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OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

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**MEMORANDUM**

**SUBJECT:** **Flubendiamide:** Ecological Risk Assessment Addendum Summarizing all Submissions and Discussions to Date

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**1. Introduction**

Flubendiamide, an insecticide, received a time-limited/conditional registration in 2008 for aerial and/or ground application to corn, cotton, tobacco, pome fruit, stone fruit, tree nuts, grapes, cucurbit vegetables, fruiting vegetables, leafy vegetables, and brassica leafy vegetables. Subsequent registration actions have expanded the list of crops to which flubendiamide may be applied to more than 200 crops. Registrant (Bayer Crops Science, BCS) submitted effects studies indicate that both the parent compound (flubendiamide) and its degradate (des-iodo) exhibit chronic toxicity to aquatic invertebrates<sup>1</sup>. Submitted fate data indicate flubendiamide slowly converts to its des-iodo degradate, which does not appreciably breakdown and is 10 times more

<sup>1</sup> Flubendiamide's mode of action is taxa-specific to an unknown degree (targets lepidopteran ryanodine receptors). EFED does not have endpoints specific to lepidopterans. There are numerous species of aquatic lepidopterans of which four are listed species. The agency policy is to use the most sensitive species endpoints from studies that meet scientific quality criteria. There are no aquatic lepidopteran toxicity studies available to address this uncertainty in quantifiable terms.

toxic to aquatic invertebrates than the parent compound. EFED modeling (DP 329613+) predicts that flubendiamide and its des-iodo degradate will accumulate in aquatic systems eventually exceeding Agency levels of concern (LOCs).

The purpose of this analysis is to: 1) briefly summarize the previous risk assessments and more recent risk analyses performed for flubendiamide; 2) evaluate recent data submissions from the registrant; 3) assess ecological risk for a proposed tree nut use amendment the registrant has proposed to retain as the sole use on future flubendiamide labels; and 4) determine if any of the recent submissions and/or analyses have changed the Agency's understanding of the risks posed by current and proposed uses of flubendiamide.

## 2. Description of Past Risk Assessment Conclusions

Flubendiamide has been subject to three ecological risk assessments prior to this document:

- June 23, 2008: DP Barcodes: 329594, 329613, 329606, and 329599
- May 17, 2010: DP Barcodes: 368029, 368036, 368040, and 368055
- December 16, 2010: DP Barcodes: 376460, 376101, and 376102

The June 23, 2008 risk assessment addressed registration proposals for two flubendiamide formulations. Flubendiamide formulation 480 SC was proposed for corn, cotton, tobacco, grapes, pome fruit, stone fruit, and tree nut crops. A second formulation, 24 WG, was proposed for use on cucurbit vegetables, fruiting vegetables, leafy vegetables, and brassica (cole) leafy vegetables. The maximum application rate was 0.156 lbs a.i./A for pome fruit. Evaluation of the physical and chemical properties indicated that flubendiamide is stable to hydrolysis, aerobic and anaerobic soil metabolism, and aerobic aquatic metabolism. Photolysis and anaerobic aquatic metabolism were reported to be the main routes of degradation for flubendiamide.

Flubendiamide degrades to NNI-0001-des-iodo (hereafter referred to as des-iodo) under anaerobic aquatic conditions ( $t_{1/2} = 364$  days) and direct aqueous photolysis ( $t_{1/2} = 11.6$  days), but rather slowly by soil photolysis ( $t_{1/2} = 70.5$  days). Flubendiamide and des-iodo were reported to have the potential for groundwater contamination in vulnerable soils with low organic carbon content, after very heavy rainfall, and/or in the presence of shallow groundwater. The risk assessment noted that flubendiamide and the des-iodo degradate overall stability/persistence profiles were suggestive of accumulation in soils, water column, and sediments with each successive application. Analysis of available ecological effects data resulted in the conclusion that both flubendiamide and the des-iodo degradate were of toxicological concern. The risk assessment concluded that there are risk concerns for to benthic invertebrates<sup>2</sup> exposed to flubendiamide and its des-iodo degradate. Furthermore, the risk assessment concluded that the formulated products 480 SC and 24 WG were also of concern for acute and chronic risks to freshwater invertebrates from direct introduction to surface waters by spray drift deposition.

The May 17, 2010 risk assessment addressed additional registration proposals for 480 SC formulation use on Christmas trees and legume vegetables including soybeans, and the 24 WG formulation for rotational plant-back interval use for legume vegetables. The conclusions of the

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<sup>2</sup> Some species of aquatic invertebrates inhabit the overlying water (water above the sediment in a water body), while others inhabit the benthic zone (in or on the sediment in a water body). Because exposure and effects endpoints can vary between overlying and benthic (or pore) water, it is sometimes necessary to specify overlying or benthic if referring to only one portion of the water body or one of these groups of aquatic invertebrates.

risk assessment were not markedly different from the 2008 risk assessment's characterization of the environmental fate, stressors of concern, nor the risk conclusions: 1) concern for long-term accumulation of the parent flubendiamide and the des-iodo degradate; 2) both flubendiamide and the des-iodo degradate as stressors of concern; and 3) risk concerns for benthic invertebrates from both flubendiamide and the des-iodo degradate to freshwater invertebrates. However, the risk assessment also addressed the potential for distance buffers between application sites and surface waters as a risk mitigation option. The risk assessment concluded that buffers, from a spray drift perspective, would have little impact on the risks of concern.

The December 16, 2010 risk assessment addressed proposed new uses of flubendiamide on alfalfa, globe artichoke, low growing berries (except cranberry), peanut, pistachio, small fruit vine climbing (except fuzzy kiwifruit), sorghum, sugarcane, sunflower, safflower, turnip greens and a proposed increased application rate on brassica leafy vegetables. The proposed new uses and increased rate pertained to the formulations SYNAPSE™ WG (39%), a water dispersible granule formulation, and BELT™ SC (24% ai), a suspension concentrate formulation. Flubendiamide was proposed for ground application, aerial application (restricted for pistachio, and small fruit vine climbing group), and chemigation. Again as in the previous risk assessments, flubendiamide and the des-iodo degradate were identified as the stressors of concern. Environmental fate and transport data indicated that flubendiamide is stable to hydrolysis, aerobic and anaerobic soil metabolism, and aerobic aquatic metabolism. Photolysis and anaerobic aquatic metabolism appeared to be the main routes of degradation for flubendiamide. Flubendiamide was expected to be slightly to hardly mobile in the environment. Des-iodo was concluded to be persistent (stable in an aerobic soil environment), and expected to be moderately mobile. As in the other risk assessments, concern was indicated for chronic risk to freshwater invertebrates from exposures in the water column and pore water from the total residues of flubendiamide and des-iodo. The December 16, 2010 risk assessment mentions that a field study on the efficacy of vegetative filter strips to reduce pesticide loading to surface waters was under review at the time of writing. However, the results of that study were not incorporated into the risk assessment.

### **3. Time-limited/Conditional Registration Requirements**

Sections 3 through 6 describe a series of less formal risk assessments that were undertaken by the Agency in response to data submissions, alternative modeling submitted by Bayer CropScience, proposed label revisions, and Agency/OPP Risk Manager requests. The results of these individual analyses are described and integrated into an overall risk assessment in Section 7.

#### *Issues surrounding the use of vegetative filter strips*

After the initial (June 23, 2008) risk assessment, the registrant argued that the 15-ft. vegetative filter strip (VFS) included on all flubendiamide labels would largely prevent transfer of flubendiamide from the field of application to downslope waterbodies, thereby limiting the accumulation of flubendiamide and des-iodo in these waterbodies and preventing exceedances of Agency LOCs. According to this argument, the Agency's modeling over-estimated exposure and therefore risk, because it could not account for the mitigation provided by the VFS.

The Environmental Fate and Effects Division (EFED) counter-argued that VFSs can be beneficial for pesticides that would degrade in the VFSs, but flubendiamide would not be expected to degrade in the VFSs due to its persistent nature. Therefore, EFED believed

flubendiamide movement would only be “temporarily delayed” by the VFS (*i.e.*, flubendiamide washed into the VFS by a runoff event would likely be transported to a downstream waterbody by a subsequent runoff event).

However, neither the registrant nor EFED had data to support either side’s argument. This uncertainty is reflected in the preliminary acceptance letter dated 7/31/2008 (a document notifying the registrant of the conditions of registration) which required the following:

1. Small-Scale Run-off/Vegetative Filter Strip Study – a run-off study to determine the magnitude of the parent, flubendiamide, retained in filter strips of various widths; and
2. Farm Pond Monitoring Program – if risk assessment, based on the results from the small-scale run-off/vegetative filter strip study and additional available data indicates that there are still risk concerns, monitoring of selected receiving waters will be required within watersheds where flubendiamide will be used.

Flubendiamide was granted a time-limited/conditional registration while the registrant generated the data necessary to address the uncertainties identified at the time of registration.

A major modeling error was identified in a cursory review (DP 382010) of the small-scale run-off/vegetative filter strip study (MRIDs 48175602, 48175604, and 48175606) submitted by the registrant in response to the first condition of registration. The Agency requested that the study be corrected and resubmitted to the Agency, but the study was never re-submitted. Therefore, the second requirement, the ‘farm pond’ monitoring program, was triggered.

#### *Requirements for Environmental Monitoring*

The registrant submitted a monitoring protocol for flubendiamide and its metabolite, des-iodo flubendiamide, in sediment and surface water (MRID 48010201). EFED recommended (DP 375361) three modifications of the proposed study. First, the submitted protocol should include water bodies that will likely represent worst case scenarios in terms of flubendiamide accumulation in sediment (*e.g.*, ponds for which the entire upstream drainage area is treated with flubendiamide). Second, the time period monitored should be extended to allow accurate accumulation rates in sediment for flubendiamide and its des-iodo degradate to be determined. Third, the registrant needs to make available sufficient quantities of the technical grade active ingredient and des-iodo degradate for analytical standards, so that the U.S. Geological Survey (USGS) can include these chemicals in their pesticide surveys.

After site selection studies in Georgia (MRID 48644901) and North Carolina (MRID 48535201), the registrant and EFED agreed to monitoring a total of three ponds (two adjacent ponds in Georgia (DP 398132) and one pond in North Carolina (DP 394006)). Both sites were selected from regions of the United States with high initial (2009) flubendiamide sales data.

In addition to the registrant’s monitoring effort, the USGS was able to add flubendiamide and des-iodo to their pesticide monitoring programs from 2012 onward (water sampling only, no sediment monitoring).

#### *Registrant-suggested Modeling Efforts*

The registrant asked the Agency to consider modeling pond overflow in MRID 49532601. The registrant documented overflow events at the ponds monitored in the farm pond study (MRIDs 49415303, 49415302, and 49415301), but did not measure overflow volumes or concentrations

in overflow for any of the ponds. In response to the registrant's request, the Agency modeled several scenarios (Appendix 1) using the "varying volume and flowthrough" option in the Surface Water Concentration Calculator (SWCC version 1.106; PRZM version 5.0; VVWM version 1.0).

Modeling overflow dramatically decreases the pond estimated environmental concentrations (EECs) in the Eastern/Southeastern United States scenarios modeled relative to the EECs based on standard EFED modeling (which uses the "constant volume, no flowthrough" option). This change in EECs is due to greater precipitation in the Eastern/Southeastern United States, which keeps the pond near full capacity and causes overflow with most runoff events (*i.e.*, little change in EECs due to changing pond volume, but does include a significant pesticide mass loss through overflow). However, EECs are higher in the Western United States using the "varying volume and flowthrough" option relative to standard EFED modeling that does not account for overflow. In the Western United States, the farm pond is often below full capacity and refills rather than overflows with most runoff events (*i.e.*, concentration increases as pond volume diminishes, while pesticide mass loss through overflow is rare).

Additionally, it is important to note that any flubendiamide or des-iodo "lost" with overflow is expected to accumulate in a different aquatic environment (*e.g.*, lakes, reservoirs, and/or estuaries) further downstream due to the persistence of these chemicals. Therefore, modeling overflow doesn't diminish the overall environmental consequences of flubendiamide applications in the Eastern/Southeastern United States and results in higher EECs in the Western United States (DP 426940).

#### *Responses to Registrant Email Inquiries*

The registrant asked the Agency to consider several topics through emails submitted 6/22/2015 and 6/30/2015. The 6/22/2015 email concerned USGS stream monitoring data, the proximity of farm ponds to crop areas with flubendiamide use, and aquatic photolysis as an explanation for the 66-day mesocosm study half-life. A response provided on 7/8/2015 (DP 427901) concluded that "the information contained in this submission would not change the conclusions of previous EFED responses subsequent to the pond studies or previous EFED risk assessments".

The 6/30/2015 email contained an attachment entitled "White Paper: Flubendiamide Benefits, Aquatic Risk Assessment Summary and Proposed Path Forward" (no MRID number) with comments on several topics: 1) pond monitoring data; 2) USGS stream monitoring; 3) the low extent of des-iodo formation in aerobic and semi-aerobic environments; 4) limited numbers of ponds adjacent to high use areas; 5) lower toxicity compared to main competitor products; 6) fate of flubendiamide and des-iodo in streams under real world conditions; 7) interpretation of 3.5-year monitoring data – farm pond accumulation; and 8) a proposed path forward. The Agency responded (DP 427973) to the 2<sup>nd</sup> email on 7/15/2015 with the same response as for the first email because the information provided did not change the conclusions of previous EFED responses subsequent to the pond studies or previous EFED risk assessments.

#### *Responses to Registrant Requests to Review Flubendiamide Analyses Prepared for Agency Managers*

In the fall of 2015, a series of presentations were made to the Office of Pesticide Programs (OPP) Risk Managers regarding flubendiamide (10/28/2015 – 12/3/2015). As part of these presentations, two series of analyses were produced at the request of the Risk Managers from the

Registration Division of OPP. Because the registrant asked to see these analyses, two memos were subsequently produced to provide a written context to analyses so that the registrant could better interpret these analyses. The first memo (DP 430747) compared four regulatory scenarios for multiple crops based on the standard EFED aquatic modeling procedures. The crops selected were those with the largest number of acres treated according to proprietary pesticide usage data available to the Agency. The regulatory scenarios assumed maximum use rates from 2009 (the year after flubendiamide was registered) to 2015 and then changed according to the regulatory scenario modeled, which included ‘no change from current label’, ‘change to one ground application forever’, ‘change to one ground application, then cancel in 2018’, and ‘cancel uses after the 2015 application’. This analysis showed that all four of the regulatory scenarios exceed Agency LOCs for all of the simulated crops because too much flubendiamide had already been applied to these simulated fields through 2015 based on the maximum application rates on current labels. Any additional applications beyond 2015 simply causes further deterioration of the aquatic environment modeled (*i.e.*, des-iodo would continue to accumulate adversely affecting greater proportions of aquatic invertebrates with similar sensitivities to the organisms from which the endpoints were derived as well as adversely affecting greater numbers of less sensitive aquatic invertebrate species as those species’ tolerances are exceeded).

The second memo (DP 430972) provided additional characterization of ecological risk through consideration of a subset of crops proposed as posing limited ecological risk to aquatic invertebrates. The crop scenarios were selected based on the 13 crops (or crop groups; *i.e.*, alfalfa, brassica leafy vegetables, cotton (AZ and CA only), cucurbit vegetables, fruiting vegetables, grape, leafy vegetables, legume vegetables, pome fruit, stone fruit, strawberry, tobacco, and tree nuts) that the registrant proposed to retain on flubendiamide labels (email from Charlotte Sanson of Bayer CropScience to Susan Lewis of USEPA on 12/15/15). The application rates, number of applications per year and annual maximum application rates were based on an email from Nancy Delaney of Bayer CropScience to Deborah McCall of USEPA on 8/12/15. Only two application scenarios (high and low exposure) were investigated for this second memo. This analysis assumed no prior use of flubendiamide and modeled different numbers of applications per year from the maximum allowed on the label down to one at the maximum single application rate.

Additional analysis of all these crops was performed prior to a meeting with the registrant and provided to the registrant at that meeting on 1/6/2016. This analysis used the same methods as described in the second memo and is attached to this memo as Appendix 3. These results confirm the range of results in the second memo (DP 430972) and provides additional results for the entire set of uses described by the BCS emails.

#### **4. Discussion of Fate and Effects Data Submitted after the Last Risk Assessment**

Several fate and effects studies have been submitted since the last comprehensive risk assessment conducted in 2010.

##### *Toxicological Data*

Subsequent to the risk assessments in 2010 additional sediment effects data were made available to the Agency. In addition, over the course of several months OPP Risk Managers requested additional perspective on the suite of effects observed in available sediment effects data at doses beyond the no adverse effect concentration (NOAEC) for the available data.

### Submissions of Sediment Toxicity Data After 2010

The registrant submitted a des-iodo degradate prolonged sediment toxicity test with *Chironomus riparius* using spiked sediment (MRID 48175605). The Agency completed a data evaluation record (DER) for this study in July of 2011. The study was classified supplemental and returned a NOAEC at the highest dose tested: time weighted average (TWA) of 52.6 µg of total recoverable residue (TRR)/kg-dw sediment; TWA 7.18 µg TRR/L overlying water; TWA 19.5 µg TRR/L pore water.

In January of 2016 the registrant submitted a flubendiamide prolonged sediment toxicity test with *C. riparius* using spiked sediment (MRID 49661801). The Agency has conducted an evaluation of the study (DP 431040) and concludes that the study is scientifically sound and suitable for use quantitatively in risk assessment. Consistent with other studies with this species and sediment, emergence of the organisms proved to be the most sensitive endpoint. The Agency's Data Evaluation Record concludes that the NOAEC is TWA 12.3 µg/L in overlying water and TWA 4.32 µg/L in pore water. The LOAEC is TWA 23.7 µg/L in overlying water and TWA 8.09 µg/L in pore water.

### Confirmation of Existing Studies

In 2015, while the evaluation of all lines of evidence was underway with respect to the efficacy of vegetative filter strips, model assumptions and surface water monitoring, the Risk Managers from the Registration Division of OPP requested that exposure modelling results be compared to the full suite of effects endpoints from the two spiked water prolonged sediment toxicity tests with *C. riparius* (MRIDs 46817022 (flubendiamide) and 46817023 (des-iodo degradate)).

EFED issued a memorandum (DP 430746) that summarized the approach for evaluation of the two studies and the findings of that effort. The resulting endpoints, expressed as TWA, follow in Tables 1 and 2.

