**APPENDIX 1-1: Regulatory History**

Diazinon was originally registered for use in the United States in 1956. Since that time, EPA, NMFS, and FWS have conducted several ecological and endangered species risk assessments. Described below are those assessments. Over time, the use of diazinon has been substantially changed in order to limit risks to humans and the environment.

1. *Final Biological Opinion on Diazinon in Response to Request for Consultation (1989)*

EPA reinitiated a formal consultation with the U. S. Fish and Wildlife Service in 1989 regarding diazinon impacts on endangered species. This consultation was on selected portions of five previous “cluster” biological opinions evaluating pesticides for certain crops (corn, cotton, soybeans, sorghum, wheat, barley, oats and rye), forestry uses pesticides, mosquito larvicides, and rangeland and pastureland pesticides. As a result, the U.S. Fish and Wildlife Service issued a formal Biological Opinion (USFWS, 1989) which identified reasonable and prudent measures and alternatives to mitigate potential effects of diazinon use on endangered species. The opinion identified 6 amphibians, 77 fishes, 32 freshwater mussels, 10 arthropods, 5 birds and 2 snakes potentially affected by the use of diazinon. Of the 132 species identified, 84 were classified as in jeopardy.

1. *Pacific Anadromous Salmonids Endangered Species Assessment (2002)*

The EPA completed an ecological risk assessment evaluating the potential effects of diazinon on the endangered Pacific Anadromous Salmonids (*Oncorhynchus spp.*) in November 2002 (USEPA, 2002). The assessment was a component of the settlement of the court case[[1]](#footnote-1) where the Washington Toxics Coalition for Alternatives to Pesticides, Pacific Coast Federation of Fisherman’s Associations and Institute for Fisheries Resources alleged that the EPA violated Section 7(a)(2) of the ESA by failing to consult on 54 pesticides due to their potential effects on Pacific salmon.The Office of Pesticide Programs (OPP) determined that the use of diazinon may affect 22 Evolutionarily Significant Units (ESUs) of federally listed Pacific salmon and steelhead and that use of diazinon may affect, but is not likely to adversely affect, 4 ESUs. The NMFS issued a Final Biological Opinion in response to OPPs determination in 2008 (NMFS, 2008). NMFS determined that the continued registration of diazinon is likely to jeopardize the continued existence of 27 listed Pacific salmonids. EPA responded to the Biological Opinion in 2009 (USEPA, 2009) stating, “Consistent with the goals of the BiOp, EPA intends to comply with the Endangered Species Act (ESA) by requiring changes to the registration of the pesticides included in the BiOp to assure that the registered use of these pesticides will not result in likely jeopardy to the continued existence of federally listed threatened or endangered species or destroy or adversely modify their designated critical habitat.” This assessment took mitigation, proposed by the 2002 IRED, into account.

1. *Diazinon Interim Registration Eligibility Decision (2004) and Registration Eligibility Decision (2006)*

In February 2000, EPA completed a screening-level ecological risk assessment (USEPA, 2000, D154949, D159643, D183157) in support of the 2002 draft Interim Reregistration Eligibility Decision (IRED) for diazinon.  The IRED was finalized in 2004 (USEPA, 2004)[[2]](#footnote-2).  The 2004 IRED was later modified into the 2006 Reregistration Eligibility Decision (USEPA, 2006)[[3]](#footnote-3) which also fully describes the results of EPA’s Ecological Risk assessments.

The IRED assessment was based on data collected in the laboratory and in the field to characterize the fate and ecotoxicological effects of diazinon. Data sources used in this assessment included: 1) registrant submissions in support of reregistration, 2) publicly available literature on ecological effects, 3) monitoring data for freshwater streams, lakes, reservoirs, and estuarine areas, 4) incident reports of adverse effects on aquatic and terrestrial organisms associated with the use of diazinon.

Primary environmental concerns were identified in the environmental fate and ecological risk assessment conducted in support of the reregistration eligibility decision for diazinon. These concerns were associated with the (now historical) uses of diazinon (USEPA, 2000, D154949, D159643, D183157) and included bird kills, contamination of surface water via runoff, and impacts on aquatic species. At that time over 6 million pounds of diazinon were used annually across the United States, with 75% used for non-agricultural purposes (*e.g.*, applied outdoors by homeowners and professional lawn care companies). The assessment concluded that outdoor use of diazinon result in exposure and risk to birds and was associated with bird kills. Potential acute and chronic effects to aquatic invertebrates, as well as chronic and sub-lethal effects to fish associated with use of diazinon were identified in that assessment.

