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OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

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SUBJECT: EFED responses to Imazapyr Phase 3 Comments

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The Environmental Fate and Effects Division (EFED) has completed its review of the Imazapyr Phase 3 Comments. In this document, EFED provides its response to comments from BASF, California Indian Basketweavers Association, Nebraska Department of Agriculture.

1) Response to BASF comments

BASF is concerned about the procedures that EPA has used in performing the assessment for nontarget terrestrial and semi-aquatic plants. Specifically, EPA has used BANKS (1988) MRID No. 40811801 for the effects endpoints. EPA considers the study supplemental or invalid (Table IIIC-14, p. 56). Elsewhere in the text (p. 10) , EPA refers to the study as supplemental and highlights that the plants were stressed and that wet weight was measured instead of dry weight.

EPA response: The study was categorized as supplemental due to stress and EPA test guidelines require dry weight and height measurements. However, the results were considered useful for risk assessment despite the deficiencies.

BASF comment: There are several other points that should be mentioned regarding the study. First, the study was done with technical a.i. diluted in acetone. EPA typically requires that nontarget plant tests be done with a representative formulation. BASF points out the Feutz and Canez study (MRID No. 43889101) was done with the 2ASU formulation.

EPA response: The Agency determined that the Banks study (MRID 40811801) was tested with TEP, which included a surfactant, Tween 20, and the Feutz and Canez study (MRID 43889101) was tested without any surfactant(s). The Banks study was tested with an adjuvant thus making it more representative of a TEP than the Feutz and Canez study with salt alone. Another reason the Agency did not use the Feutz and Canez study was that it was only conducted with 3 species as opposed to the required 10 species.

BASF comment: Second, the report calculates EC25 and EC50 values using simple linear regression. It appears that EPA has calculated the EC05 values used in the assessment. However, there are no details provided as to the model used or the fit of that model to the data. BASF is unaware of a DER for the Banks study.

EPA response: Based on the October 21, 1994 memorandum; the lack of a No Observed Adverse Effect Concentration (NOAEC) will not invalidate a terrestrial plant study as long as the slope is adequate for calculation of valid EC50, EC25, and EC05 values from the most sensitive endpoints. Studies that lack a NOAEC but meet the above criteria will be classified supplemental.

However, most of the invalid NOAECs were calculated to be above the EC25, the EC05 was obtained from the Bruce and Versteeg method. Therefore, the Agency calculated EC05s with which to assess potential effects to endangered species.

Statistical Method: Data for plant length, and shoot weight for the seedling emergence and vegetative vigor tests were analyzed to determine the NOAEC, EC_{05}, EC_{25}, and slope values. Continuous data (height and weight) were assessed for normality and homogeneity of variance prior to all analyses. Treatment effects were assessed using Williams' tests. The EC_x estimates were done using the Bruce and Versteeg method via Nuthatch software. The Seedling Emergence and Vegetative Vigor DERs for the Banks and Feutz/Canez studies are attached

2) Response to comments on Imazapyr from the **California Indian Basketweavers Association**

Issue 1 pertained to tolerance setting, EFED is only responding to issues 2-7.

Issue 2. The risk assessment assumes that forestry pesticides are applied only "1-2 times during a 20-30 year conifer rotation" (Table II-A-3, U.S. EPA 2005). This assumption is not factual in California's forests, and may not realistically capture the effects of forestry herbicide use on non-target plants and animals. Analysis of data on file at the California Department of Pesticide Regulation documents that forestry herbicide applications occur dozens of times at the subwatershed level annually and commonly every three to five years, and more frequently in some locations. Multiple re-application is commonplace even on individual acres, but where impacts are recurring at the subwatershed scale they should be considered as cumulative, multiple impacts to the species at risk throughout the watershed—and not only a single application to an individual acre.