**Table 1. Flubendiamide Effects Endpoints (mg/L) from MRID 46817022**

Concentration Based on Nominal Treatment	Concentration Based on Time Weighted Average (TWA)	Effect Observation
Overlying Water		
0.04	0.015504356*	NOEC Percent emergence
0.08	0.029875**	LOEC 22% inhibition
0.16	0.062017426*	100% inhibition
Pore Water		
0.04	0.001513025*	NOEC Percent emergence
0.08	0.0025**	LOEC 22% inhibition
0.16	0.006052101*	100% inhibition

\* based on nominal treatment and average ratio of nominal:TWA

\*\* based on measured TWA

**Table 2. Des-iodo Effects Endpoints (mg/L) from MRID 46817023**

Concentration Based on Nominal Treatment	Concentration Based on Time Weighted Average (TWA)	Effect Observation
Overlying Water		
0.004	0.00189775*	NOEC Percent emergence
0.008	0.004135578**	LOEC 17% inhibition
0.016	0.008271157**	33% inhibition
0.032	0.015995*	80% inhibition
Pore Water		
0.004	0.00027825*	NOEC Percent emergence
0.008	0.000737285**	LOEC 17% inhibition
0.016	0.00147457**	33% inhibition
0.032	0.00391375*	80% inhibition

\* based on nominal treatment and average ratio of nominal:TWA

\*\* based on measured TWA

A comparison of the past risk assessment use of the flubendiamide endpoints from MRID 46817022 is presented below (Table 3), and shows that TWA concentrations were not reported in previous risk assessments for the NOAEC in overlying and pore waters and that previous risk assessments reported the LOAEC as a single post application measured dose of 69 µg/L in overlying water and 3 µg/l in pore water.

**Table 3. Current Flubendiamide Endpoints from the Spiked Water 28-day *Chironomus riparius* (MRID 46817022) Compared with Previous Assessments (µg/L)**

Risk Assessment	Overlying Water Concentrations Based on Time Weighted Average		Pore Water Concentrations Based on Time Weighted Average	
	NOAEC	LOAEC	NOAEC	LOAEC
June 2008	Not Calculated	69 (single measured value)	Not Calculated	3 (single measured value)
May 2010	Not Calculated	69 (single measured value)	Not Calculated	3 (single measured value)
December 2010	Not Calculated	69 (single measured value)	Not Calculated	3 (single measured value)
Current	15	29.8	1.5	2.5

A comparison of the past risk assessment use of the des-iodo degradate endpoints from MRID 46817023 is presented below in Table 4, and shows that TWA concentrations are the same as previous risk assessments for the NOAEC in overlying and pore waters and that previous risk assessments did not report a TWA for the LOAEC.

**Table 4. Current Des-iodo Endpoints from the Spiked Water 28-day *Chironomus riparius* (MRID 46817023) Des-iodo Compared with Previous Assessments (µg/L)**

Risk Assessment	Overlying Time Weighted Average		Pore Time Weighted Average	
	NOAEC	LOAEC	NOAEC	LOAEC
June 2008	1.9	Not Calculated	0.28	Not Calculated
May 2010	1.9	Not Calculated	0.28	Not Calculated
December 2010	1.9	Not Calculated	0.28	Not Calculated
Current	1.90	4.14	0.28	7.4

## Final Suite of Available Effects Endpoints

The following is the final suite of flubendiamide and des-iodo endpoints for *C. riparius* in spiked water and spiked sediment tests. Flubendiamide's mode of action is purported to be taxa-specific, principally targeting the lepidopteran ryanodine receptor. The extent to which the receptor affinity for the compound and its degradate changes across invertebrate taxa is not well understood for all aquatic invertebrates and so there remains uncertainty as to the representation of any given species to all species within a taxonomic group. However, effects endpoints based on the test organism *C. riparius* (not a lepidopteran) remain the most sensitive available and, consistent with EPA policy, are the basis for the risk assessment.

**Table 5. Current Flubendiamide and Des-iodo Endpoints for *Chironomus riparius* in Spiked Water and Spiked Sediment Tests**

Overlying Water TWA (µg/L)	Pore Water TWA (µg/L)	Endpoint Label
<i>Flubendiamide – Spiked Water 28-Day (MRID 46817022)</i>		
15.5	1.51	NOAEC Percent emergence
29.9	2.50	LOAEC 22% inhibition
62.0	6.05	100% inhibition
<i>Flubendiamide – Spiked Sediment (MRID 49661801) (in review)</i>		
12.3	4.32	NOAEC Percent emergence
23.7	8.09	LOAEC Percent emergence
<i>Des-iodo – Spiked Water 28-Day (MRID 46817023)</i>		
1.90	0.278	NOAEC Percent emergence
4.14	0.737	LOAEC 17% inhibition
8.27	1.47	33% inhibition
16.0	3.91	80% inhibition
<i>Des-iodo – Spiked Sediment (MRID 48175605)</i>		
7.18	19.5	NOAEC (Highest dose tested)
>7.18	>19.5	LOEC

## Registrant Endpoint Selection

In December 2014 the registrant submitted a document containing their perspective on flubendiamide and des-iodo degradate sediment toxicity endpoints (MRID 49415302). The following is a summary of the registrant's endpoint selection:

- Flubendiamide Sediment Toxicity Study, Spiked Water (MRID 46817022) – results based on nominal initial overlying water
  - EC<sub>50</sub> 59 µg a.i./L
  - EC<sub>15</sub> 45 µg a.i./L
  - NOAEC 40 µg a.i./L
- Flubendiamide Sediment Toxicity Study, Spiked Sediment (MRID 49661801)
  - NOAEC 156 µg/kg sediment (dry weight)
  - NOAEC 2.56 µg a.i./L (pore water)
- Des-iodo Degradate Sediment Toxicity Study, Spiked Water (MRID 46817023) – results based on nominal initial overlying water
  - EC<sub>50</sub> 18.6 µg/L
  - EC<sub>15</sub> 9 µg/L
  - NOAEC 4.0 µg/L

- Des-Iodo Degradate Sediment Toxicity Study, Spiked Sediment (MRID 48178605)
  - NOAEC 55 µg/kg sediment (dry weight)
  - NOAEC peak pore water 31.3 µg des-iodo/L
  - NOAEC mean measure pore water 22 µg des-iodo/L
- Flubendiamide *Daphnia magna* Reproduction Study, Spiked Water (MRID 46816944)
  - NOAEC 33 µg/L

#### *Fate Data*

The flubendiamide fate data interpretation has not changed since the 2008 and 2010 risk assessment. Additional laboratory fate data was requested and submitted for des-iodo after the time-limited/conditional registration. All of this des-iodo data indicated that des-iodo does not degrade in the environment with the exception of the recently (1/5/2016) submitted des-iodo aquatic photolysis study, described below.

#### Des-iodo Aquatic Photolysis Study

The registrant submitted a 10-day, aqueous photolysis study (MRID 49661701) that estimates a 79-day half-life for des-iodo when expressed as an environmentally relevant half-life for June in Phoenix, AZ. At the end of the 10-day study, 77% of the des-iodo remained as untransformed des-iodo. The other 23% had transformed into 14 degradates and CO<sub>2</sub>. Because so many degradates together make up so little mass, no degradate exceeded 6% and only two degradates could be identified. None of the degradates have toxicity data, so none can be ruled out as toxic degradates of concern other than CO<sub>2</sub>. Potentially, these degradates may be: more toxic than des-iodo; as toxic as des-iodo; or less toxic than des-iodo. Assuming that all of the degradates other than CO<sub>2</sub> are as toxic as des-iodo would produce a half-life for the entire mass of toxic metabolites (total toxic residue half-life) exceeding 1000 years. Therefore the 79-day aquatic photolysis half-life for des-iodo estimated in MRID 49661701 should be considered an optimistic estimate. Other caveats in using this half-life are discussed in Section 5.

### **5. Modeling Based on Tree Nut Use in California**

The Agency received a new proposed label for flubendiamide on 1/8/2016 that limits use to tree nuts in California only and further limits application rates for tree nut uses below that on the current label. Up to three applications can be made to tree nuts, therefore modeling was conducted for one to three applications per year. Modeling this proposed use in this memo allows the Agency to perform an assessment of not only the reduced application rates, but also incorporate the 79-day aqueous photolysis half-life for des-iodo into this assessment (previous analyses had not used this half-life estimate since it was only submitted to the Agency on 1/5/2016).

Risk, based on the time-weighted average concentration endpoints (DP 430746) and on the registrant-suggested endpoints, is displayed over time in the graphs of Figure 1 of Appendix 3. It should be noted that EFED does not believe that the registrant-submitted toxicity endpoints are appropriate because they appear to be based on the nominal concentrations to which the test organisms were intended to be exposed rather than the measured, time-varying concentrations to which the organisms were actually exposed.

Flubendiamide airblast applications to tree nuts were modeled using the California almond scenario based on an application rate of 0.125 lbs ai/A with a 7-day application interval and up to

three applications per year. The scenario modeled assumes that flubendiamide has not previously been used in the fields to which it is to be applied and includes a 30-ft spray drift buffer zone around aquatic areas based on the new proposed label (previous modeling had only included a 15-ft spray drift buffer zone which was correct based on the spray drift language of the previous labels).

Because flubendiamide and its des-iodo degradate are expected to persist and accumulate in the environment, the ecological risk posed by these chemicals in aquatic environments is expected to increase over time. Therefore, the number of applications per year EECs are compared in a set of graphs for each number of applications per year simulation depicting how ecological exposure changes over time for flubendiamide in pore water, des-iodo in overlying water, and des-iodo in pore water (flubendiamide in overlying water didn't exceed Agency LOCs and therefore, is not presented).

Predicted changes in aquatic exposure over time are displayed in Figure 1 of Appendix 3<sup>3</sup>. To provide an estimate of the ecological effects to be anticipated at different risk quotient levels, the no observed adverse effect concentration (NOAEC) and any additional treatment levels that showed a significant effect above the NOAEC (MRIDs 46817022, 46817023, 46816944 and 49661801) were included in the graphs of Figure 1 of Appendix 3. Analyzed endpoints include both the Agency endpoints based on time-weighted averages (Table 5 and DP 430746) and the registrant-suggested endpoints (MRID 49415302) that are not supported by the Agency guidance (DP 430746). Appendix 4 reports the input parameters used in this analysis. Results are discussed in Section 7.

## **6. Confirmation of Risk from Lowest Exposure Scenario**

The Risk Managers from the Registration Division of OPP requested that exposure modeling be conducted with the lowest possible exposure scenario in conjunction with the half-life from the recently submitted des-iodo photolysis study (MRID 49661701; discussed in Section 4). In the document that evaluated ecological risk for 13 crops proposed as posing limited ecological risk to aquatic invertebrates (DP 430972) there was at least one crop use with more limited exposure than the tree nut use from the latest proposed label (Section 5). However, DP 430972 was prepared before the des-iodo photolysis study was submitted to the Agency. Including the photolysis half-life with the lowest exposure scenario from DP 430972 (ground application to cucurbit vegetables) would produce a lower exposure than had been modeled. Therefore to ensure that the Agency considered the lowest exposure (the scenario most favorable to the registrant and least likely to exceed Agency LOCs), the lowest exposure scenario from DP 430972 was modeled with the des-iodo photolysis half-life using the modeling assumptions from the tree nut use in Section 5 (a 30-ft spray drift buffer and applied assuming that flubendiamide had not been previously applied to the modeled field under the higher application rates of the current labels). The same assessment methods described for assessment of tree nuts (Section 5) were used also used in this analysis. Graphical results are provided in Appendix 3 Figure 2. Discussion of results occurs in Section 7.

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<sup>3</sup> Note that these graphs are presented in concentration units ( $\mu\text{g/L}$ ) rather than risk units as in previous analyses (DP 430747 and 430972) and Appendix 2.

## 7. Integration of New Information into the Risk Assessment

### *Results from the Farm Pond Monitoring Study (DP 412791+)*

At the end of three years of monitoring, the registrant submitted the farm pond monitoring reports (MRIDs 49415303, 49415302, and 49415301). EFED identified several issues (variability in crops grown, variability in the date of application(s), variability in the application rates, magnitude of the study application rates compared to the maximum annual label application rates, installation of grass waterways in the GA ponds' watershed, dilution of pore water and sediment samples with underlying uncontaminated material) with this monitoring data (DP 412791+). Despite these issues, EFED believed the monitoring data showed clear evidence that both flubendiamide and des-iodo accumulated in the ponds monitored<sup>4</sup>. The accumulation measured in the first three years of the pond data least impacted by the identified issues largely matched the initial 3 years of concentration predictions of EFED's aquatic exposure modeling. Because EFED's modeling does not account for the effect of VFSs, but still largely matched the monitoring data, EFED believes the effect of VFSs is not large enough to mitigate the ecological risks posed by flubendiamide applications. EFED concluded the original and subsequent ecological risk assessments performed by the Agency (DP 329594+, 368029+, and 376460+) adequately reflect the risks posed by flubendiamide applications and rejects the registrant's argument that the label-required 15-ft VFSs would prevent accumulation from exceeding Agency LOCs (DP 412791+).

### *Analysis of Results from Four Regulatory Scenarios for Multiple Crops (DP 430747)*

When considering the time-weighted average endpoints (upper set of graphs on each page in Appendix 1 Figure 1), all four of the regulatory scenarios exceed Agency LOCs for all of the simulated crops. Consistently, the greatest exceedances occur for des-iodo in pore water. Note that many of these scenarios achieve exposure levels that resulted in 80% emergence inhibition in the des-iodo chronic laboratory toxicity study (MRID 46817023). (80% emergence inhibition indicates that 80% of the test organisms were unable to emerge as the adult, reproductive life-stage from the sediment where the juveniles reside, while only 20% were able to emerge and potentially complete their life-cycle.) Such adverse impacts would directly impact aquatic invertebrates in ponds, lakes, reservoirs, estuaries, areas of sediment accumulation in flowing waterbodies and any non-flowing waterbodies where des-iodo would accumulate downstream of lands where flubendiamide is used as well as result in indirect impacts to fish and wildlife for which aquatic invertebrates serve as the basis for their food chain.

Flubendiamide and its des-iodo degradate pose a risk long after a regulatory action may take place (*i.e.*, there is a time-lag between mitigation and the maximum risk). For example, under the "cancel now" regulatory scenario (light blue dots in Figure 1), flubendiamide applications to the watershed above the modeled pond stop after 2015. However, risk from des-iodo in pore water does not level-off (stop increasing) for more than a decade after. This time-lag is due to the time required to transport the flubendiamide from the field to the pond and for flubendiamide in the pond to convert into des-iodo.

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<sup>4</sup> The fitted trends increase with time (accumulate) in all of the 18 time-series data sets collected from these ponds [3 ponds × 3 media (water column, sediments, and pore water) × 2 chemicals = 18 time series data sets]. Fitting these trends as exponential trends (*i.e.*, fitting a linear trend to the natural log of the concentration observations) indicated that 13 of these 18 trends were statistically significant at the  $p = 0.05$  level of confidence. Continued monitoring after the three year study period ended produced statistically significant trends in all 18 time series.

As a final note concerning the graphs based on time-weighted average endpoints, exceedances tend to occur quite early in the temporal trends. For example, all of the des-iodo pore water graphs based on the time-weighted average endpoints exceed Agency LOCs within 2 years. Considering that flubendiamide applications could have started in 2009 for these crops, these projected exceedances could have occurred as early as five years ago.

Even if risk were judged by the less sensitive endpoints suggested by the registrant (lower set of graphs on each page in Appendix 1 Figure 1), all but two of the regulatory scenarios exceed Agency LOCs. These two regulatory scenarios are the “Change to one ground application then cancel after 2018” and “Cancel now” scenarios for the leafy vegetables (based on the CA lettuce scenario, with ground applications initially in the first time period).

*Analysis Results from High and Low Exposure Analysis for 13 Crop Uses (DP 430972)*

Based on the two crops modeled to capture the range of flubendiamide risk from the registrant-proposed crops to be retained, both the high and low exposure/risk crop scenarios exceed Agency LOCs (based on the time-weighted average endpoints). There is risk for all of the numbers of applications modeled for both high and low scenarios even though the scenarios assumed that flubendiamide was applied to fields to which flubendiamide had never before been applied. The low exposure scenario exceeds Agency LOCs in: three years at six, five, or four applications per year; four years at three applications per year; six years at two applications per year; and nine years with only one application per year. The high exposure scenario applying two applications per year (the most allowed by the registrant proposal) exceeds Agency LOCs in two years, while the first exceedance occurs in three years with only one application per year.

Based on the TWA endpoints, all of the crop scenarios exceed exposure levels that resulted in 80% emergence inhibition in the des-iodo chronic laboratory toxicity study (MRID 46817023) within the 30 years simulated except: ground application to cucurbit vegetables at two applications per year (would exceed 80% emergence inhibition after 30 years) and one application per year (exceeds 33% emergence inhibition); airblast application to grapes at one application per year (would exceed 80% emergence inhibition after 30 years); and airblast application to stone fruit at one application per year (would exceed 80% emergence inhibition after 30 years). Again such adverse impacts would directly impact aquatic invertebrates in ponds, lakes, reservoirs, estuaries, areas of sediment accumulation in flowing waterbodies and any non-flowing waterbodies where des-iodo would accumulate downstream of lands where flubendiamide is used as well as indirectly impact fish and wildlife for which aquatic invertebrates serve as the basis for their food chain.

Although the Agency does not agree with the use of the nominal-based endpoints that were suggested by the registrant, with respect to the registrant-suggested endpoints, the low exposure scenario exceeds Agency LOCs in 11 years at six applications per year, 13 years at five applications per year, 16 years at four applications per year, and 21 years at three applications per year. The low exposure scenario based on either one or two applications per year does not exceed LOCs within the 30 years simulated based on the registrant-suggested endpoints. However, both application patterns of one or two applications per year would be expected to eventually exceed if applications continued long enough. The high exposure scenario based on two applications per year exceeds LOCs based on the registrant-suggested endpoints in eight years, while the first exceedance occurs in 11 years with only one application per year.

Therefore, when considering the registrant's less conservative proposed endpoints, use of flubendiamide still results in risk concerns for aquatic invertebrates.