Water monitoring data reviewed in the assessment demonstrated that the use of diazinon had resulted in contamination of surface water, and concluded that impacts were likely to be particularly significant in urban settings, resulting in exposure and risk to sensitive aquatic organisms. The assessment summarized available monitoring data and reported that diazinon had been detected in drinking water reservoirs, large and smaller rivers, and in major aquifers. The assessment also included a summary of reports of detections of diazinon in effluent from wastewater treatment facilities, or publicly owned treatment works (POTW’s), which have been cited as out of compliance with the Clean Water Act and the National Pollution Discharge Elimination System (NPDES). Also, the assessment indicated that diazinon had resulted in the initiation of Total Maximum Daily Loads (TMDLs) in California, where 53 water bodies were listed as impaired as a result of diazinon. TMDLs had been initiated in virtually every major urban area of the state as a result.

Diazoxon, a degradate of toxicological concern, was also found at levels approximately 2.5% of the parent in streams and rivers in California. Preliminary laboratory studies were summarized and suggested that chlorination of drinking water removed diazinon from treated water, transforming it to diazoxon. The assessment concluded exposure to diazoxon formed as a result of treatment could not be precluded, as preliminary evidence suggested that diazoxon could persist long enough to pass through the distribution system to the tap in some systems depending on the sequence of treatment.

The 2002 *“Final Revised Environmental Fate and Ecological Risk Assessment Chapter for the Reregistration Eligibility Decision on Diazinon*” also noted that diazinon was one of the most frequently detected pesticides in air, rain, and fog, suggesting possible long-range atmospheric transport into regions beyond normal areas of use (USEPA, 2002, D183157).

The EPA identified mitigation measures in the 2004 IRED to address unacceptable risks to agricultural workers, birds, and other wildlife that included elimination of aerial applications, reduction in the dormant season use (almonds and other orchard crops), and overall use reduction.

Based on a December 2000 agreement with the technical registrants, all indoor and outdoor residential uses of diazinon were phased-out or cancelled by 2005 (USEPA, 2012). All registrations for granular products have also been cancelled (Federal Register Vol. 72, No. 142, July 25, 2007, 40875)[[4]](#footnote-4). Many additional risk mitigation measures identified in the 2002 IRED have been implemented, including: removal of aerial applications for all uses except lettuce and cancellation of all seed treatment uses.

1. *Aquatic Life Criteria (2005)*

The Clean Water Act requires the EPA to publish water quality criteria that accurately reflect the latest scientific knowledge on the kind and extent of all identifiable effects on health and welfare which might be expected from the presence of pollutants in any body of water. An Aquatic Life Ambient Water Quality Criteria document was published for diazinon in 2005 (USEPA, 2005). The criteria concentrations reflect the level of a pollutant or other measurable parameter that allows for protection of aquatic life in our nation’s water as developed under Section 304(a) of the Clean Water Act of 1972. The recommendation of the document in regards to freshwater aquatic life includes the following: “Freshwater aquatic life should not be affected if the one-hour average concentration of diazinon does not exceed 0.17 micrograms per liter more than once every three years on the average (acute criterion) and if the four-day average concentration of diazinon does not exceed 0.17 micrograms per liter more than once every three years on the average (chronic criterion).” The saltwater aquatic life criteria state the following: “Saltwater aquatic life should not be affected if the one-hour average concentration of diazinon does not exceed 0.82 micrograms per liter more than once every three years on the average (acute criterion) and if the four-day average concentration of diazinon does not exceed 0.82 micrograms per liter more than once every three years on the average (chronic criterion)” (<http://water.epa.gov/scitech/swguidance/standards/criteria/aqlife/pollutants/diazinon/diazinon-fs.cfm>). While these recommended criteria do not, in themselves, impose any requirements, states and authorized tribes can use them to develop water quality standards.

1. *Barton Springs Salamander Endangered Species Assessment (2007)*

In 2007, EPA completed an endangered species risk assessment evaluating the potential effects of diazinon on the Barton Springs salamander (*Eurycea sosorum*) (USEPA, 2007b). The assessment was a component of the settlement of the court case “*Center for Biological Diversity and Save Our Springs Alliance v. Leavitt, No. 1:04CV00126-CKK”.* Conclusions regarding diazinon use in the Barton Springs salamander action area were:

* diazinon would have no direct acute effect on the salamander;
* diazinon use would not likely adversely affect the salamander through direct chronic effects;
* diazinon was not likely to adversely affect the salamander through effects on it prey; and
* diazinon use would have no effect on the salamander’s habitat.
1. *California Red-legged Frog Endangered Species Assessment (2007)*

In 2007, the EPA completed a risk assessment of the potential effects of diazinon on the threatened California red-legged frog (*Rana aurora draytonii*; CRLF) arising from current uses of diazinon on several fruit, nuts, vegetables and outdoor ornamental crops (USEPA, 2007a). Uses included in this 2007 assessment reflected post-RED mitigations. This endangered species risk assessment was part of the *Center for Biological Diversity (CBD) vs. EPA et al*. (Case No. 02-1580-JSW(JL)) settlement entered in the Federal District Court for the Northern District of California on October 20, 2006. The assessment resulted in a determination that the use of pesticide products containing diazinon is likely to adversely affect the CRLF. This determination is based on the potential for diazinon to both directly and indirectly affect the species and result in modification to designated critical habitat.

