**APPENDIX 1-1: Regulatory History and Past Assessments for Malathion**

There is a long history of assessments for malathion because malathion has been used as a pesticide since the 1950s. The following sections summarize the most recent assessments and those issues most salient to endangered species.

### *Malathion Registration Eligibility Decision, 2006*

In 2006, the Agency completed a screening-level ecological risk assessment in support of the Reregistration Eligibility Decision (RED) for malathion (USEPA 2006a). The RED was finalized as part of the organophosphate cumulative assessment (USEPA 2006b). The RED assessment was based on data collected in the laboratory and in the field to characterize the fate and ecotoxicological effects of malathion. 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 malathion.

The ecological risk assessment in the RED concluded that use of malathion poses a high risk of mortality to fish and aquatic invertebrates from acute toxicity. Almost all uses are expected to pose a high risk of adversely affecting aquatic invertebrate populations, especially in urban streams and wetlands. High acute risk is also expected to fish and amphibians for uses with higher application rates or repeated applications. Numerous incidents of fish kills confirm the acute risk to fish. Use of malathion is generally not expected to pose a high risk of mortality to terrestrial wildlife (birds, mammals, and reptiles, terrestrial stages of amphibians) although the acute level of concern (LOC) is exceeded for some uses with high application rates and repeated applications. Use of malathion poses a risk of impairing reproduction in birds, and may cause other sublethal effects in wildlife. Although no risk assessment was conducted for beneficial insects, the RED concluded that use of malathion poses a hazard to bees and other insect pollinators based on evidence from toxicity studies, field studies, and incidents. Bees may be harmed from direct exposure, exposure to foliar residues, and exposure to residues on pollen brought back to the hive.

The ecological risk assessment in the RED concluded that use of malathion could potentially harm all taxa of threatened and endangered animals. Risk quotients exceeded the level of concern for threatened and endangered species of fish, aquatic invertebrates, birds, and mammals.

### *Organophosphate Cumulative Assessment, and Malathion Reregistration Eligibility Decision, 2006*

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

### *California Red-legged Frog Endangered Species Assessment*

The Agency recently completed an endangered species risk assessment of the potential effects of malathion and maloxon on the threatened California red-legged frog (*Rana aurora draytonii*; CRLF) arising from uses of malathion (USEPA 2007a). Uses included in this 2007 assessment reflected some 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 malathion is likely to adversely affect the CRLF. This determination is based on the potential for malathion use to both directly and indirectly affect the species and result in modification to designated critical habitat.

Toxicity values used in this document are in some cases different than those used in the malathion RED and those used in the current assessment of risk to the Delta smelt (DS) and California tiger salamander (CTS). Although the RED was published in 2006, following completion of the organophosphate cumulative assessment, the ecological risk assessment was compiled in 1999, prior to the regular incorporation of open literature ecotoxicological (ECOTOX) data into EFED risk assessments. Review of the open literature data resulted in a number of lower toxicity endpoints used in the CRLF assessment. Risk conclusions are similar, in that listed species LOCs are exceeded, but the risk quotients (RQs) presented in the CRLF assessment are higher than corresponding RQs in the RED. In this current assessment for the DS and CTS, open literature data have been further evaluated and toxicity endpoints have been further revised. Some of the toxicity endpoints were revised higher relative to those used in the CRLF document, and thus some of the RQs have decreased in this current assessment relative what was reported in the CRLF assessment.

### *Pacific Anadromous Salmonids Endangered Species Assessment*

The Agency completed an endangered species risk assessment of the potential effects of malathion on 26 listed Evolutionarily Significant Units (ESUs) of Pacific salmon and steelhead arising from FIFRA regulatory actions regarding use of malathion (USEPA 2004). This risk assessment was part of the *Washington Toxics Coalition vs. EPA* (Case No. C01-132C) order entered in the Federal District Court for the Western District of Washington on July 2, 2002. The assessment concluded that malathion is toxic to fish as well as to organisms that serve as food for threatened and endangered Pacific salmon and steelhead. The final conclusion was that the uses (at that time) of malathion (and its degradate malaoxon) may affect 24 of these ESUs.

On November 18, 2008, the National Oceanic Atmospheric Administration National Marine Fisheries Service (NMFS) issued a final biological opinion on the effect of pesticide products containing malathion, chlorpyrifos, or diazinon on 28 listed Pacific salmonids (National Marine Fisheries Service, 2008). This opinion concluded that the effects of registration of pesticide products that contain malathion or the two other active ingredients is likely to jeopardize the continued existence of 27 of the 28 species of Pacific salmonids. They concluded that these pesticides are not likely to jeopardize the continued existence of Ozette Lake Sockeye salmon, but may adversely affect that species. Furthermore, they concluded that registration of these products is likely to destroy or adversely modify 25 of the 26 critical habitats that have been designated for these Pacific salmonids. The only critical habitat that they concluded would not be adversely modified is that of the Ozette Lake Sockeye salmon. This Biological Opinion is available on the internet (http://www.nmfs.noaa.gov/pr/pdfs/pesticide\_biop.pdf).

USEPA. 2004. Malathion use as a mosquitocide and potential risk to listed salmonids. Office of Prevention, Pesticides, and Toxic Substances. Office of Pesticide Programs. Washington, D.C. EPA DP308617. pp 9.

USEPA. 2006a. Reregistration Eligibility Decision for Malathion: Case No. 0248. Office of Prevention, Pesticides, and Toxic Substances. Office of Pesticide Programs. Washington, D.C. EPA 738-R-06-030. pp 188.

USEPA. 2006b. Organophosphorus Cumulative Risk Assessment 2006 - Update. Prevention, Pesticides and Toxic Substances (EPA-HQ-OPP-2006-0618-0002). <https://archive.epa.gov/pesticides/reregistration/web/pdf/phosalone_red.pdf>

USEPA. 2007a. Risks of Malathion Use to Federally Listed California Red-legged Frog (*Rana aurora draytonii)*. Environmental Fate and Effects Division. Office of Pesticide Program.

USEPA. 2007b. Maximum Number of Crop Cycles Per Year in California for Methomyl Use Sites. Memo from Monisha Kaul (BEAD) to Melissa Panger (EFED). Dated 27 February 2007

USEPA. 2009. *County-Level Usage for Malathion, EPTC, Phosmet, and Potassium Nitrate in California in Support of a San Francisco Bay Endangered Species Assessment.* Memorandum from Monisha Kaul, Biological and Econimic Analysis Division, to Katrina White, Environmental Fate and Effects Division. December 23, 2009.