#### *Tree Nut Assessment Results*

Based on the time-weighted average endpoints, the currently proposed flubendiamide tree nut use results in risk that exceeds Agency LOCs for all numbers of applications modeled. The tree nut scenario exceeds Agency LOCs in two years at three applications per year and three years at two or one application(s) per year. All of the numbers of applications per year modeled exceed exposure levels that resulted in 80% emergence inhibition in the des-iodo chronic laboratory toxicity study (MRID 46817023) within the 30 years simulated even though these scenarios also assumed that flubendiamide was applied to fields to which flubendiamide had never before been applied.

Although the Agency does not agree with the use of the nominal-based endpoints that were suggested by the registrant, the proposed tree nut scenario exceeds Agency LOCs using these endpoints in 10 years at three applications per year, 11 years at two applications per year, and 21 years at one application per year. Therefore, when considering the registrant's less conservative proposed endpoints, use of flubendiamide still results in risk concerns for aquatic invertebrates.

Recall that the tree nut use is based on the newly proposed label that includes an expanded spray drift buffer and uses the maximum photolysis estimate (*i.e.*, most degradation due to photolysis and therefore, most favorable to the registrant's position). Comparing the results of this analysis for tree nuts to a model run assuming no photolysis (but, retains the 30-ft spray drift buffer) decreases the 21-day average des-iodo overlying water EEC at year 30 by 24.1% (17.0 µg/L *vs.* 12.9 µg/L). The reason for the 24% decrease in exposure is that des-iodo has a low  $K_{OC}$  and therefore, tends to spend more time in the water column where photolysis could occur than chemicals with higher  $K_{OC}$ s.

However, there are several reasons to suspect that such a large photolysis effect would not occur in the environment. First, the SWCC does not account for the change of light intensity as the sun changes position throughout the year. In pure water (no interference due to suspended sediment, algae, *etc.*), the light intensity is greatest when the sun is directly overhead (typically near the summer solstice in the United States) and least during the winter solstice, when the sun's daily maximum elevation in the sky is at its lowest. The 79-day aquatic photolysis half-life estimate is for June in Phoenix, AZ and likely represents an over-estimate for the rest of the year in Phoenix. For parts of the United States further north, this half-life is likely an over-estimate throughout the year.

Second, waters draining, or downstream of, agricultural land tend to have high concentrations of dissolved or suspended sediment and nutrients compared to the pure water in which aquatic photolysis is measured. These impurities can block light penetration. Therefore after individual storm events and/or throughout the rainy season, aquatic photolysis is likely greatly over-estimated. Nutrients promote the growth of aquatic plants and algae which can block or limit light penetration for much of the time of the year when sunlight is most intense in the Northern United States or the entire year in the Southern United States (Note that in Figure 1 of DP 412791+, the Georgia ponds are a deep shade of green in images taken from September of 2010 and 2013.)

Thirdly, there is a mass transfer issue of des-iodo from the benthic sediment (where the des-iodo would form and the majority of it would remain) to the water column (where aqueous photolysis could occur). In the SWCC, equilibrium is re-established between the benthic and overlying water on a daily basis. Therefore any des-iodo degraded in the upper portion of the water column where photolysis is greatest is replaced with des-iodo from the bottom sediment within 1 day. In the actual environment, this transfer would likely be much slower as the des-iodo has to desorb from the sediment and is impeded by thermal stratification in waterbodies throughout much of the year, especially during the summer when aqueous photolysis would potentially be at its maximum.

Additionally as discussed previously, the degradates produced through aqueous photolysis may more be more or less toxic than des-iodo. Most of these degradates are unidentified and none have toxicity data. Therefore, toxicity may not diminish as des-iodo degrades through aqueous photolysis.

Note that EFED believes the SWCC performs quite well under more typical situations where pesticides degrade in shorter amounts of time (*e.g.*, wintertime photolysis is not an issue if most of the chemical has degraded within 60 days of a spring/summer application). It is specifically due to the persistence of flubendiamide and des-iodo that the assumptions of the SWCC have to be examined in such great detail. Further note that the farm pond monitoring results agreed quite well with modelling predictions (Figure 6 in DP 412791+) using modeling parameters that did not include the photolysis half-life. This provides further support that the 79-day half-life overestimates the actual aqueous photolysis rate under environmental conditions.

Comparing the results of this analysis for tree nuts to a model run assuming no photolysis with a *30-ft spray drift buffer* to a model run assuming no photolysis with a *15-ft spray drift buffer* decreases the 21-day average des-iodo overlying water EEC at year 30 by 3.5% (17.6 µg/L vs. 17.0 µg/L). Therefore the combined effect of including the new des-iodo photolysis half-life and extended spray drift buffer decreases the 21-day average des-iodo overlying water EEC at year 30 by 26.7% (17.6 µg/L vs. 12.9 µg/L).

#### *Cucurbit Vegetable Assessment Results (Lowest Exposure Scenario Combined with the Recent Des-iodo Photolysis Half-life Estimate)*

Based on the time-weighted average endpoints, the optimistic des-iodo aqueous photolysis half-life, and a proposed 30-ft spray drift buffer, the cucurbit vegetable use (which results in the lowest exposure) results in risk that exceeds Agency LOCs for all numbers of applications per year modeled. The cucurbit vegetable scenario exceeds Agency LOCs in three years at six, five, and four applications per year, four years at three applications per year, six years at two applications per year, and nine years at one application per year. Number of applications per year scenarios exceed exposure levels that resulted in 80% emergence inhibition in the des-iodo chronic laboratory toxicity study (MRID 46817023) within the 30 years simulated for six, five, four, or three applications per year. Two applications per year exceeds the 33% emergence inhibition within the 30 years simulated, while one application per year would exceed the 33% emergence inhibition sometime after the 30 years simulated. Again such adverse impacts would directly impact aquatic invertebrates in ponds, lakes, reservoirs, estuaries, areas of sediment accumulation in flowing waterbodies and any non-flowing waterbodies where des-iodo would

accumulate downstream of lands where flubendiamide is used as well as indirectly impact fish and wildlife for which aquatic invertebrates serve as the basis for their food chain.

Although the Agency does not agree with the use of the nominal-based endpoints that were suggested by the registrant, the cucurbit vegetable scenario using the optimistic des-iodo aqueous photolysis half-life and proposed 30-ft spray drift buffer, exceeds Agency LOCs in 12 years at six applications per year, 14 years at five applications per year, 18 years at four applications per year, and 25 years at three applications per year. The lowest exposure scenario based on either one or two applications per year does not exceed LOCs within the 30 years simulated based on the registrant-suggested endpoints. However, the two applications per year scenario would be expected to eventually exceed if applications continued long enough, while the one application per year scenario probably would not. Additionally note that all the caveats concerning the des-iodo photolysis half-life discussed for tree nuts apply equally well to the cucurbit vegetable assessment. Therefore, when considering the registrant's less conservative proposed endpoints, use of flubendiamide still results in risk concerns for aquatic invertebrates for all numbers of applications per year except a single application per year, and only under the most optimistic of assumptions.

## 8. Results from USGS Monitoring

USGS data (2012 – early 2014) showed detection of flubendiamide and/or des-iodo in filtered samples at 26 sites in 14 states (river and stream sites only, no ponds). California, Georgia, North Carolina, Mississippi, and Louisiana had multiple sites with frequent detections (Figure 1). The USGS monitoring effort complimented the targeted monitoring of the registrant by providing a nationwide (though non-targeted) scale in which to interpret the registrant's monitoring results. These widespread, non-targeted, filtered USGS detections are comparable to concentrations collected downstream from the monitored ponds, which indicates that there may be depositional zones similar to the monitored ponds upgradient from the widespread detections that have concentrations similar to those in the monitored ponds (which are well estimated by EPA modeling that assumes the des-iodo degradate is stable to aqueous photolysis).

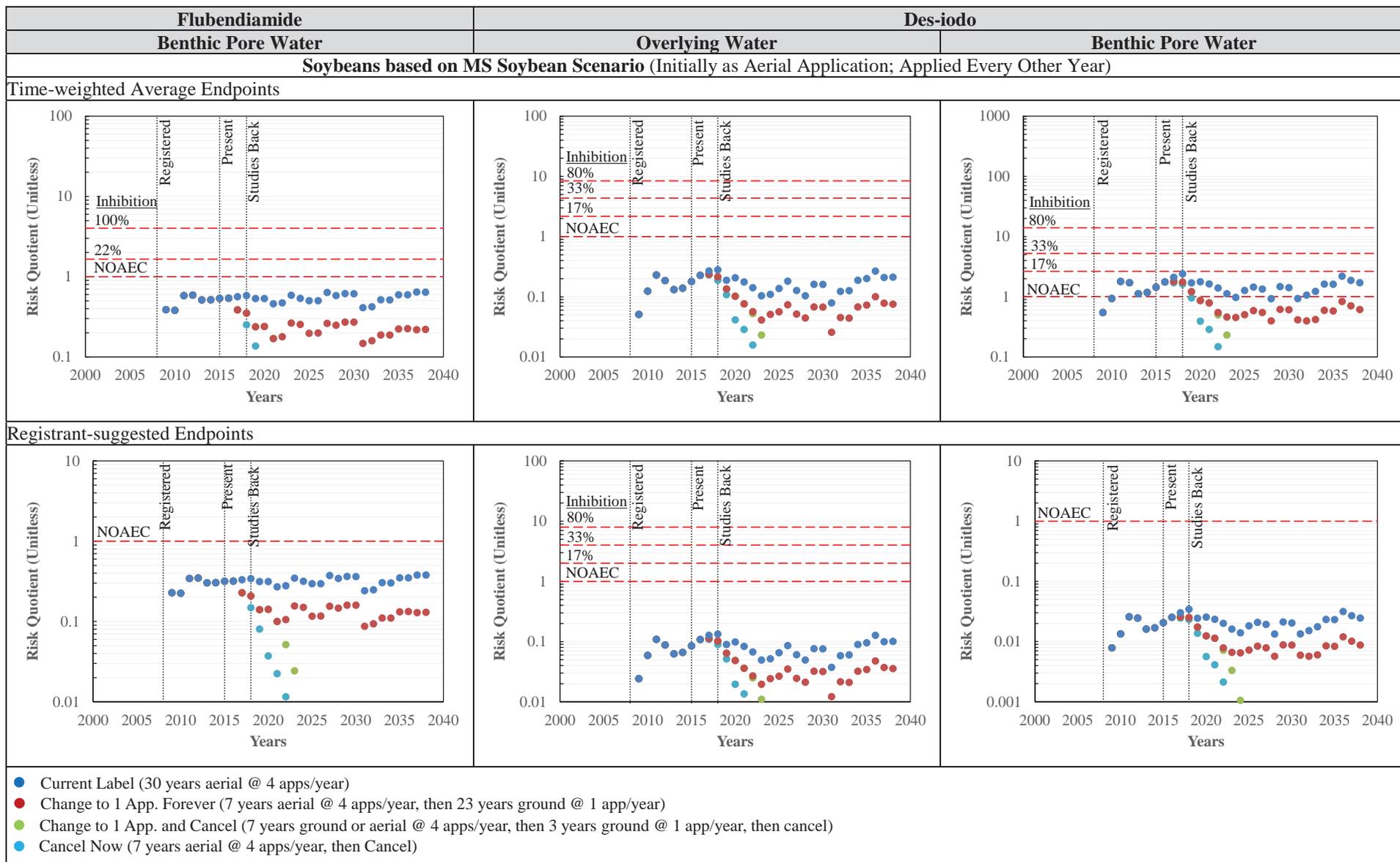


Figure 1. Flubendiamide detections in surface water samples collected by the USGS and registrant.

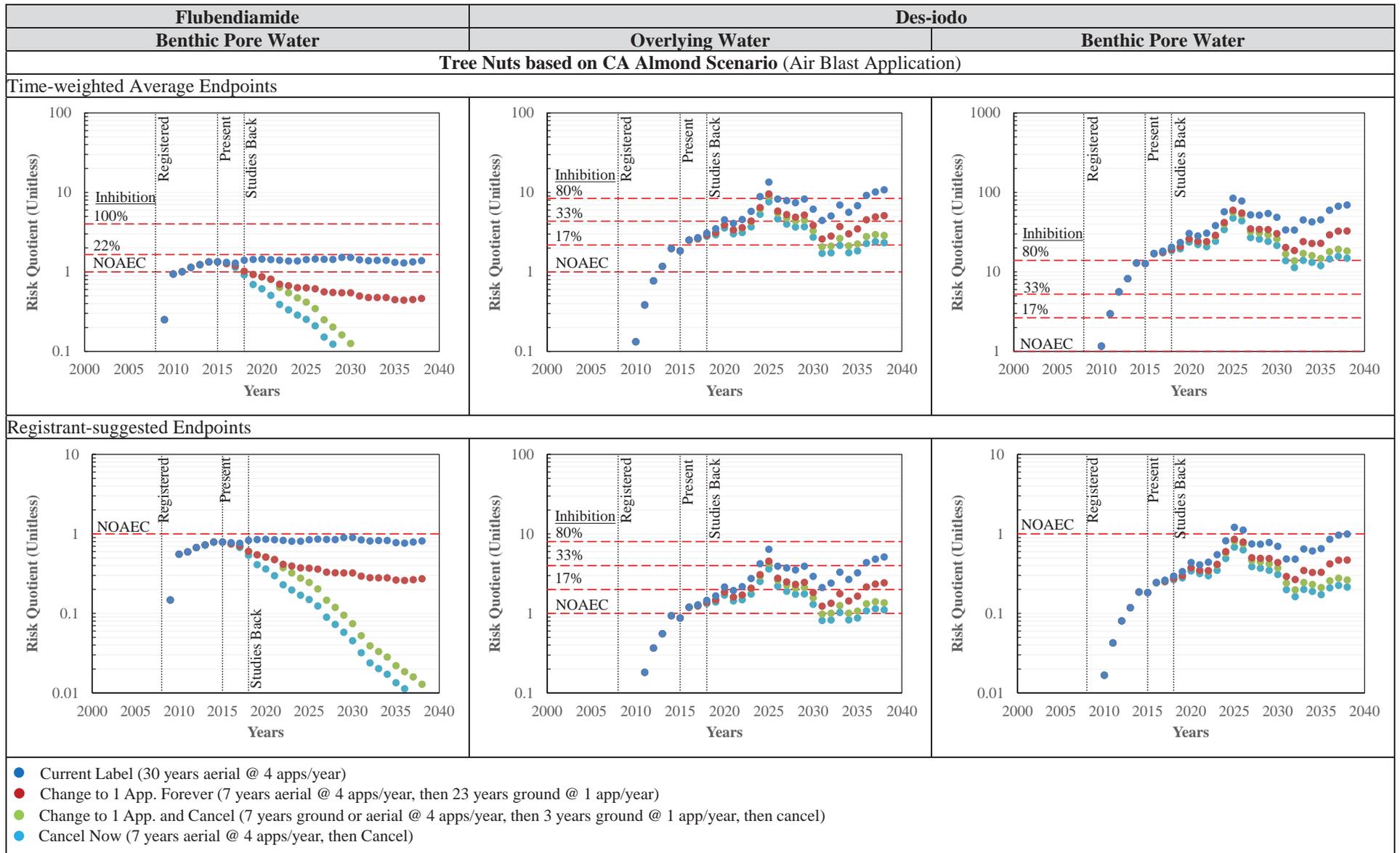
## 9. Conclusions

After review of the all of the data submissions and previous risk assessments, EFED's conclusions on the environmental risks posed by flubendiamide at the time of writing are consistent with those identified in 2008. EFED originally concluded that "Flubendiamide and its degradate's overall stability/persistence suggests that they will accumulate in soils, water column, and sediments with each successive application" (DP 329613+). EFED's analysis of the registrant's field monitoring (farm pond) study concludes that there is 1) accumulation of both flubendiamide and des-iodo in the water column, sediment, and pore water for all ponds monitored; and 2) definitive evidence that VFSs do not sufficiently control off-site transport of these chemicals to downstream waterbodies. In addition, stream and river monitoring conducted by the registrant and the U.S. Geological Survey over much of the United States indicates: 1) the failure of VFSs to contain these chemicals is a widespread occurrence; and 2) the potential for water quality impacts is also widespread. Based on the California almond scenario presented above as well as the other recent modeling (DP 430747, 430972, and Appendix 2), significant effects to aquatic organisms due to the use of flubendiamide could potentially occur in as little as 2 years. While the registrant has raised many issues as discussed in detail above and in the referenced documents, none have been persuasive that the original and subsequent risk assessment conclusions were inaccurate nor have they diminished confidence in those conclusions. Considering all the evolving lines of evidence, there is increased confidence in the conclusions contained in EFED's past risk assessments for flubendiamide.

