Bayer CropScience

February 25, 2019

Imidacloprid Criteria Comment Letter
Attn: Peter Meertens
Central Coast Regional Water Quality Control Board
895 Aerovista Place, Suite 101
San Luis Obipso, CA 93401

RE: Comments on "Derivation of Imidacloprid Water Quality Criteria – Draft Technical Report"

Dear Mr. Meertens,

Bayer CropScience ("BCS") appreciates the opportunity to comment on the draft report "Derivation of Imidacloprid Water Quality Criteria" by Bower and Tjeerdema from the University of California – Davis. Imidacloprid is a critical tool for growers in CA and throughout the world and BCS is committed to environmentally responsible and sustainability use. As the initial developer and registrant of imidacloprid, we have a deep understanding of it's properties and want to ensure the hazards and aquatic risks of imidacloprid are accurately represented.

We understand how the draft water quality criteria were calculated, but the following limitations of the method have led to information highly relevant to water quality criteria derivation being excluded:

1) Inability to deal with lack of toxicity for insensitive species and characterization of such instances as knowledge gaps
2) Exclusion of reliable acute and chronic data for acute-to-chronic rations unless acute and chronic data are generated in the same study, by the same lab, or with identical dilution water.
3) Exclusion of mesocosm data because studies were performed with formulations in order to investigate potential toxicity following actual product use scenarios

It concerns us that someone reviewing the report, unfamiliar with imidacloprid, would be left with the impression that the aquatic toxicity database is data poor, when nothing could be farther from the truth. The comments that follow include general and technical remarks on methodological updates necessary for water quality criteria derivation of selective compounds such as imidacloprid, as well as potential errors for consideration.

Thank you for your consideration of our comments and we would be happy to discuss them in more detail with you.

Sincerely,

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Detailed Technical Comments

Available Aquatic Toxicity Data

Imidacloprid has one of the most well characterized aquatic organism toxicity profiles of all insecticides. Thanks to vast product development and independent research efforts, a wealth of data from laboratory to environmentally relevant field studies are available for establishment of robust thresholds for protection of aquatic organisms of interest (i.e. water quality criteria) and characterizations of potential risks associated with chemical detections from water monitoring programs. To date the aquatic toxicity database is comprised of >150 laboratory and >30 mesocosm studies covering ~28 taxa and providing more than 240 endpoints. The draft imidacloprid criteria provides a review of 41 of these studies. However, as discussed in the following paragraphs, because of methods used only 2 imidacloprid specific data points were used quantitatively for calculation of the acute and chronic criteria. Although it is unreasonable to expect all the data points to be appropriate for the derivations, incorporating more of this information into criteria derivation process would produce more accurate and robust criteria.

While the authors of the draft imidacloprid water quality criteria should be commended for their extensive efforts to identify relevant toxicity data, the UC Davis *Methodology for Derivation of Pesticide Water Quality Criteria for the Protection of Aquatic Life* (methodology) used to derive the criteria is inappropriate for selective compounds such as imidacloprid resulting in derivation of flawed criteria. Restrictions set forth by the methodology prevent leveraging of the wealth of data available for imidacloprid and rather than provide scientifically sound criteria, introduces uncertainty via omission of available robust and reliable scientific data. Data were excluded from criteria calculation on the basis of (1) adverse effects not being observed, (2) data generated with an imidacloprid formulation, and (3) acute and chronic data were not generated in the same test, by the same lab, or with the same dilution water. Additional uncertainty was introduced to the criteria with the safety factor and toxicity extrapolation techniques (e.g., acute-to-chronic ratio) used in place of relying on available quantitative study data. The following section will discuss the methodological issues in more detail followed by a section dedicated to technical corrections and recommendations for author consideration.

Methodology constraints that impede the derivation of robust Imidacloprid Water Quality Criteria

Omission of toxicity studies with no adverse effects and the use of assessment factors:

Imidacloprid is considered a selective insecticide. Unlike legacy, more broad spectrum insecticides (e.g., chlorpyrifos) for which the UC Davis method (Methodology) was developed, sensitivity to imidacloprid is limited to particular pest and non-target taxa. For example, in the aquatic arena insects such as *Chironomus dilutus* (formally *C. tentans*) are sensitive to imidacloprid exposure while fish are insensitive with several studies unable to produce definitive (not greater than) LC_{50} or NOECs even when fish are exposed to imidacloprid at the limit of solubility. The Methodology was not designed for this selective nature as indicated by the requirement for definitive (uncensored) endpoints for a minimum of 5 different taxa including salmonid, warm water fish, planktonic crustacean, benthic crustacean and insect in order to meet the criteria for the Species Sensitivity Distribution (SSD) approach to deriving criteria. For selective compounds it is not expected that definitive endpoints (acute LC/EC_{50} or chronic NOEC)will be obtained for all five taxa thereby eliminating the option of using an SSD and

defaulting to an assessment (safety) factor approach regardless of the number of reliable studies available.

