**APPENDIX 1-1. Regulatory History and Past Assessments for Chlorpyrifos**

Chlorpyrifos was first registered as an insecticide in 1965. Since it was registered, the following restrictions have been placed on pesticide products containing chlorpyrifos in the U.S.:

* In June 2000, the EPA eliminated all homeowner uses, except ant and roach baits in child resistant packaging. In addition, termiticide uses were phased out.
* In 2000, EPA required that all uses of chlorpyrifos products in the U.S. be discontinued on tomatoes. The use on apples was restricted to pre-bloom and dormant application. The grape tolerance was lowered to reflect the labeled dormant application.
* In 2002, EPA reduced application rates and/or maximum number of applications per season for chlorpyrifos on alfalfa, citrus, corn, cotton, peanuts, sorghum, soybeans, sugar beets, sunflowers, and tree nuts.
* In 2012, EPA further limited the use of chlorpyrifos by lowering pesticide application rates and creating “no-spray” buffer zones around treated agricultural fields within a certain proximity of sensitive sites.Sensitive sites are areas frequented by non-occupational bystanders (especially children). These include residential lawns, pedestrian sidewalks, outdoor recreational areas such as school grounds, athletic fields, parks and all property associated with buildings occupied by humans for residential or commercial purposes. Sensitive sites include homes, farm worker housing, or other residential buildings, schools, daycare centers, nursing homes and hospitals. Sensitive sites do not include non-residential agricultural buildings, including barns, livestock facilities, sheds, and outhouses.

Chlorpyrifos is currently undergoing registration review, a program that re-evaluates all pesticides on a 15-year cycle. In 2009, registration review of chlorpyrifos was initiated by the publication of the Preliminary Work Plan. All documents related to the registration review can be located in docket number EPA-HQ-OPP-2008-0850 located at [www.regulations.gov](http://www.regulations.gov). Additionally, the Agency has conducted previous ecological risk assessments for chlorpyrifos. Each of the previous risk assessments is briefly discussed below.

 ***Chlorpyrifos Interim Registration Eligibility Decision, 2002***

The Agency completed a screening-level ecological risk assessment (dated October 1999 and revised March and June 2000) in support of the Interim Reregistration Eligibility Decision (IRED) for chlorpyrifos (U.S. EPA, 2002). Completion of the organophosphate (OP) cumulative assessment (U.S. EPA, 2006b) resulted in finalization of the IRED as a Reregistration Eligibility Decision (RED) (U.S. EPA, 2006a), which is described below.

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

Risk quotients (RQs) based on estimated environmental concentrations (EECs) derived from both monitoring data and exposure modeling and the available toxicity information indicated that a *single* application of chlorpyrifos posed high risks to small mammals, birds, fish and aquatic invertebrate species for nearly all registered outdoor uses. Multiple applications of chlorpyrifos resulted in higher estimated exposures and risks. Bioconcentration of chlorpyrifos in aquatic environments was purported to result in additional acute and chronic risks to aquatic birds and mammals feeding adjacent to treated areas.

The presumption of risk to non-target aquatic and terrestrial animals was supported by field studies and adverse ecological incidents. Three extensive terrestrial field studies on corn in Iowa, citrus in California, and golf courses in central Florida, report cholinesterase-inhibition effects and chlorpyrifos-related mortality in non-target organisms. Chlorpyrifos-related mortalities were reported in small mammals, birds, reptiles, and amphibians as determined by measurable chlorpyrifos residues in the carcasses. Measured chlorpyrifos levels on foliage samples and water samples reported in all three studies generally exceeded the model-predicted exposures. Aquatic field studies where chlorpyrifos has been applied directly to water for insect control have shown adverse effects on non-target species, including fish recruitment and growth and near elimination of some aquatic invertebrate populations.

To mitigate ecological risks the technical registrants agreed to label amendments that included the use of buffer zones to protect water quality, fish and wildlife, reductions in application rates, number of applications per season, seasonal maximum amounts applied, and increases in the minimum intervals for retreatment. In addition, the residential uses of chlorpyrifos were eliminated, the termiticide use was phased out, and the application rate on golf courses has been reduced from 4 to 1 lb/ai/A. Additionally, no-spray buffers around surface water bodies, as well as rate reductions for agricultural uses were implemented as a result of this IRED.