**Appendix 1. Comparison of Four Regulatory Scenarios for Multiple Crops based on the Registrant-suggested Aquatic Modeling Procedures Including Pond Overflow**



**Appendix 1 Figure 1. Comparison of Four Regulatory Scenarios for Nine Crops Using both Time-weighted and Registrant-suggested Endpoints**

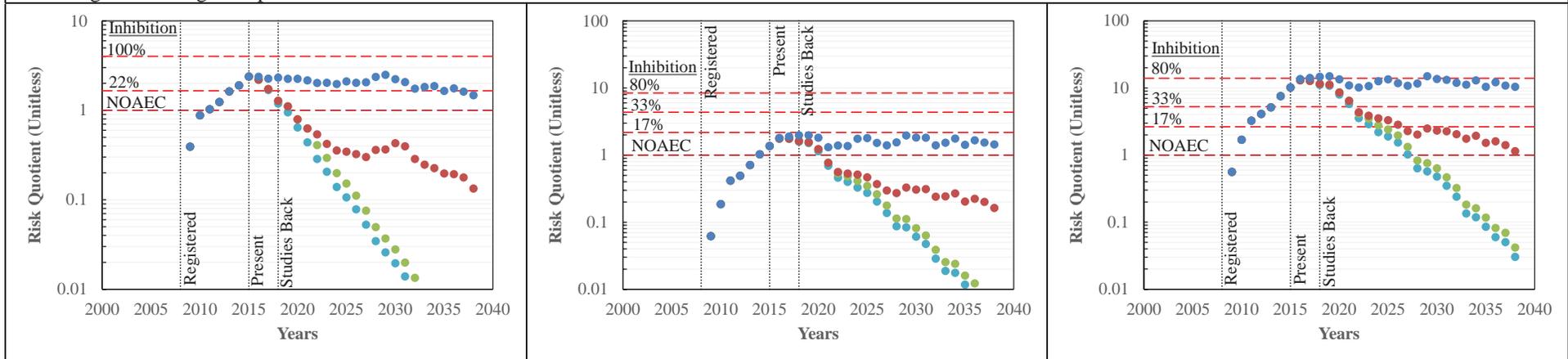


Appendix 1 Figure 1. Continued

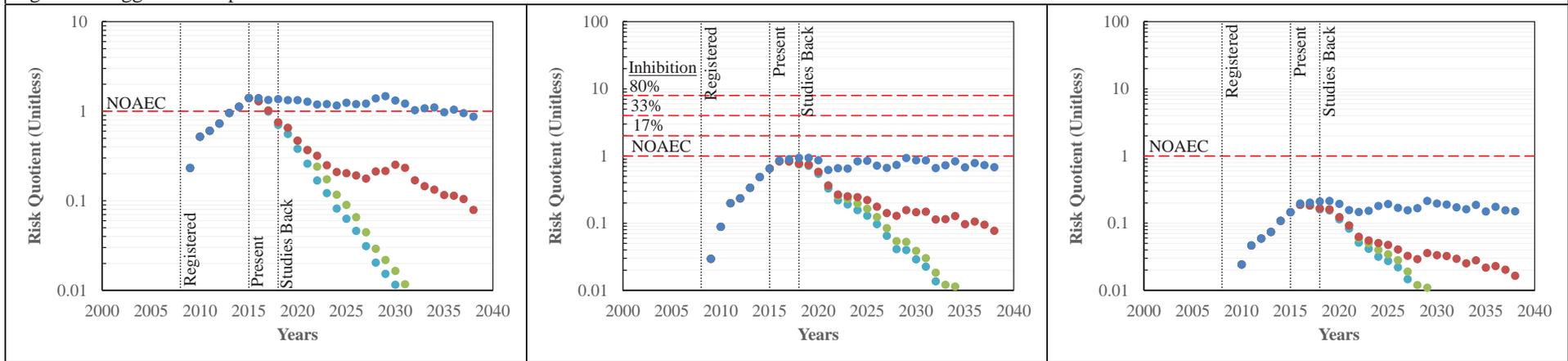
<b>Flubendiamide</b>	<b>Des-iodo</b>	
<b>Benthic Pore Water</b>	<b>Overlying Water</b>	<b>Benthic Pore Water</b>

**Tobacco based on NC Tobacco Scenario (Initially as an Aerial Application)**

Time-weighted Average Endpoints



Registrant-suggested Endpoints



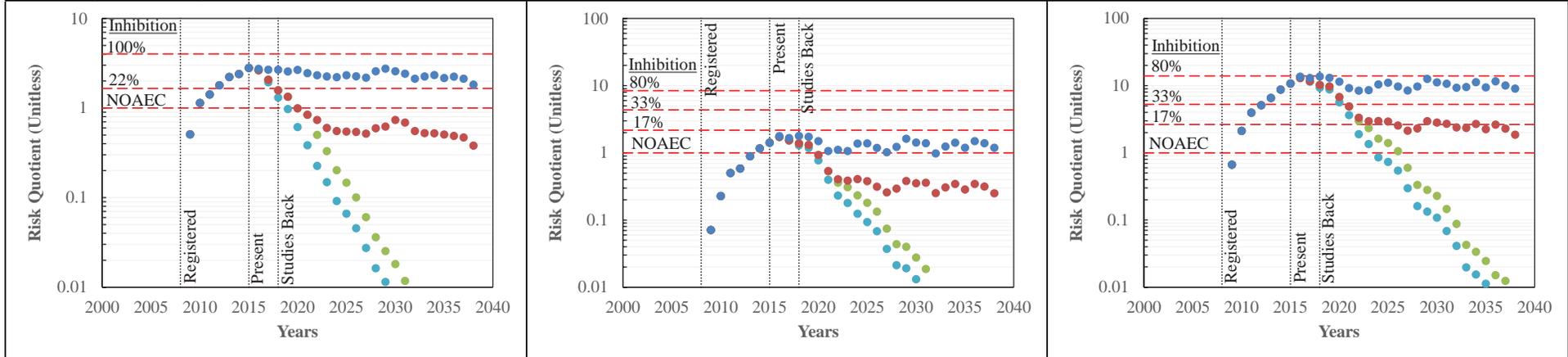
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- Change to 1 App. and Cancel (7 years ground or aerial @ 4 apps/year, then 3 years ground @ 1 app/year, then cancel)
- Cancel Now (7 years aerial @ 4 apps/year, then Cancel)

**Appendix 1 Figure 1. Continued**

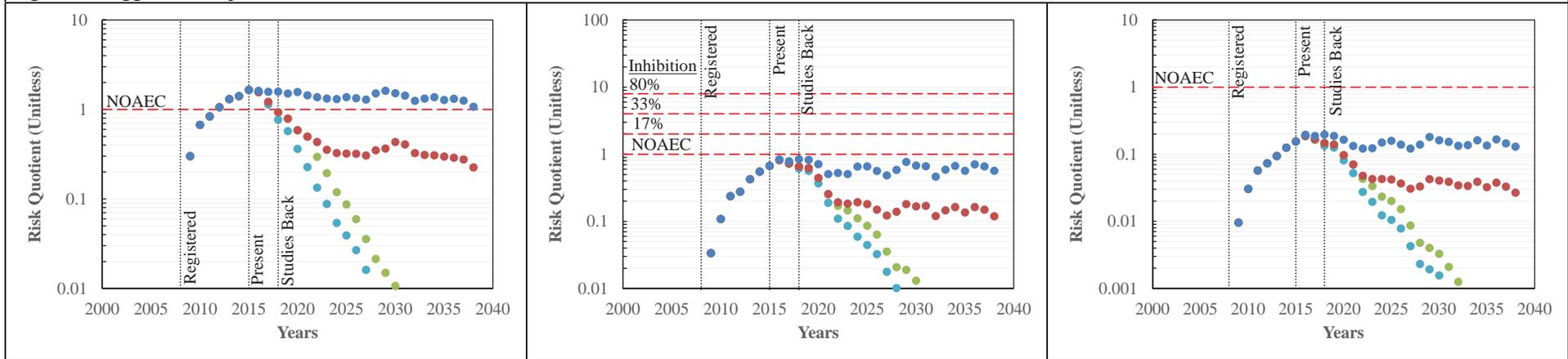
<b>Flubendiamide</b>	<b>Des-iodo</b>	
<b>Benthic Pore Water</b>	<b>Overlying Water</b>	<b>Benthic Pore Water</b>

**Peanuts based on NC Peanuts Scenario (Initially as an Aerial Application)**

**Time-weighted Average Endpoints**



**Registrant-suggested Endpoints**



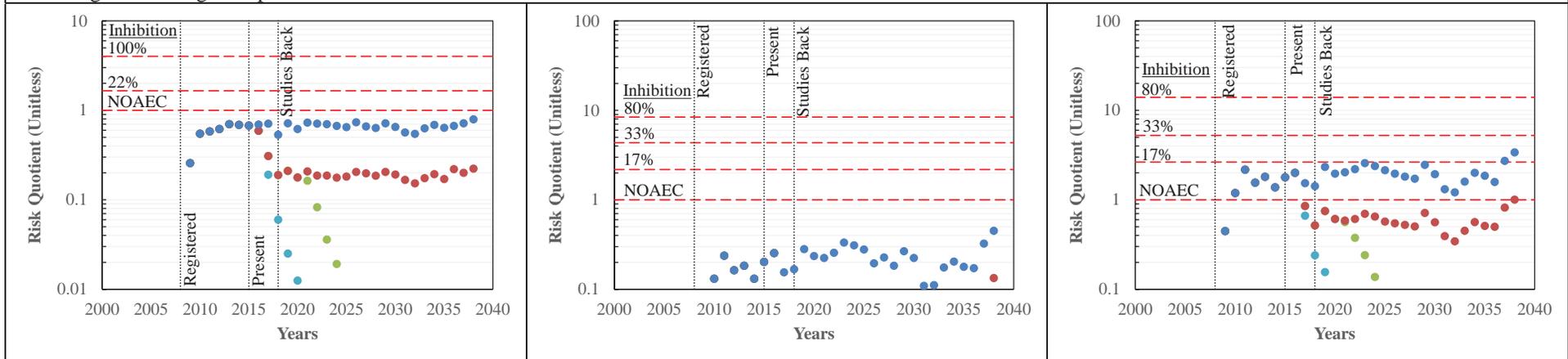
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- Cancel Now (7 years aerial @ 4 apps/year, then Cancel)

**Appendix 1 Figure 1. Continued**

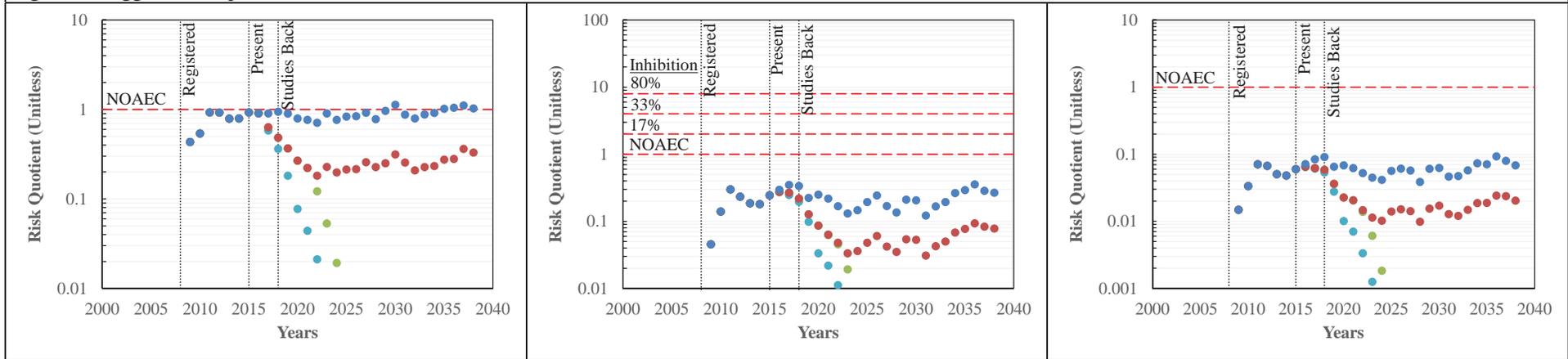
Flubendiamide		Des-iodo	
Benthic Pore Water		Overlying Water	Benthic Pore Water

**Cucurbits based on FL Cucumber Scenario (Initially as an Aerial Application)**

**Time-weighted Average Endpoints**



**Registrant-suggested Endpoints**



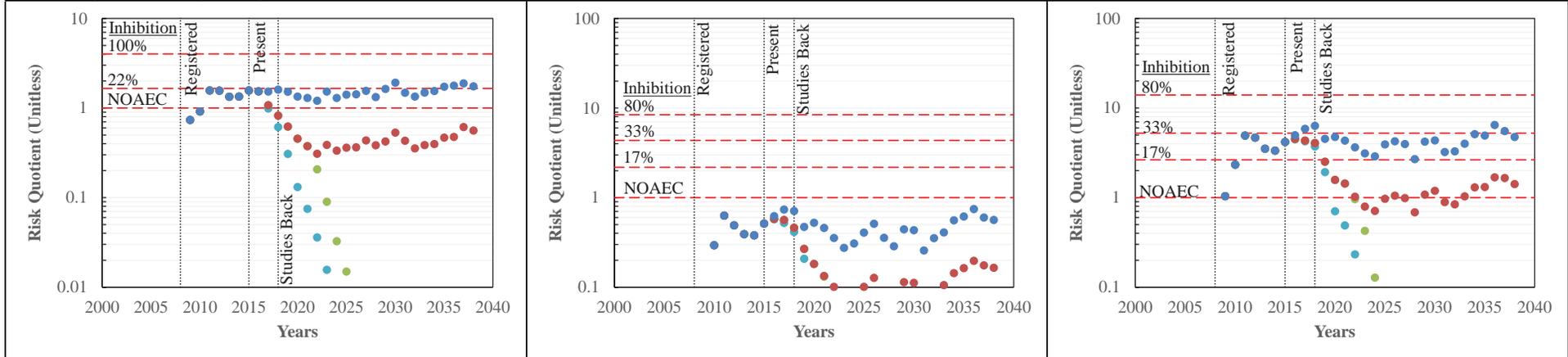
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**Appendix 1 Figure 1. Continued**

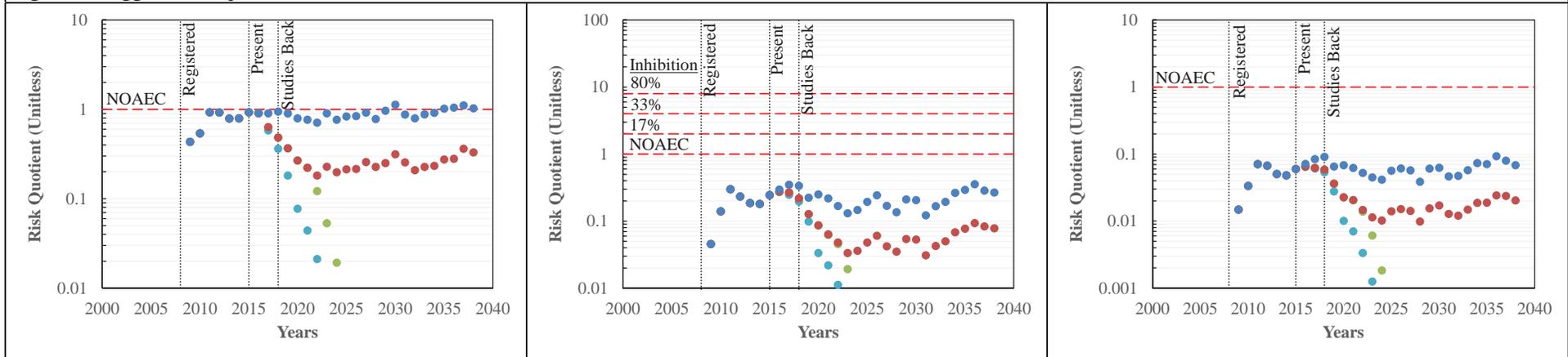
Flubendiamide	Des-iodo	
Benthic Pore Water	Overlying Water	Benthic Pore Water

Cotton based on MS Cotton Scenario (Initially as an Air Application)

Time-weighted Average Endpoints



Registrant-suggested Endpoints



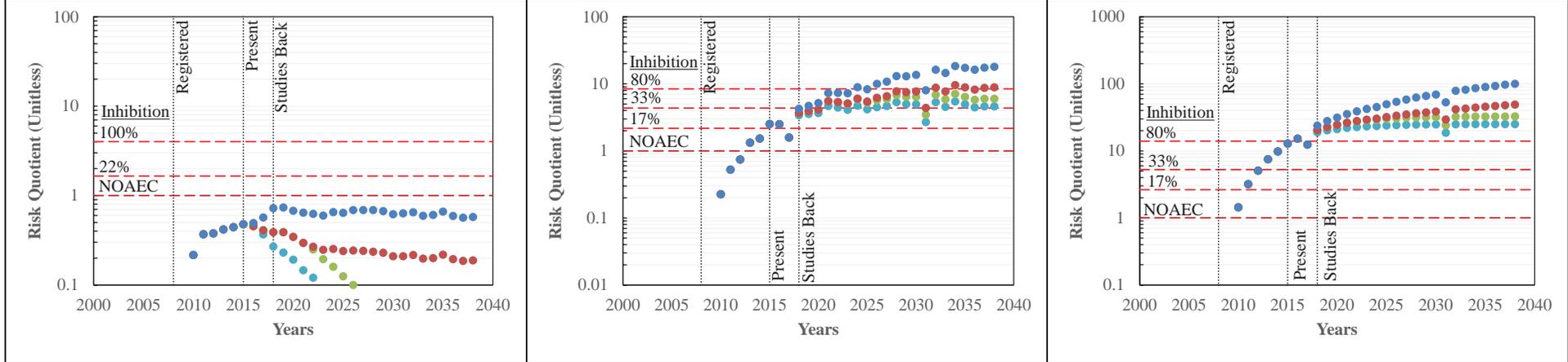
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Appendix 1 Figure 1. Continued

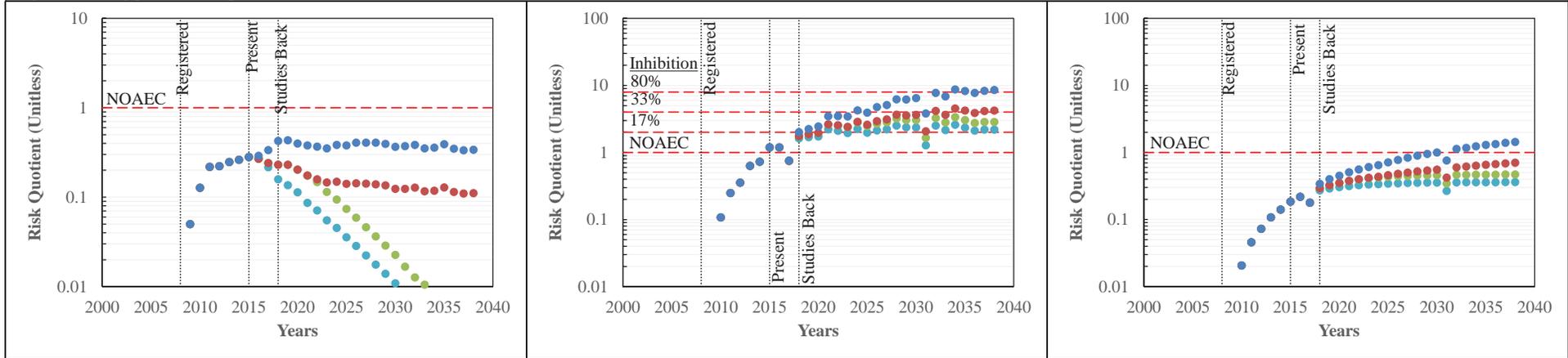
Flubendiamide		Des-iodo	
Benthic Pore Water		Overlying Water	Benthic Pore Water