Response to Issue 2: The information available to the Agency on usage of imazapyr on forests indicated it would only be applied 1-2 times in multiple years, ie 10 years, or 20-30 years. However, our exposure and risk modeling is not affected (reduced) by that assumption. We modeled a single application and drew conclusions of risk based on that application. For risk to terrestrial plants, repeat applications in different parts of a watershed would not result in higher, local exposure or risk because the terrestrial plant scenario is at the field level. Other treatments in other fields, whether in the same watershed or not, would still be represented at the field level by the model. For aquatic risk, a single application resulted in a conclusion of significant risk for plants. The scenario modeled was actually a pond, with no inflow or outflow, so it would not take into account the dilution that would occur in a watershed stream. The scenario modeled also assumed the entire watershed was treated at one time. So the multiple applications that might be possible in different areas of a given watershed would be unlikely to result in higher exposures than calculated using the tier one surface exposure model GENEEC2.

The risk assessment also models Estimated Environmental Concentrations (EECs) with one application of imazapyr at 0.9 and 1.5 lb ae/A per year for non-crop terrestrial uses (U.S. EPA 2004). This also underestimates the actual rates of applications on forest lands where a subwatershed may be sprayed multiple times in one year.

Response to Issue 2 cont'd: The application rates were those available to Agency based on label analysis. Applications at rates higher than the label were not assessed. The model used by the Agency at this screening level is not capable of modeling multiple applications to different parts of a given watershed. See the comment above discussing the nature of the scenario modeled by the Agency that assumes 100% of a watershed is treated simultaneously. The EECs presented are considered to be representative of the exposure from forestry use under conditions that maximize exposure.

Issue 3. In a 2003 memorandum from Larry Turner, EPA Environmental Field Branch Field and External Affairs Division to his branch chief, relative to forestry herbicide uses of imazapyr, Mr. Turner states that "California, Washington, and Oregon all have restrictions regarding how close to water forest herbicides may be applied. In most situations, trees may no longer be harvested very near the edge of the water, which would result in negligible site preparation applications of imazapyr near the water." This statement is not factually correct and we are concerned that similar assumptions may have been used to prepare the current risk assessment.

The risk assessment should not assume that forestry applications do not occur near water. In California, timber harvests do in fact occur directly up to the stream channel and

Response to Issue 3: The Agency risk assessment did not model the exposure from forestry use or any other use pattern in any way assuming setbacks or buffers from waterbodies. Our model assumed treatment occurred adjacent to the waterbody in which EECs were estimated.

[illegible] endangered salmonids. Spraying permitted in the headwaters of streams will impact threatened or endangered species downstream through sediment residency, sublethal effects, loss of riparian and aquatic vegetation and other factors.

Response to Issue 3 cont'd: In response to the concern for downstream indirect effects, this is taken into account in the Agency risk assessment where it discusses indirect affects, it mentions effects due to loss of habitat. The outcome from loss of habitat would be potential loss of vegetation and possibly increased sedimentation. At this stage of the Agency's assessment for endangered species, the specific possible impacts from indirect effects have not been fully explored, and remain a possibility.

Stream buffers should be required for application near any stream of at least 100 yards for any application applied as a mixture of two or more chemicals. Incident report #10000022-001 cited in the docket demonstrated drift up to 85 feet and run off up to 60 feet away killed mature birds, nesting birds, fish and algae.

Response to Issue 3 cont'd: The degree to which the 100 yard buffer would reduce risk is uncertain in that exposure is expected to occur both from drift and runoff. Buffers that are effective to reduce spray drift may not be effective to reduce runoff. However, it is assumed, as a general principle, that any setback from water bodies would reduce the probability and possibly the level of exposure in that waterbody.

As noted in the science chapter discussion of this incident, because of the mode of action of imazapyr, and the way it affects the ALS enzyme, which is only found in plants, it is considered unlikely that imazapyr itself directly killed birds and fish. It is likely this incident reflects consequences of exposure to other pesticides also applied. However, this does not diminish the possibility of adverse effects to plant communities that might adversely affect animals living in, or depending on these plants.

Issue 4. Plants that are routinely killed with herbicides in the practice of converting native forests into tree farms or plantations include many different species of oak, huckleberry, manzanita, deer brush, thimbleberry and wild raspberry, kitkitdizzee, willow, bitter cherry and Sierra plum, hazel, sour berry or sumac, dogwood, redbud, buck brush, tobacco brush, gooseberry and wild currant, elderberry, bear grass, deer grass, and many other plants. The extreme toxicity of imazapyr to plants virtually guarantees that non-target impacts will occur to these species from drift.

