Revised Draft Criteria for Biodegradability Claims
On FIFRA Registered Products
April 2011

Purpose: EPA's Office of Pesticide Programs (OPP) has undertaken a Pilot Program to assess the potential benefits of allowing "factual statements" regarding some environmentally preferable characteristics of registered pesticide products. Biodegradability is a critical concern with "down the drain" products which can be aquatically toxic. In order to recognize the value of "biodegradable surfactants" and to incentivize the development of entirely biodegradable products, OPP has developed the following criteria and standards which products must achieve prior to making biodegradability statements under the Pilot Program. EPA will evaluate the results of the Factual Statements Pilot Program prior to making any decision regarding the permissibility of these and other piloted statements going forward.

I. "All Ingredients" Claim

Example Claim: "100% Biodegradable. All ingredients in this product are readily biodegradable in water."

1. Surfactants will be screened using the DfE Criteria for Surfactants, which considers biodegradability as well as aquatic toxicity. All other ingredients in the candidate product must achieve the pass level in a Ready Biodegradability Test. Per OECD and OCSPP guidelines, the pass level must be reached in a 10-day window for all methods, with the exception of OECD Test Guideline 301C, and the MITI method in OCSPP Harmonized Guideline 835.3110. For these two methods, the 10-day window is not applicable. (See list of test methods below.)
2. Other criteria: The product cannot contain any ingredients considered carcinogens, mutagens, or reproductive toxicants by one of the authorized bodies listed in Tables 1, 2 and 3. Products classified as FIFRA Toxicity Category III or IV are eligible to make this claim. Concentrate products classified as Category II are eligible to make the claim only on non-product label material (i.e. Website, Technical Bulletins, etc.).

Rationale: Biodegradability does not guarantee low toxicity. Chemicals known to be rapidly biodegradable have also been identified as carcinogens, mutagens or reproductive toxicants (CMR) To ensure that these products do not pose an unacceptable risk to human health, or the environment, only products that do not contain ingredients considered to be CMRs will be eligible to make a biodegradability claim.

I. Surfactant Class Based Claims

Example Claim: "The surfactants contained in this product are biodegradable."*
(*Surfactants are cleaning agents)

1. Each surfactant ingredient in the product for which the claim is being made must meet the EPA Design for Environment (DfE) Criteria for Surfactants.
2. Other criteria: The product cannot contain any ingredients considered carcinogens, mutagens, or reproductive toxicants by one of the authorized bodies listed in Tables 1, 2 and 3.

Rationale: Some surfactants used in cleaning/disinfecting products pose aquatic toxicity concerns for numerous species and their degradation products may persist; nonylphenol ethoxylates (NPEs) are an example. OPP has decided to recognize the use of surfactants which protect aquatic life by rapid biodegradation to less toxic compounds by allowing the label to contain a claim of "biodegradable surfactants." EPA's DfE Criteria for Surfactants examines a surfactant's rate of biodegradation, degradation products, and level of aquatic toxicity. Only surfactants which meet these criteria will be eligible to make the claim. To ensure that the remaining ingredients in these products do not pose an unacceptable risk to human health or the environment, only OPP registered products which contain no ingredients considered to be CMRs will be eligible to make this claim.

II. Acceptable Test Methods

OCSPP (formerly OPPTS) Harmonized Guideline 835.3110 - Ready Biodegradability
OCSPP (formerly OPPTS) Harmonized Guideline 835.3140 - Ready Biodegradability – CO2 in Sealed Vessels (Headspace Test)
OECD Test Guideline 301A: DOC Die-Away
OECD Test Guideline 301B: CO2 Evolution
OECD Test Guideline 301C: Modified MITI (I)
OECD Test Guideline 301D: Closed Bottle
OECD Test Guideline 301E: Modified OECD Screen
OECD Test Guideline 301F: Manometric Respirometery
OECD Test Guideline 310: CO2 in sealed vessels

Criteria for Review of Listed Carcinogens, Mutagens and Reproductive Toxicants in FIFRA Registered Products Making a Biodegradability Claim
April 2011

The following criteria will be used to screen FIFRA registered products seeking to make a biodegradability claim to determine that a candidate products does not contain a carcinogen, mutagen or reproductive toxicant listed by the following recognized authoritative bodies: EPA, NTP, IARC and the EU.

1) **Carcinogenicity**

Products containing an ingredient considered to be a carcinogen by one of the authoritative bodies in Table I are not eligible to make the claim.

Table 1 – Carcinogens

Authoritative Body	**Criteria**
National Toxicology Program (NTP)	Known to be Human Carcinogen Reasonably Anticipated to be Human Carcinogen
U.S. Environmental Protection Agency (EPA)	(2005/1999) Carcinogenic to humans, Likely to be carcinogenic to humans, or Suggestive evidence of carcinogenic potential (1996) Known/Likely (1986) Group A – Human Carcinogen, Group B – Probable human carcinogen, or Group C – Possible human carcinogen
International Agency for Research on Cancer (IARC)	Group 1 – Carcinogenic to humans Group 2A – Probably carcinogenic to humans Group 2B – Possibly carcinogenic to humans
EU CMR List	Category 1 – Known to be carcinogenic to humans Category 2 – Should be regarded as if carcinogenic to humans Category 3 – Cause for concern for humans owing to possible carcinogenic effects
EU Risk Phrases	R45: May cause cancer R49: May cause cancer by inhalation R40: Limited evidence of a carcinogenic effect *And all combination risk phrases containing one or more of the above.*

2) **Mutagenicity**

Products that contain an ingredient considered to be a mutagen or genetic toxicant by one of the authoritative bodies in Table 2 are not eligible to make the claim.

Table 2 – Mutagenicity and Genetic Toxicity

Authoritative Body	Criteria
EU CMR List	Category 1 – Substances known to be mutagenic to humans Category 2 – Substances which should be regarded as if they are mutagenic to humans Category 3 – Substances which cause concern for human owing to possible mutagenic effects
EU Risk Phrases	R46: May cause heritable genetic damage R68: Possible risk of irreversible effects *And all combination risk phrases containing one or more of the above.*

3) **Reproductive and Developmental Toxicity**

Products which contain an ingredient considered to be a reproductive or developmental toxicant by one of the authoritative bodies in Table 3 are not eligible to make the claim.

Table 3 – Reproductive/Developmental Toxicity

Authoritative Body	Criteria
EU CMR List	Category 1 – Known to impair fertility in humans or known to cause developmental toxicity in humans Category 2 – Should be regarded as if they impair fertility in humans or cause developmental toxicity to humans Category 3 – Cause concern for human fertility or possible developmental toxic effects
EU Risk Phrases	R60: May impair fertility R61: May cause harm to the unborn child R62: Possible risk of impaired fertility R63: Possible risk of harm to the unborn child R64: May cause harm to breastfed babies *And all combination risk phrases containing one or more of the above.*