**Fruiting based on CA Tomato Scenario (Initially as a Ground Application)**

**Time-weighted Average Endpoints**



**Registrant-suggested Endpoints**



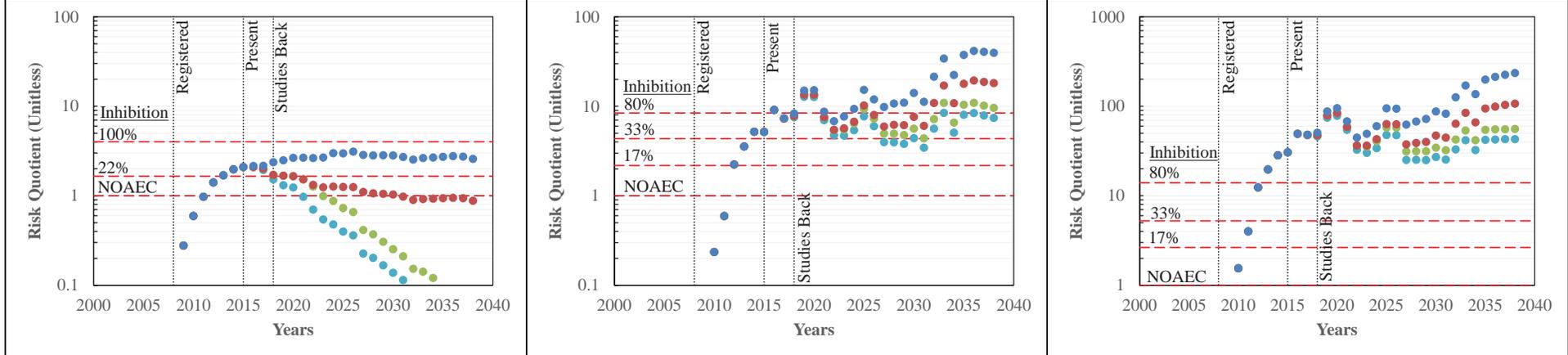
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**Appendix 1 Figure 1. Continued**

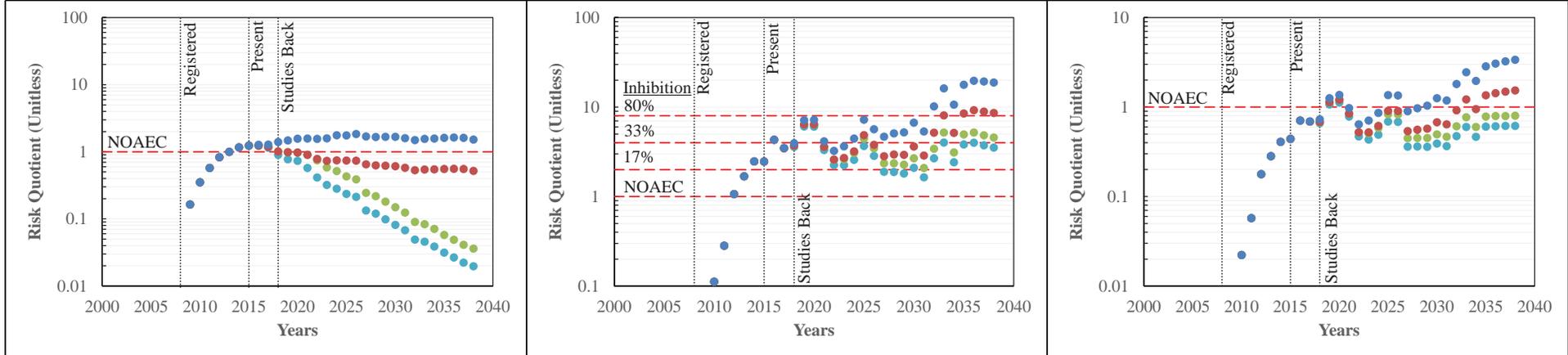
Flubendiamide	Des-iodo	
Benthic Pore Water	Overlying Water	Benthic Pore Water

**Leafy Vegetables based on CA Lettuce Scenario (Initially as a Ground Application)**

**Time-weighted Average Endpoints**



**Registrant-suggested Endpoints**



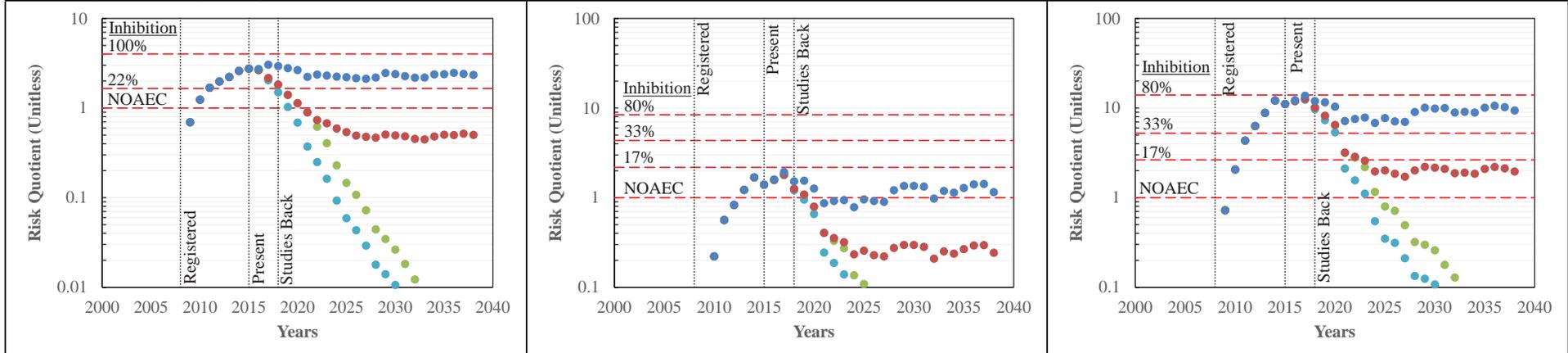
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- Change to 1 App. and Cancel (7 years ground or aerial @ 4 apps/year, then 3 years ground @ 1 app/year, then cancel)
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**Appendix 1 Figure 1. Continued**

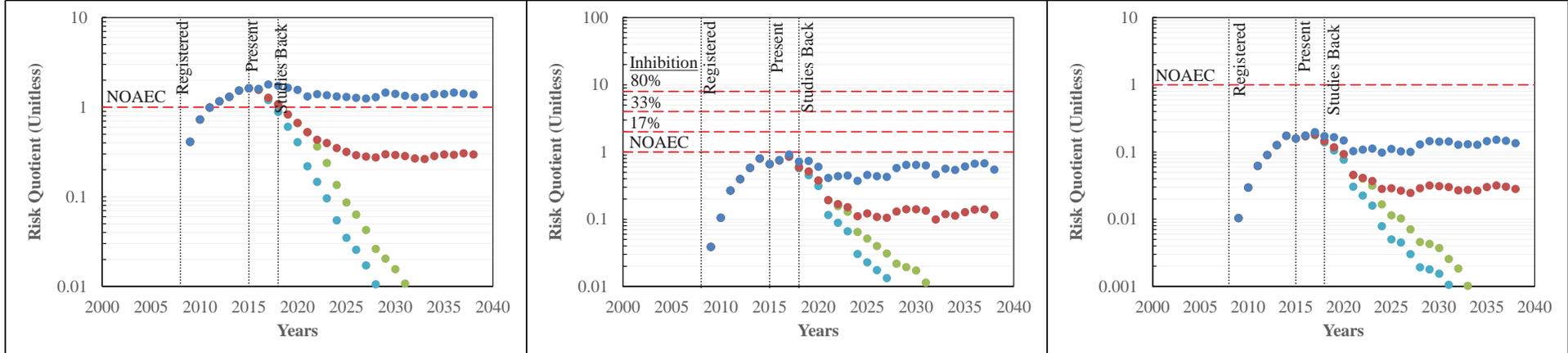
<b>Flubendiamide</b>	<b>Des-iodo</b>	
<b>Benthic Pore Water</b>	<b>Overlying Water</b>	<b>Benthic Pore Water</b>

**Alfalfa based on PA Alfalfa Scenario (Initially as a Aerial Application)**

**Time-weighted Average Endpoints**



**Registrant-suggested Endpoints**



- Current Label (30 years aerial @ 4 apps/year)
- Change to 1 App. Forever (7 years aerial @ 4 apps/year, then 23 years ground @ 1 app/year)
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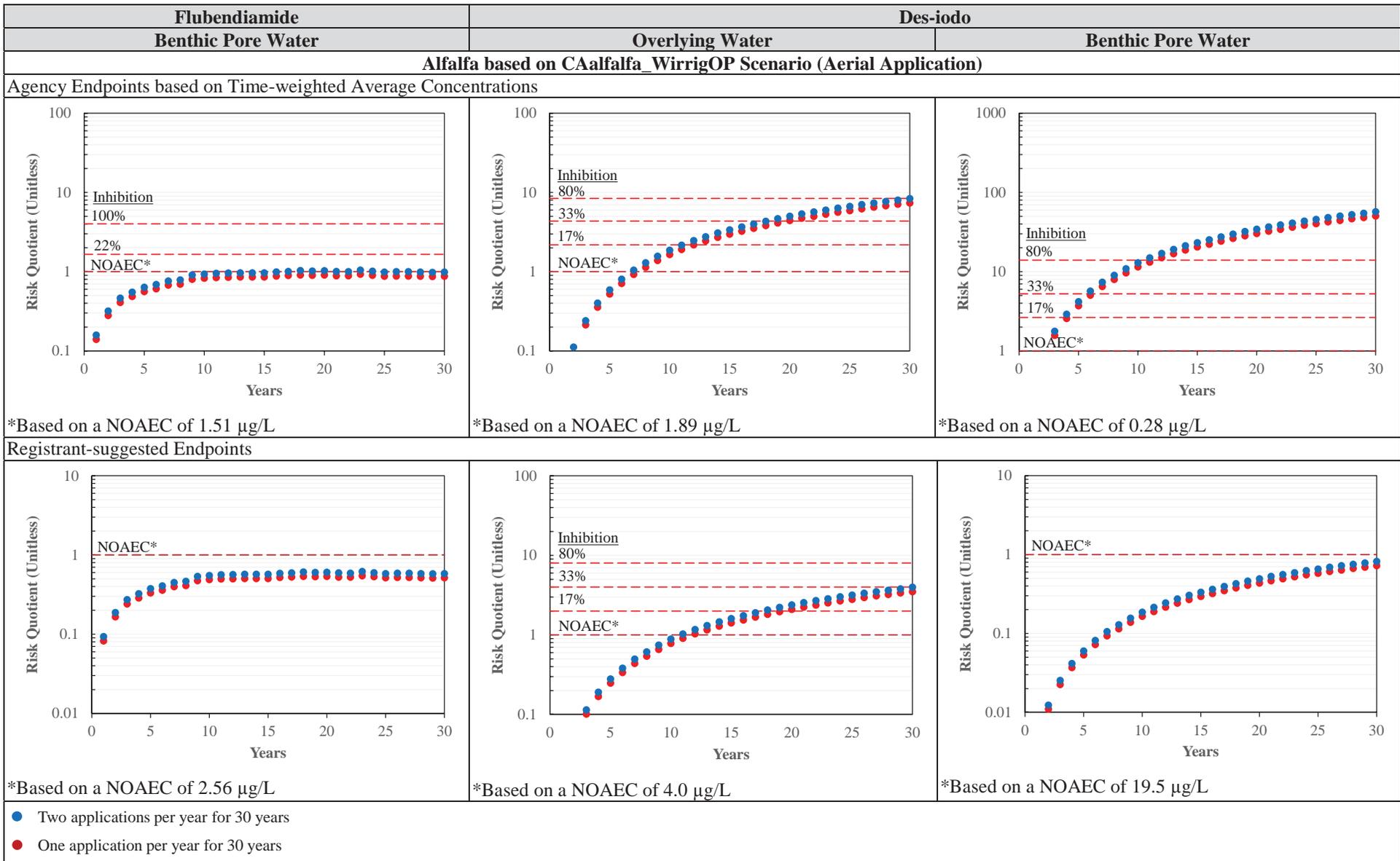
**Appendix 1 Figure 1. Continued**

## Appendix 2. Regulatory Scenario Comparisons Using Time-weighted Average Concentration Endpoints and Registrant-suggested Endpoints

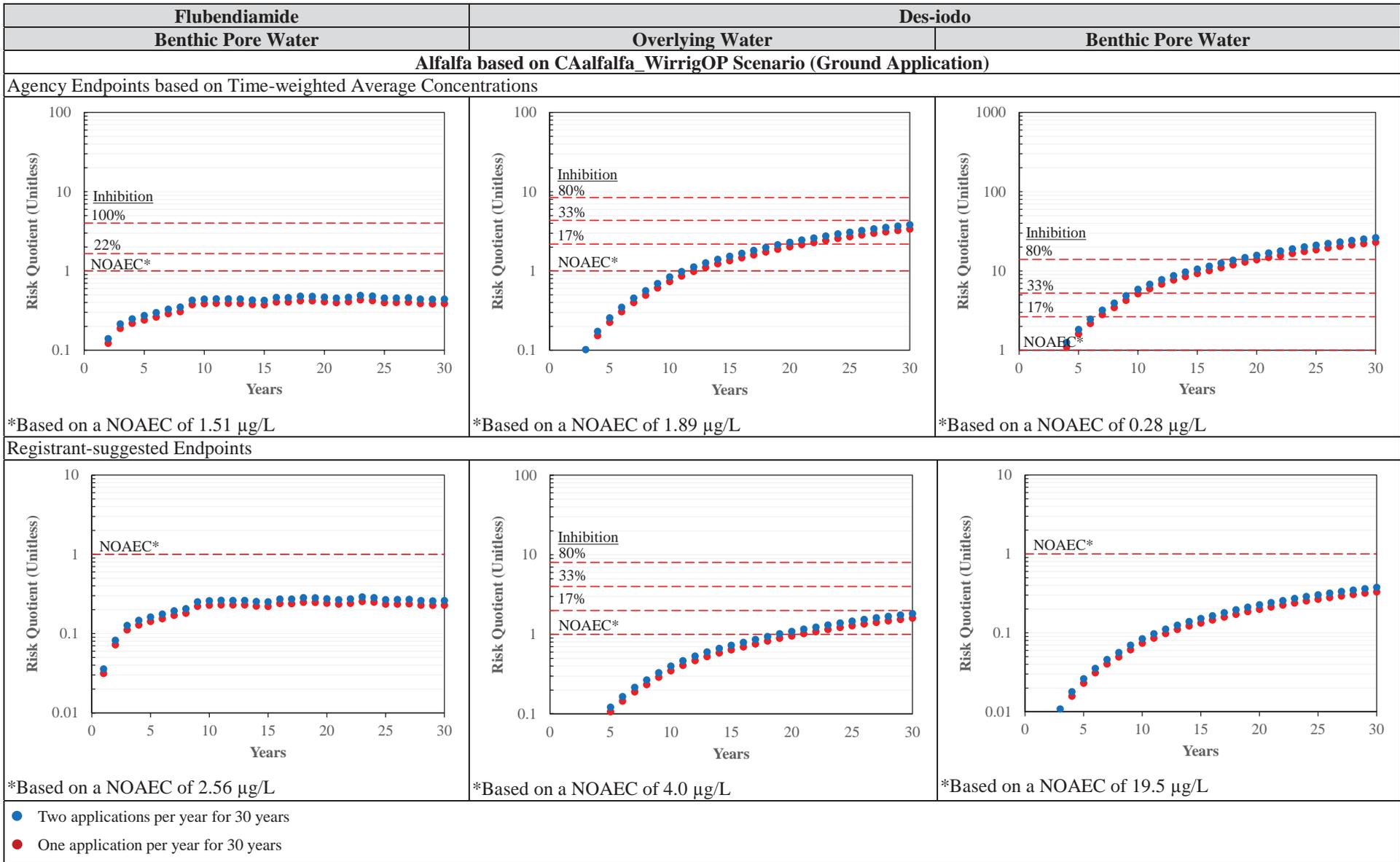
**Appendix 2 Table 1. Comparison of Time to Exceed Agency Levels of Concern in Years using both the Time-weighted Average Endpoints and the Registrant-suggested Endpoints for the Crops Retained in Bayer CropScience's Proposal.**

BELT Label Uses	Application Type: A = Aerial AB = Airblast G = Ground	Time to Exceed Agency Levels of Concern (Years) based on the Number of Applications (App.) <sup>1</sup>												Application Characteristics		
		Time-weighted Average Endpoints						Registrant-suggested Endpoints						Maximum Single Application Rate (lbs ai/A)	Maximum # of Applications (Minimum Reapplication Interval)	Maximum Annual Application Rate (lbs ai/A)
		1 App.	2 App.	3 App.	4 App.	5 App.	6 App.	1 App.	2 App.	3 App.	4 App.	5 App.	6 App.			
Alfalfa	A	3	3	NA				12	11	NA				0.125	2 (21)	0.141
	G	4	4	NA				21	19	NA						
Brassica Leafy Vegetables	A	3	2	2	2	NA		10	7	6	5	NA		0.075	4 (5)	0.282
	G	3	3	2	2	NA		12	8	7	6	NA				
Cotton (AZ and CA only)	A	3	3	NA				15	11	NA				0.094	2 (5)	0.141
	G	5	4	NA				26	18	NA						
Cucurbit Vegetables	A	5	3	3	2	2	2	28	16	12	10	8	7	0.047	6 (7)	0.282
	G	9	5	4	3	3	3	>30	>30	21	16	13	11			
Fruiting Vegetables	A	4	3	3	2	2	2	21	13	10	8	7	7	0.047	6 (3)	0.282
	G	5	4	3	3	3	3	29	18	13	11	9	8			
Grapes	G	7	5	4	NA			>30	22	20	NA			0.125	3 (5)	0.282
Leafy Vegetables	A	3	2	2	2	2	2	14	9	7	6	6	5	0.047	6 (3)	0.282
	G	4	3	2	2	2	2	15	10	8	7	6	6			
Legume Vegetables	A	3	2	2	NA			13	8	5	NA			0.094	3 (5)	0.282
	G	4	3	2	NA			18	11	6	NA					
Pome Fruit	AB	5	4	NA				27	17	NA				0.156	2 (7)	0.282
Stone Fruit	AB	6	4	4	NA			>30	19	18	NA			0.125	3 (7)	0.282
Strawberry	A	3	2	2	2	NA		10	7	5	5	NA		0.075	4 (3)	0.282
	G	3	2	2	2	NA		11	7	6	5	NA				
Tobacco	A	3	2	NA				13	11	NA				0.094	2 (5)	0.141
	G	4	3	NA				19	15	NA						
Tree Nuts	AB	3	3	2	NA			18	10	9	NA			0.125	4 (7)	0.282

<sup>1</sup> It may seem that stopping flubendiamide applications just before the Agency Levels of Concern (LOCs) are exceeded based on the information provided in Appendix 2 Table 1 might be a reasonable mitigation option. For example based on the time-weighted average endpoints, applying one application per year by ground application methods to cucurbit vegetables first exceeds Agency LOCs in year nine; therefore limiting similar flubendiamide applications to eight years might seem to prevent Agency LOC exceedances. However, there is a multi-year time-lag between application and attaining the maximum risk level from prior applications. Under the aforementioned cucurbit application scenario: stopping applications after year eight or seven still results in an exceedance later in year 9; stopping after year six only delays LOC exceedance to year 10; stopping after year five delays LOC exceedance to year 13; stopping after year four delays LOC exceedance to year 24; stopping after year three or less delays LOC exceedance beyond the 30 years simulated.



