and 4 other non-target incidents. Again, it is not surprising that the vast majority of reported incidents were to plants since fomesafen is an herbicide.

The total number of actual incidents associated with the use of fomesafen may be higher than what is reported to the Agency. Incidents may go unreported for a variety of reasons such as affected organisms were not found and effects were not immediately apparent or readily attributed to the use of a chemical. As such, the absence of incident reports cannot be construed as the absence of incidents and likewise, the number of incident reports cannot be assumed to fully account for the actual number of incidents.

## Conclusions

Potential risk concerns for the proposed uses are the same as identified for previously assessed uses; that is, direct risk concerns primarily for terrestrial plants and mammals, with low potential for risk to birds. This is the first fomesafen risk assessment to consider risk to honeybees using the most recent pollinator guidance (USEPA 2014); therefore, risk conclusions for honeybees presented here supersede conclusions from past risk assessments. The overall risk picture for honeybees is incomplete and uncertain even though the submitted data suggest low risk from the proposed and existing uses (*i.e.*, chronic risk to adult honeybees, and acute and chronic risk to larval bees is uncertain due to the lack of data).

Uncertainty with Fomesafen's Fate Data

Based on a review of the currently available fomesafen fate studies, there appears to be existing fate studies that produce a disproportionate amount of uncertainty in the Agency's risk assessment process. Repeating these studies using improved analysis methods, or providing clarifying information, may diminish these uncertainties and potentially mollify some of the Agency's risk concerns. These studies are discussed below.

*Hydrolysis*

The submitted fomesafen hydrolysis study (Accession No. 071059) does not conform to Agency guidelines. In this study, radiolabeled fomesafen was considered "stable" (did not degrade during the study). However, abiotic hydrolysis was only measured at two pHs (3 and 11) at 40°C, which is not in conformance with Agency guidelines (*e.g.*, pH 5, 7, and 9). Additionally, dark controls for aqueous photolysis study (another measure of hydrolysis rate) were stable (no degradation) at pH 7 at 25°C (MRID 40451101). If a better-designed hydrolysis study were able to detect a "non-stable" degradation rate, estimated fomesafen aquatic ecological exposure and exposures through surface and especially ground water sources could be reduced.

Potentially if degradation can be demonstrated at a set of higher temperatures for fomesafen, an accurate rate of degradation at 25°C could be predicted using the Arrhenius equation. If this study is repeated, the pHs studied should follow Agency guidelines (*e.g.*, pH 5, 7, and 9). Additionally, three temperatures differing by at least 10°C are typically required to demonstrate a satisfactory Arrhenius temperature relationship. Establishing even a degradation rate with a multiyear half-life would reduce groundwater drinking water exposure since water may take decades to reach a depth from which drinking groundwater is drawn. The hydrolysis rate would affect surface drinking water and aquatic ecological exposures to a lesser degree.

*Metabolism Studies*

There are two guidance documents that may affect how the degradation half-lives are calculated. The half-lives used in the fomesafen previous assessments (on which this document was based) used a single first-order model of degredation. Current guidance[2] is to use the best fit of three degradation models (one of which is single first-order).

[2] USEPA. 2015. Standard Operating Procedure for Using the NAFTA Guidance to Calculate Representative Half-life Values and Characterizing Pesticide Degradation. Environmental Fate and Effects Division. Office of Pesticide Programs. United States Environmental Protection Agency. March 23, 2015.

The second guidance document[3] considers unextracted residues in half-life calculation. Historically, the Agency has calculated degradation rates and associated half-lives that overlooked the potential for unextracted residues to contribute to risk. Current guidance addresses this potential risk calculating aquatic exposure in two ways to bracket potential exposure with a high estimate (based on half-life calculations that includes the extracted chemicals of concern and unextracted residues) and a low estimate (based on half-life calculations that includes only the extracted chemicals of concern). This method from the current guidance results in a low range of risk estimates (low uncertainty) for studies with little unextracted residues and a high range of risk estimates (high uncertainty) for studies with considerable unextracted residues. Typically, this is only performed if the maximum unextracted residues exceed 10% during a study.

In the available aerobic soil metabolism study, radiolabeled fomesafen was applied at two rates with the lower rate applied to soils at two different soil moisture levels. At the lower application rate (0.45 lbs a.i./A) and lower moisture level, fomesafen had first order half-lives of 796, 697, 1085, and 548 days with maximum unextracted residues of 16.6, 12.7, 17.9, and 31.9%. At the lower application rate (0.45 lbs a.i./A) and higher moisture level, fomesafen had first order half-lives of 1010, 1250, 666, 572, and 216 days with maximum unextracted residues of 18.9, 13.3, 13.9, 25.3, and 33.3%. At the 4.5 lbs a.i./A application rate, fomesafen had a first order half-life of 1063 days with a maximum unextracted residue of 16.6% (MRID 00135660).

In the anaerobic aquatic metabolism study (MRID 47865308), radiolabeled fomesafen was applied to three soil:water systems producing total system half-lives of 4.0, 3.6, and 5.1 maximum unextracted residues of 33, 30, and 13%, respectively.

In the aerobic aquatic metabolism study, radiolabeled fomesafen was applied at two rates. At 0.45 lbs a.i./A, fomesafen had a first-order half-lives of 8.7, 19.9, 13.2, and 16.5 weeks and unextracted residues of 38, 42, 50, and 38%, respectively. At 0.9 lbs a.i./A, fomesafen had first-order a half-lives of 4.2 and 6.1 weeks with maximum unextracted residues that are not legible (MRID 00135659).

However before the guidance can be applied, the Agency needs a more legible copy of the study that contains the aerobic aquatic metabolism results. At the time this study were submitted to the Agency, the Agency's practice was to microfiche the studies. Later these studies were converted to pdfs. Between the two procedures much of the resolution was lost. The study needed is:

Bewick, D.; Zinner, C.; White, R. (1983) Fomesafen: Degradation in Soil under Flooded Conditions in the Laboratory: Report Series RJ 0269B. (Unpublished study received Nov 22, 1983 under 10182-83; prepared by Imperial Chemical Industries, Ltd., Eng., submitted by ICI Americas, Inc., Wilmington, DE; CDL: 072158-C)

**References**

USEPA. 2008. Environmental Fate, Ecological Risk and Endangered Species Assessment in Support of the Registration Review of Fomesafen Sodium (PC 123802). Environmental

[3] USEPA. No date. Guidance for Addressing Unextracted Residues in Laboratory Studies. Environmental Fate and Effects Division. Office of Pesticide Programs. United States Environmental Protection Agency.

Fate and Effects Division, Office of Pesticide Programs, United States Environmental Protection Agency. DP 337939. December 29, 2008.

USEPA. 2010. Ecological Risk Assessment Addressing the Proposed Registration of the Fomesafen for use on Tomatoes, Potatoes, and Peppers. Environmental Fate and Effects Division, Office of Pesticide Programs, United States Environmental Protection Agency. DP 365204+. March 25, 2010.

USEPA. 2013. Fomesafen: Ecological Risk Assessment to Support IR-4 Petition for Use on Lima Beans. Environmental Fate and Effects Division, Office of Pesticide Programs, United States Environmental Protection Agency. DP 411393. July 16, 2013.