1. NMFS BiOP of Organophosphate Pesticides and Their Effects to Pacific Salmon and Steelhead (2008)

In 2008, NMFS completed a Biological Opinion (BiOp) on three registered organophosphate (OP) pesticides (chlorpyrifos, diazinon, and malathion) and their potential effects to 28 threatened or endangered Pacific salmon and steelhead species in the states of California, Idaho, Oregon, and Washington (Pacific Northwest states or PNW states). The NMFS BiOp concluded that for all but one of these species, continued use of the three OP pesticides would result in jeopardy to the species if additional restrictions were not imposed. Six items were recommended by NMFS to reduce pesticide exposure to a level where no likely jeopardy would be expected. These included 1) a requirement for spray drift buffers, 2) a wind speed restriction, 3) a requirement for a non-cropped vegetative runoff buffer, 4) a soil moisture/48 hours storm restriction, 5) a fish mortality incident reporting requirement, and 6) an effectiveness monitoring program for off-channel habitats.

1. *EPA Registration Review Problem Formulation (2008)*

In 2008, EPA formally initiated registration review for diazinon. In 2008, the EPA completed the preliminary problem formulation for the ecological risk, environmental fate, endangered species, and drinking water assessments to be conducted as part of the Registration Review (USEPA, 2008, D349527). The problem formulation draws information from both open literature and studies submitted by the technical registrants in response to data requirements. This document provides an overview of what is currently known regarding the environmental fate and ecological effects associated with diazinon and its degradates and outlines uncertainties regarding attributes of the parent compound and its transformation products. It describes the preliminary ecological risk hypothesis and the processes that will be used during the completion of drinking water and ecological risk assessments in support of registration. Additionally, it identifies whether additional data would help to reduce uncertainties in the risk assessment.

1. *EPA Implementation of the NMFS biological opinion (BiOp) issued in 2008 (2009)*

In 2009, the EPA completed a report on the implementation measures to meet its obligation under Section 7(a)(2) of the Endangered Species Act (ESA) (USEPA, 2009). EPA provided details on how it will implement the recommendations from NMFS, including use of Bulletins Live[[5]](#footnote-5) to relay the geographically specific new labeling information to pesticide users. The implementation measures included:

1. spray drift buffers based on application rate, spray droplet size, and water body size,
2. no applications when wind speeds exceed 10 miles per hour,
3. 100 foot no-use buffer between an application and habitat,
4. applications should not occur when fields are saturated or when a storm event is likely to produce runoff within 48-hours after application,
5. fish mortality incident reporting, and
6. monitoring of off-channel habitats.
7. *Tide Water Goby and Delta Smelt Endangered Species Assessment (2012)*

In 2012, EPA completed an analysis on the risks of diazinon use *to* Delta Smelt (*Hypomesus transpacificus*) and the Federally Endangered Tidewater Goby (*Eucyclogobius newberryi*). This endangered species risk assessment was part of the stipulated injunction ordered by the Federal District Court for the Northern District of California in the case Center for Biological Diversity (CBD) vs. EPA *et al*. (Case No. 07-2794-JCS). The assessment resulted in a determination that the use of pesticide products containing diazinon is likely to adversely affect the tidewater goby and delta smelt. Additionally, EPA determined that there is the potential for modification of the designated critical habitat for the delta smelt and tidewater goby from the use of diazinon.

1. *Update on Outstanding Data Gaps for Diazinon Registration Review (2012)*

In 2012, the EPA responded to a registrant inquiry in regards to the registration review data gaps for diazinon (USEPA, 2012, D393321). In the response, EPA completed a review of all submitted fate data and determined the status of all data reviews. The document updates and prioritizes data needs discussed in the preliminary problem formulation (USEPA, 2008, D349527) and discusses uncertainties if data are not received.

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1. Filed in the U.S. District Court for the Western District of Washington, Civ. No.l 01-132. [↑](#footnote-ref-1)
2. <http://archive.epa.gov/pesticides/reregistration/web/pdf/diazinon_ired.pdf> [↑](#footnote-ref-2)
3. <http://www3.epa.gov/pesticides/chem_search/reg_actions/reregistration/red_PC-057801_31-Jul-06.pdf> [↑](#footnote-ref-3)
4. <http://www3.epa.gov/pesticides/chem_search/reg_actions/reregistration/frn_PC-057801_25-Jul-07.pdf> [↑](#footnote-ref-4)
5. <http://www.epa.gov/espp/bulletins.htm> [↑](#footnote-ref-5)