**Appendix 2 Figure 1. Comparison of Potential Regulatory Scenarios Using Time-weighted Average Concentration Endpoints and Registrant-suggested Endpoints.**

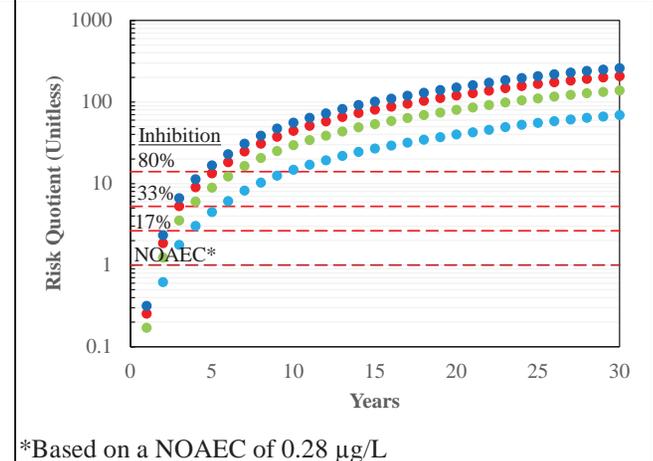
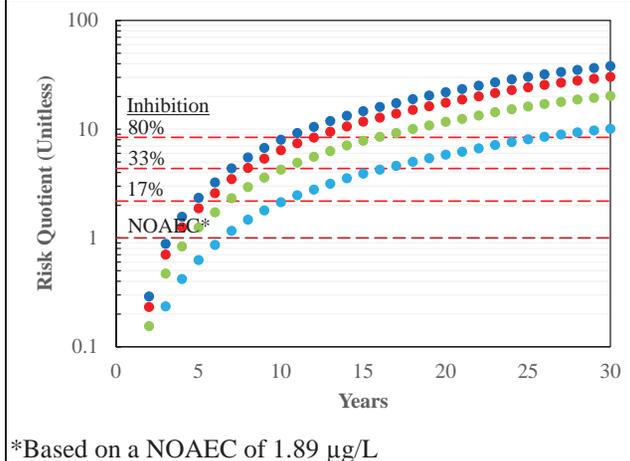
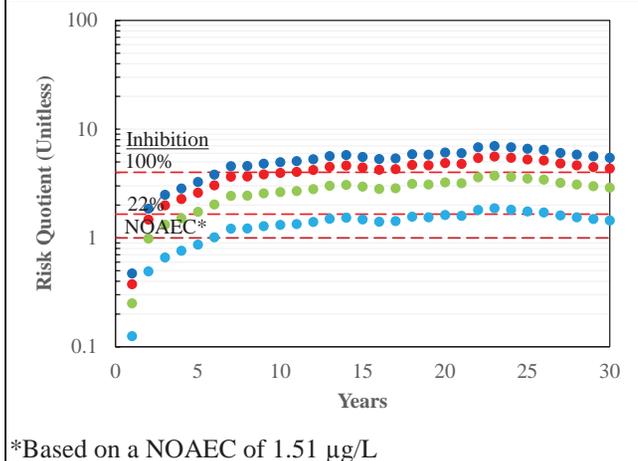


Appendix 2 Figure 1. Continued.

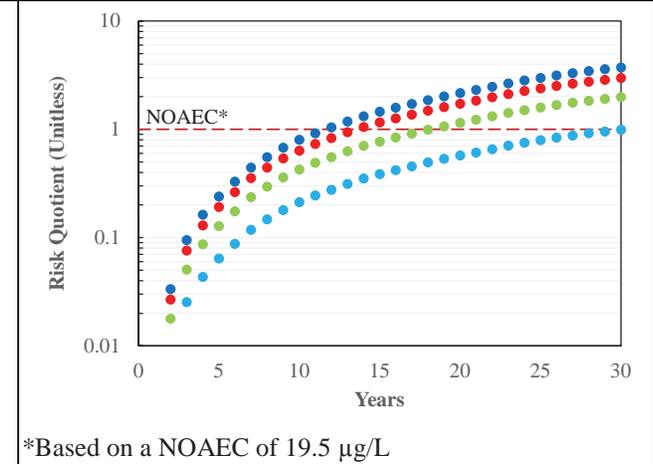
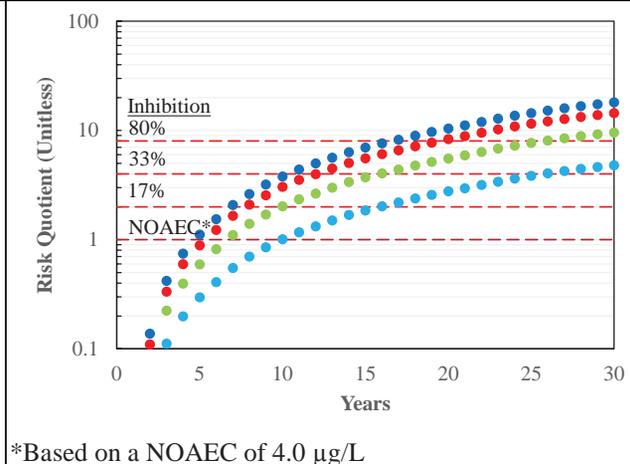
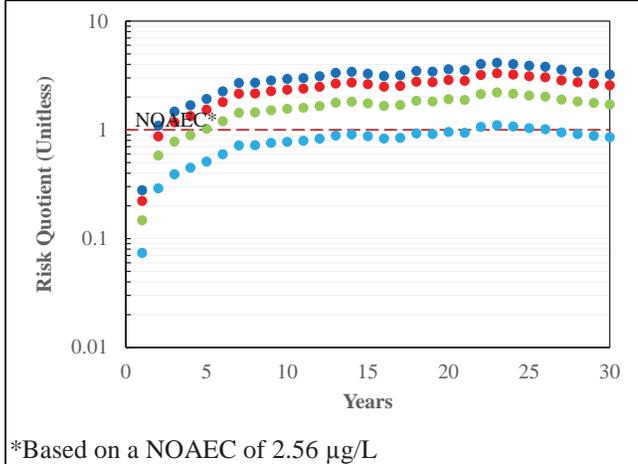
Flubendiamide	Des-iodo	
Benthic Pore Water	Overlying Water	Benthic Pore Water

**Brassica Leafy Vegetables based CAColeCropRLF\_V2 Scenario (Aerial Application)**

Agency Endpoints based on Time-weighted Average Concentrations

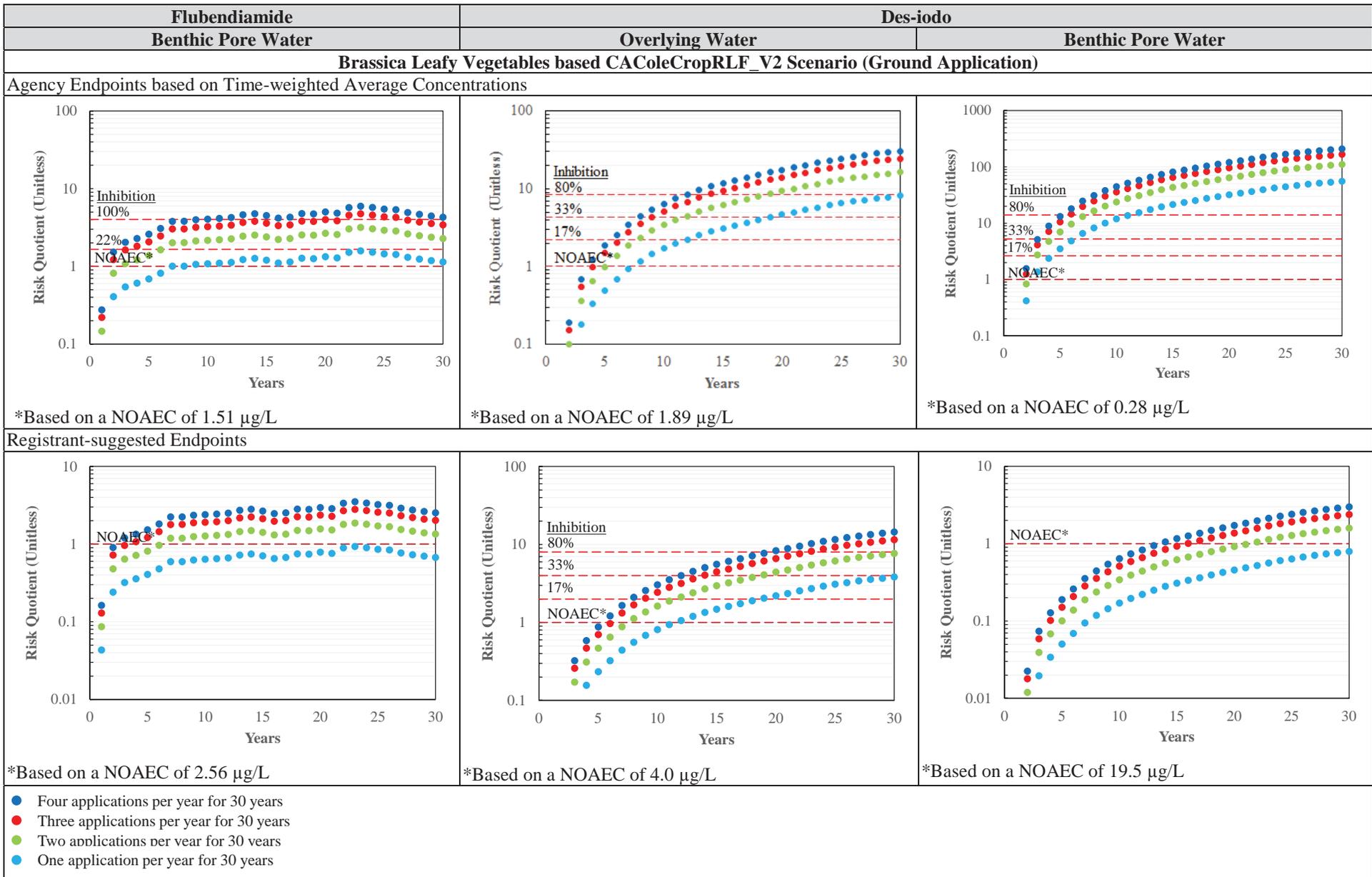


Registrant-suggested Endpoints



- Four applications per year for 30 years
- Three applications per year for 30 years
- Two applications per year for 30 years
- One application per year for 30 years

Appendix 2 Figure 1. Continued.

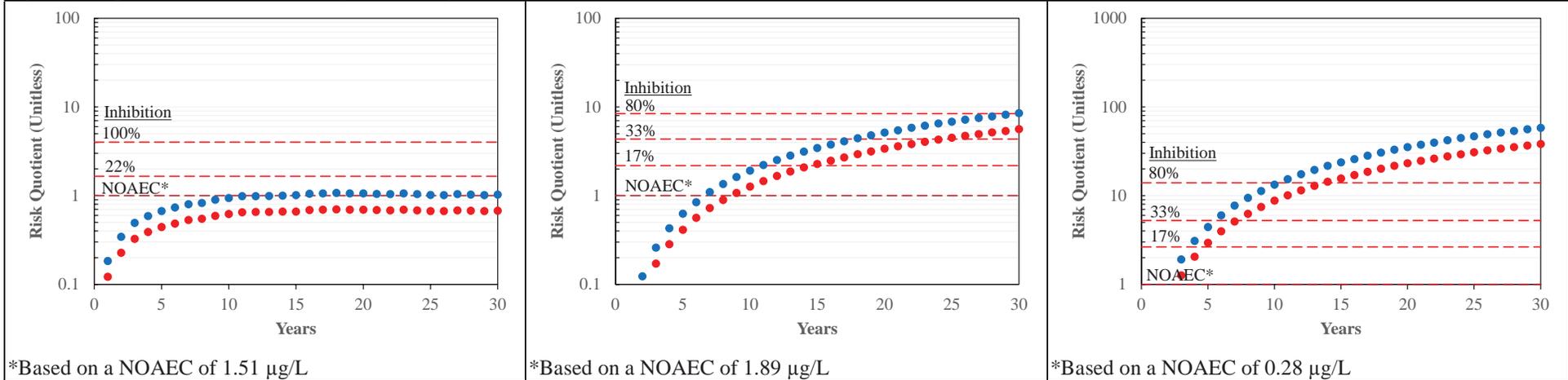


Appendix 2 Figure 1. Continued.

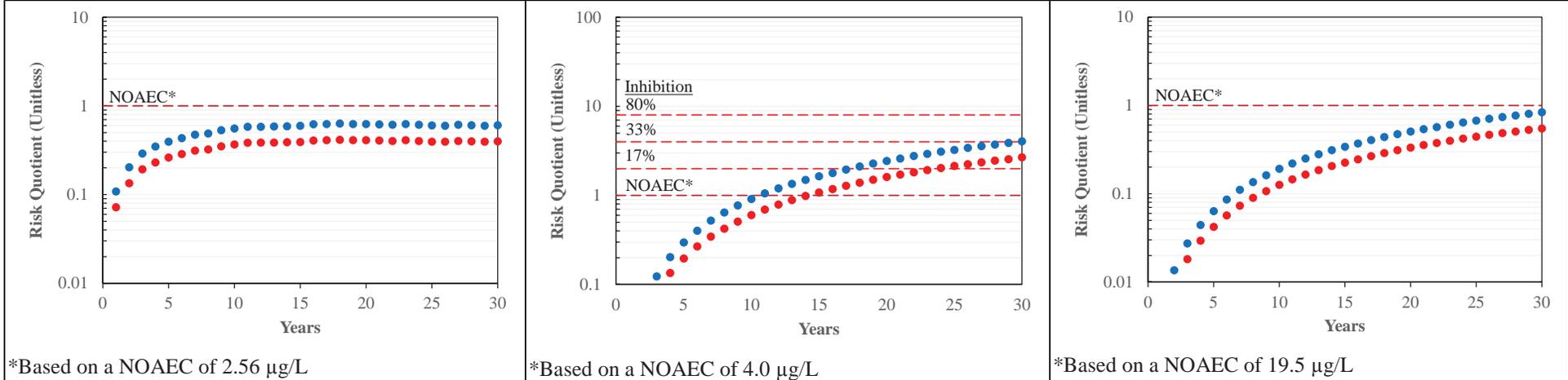
Flubendiamide	Des-iodo	
Benthic Pore Water	Overlying Water	Benthic Pore Water

**Cotton (AZ and CA only) based CAcotton\_WirrigSTD Scenario (Aerial Application)**

Agency Endpoints based on Time-weighted Average Concentrations



Registrant-suggested Endpoints



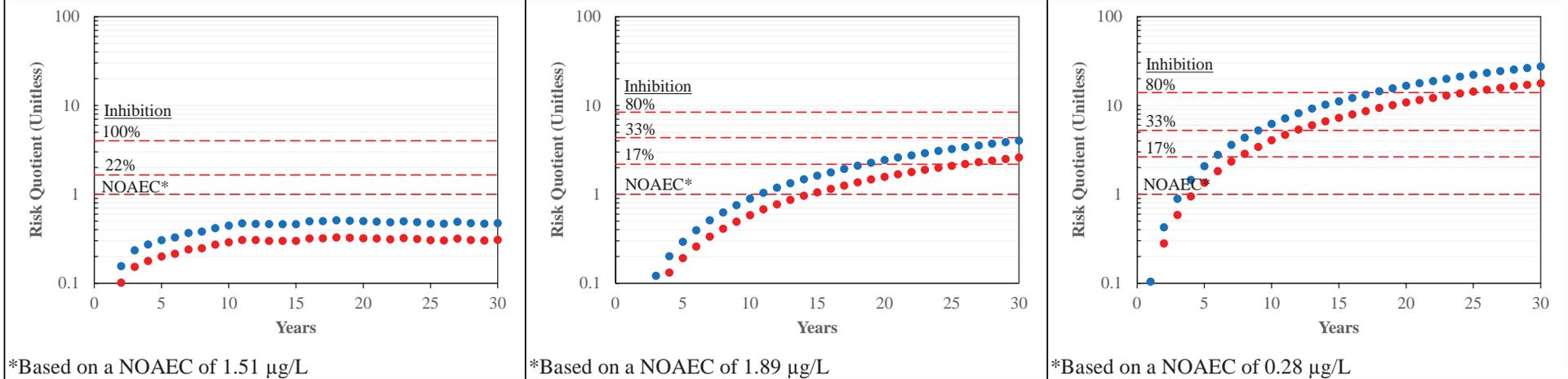
- Two applications per year for 30 years
- One application per year for 30 years

**Appendix 2 Figure 1. Continued.**

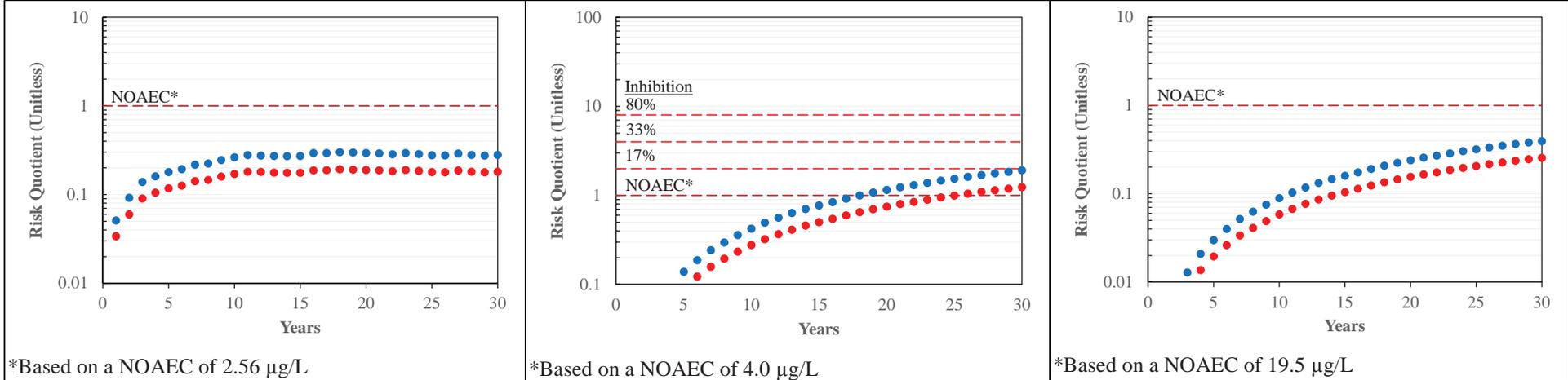
Flubendiamide	Des-iodo	
Benthic Pore Water	Overlying Water	Benthic Pore Water