Response to Issue 4: This comment is reflected in the science chapter's risk conclusions. The Agency is not aware that imazapyr is used in the practice of converting native forest to tree farms. However, labeled uses were modeled, and the exposure from such a treatment would not be different than what was modeled in the Agency's risk assessment assuming it is used according to the label.

Issue 5. Imazapyr is frequently used as a roadside or rights of way spray. Roads provide a direct conduit for chemical transport into streams and other waterbodies. A total of 4,318,165 pounds of pesticides, mostly herbicides, were reported used on roadsides in California in 2004. Over 1,187 pounds of imazapyr were used for rights of way but diuron use increased to 694,280 pounds for rights of way. The combination of these chemical uses is a significant risk for contamination of water bodies. Roadside spraying is not conducted once a year but frequently is conducted three times a year by country road maintenance departments.

Response to Issue 5: The information obtained by the Agency either indicated single applications of imazapyr, or did not specify the number of applications. Since even with a single application, risk was concluded for aquatic plants from the roadside or rights of way use. If multiple applications were permitted, the risk numbers might be higher, but the pattern of LOC exceedances would not change. Multiple applications may also extend the duration of risk; however, the model would not show the effect of this increased duration. It is also important to note that the modeling used to assess the roadside use pattern assumed a large contiguous treated area that would take into account repeated sequential applications.

Issue 6. The Risk Assessment cites there is little to no data concerning: the environmental effects of imazapyr used as a mixture; differential species impacts; degradates and metabolites, and field studies. The Level 1 Ecological Risk Assessment states:

Recommendation. Field studies should be required to accurately assess the real impacts to native plants and wildlife from the use of imazapyr in forestry applications. The products should be tested for drift and dissipation in the field as full formulation products as they will be actually applied in the field—as mixtures, and at realistic application rates (repeated annual applications at the subwatershed scale). These impacts should be assessed in a cumulative assessment as well, in order to capture the additive effects of multiple applications of other similar herbicides that may also be applied to the same forest lands.

Response to Issue 6: As indicated earlier, assessing risk to terrestrial organisms from multiple applications in different parts of a watershed would not result in higher exposure to local habitats since

exposure to terrestrial plants is not linked to a watershed scenario. As for assessing risk to plants from formulations, currently the Agency assesses risk based on toxicity from formulations or of mixtures of ai with adjuvants to account for the influence of the formulations. So the potential effects of formulations in the environment is accounted for in the toxicity data. Exposure to plants is expressed in ai or ae, but is estimated assuming a formulation was applied. As for assessing risk from mixtures, the Agency does not currently have a process to assess risk from and regulate based on mixtures.

Issue 7. Imazapyr poses a high risk to non-target vegetation due to its unusual ability to impact plant reproduction even when obvious harm is not evident. EPA researchers have shown that:

> "...chlorsulfuron and perhaps other sulfonylurea herbicides appear to have influences on plant reproductions which are not characteristic of many common herbicides. This property would have gone unnoticed during the registration process since registrants are not required to submit any test data collected on mature and/or reproducing plants...It is accepted that chlorsulfuron and other sulfonylurea herbicides are 100 times more toxic to the vegetative growth of plants than older, commonly used herbicides such as atrazine and 2,4-D. Our data indicate that sulfonylurea herbicides are even more toxic to plant reproduction....Analysis of spray-drift data collected under field conditions have been reported by Bird (1992) to range, depending upon meteorological conditions, from 0.02 to 2% of the application rate at distances as great as 1.4 mile from the application zone." (Fletcher et al. 1996).

Response to Issue 7: The comment presents statements from the Agency risk assessment. It should be clarified that the phrase "It is accepted" does not connotate that the risk represented by the toxicity is "accepted" from a regulatory standpoint. The phrase means the information is "accepted" from a scientific standpoint.

3) Comments from **Pesticide Program, Nebraska Dept of Agriculture**

> There is a potential error in APPENDIX H: Summary of Endangered Threatened Species. On page 557 of this document, the southern clubshell mussel (Pleurobema decisum) is listed for Boyd County, Nebraska. In visiting with the Nebraska Game and Parks Commission, they have no record of this species in the state. They do, however, have documented occurrences of the clubshell mussel (Pleurobema clava).

