Lactofen Final Work Plan for Registration Review

July 2007

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Lactofen Final Work Plan (FWP)
For Registration Review
July 2007

Approved by: _____

Peter Caulkins, Acting Director
Special Review and Reregistration Division

Date: 7/2/07

Introduction:
This is the Environmental Protection Agency's (EPA's) ***Final Work Plan*** for the registration review of lactofen. This work plan includes the expected registration review time line. The work plan also addresses public comments received concerning the ***Preliminary Work Plan*** in the ***Summary Document*** which was posted in the lactofen registration review docket, or any other comments concerning initial docket postings. The ***Summary Document*** provided information on what EPA knows about the pesticide and what additional risk analyses and data or information the Agency believes are needed to make a registration review decision.

The Agency is implementing the new registration review program and plans to review each registered pesticide every 15 years to determine whether it continues to meet the Federal Insecticide Fungicide and Rodenticide Act (FIFRA) standard for registration. Changes in science, public policy, and pesticide use practices will occur over time. The registration review program is intended to make sure that, as the ability to assess risk evolves and as policies and practices change, all registered pesticides continue to meet that statutory standard. The public phase of registration review begins when the initial docket is opened for each case. Information on this program is provided at: http://www.epa.gov/oppsrrd1/registration_review/.

Comments Received on Preliminary Work Plan:
EPA received comments during the public comment period on the initial lactofen docket. However, these comments, which are addressed in this document, did not change the data and risk assessment needs, and timeline detailed in the Preliminary Work Plan. This document makes final the work plan for the lactofen registration review process. A listing of the comments and responses are in the "Summary of Comments and Agency Responses" part of this document.

Risk Assessment and Data Needs:
The Agency will conduct a comprehensive ecological risk assessment, including an endangered species assessment for all uses. The Agency will also conduct occupational risk assessments for some uses.

Ecological Risk:

- Ecological risk assessments for most lactofen uses were completed several years ago, and the Agency has not conducted a risk assessment that supports a complete endangered species determination.

- The Agency needs the following data in order to conduct a complete ecological risk assessment, including an endangered species assessment, for all uses:
    - (GLN 850.4250) Vegetative Vigor (Tier 2) for lactofen
    - (GLN 850.4225) Seedling Emergence (Tier 2) for lactofen
    - (GLN 850.1350) Reproduction Estuarine/Marine Invertebrates for lactofen and degradate (acifluorfen)
    - (GLN 850.1400) Freshwater Fish Early-Life Stage for degradate (acifluorfen)

- (GLN 850.2300) Avian Reproduction Test with two species: bobwhite quail and mallard duck for lactofen

The ecological risk assessment will allow the Agency to determine whether lactofen use has "no effect" or "may affect" federally listed threatened or endangered species (listed species) or their designated critical habitat. If the assessment indicates that lactofen "may affect" a listed species or its designated critical habitat, the assessment will be refined. The refined assessment will allow the Agency to determine whether use of lactofen is "likely to adversely affect" the species or critical habitat or "not likely to adversely affect" the species or critical habitat. When an assessment concludes that a pesticide's use "may affect" a listed species or its designated critical habitat, the Agency will consult with the U.S. Fish and Wildlife Service and National Marine Fisheries Service (the Services), as appropriate.

Human Health Risk:

- The Agency believes that previously completed dietary assessments are adequate and that there is no dietary risk that exceeds the Agency's level of concern (LOC). Thus, no additional data are needed.
- Occupational risk assessments are needed for uses on soybeans and cotton; however, no additional data are needed to complete these assessments.

Timeline:

EPA has created the following estimated timeline for the completion of the lactofen registration review. The Agency may conduct the occupational assessment for cotton and soybean uses much earlier in the process, allowing mitigation (if necessary) to occur well before the end of 5 years.

Activities	**Estimated Month/Year**
Phase 1: Opening the docket	
Open Public Comment Period for Lactofen Docket	Jan. 2007
Close Public Comment Period	Apr. 2007
Phase 2: Case Development	
Develop Final Work Plan (FWP)	July 2007
Issue DCI	2Q 2008
Data Submission	2Q 2010
Open Public Comment Period for Preliminary Risk Assessments	3Q 2011
Close Public Comment Period	3Q 2011
Phase 3: Registration Review Decision	
Open Public Comment Period for Proposed Reg. Review Decision	2012
Close Public Comment Period	2012
Final Decision and Begin Post-Decision Follow-up	2012
Total (years)	5

Summary of Comments and Agency Reponses:

Three comments were received during the public comment period on the preliminary lactofen docket. One comment was from a citizen, one was from the FIFRA Endangered Species Task Force, and the final comment was from the technical registrant, Valent. Valent's comments were substantive and were the only comments specific to the lactofen work plan. The following are the comments and the Agency's responses.