**Cotton (AZ and CA only) based CAcotton\_WirrigSTD Scenario (Ground Application)**

Agency Endpoints based on Time-weighted Average Concentrations



Registrant-suggested Endpoints



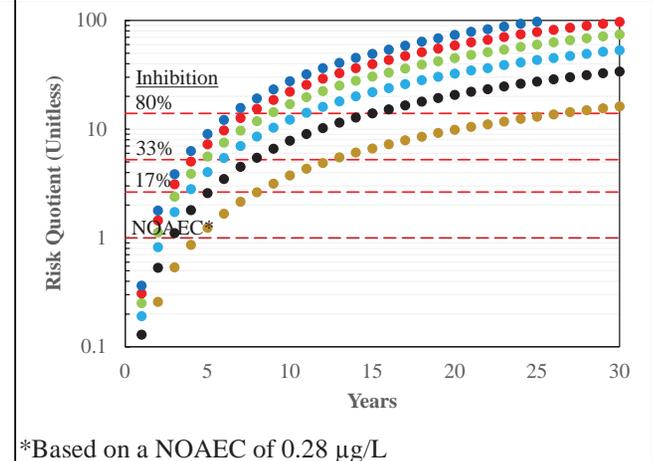
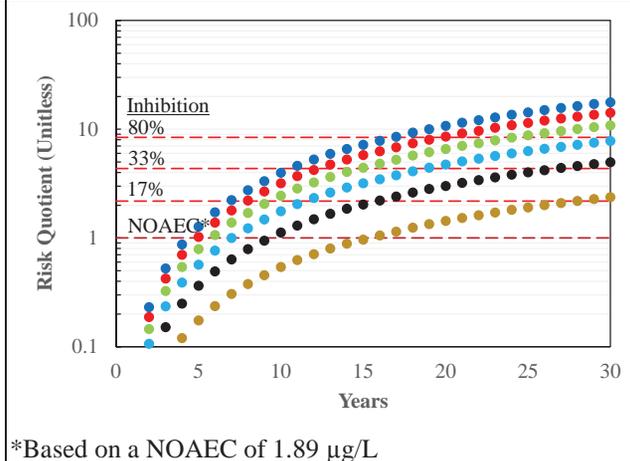
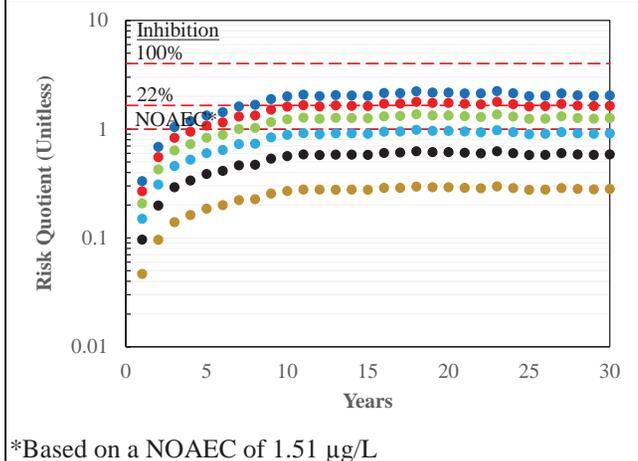
- Two applications per year for 30 years
- One application per year for 30 years

**Appendix 2 Figure 1. Continued.**

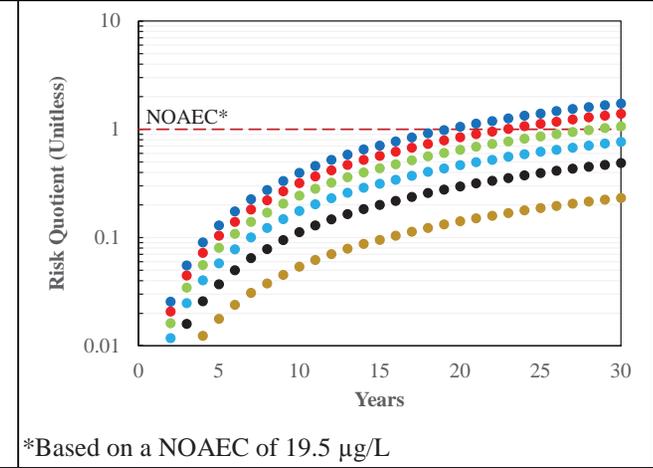
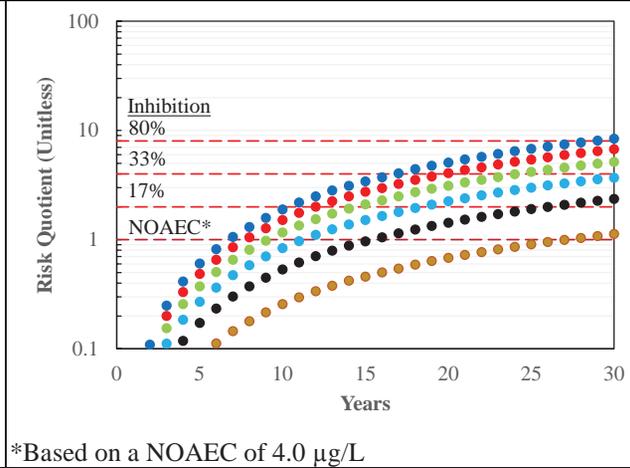
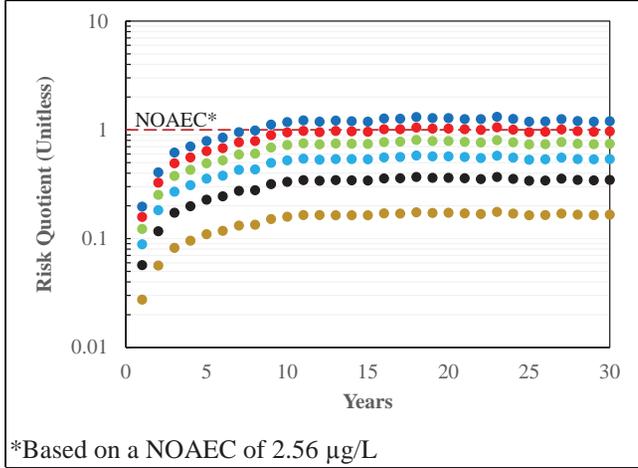
Flubendiamide	Des-iodo	
Benthic Pore Water	Overlying Water	Benthic Pore Water

**Aerial Low Exposure Scenario: Cucurbit Vegetable based on CAMElonsRLF\_V2 Scenario (Aerial Application)**

Agency Endpoints based on Time-weighted Average Concentrations



Registrant-suggested Endpoints



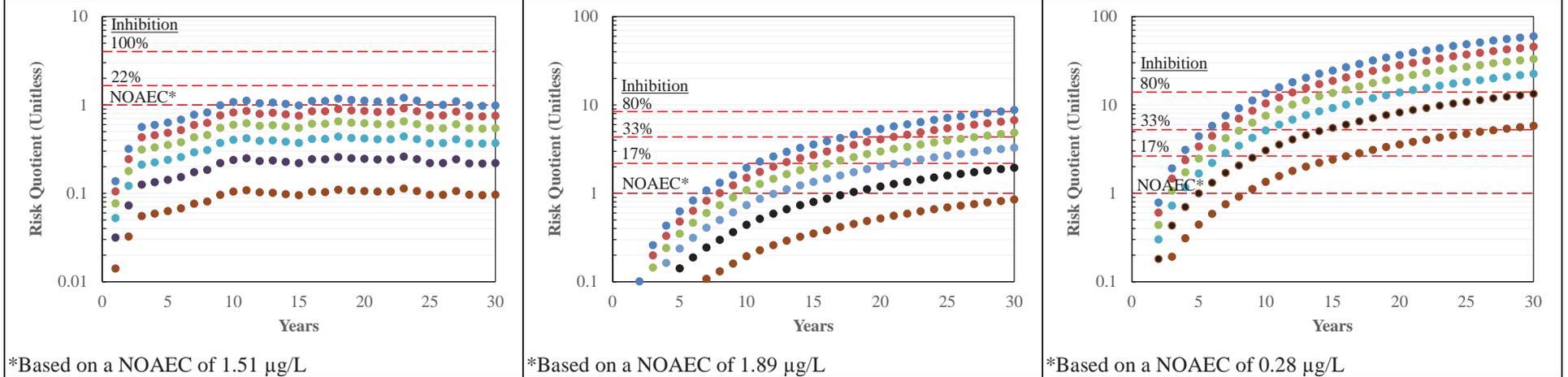
- Six applications per year for 30 years
- Five applications per year for 30 years
- Four applications per year for 30 years
- Three applications per year for 30 years
- Two applications per year for 30 years
- One application per year for 30 years

Appendix 2 Figure 1. Continued.

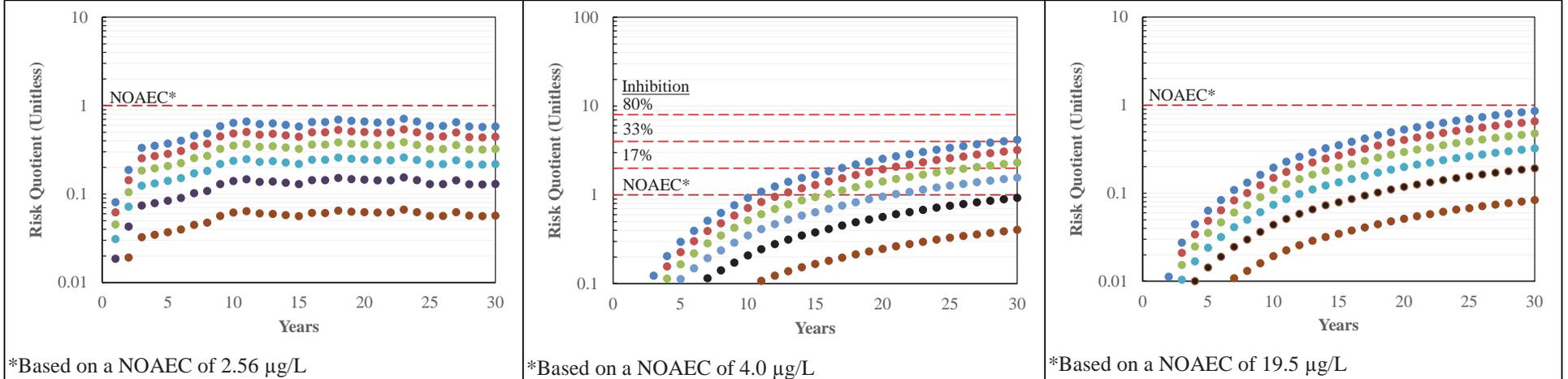
Flubendiamide	Des-iodo	
Benthic Pore Water	Overlying Water	Benthic Pore Water

**Ground Low Exposure Scenario: Cucurbit Vegetable based on CAMElonsRLF\_V2 Scenario (Ground Application)**

Agency Endpoints based on Time-weighted Average Concentrations



Registrant-suggested Endpoints



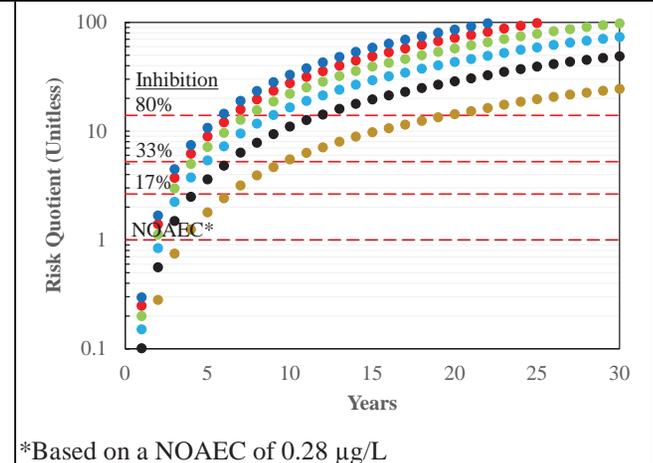
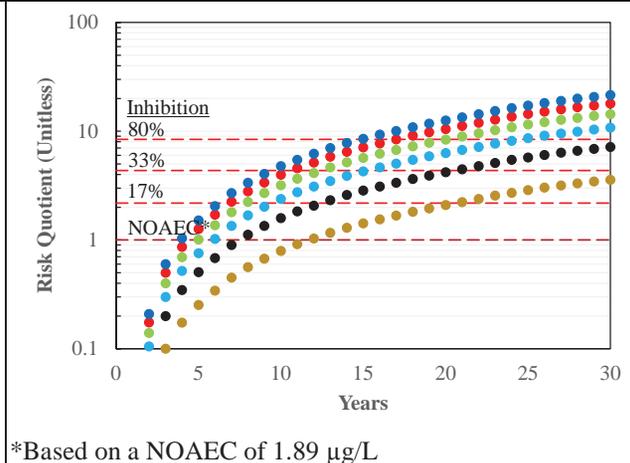
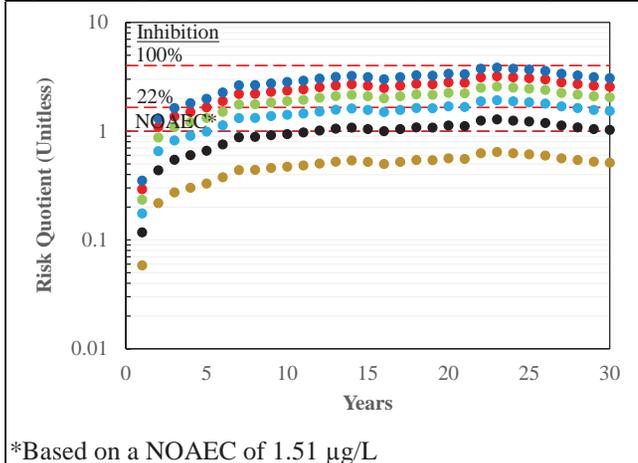
- Six applications per year for 30 years
- Five applications per year for 30 years
- Four applications per year for 30 years
- Three applications per year for 30 years
- Two applications per year for 30 years
- One application per year for 30 years

Appendix 2 Figure 1. Continued.

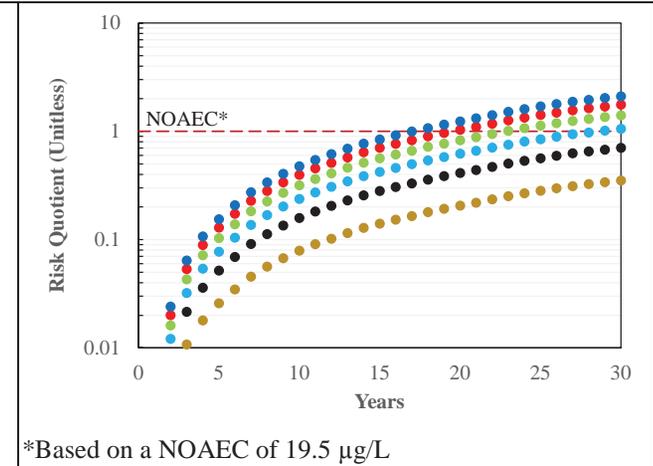
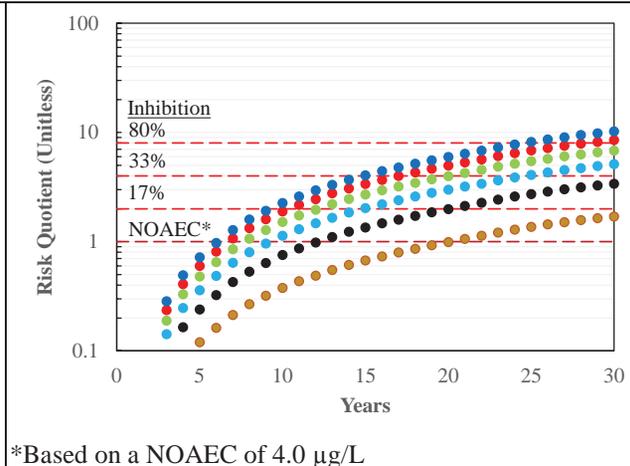
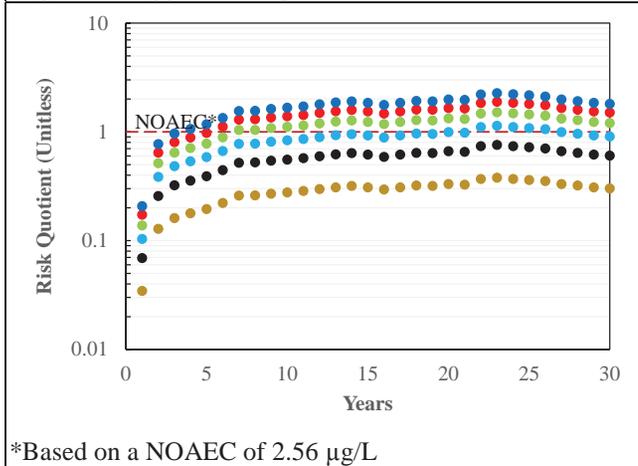
Flubendiamide	Des-iodo	
Benthic Pore Water	Overlying Water	Benthic Pore Water

