Chlorothalonil Draft Biological Opinion (BiOp) Talking Points March 24, 2011

BACKGROUND:

- Chlorothalonil is being reviewed as part of series of lawsuits in the Pacific Northwest United States (PNW) requiring the National Marine Fisheries Service (NMFS) to prepare biological opinions on more than 30 pesticide chemicals, as a requirement under the Endangered Species Act (ESA).
- Under the ESA, a BiOp must be based on "the best scientific and commercial data available." A BiOp that is **not** based on "the best scientific and commercial data ..." could result in EPA imposing unnecessary and potentially onerous label restrictions, which could make chlorothalonil unavailable for use on thousands of acres.
- Chlorothalonil is in the fourth group of chemicals going through this process.
- The Draft BiOp was released on March 3rd, 2011. Comments are due to EPA by April 12th, 2011.
- The Draft BiOp makes incorrect broad "jeopardy" and "habitat modification" opinions based on flawed risk assessments, which impact chlorothalonil use in four Western states. Syngenta intends to vigorously defend chlorothalonil uses and scientifically respond to the NMFS assertions. We have requested at least a 60-day extension of the comment period.
- NMFS is under a court deadline to finalize the draft BiOp by April 30th although the Service can request additional time to finalize the document.

IMPORTANCE OF CHLOROTHALONIL:

- Registered since 1970. Has over 65 crops and 125 diseases and is registered globally.
- Critical disease management tool for integrated pest management (IPM)
- Vital tool for fungicide resistance management. Fungicides have become an integral part of efficient food production. The loss of some key fungicides to agriculture through resistance is a problem that affects us all. It may lead to unexpected and costly crop losses to farmers causing local shortages and increased food prices.
 - The potential for resistance has increased since the advent of highly effective compounds with specific sites of action. While these newer compounds may show marked improvements in performance, experience has shown that these compounds are prone to resistance development. As reliance on these fungicides grows, action is required to safeguard their effectiveness.
 - Chlorothalonil is a non-systemic foliar fungicide with protective action against a broad spectrum of plant diseases.
 - With a multiple site mode of fungicidal action the estimate of inherent risk of resistance development to chlorothalonil is low making it an excellent resistance management partner for fungicides with single-site modes of action.
- Commonly used on potatoes, tomatoes, vegetable crops, peanuts, turf and ornamentals; and early season applications on stone fruit and almonds.
- In the Pacific Northwest, the key uses are:

- PNW potatoes approximately 35% of the (180,000 Acres) acres are treated with chlorothalonil
- PNW vegetables approximately 17 % (167,000 Acres) of the acres are treated with chlorothalonil
- Fruit and Nut Crops approximately 14,000 acres of 1,428,000 A are treated with chlorothalonil at a average rate of 4 pt/A (3 lb ai/) (ca 1%)
- Grasses Grown for Seed primarily OR
 - Approximately 16,000 A of the 385,000 planted are treated (4%)
- PNW Golf Turf: Approximately 29,047 of the 190,243 acres of managed golf turf are treated (15%)
- Highly utilized in minor crops ongoing IR-4 projects underway for additional minor uses

KEY POINTS:

- We share a common goal with EPA and NMFS: to assure that our products do not impact listed species.
- Risk assessments and risk management decisions should be grounded in the best scientific and commercial data available.
- The current process is broken: The chlorothalonil draft BiOp illustrates how the process followed by NMFS --
 - Is flawed and inefficient
 - May lead to burdensome lawsuits and unwarranted regulatory burdens on pesticide product end users
 - Has the potential to unnecessarily increase food and disease control costs with no improvement in the protection of listed endangered species
 - Inadequate time Virtually no time for key stakeholders, including registrants, agronomic experts, applicators/farmers, USDA, IPM experts, states, etc., to provide necessary input on the draft BiOp. Similarly, no time for NMFS to respond to comments in any meaningful way.
 - Draft was made available on March 3rd 1087 page highly technical document containing multiple active ingredients
 - EPA and NMFS met with USDA, Syngenta and other registrants on March 10th (7 days)
 - Comments deadline as soon as possible but no later than April 12th (28 days from applicant meeting)
 - NMFS to review, evaluate and incorporate comments, finalize BiOp by April 30th (18 days)
 - Lacks transparency
 - Missing information/data
 - Example: The "specific considerations" that are the basis of the assessment for each salmon population were left out of the BiOp. Therefore, the essential information on which to comment is not available. "We will be providing additional information that details

specific considerations for each decision". –excerpt from Chlorothalonil BiOp, March 3, 2011

- Failure to provide rationale/basis for not using available and highly relevant data and information
 - Example: Syngenta has submitted more than 20 volumes of data and analyses for the consultation. In the 1087 pages of the draft BiOp there is only a single citation to one of these volumes
- Failure to use best available science
 - Selective use of exposure and toxicity data in the chlorothalonil draft BiOp
 - Incorrect environmental fate data and unrealistic exposure models leading to grossly overestimated environmental concentrations
 - Did not include highly refined spatial analyses demonstrating that potential overlap of use sites with habitat streams is minimal
 - Discounted extensive chlorothalonil monitoring data (>10,000 data points) developed by state and federal agencies and universities showing residues are rarely detected and are well below toxicity endpoints.
 - Did not use best available fish or invertebrate toxicity data, and used inconsistent approaches to evaluating those data
 - Did not include data from 16 formulation toxicity studies confirming that formulations, inerts and mixtures are less toxic than active ingredient to fish and invertebrates.
- Lack of specific Reasonable and Prudent Alternatives (RPAs) and Reasonable and Prudent Measures (RPMs)
 - RPAs and RPMs in the draft BiOp are vague and open-ended, and put no boundaries on restrictions that might be imposed on chlorothalonil.

SUBMITTING YOUR COMMENTS (due April 12th, 2011):

You may submit comments to EPA on the draft BiOp by one of the methods listed below. Comments should be identified by the docket identification number EPA-HQ-OPP-2008-0654 and include the name of the pesticide to which the Biological Opinion pertains.

- Federal eRulemaking Portal: <u>http://www.regulations.gov</u>. Follow the on-line instructions for submitting comments.
- Mail: Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW, Washington, DC 20460-0001.
- Delivery: OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Rm. S-4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. Deliveries are only accepted during the Docket's normal hours of operation (8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays). Special arrangements should be made for deliveries of boxed information. The Docket Facility telephone number is (703) 305-5805.