UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

January 29, 2016

PC Code: 027602
DP Barcode: 431377

MEMORANDUM

SUBJECT: **Flubendiamide:** Addendum to Clarify Invertebrate Terminology in January 28, 2016 Ecological Risk Assessment Addendum Summarizing all Submissions and Discussions to Date

FROM: Edward Odenkirchen, Ph.D., Senior Advisor
Divisional Front Office Staff
Environmental Fate and Effects Division (7507P)

THRU: Sujatha Sankula, Ph.D., Branch Chief
Environmental Risk Branch 1
Environmental Fate and Effects Division (7507P)

SUJATHA SANKULA

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DN: c=US, o=U.S. Government, ou=USEPA, ou=Staff, cn=SUJATHA SANKULA, dnQualifier=0000034075
Date: 2016.01.29 14:13:09 -05'00'

TO: Carmen Rodia, Risk Manager Reviewer
Richard Gebken, Risk Manager, PM Team 10
Debbie McCall, Branch Chief
Invertebrate-Vertebrate Branch 2
Registration Division (7505P)

The Registration Division (RD) requested that the Environmental Fate and Effects Division (EFED) provide additional explanation regarding the terminology used to describe invertebrates of concern in freshwater systems in the January 28, 2016 Ecological Risk Assessment Addendum Summarizing all Submissions and Discussions to Date (DP Barcode 431037) and to explain more fully how, conceptually, the risk findings are best related to aquatic invertebrates.

A variety of terms of art can be used to describe invertebrate species within freshwater aquatic systems and this document will source terms from the Aquatic Biodiversity Glossary (USEPA 2010) and the Glossary of Aquatic Ecological Terms (USEPA 1972).

The term invertebrate in Office of Pesticide Programs (OPP) EFED ecological risk assessments refers to animals without back bones. Aquatic invertebrates would be those invertebrates that are associated with aquatic systems. Commonly, the OPP/EFED suite of effects testing requirements, for practical reasons, involve toxicity testing with macroinvertebrates: "animals without backbones of a size large enough to be seen by the unaided eye and which can be retained by a U.S. Standard No. 30 sieve (28 meshes per inch, 0.595 mm openings)", but it is possible that effects endpoints derived from such organisms could be extrapolated to similar

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effects in other complex multicellular organisms that fall within the microinvertebrates: "animals without backbones that are not large enough to be seen by the unaided eye; they will not be retained by a U.S. Standard No. 30 sieve (28 meshes per inch, 0.595 mm openings). For the purposes of this document, focus will be placed on macroinvertebrates.

Aquatic macroinvertebrates in freshwater systems may occupy different habitats within an aquatic system. Some may be part of the zooplankton *"tiny, sometimes microscopic, floating aquatic animals"* or free swimming animals *"actively moving about in water or capable of moving about in the water"* within the water column. Others may be part of the benthos *"Organisms growing on or associated principally with the bottom of waterways. These include: (1) sessile animals such as sponges, barnacles, mussels, oysters, worms, and attached algae; (2) creeping forms such as snails, worms and insects; (3) burrowing forms, which include clams, worms, and some insects; and (4) fish whose habits are more closely associated with the benthic region than other zones;* e.g. *flounders."*

In the case of aquatic effects testing with flubendiamide and the des-iodo degradate, effects endpoints are available for aquatic macroinvertebrates that are free swimming in the water column (*e.g., Daphnia magna*) as well as macroinvertebrates that are associated with the benthos (*e.g., Lumbriculus variegatus, Hyalella azteca, Centroptilum triangulifer, Chironomus tentans* and *Chironomus riparius).* Acute short term lethality or motility studies are available for all the above species using water-only exposures. For chronic exposure effects, data are available for *D. magma* in a water-only test, which is achievable because the organism can thrive in a water-only environment. However, for longer term exposures with *C. riparius*, the testing systems must employ a sediment phase because the organisms cannot thrive in a water-only testing environment. In the case of the *C. riparius* long-term studies, initial chemical exposure was conducted either as a water column spike or a sediment spike, and effects endpoints were expressed in terms of both water column concentrations and sediment pore water concentrations of the test materials. These later endpoints figure prominently in the EFED risk assessments and the endpoints are frequently referred to as benthic invertebrate effects endpoints because the test organism is indeed an invertebrate of the benthos.

EFED consulted two guiding documents for determining policy to describe a consistent and reasonable approach for relating the available toxicity information to the various aquatic invertebrates in aquatic systems. The Overview of Ecological Risk Assessment Process in the Office of Pesticide Programs, U.S. Environmental Protection Agency (USEPA 2004) describes the use of limited effects testing in a surrogate approach where testing of a few species within a taxa group is used to represent a variety of organisms within that group. The document also indicates that effects endpoints for risk assessment reasonably come from the most sensitive species tested within that taxa group. Of all the aquatic invertebrate species tested for flubendiamide, the chronic endpoints from *C. riparius* indicate that this species is the most sensitive tested aquatic invertebrates. As a second policy check, EFED consulted guidance entitled "Toxicity Testing and Ecological Risk Assessment Guidance for Benthic Invertebrates" (USEPA 2014), which suggests that endpoints from water-only toxicity tests with invertebrates are important risk evaluation tools to ascertain potential risk to sediment organisms because

bioavailability in benthic organisms is largely mediated by dissolved concentrations of the toxicant in sediment pore waters or overlying water. It then follows that risk estimates based on water column environmental exposures compared with overlying water expressed endpoints from sediment toxicity tests with invertebrates would have reasonable applicability as a surrogate for risks to aquatic invertebrates existing in the water column because the dissolved water concentration of the toxicant remains the important source of exposure.

Conclusion

The risk assessment results for flubendiamide, conducted using water column and pore water estimates of exposure and compared with effects endpoints from the benthic macroinvertebrate *C. riparius* are appropriate sensitive indicators of risks to invertebrates occupying the benthos including sessile and mobile invertebrate organisms growing on or associated principally with the bottom of waterways. The risk findings are also reasonably applied to invertebrates existing within the water column. In both cases, the standard issue of the use of toxicological surrogates to represent effects in a given taxa is discussed in USEPA 2004.

The most appropriate description of invertebrates of concern in the context of the flubendiamide risk assessment would best be termed risks to **invertebrates of aquatic systems** as this would be inclusive of invertebrates (macro and potentially micro) in a variety of water column and benthic associated habitats within a given aquatic system where exposure to either overlying water or benthic pore water could occur.

References

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USEPA. 2014. Toxicity Testing and Ecological Risk Assessment Guidance for Benthic Invertebrates. Memorandum from Donald Brady, Director of the Environmental Fate and Effects Division. April 10, 2014.