Comment:

Acifluorfen and lactofen should go through registration review at the same time because they share a common degradate acifluorfen. A simultaneous review of acifluorfen and lactofen would facilitate a process whereby registrants of both active ingredients could cost-share, conducting a single study to satisfy guideline requirements for their respective chemicals.

Response:

Sodium acifluorfen (PC Code: 114402) and lactofen (PC Code: 128888) are registered pesticides; while acifluorfen is a degradation product of both lactofen and sodium acifluorfen. The schedules for the two registered pesticides are based on the date of their last comprehensive risk assessments. Lactofen was first registered in 1987, and therefore was not subject to reregistration. Accordingly, it was scheduled for registration review earlier than sodium acifluorfen, which had a recent Reregistration Eligibility Decision (RED).

Comment:

The acifluorfen studies used to select endpoints for lactofen were not reviewed by EPA.

Response:

The acifluorfen studies used to select endpoints have been reviewed by Agency scientists. The Agency is committed to using the most appropriate data available. With no other information available, we believe that the endpoints selected are appropriate. If Valent disagrees with the endpoints selected, they could conduct and submit guideline studies to the Agency.

Comment:

Lactofen is not nor has it ever been registered for forestry uses. Lactofen use on strawberries is a non-food use.

Response:

The Agency agrees with this comment. Lactofen is registered for use on conifer seedlings which are treated in a nursery. There are no forestry uses for lactofen. In addition, the use of lactofen on strawberries is a non-food use because lactofen is applied to the seedlings.

Comment:

Valent disagrees with the Agency's request for an aquatic toxicity study for the three active ingredients, lactofen, sodium acifluorfen, and flumiclorac-pentyl. Lactofen and flumiclorac-pentyl are no longer being co-formulated. Further, lactofen quickly breaks down to acifluorfen.

Response:

This comment refers to a January 2006 DCI that requested a fish early life stage toxicity study under varying light conditions. This DCI was issued to a group of registrants who hold technical registrations for light-dependent peroxidizing herbicides (LDPHs). Lactofen belongs to this LDPH class. These data are needed on this class of compounds in order to refine how different wavelengths of light affect the toxicity of the LDPH on aquatic organisms. The ***Summary Document*** for lactofen did not address the aquatic toxicity study referenced because the Agency and the technical registrants are currently discussing these data needs in terms of protocols and the compounds which are to be assessed. The comprehensive ecological risk assessment for lactofen, will take into account the LDPH compounds and their effect on aquatic organisms.

Comment:
Valent disagrees with the statement in section 1.7, conceptual model, that "some [lactofen] may also volatilize."
Response:
EPA would agree that volatilization is not likely to contribute significantly to the dissipation of lactofen.

Comment:
In another document, EPA says, "acifluorofen has previously been detected in ground water in sodium acifluorfen prospective ground water (PGW) study but not in a retrospective sodium monitoring study (five states)".
Response:
The results show the influence of variable conditions where the pesticide is used (including insufficient precipitation for leaching). The Agency has never implied that all use sites would result in ground water concentrations observed in the PGW study. Based upon the information submitted with the PGW study, the results are valid and the agronomic practices used are typical to the area.

Comment:
The registrant questioned whether or not acifluorfen leaches to ground water.
Response:
The National Water Quality Assessment (NAWQA) Program and other monitoring studies are not targeted for lactofen or sodium acifluorfen—thus the detections, though limited, are unexpected. The PGW studies are conducted where there is known application of the pesticide in question (plus a tracer), thus there is no question concerning the hydrologic connection between the use area (soil surface) and ground water.
The Agency acknowledges that the PGW sites are probably skewed towards the "vulnerable". Study sites are selected to not only represent vulnerable conditions, but also where some meaningful results can be obtained in a reasonable time period.

Comment:
The 3x uncertainty factor is inappropriately used in the human health scoping document.
Response:

Valent submitted a request to waive the rabbit developmental study in 2005, including additional background information on the two prior studies. The Agency has reviewed their request, and concurred with their position that sufficient information has been submitted on developmental effects in rabbits. No further studies are needed, and thus a database uncertainty factor is no longer required. However, a 3X uncertainty factor is necessary because a NOAEL was not identified in the study that the Agency is now using for acute dietary endpoint selection. An uncertainty factor of 3X is expected to be protective of infants and children, and will be used for the LOAEL to NOAEL extrapolation.

Comment:
Endpoints selected for aquatic organisms are incorrect in section 1.9.2, table 2 of the problem formulation document.
Response:
The discrepancies between the endpoints in table 2 and those cited by Valent may be due to the different studies or species selected for calculation of the endpoints. However, the Agency has reviewed the endpoints that Valent provided, and will consider them further when conducting the comprehensive ecological risk assessments for lactofen.

Next Steps:
A DCI will be developed regarding the data gaps listed under the "Risk Assessment and Data Needs" section. Occupational and residential exposure and ecological risk assessments will be conducted for the uses (detailed above) that require these assessments.