The Agency acknowledges this error, and has modified the endangered species list, Appendix H.

4) **EFED deferred response to error-only comments concerning aquatic exposure estimations**

(pp. 4-6)

BASF responded that the Agency chose to use GENEEC as the aquatic exposure estimation model when a suitable Forestry/Non-crop Tier II scenario and a corn scenarios exists, and then requested that a Tier II exposure assessment be conducted.

EFED Response: The corn scenario used by BASF is only one of 10 standard scenarios available for Tier II aquatic modeling, and would not be representative of all use sites nationally. Additionally, the application rate for use of Imazapyr on corn is much lower than labeled use rates for non-food uses that there is little benefit in investing the degree of effort necessary to conduct a Tier II evaluation for corn.

The forestry scenario cited by BASF as a suitable non-crop scenario was developed for the OP cumulative assessment, and was not intended to be representative enough of typical use sites to be used in a national assessment. An informal range finding experiment was conducted by running the Agency Oregon Christmas tree scenario using weather data files for other geographic locations. Varying only the meteorological data resulted in a great deal of variation in estimated concentrations. These results indicated that a suitable Forestry/Non-crop scenario is not currently available, and new scenarios would need to be developed in order to conduct a Tier II aquatic assessment for Imazapyr.

BASF then requested that a "correction factor" be applied to the estimated concentrations, and cited an article by Jackon et al as justification for applying the factor.

EFED Response: In a prepublication peer review for the *Journal of Agricultural and Food Chemistry*, Elizabeth Behl and Nelson Thurman submitted comments reflecting Agency analysis of an article titled *Comparison of Regulatory Method Estimated Drinking Water Exposure Concentrations with Monitoring Results from Surface Water Supplies* written by Scott Jackson, BASF Corporation et al. A summary of those comments, outlining Agency concerns about suggestions regarding the application of a correction factor for modeled estimated surface water concentrations proposed in that article appears below.

The basis of the comparison made in this article is fundamentally flawed. The endpoints derived from Agency modeling and the reported monitoring results are wholly different. For the conclusions presented in this article to be valid, the authors would have needed to demonstrate that the monitoring data used for the comparisons represented the full range of use conditions for each of the pesticides used in the comparison. The paper did not provide adequate detail about (1) the differences in the endpoints for modeling and monitoring, (2) the assumptions and inputs used in modeling, or (3) the design of the monitoring study. It did not describe the nature of the EPA models, or how these models are used. These details are important in interpretation of results, in supporting both the author's recommendations to develop adjustment factors, and the author's judgment on the validity of the conceptual model. Additionally, the author's description of how EPA's endpoints are derived was inadequate. Application rates, application frequencies, and percentage cropped area adjustment factors used in modeling should

have closely represented actual pesticide use and usage in each of the 12 watersheds monitored. This could not be determined because the authors had not provided the information necessary to interpret monitoring study results. The study authors failed to compare a representative monitoring dataset to the screening model estimates, did not design the monitoring to capture a maximum concentration from a large rainfall event, and did not provide details of pesticide usage in the watershed. As a result, statistical analysis of the data cannot provide meaningful results. Given the flaws in the overall methodology used for comparison, the adjustment factor development has no basis, and conclusions about the adequacy of EPA's conceptual model for water modeling is not supported by the published analysis.

In summary, the authors of the report merely ran the Agency aquatic screening models for every chemical included on USGS's analytical list, whether the pesticides were actually used in any of the watersheds or not. Then they compared those screening level estimates, which are intended to represent a 1-in-10-year concentration in an intensive use area, to whatever concentrations where reported in an 18-month study covering 12 reservoirs. These 12 reservoirs weren't necessarily representative of high pesticide use areas (it definitely underrepresented midwestern reservoirs, which are generally more vulnerable because of the intensity of agriculture), and were certainly not representative of particularly runoff-prone rainfall years. Indeed, many of the reservoirs were sampled during drought periods (from the USGS report). From that analysis, they derived a "correction" factor that, at best, is only applicable to those 12 reservoirs during lower-than normal rainfall years. That's not particularly conducive to leading to a reasonable certainty of no harm.