This is the case for imidacloprid. Despite the use of solvent (DMF) to assist dissolving technical imidacloprid in an acute warm water fish study submitted to EPA and CDPR (MRID 42055314), imidacloprid exposure at the limit concentration (defined by the limit of solubility) was not able to illicit sufficient toxicity to warm water fish to calculate an LC_{50}. A lack of toxicity at the limit concentration was also observed in the chronic fish study (MRID 48671403) producing a NOEC greater than the highest test level. The highest treatment levels included in in the acute and chronic studies are approximately 4 orders of magnitude higher than the upper end of imidacloprid surface water detections in California. Testing above the limit of solubility is not an option as the material will precipitate, settle out and collect on the bottom of the test vessel. In this case, the exposure concentration defined by the analytical confirmation of imidacloprid in water remains at the solubility limit despite the additional material added. While there is no definitive endpoint, the imidacloprid data set does satisfy the purpose of the 5 taxa requirement, which is to ensure that toxicity information for a wide range of taxa, representing the full aquatic community, are available for deriving a water quality criteria.

Although there is no option for deriving a definitive (not greater than value) warm water fish endpoint and it is clear that the taxa are not sensitive to imidacloprid exposure, the methodology ignores the lack of sensitivity and defers the derivation of criteria to an assessment (safety) factor approach. The assessment factor (AF) approach relies on the lowest available RR rated endpoint and applies a “safety” factor to it based on the assumption that taxa without suitable endpoints are more sensitive than available data predict. The approach is designed for compounds with very limited data, not imidacloprid which has one of, if not the, most robust aquatic toxicity data package of all insecticides. Further, this approach ignores all but the most sensitive acute endpoint and rather than acknowledge that warm water fish are insensitive, it implicitly assumes that the concentration defined by the lowest endpoint is not suitably low enough for protection of warm water fish.

A more flexible approach to how the current methodology is being applied should be considered for selective products which often have non-definitive endpoints for taxa required by the methodology due to lack of sensitivity. For imidacloprid we recommend quantitative criteria establishment efforts focused on the most sensitive taxa of interest (i.e., aquatic invertebrates) as documented in the scientific publications of Moore et al. 2016 and Whitfield-Aslund et al. 2017. The data for non-sensitive taxa would still be used, but in a qualitative manner, since they provide information to conclude that certain parts of the aquatic community are insensitive. If an SSD approach is used, the technical advantage of focusing exclusively on the most sensitive taxa is bi- and multimodal distributions of toxicity data are avoided resulting in a better curve fit to the toxicity data distribution and a more robust estimate of hazard concentrations. EPA’s original 1985 Water Quality Criteria guidance essentially takes this approach since the actual regression to derive a criterion relies on just the 4 data point (typically the lowest values) around the desired criterion.

Acute to chronic ratio approach for derivation of chronic value:

Restricting data for acute-to-chronic ratio (ACR) estimates to acute and chronic tests performed as part of the same study, in the same lab, or with the same dilution water is unnecessary and omits quantitative data deemed by the authors of the criteria as reliable. Studies rated by the authors as reliable followed appropriate testing methodologies, with many of the studies adhering to internationally recognized test guidelines (e.g., OECD or US EPA OCSPP guidelines) that

have been inter and intra laboratory validated across the world, and therefore can be used for ACR calculations with confidence. Omitting these data, and relying instead on default ACR values defined by the methodology does not result in water quality criteria based on the best available science. The authors should amend the methodology and use the reliable quantitative data available to ensure the water quality criteria are scientifically valid and robust.

Clarifications and Corrections

Wildlife dietary values and bioaccumulation potential for animals with significant food sources in water (pg 9 and 16-18):

Two hen metabolism (MRID 42556116, 42556117) and rat metabolism studies (MRID 42256356) are available to address ADME and potential for bioaccumulation. The rapid depuration of imidacloprid observed in these studies demonstrates bioaccumulation is not a concern for terrestrial vertebrates.

Lack of acceptable mesocosm studies (pg 10):

Over thirty-five microcosm and mesocosm (cosm) studies investigating potential impacts of imidacloprid exposure on aquatic invertebrates or aquatic communities are available. These studies are representative of the potential exposure and impacts in the environment from product use and as such often use formulated products for the investigation to mimic actual use conditions. As these studies are designed to be more environmentally relevant and have a lower degree of uncertainty associated with extrapolation from laboratory studies to the field, the methodology should be revised to consider data from relevant formulated studies and not only studies performed with the technical material. However, even under current restrictions Moring et al. 1992 (MRID 42256306) should be used for the imidacloprid water quality criteria derivation as this high quality study was performed with technical imidacloprid and reports a NOEC of 6 µg ai/L based on observed recovery.

References:

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