***Organophosphate Cumulative Assessment, and Chlorpyrifos Reregistration Eligibility Decision, 2006***

Because the Agency determined that chlorpyrifos shares a common mechanism of toxicity with the structurally-related organophosphate insecticides, a cumulative human health risk assessment for the organophosphate (OP) pesticides was necessary before the Agency could make a final determination of reregistration eligibility of chlorpyrifos. This cumulative assessment was finalized in 2006 (U.S. EPA, 2006b). The results of the Agency’s ecological assessments for chlorpyrifos are discussed in the July 31, 2006, final Reregistration Eligibility Decision (RED) (U.S. EPA 2006a).

The OP cumulative relied on a combined assessment methodology of modeling and monitoring data for human health exposure via drinking water. Unlike other assessments, the cumulative approach focused on regions of high OP use. No ecological risks were evaluated in the OP cumulative process. Unlike the IRED, the cumulative assessment included a qualitative evaluation of the impact of oxon formation via drinking water treatment (*i.e*., chlorination) effects. For chlorpyrifos, this included laboratory toxicity information which indicated that chlorpyrifos-oxon was more toxic than the parent (Chambers and Carr, 1993).

 ***Aquatic Life Criteria***

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, including ground water. An Aquatic Life Ambient Water Quality Criteria document was published for chlorpyrifos in 1986 (U.S. EPA, 1986). The recommendation of the document in regards to freshwater aquatic life states the following: “Freshwater aquatic life should not be affected if the four-day average concentration of chlorpyrifos does not exceed 0.041 micrograms per liter (μg/L) more than once every three years on the average and if the one-hour average concentration of chlorpyrifos does not exceed 0.083 μg/L more than once every three years on the average.” While these recommended criteria do not, in themselves, impose any requirements, states and authorized tribes can use them to develop water quality standards.

***Past Endangered Species Assessments***

EPA and the Services have consulted many times on listed species and chlorpyrifos in the past (most consultations occurred in the 1980’s). Some of the consultations involved chlorpyrifos and specific uses [*i.e*., peanuts (1981); and soybean, citrus, alfalfa, and sunflower (1982)] while others involved multiple chemicals and particular uses (*i.e*., ‘clusters’) [*i.e*., corn cluster (1983); cotton, soybean, sorghum, and grain cluster (1983); and mosquito larvicide cluster (1984)]. There have been two more recent Biological Evaluations (BEs) conducted by EPA[[1]](#footnote-1). These are briefly described below.

In 2003, EPA conducted a risk assessment for chlorpyrifos on 26 Evolutionary Significant Units (ESUs) of listed Pacific salmon and steelhead and one chinook salmon ESU proposed for listing. EPA determined that that was a potential to affect 19 of the ESUs; that chlorpyrifos was a not likely to affect 6 ESUs; and that there would be no effect for 2 ESUs.

In 2009, EPA conducted a Biological Evaluation (BE) for chlorpyrifos and several species found in California [*i.e*., California red-legged frog (*Rana aurora draytonii*), California tiger salamander (*Ambystoma californiense*), Delta smelt (*Hypomesus transpacificicus*), Bay checkerspot butterfly (*Euphydryas editha bayensis*), valley elderberry longhorn beetle (*Desmocersus californicus dimorphus*), San Francisco garter snake (*Thamnophis sirtalis tetrataenia*), California clapper rail (Ra*llus longirostris obsoletus*), salt marsh harvest mouse (*Reithrodontomys raviventris*), California freshwater shrimp (*Syncaris pacifica*), and San Joaquin kit fox (*Vulpes macrotis mutica*)] and their designated critical habitat, if applicable. EPA made a May Affect and Likely to Adversely Affect determination for all of the species and critical habitats assessed.

These assessments will be discussed in more detail in the ‘Consultation History’ section of the Biological Opinion developed as part of Step 3.

1. For the documents associated with the more recent biological evaluations, see [http://iaspub.epa.gov/apex/pesticides/f?p=CHEMICALSEARCH:23:0#](http://iaspub.epa.gov/apex/pesticides/f?p=CHEMICALSEARCH:23:0) [↑](#footnote-ref-1)