**Fruiting Vegetables based on CARowCropRLF\_V2 Scenario (Aerial Application)**

Agency Endpoints based on Time-weighted Average Concentrations



Registrant-suggested Endpoints



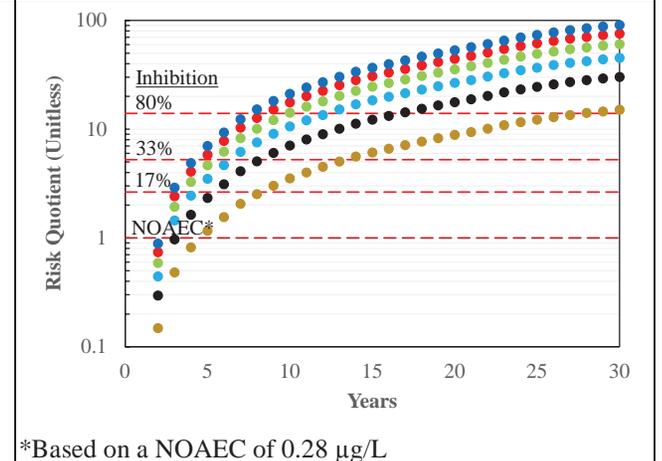
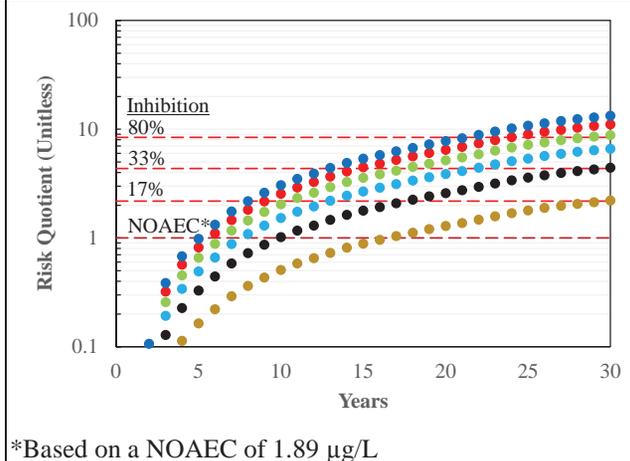
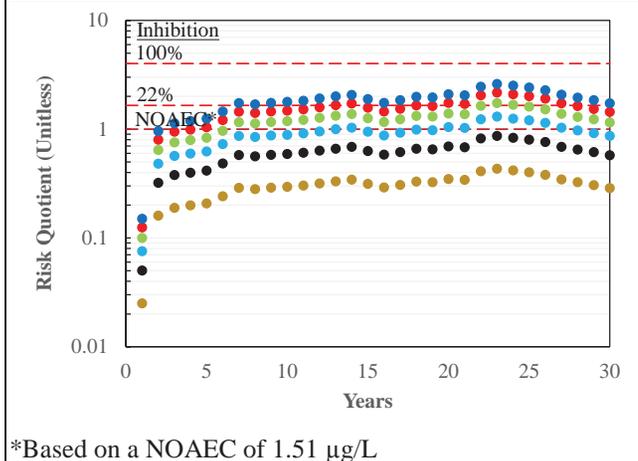
- Six applications per year for 30 years
- Five applications per year for 30 years
- Four applications per year for 30 years
- Three applications per year for 30 years
- Two applications per year for 30 years
- One application per year for 30 years

Appendix 2 Figure 1. Continued.

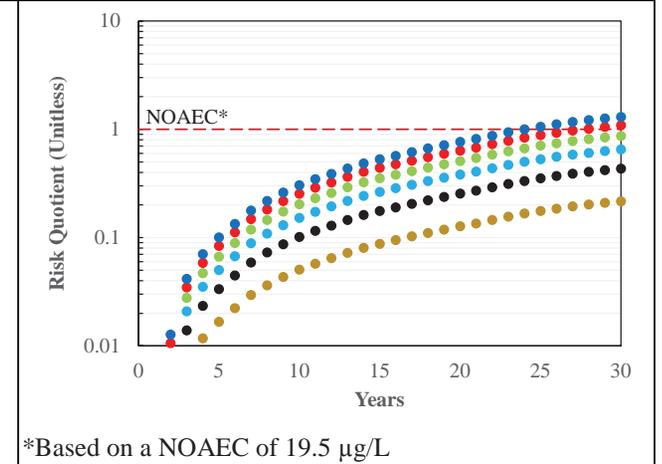
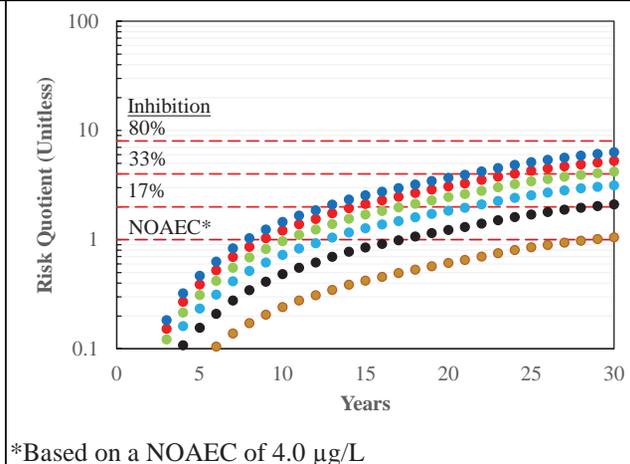
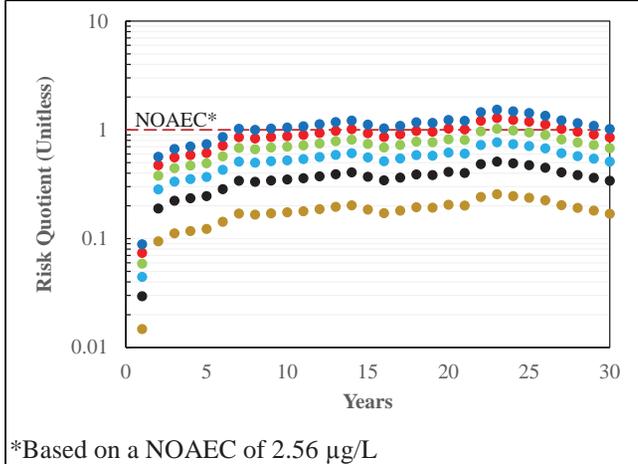
Flubendiamide	Des-iodo	
Benthic Pore Water	Overlying Water	Benthic Pore Water

**Fruiting Vegetables based on CARowCropRLF\_V2 Scenario (Ground Application)**

Agency Endpoints based on Time-weighted Average Concentrations

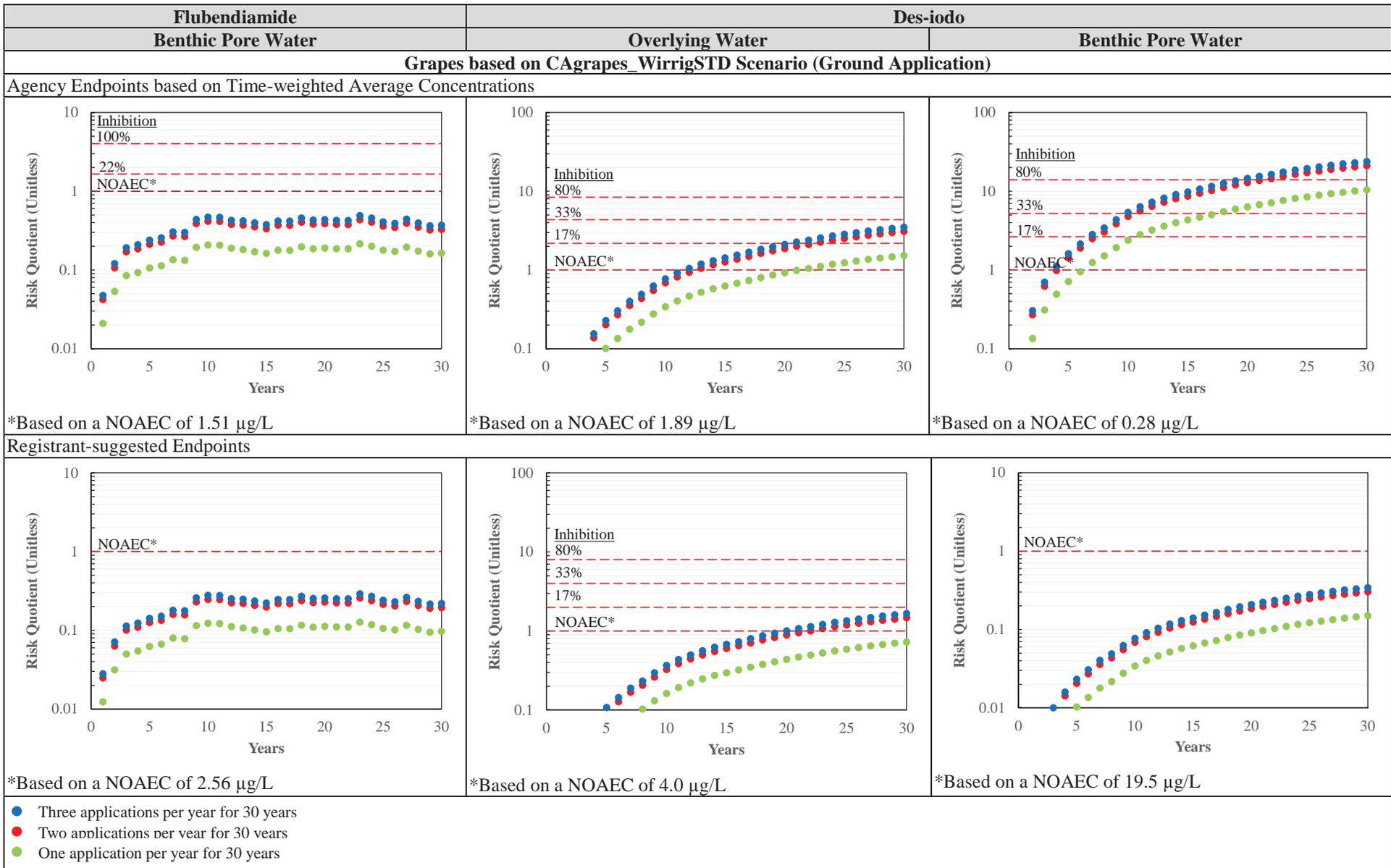


Registrant-suggested Endpoints



- Six applications per year for 30 years
- Five applications per year for 30 years
- Four applications per year for 30 years
- Three applications per year for 30 years
- Two applications per year for 30 years
- One application per year for 30 years

Appendix 2 Figure 1. Continued.

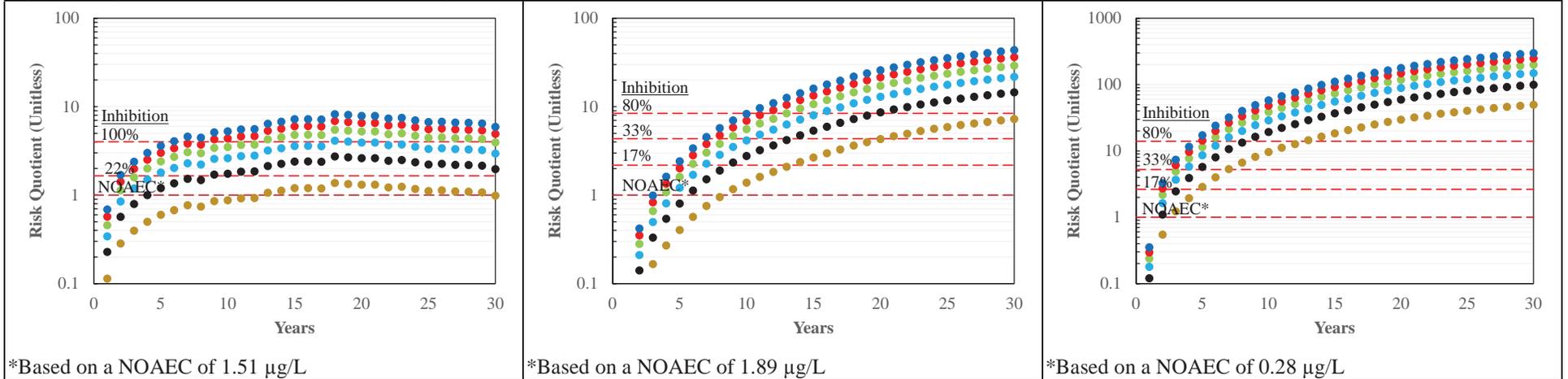


Appendix 2 Figure 1. Continued.

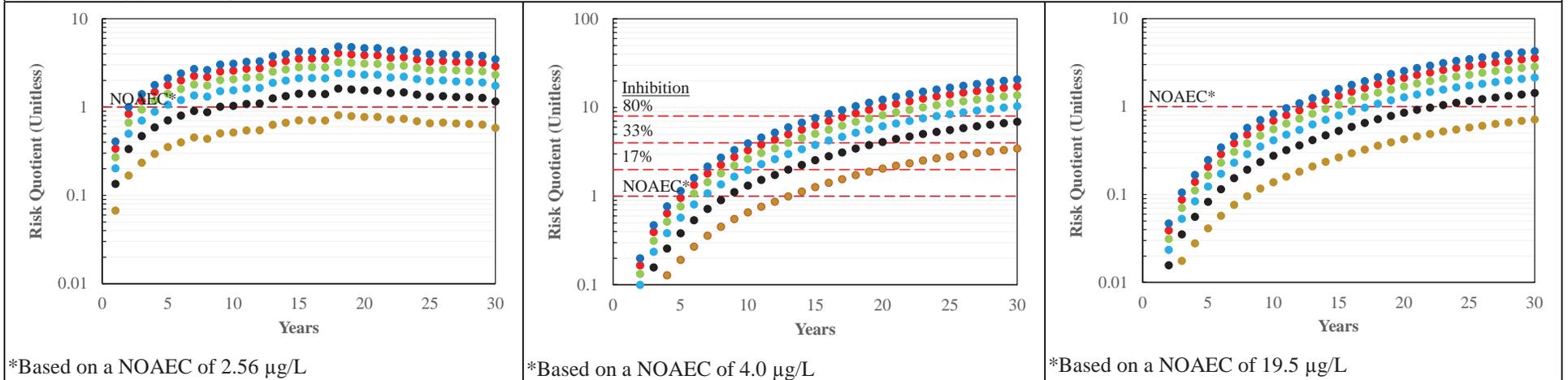
Flubendiamide	Des-iodo	
Benthic Pore Water	Overlying Water	Benthic Pore Water

**Leafy Vegetables based on CAlettuceSTD Scenario (Aerial Application)**

Agency Endpoints based on Time-weighted Average Concentrations



Registrant-suggested Endpoints



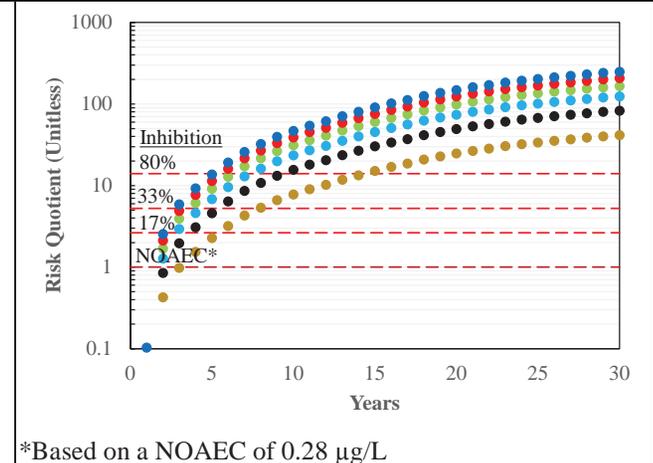
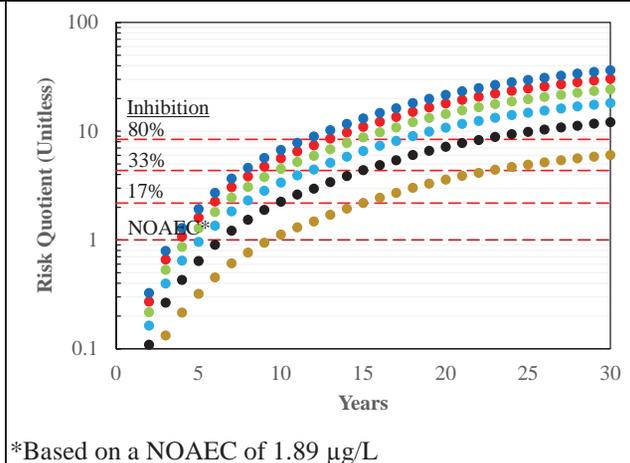
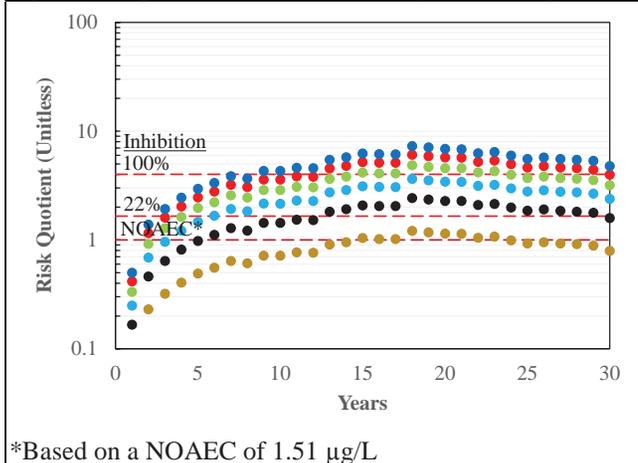
- Six applications per year for 30 years
- Five applications per year for 30 years
- Four applications per year for 30 years
- Three applications per year for 30 years
- Two applications per year for 30 years
- One application per year for 30 years

Appendix 2 Figure 1. Continued.

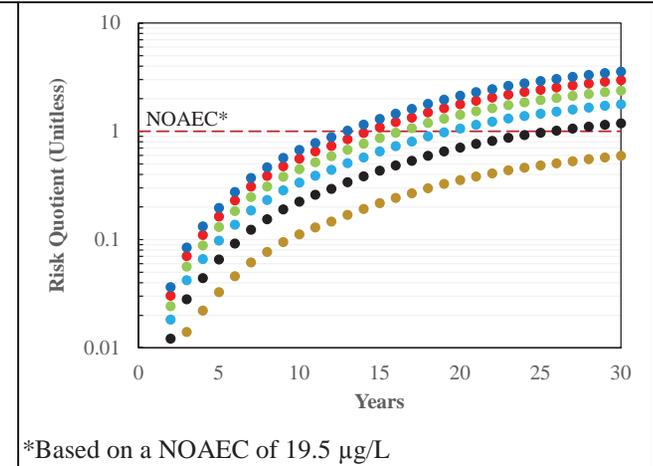
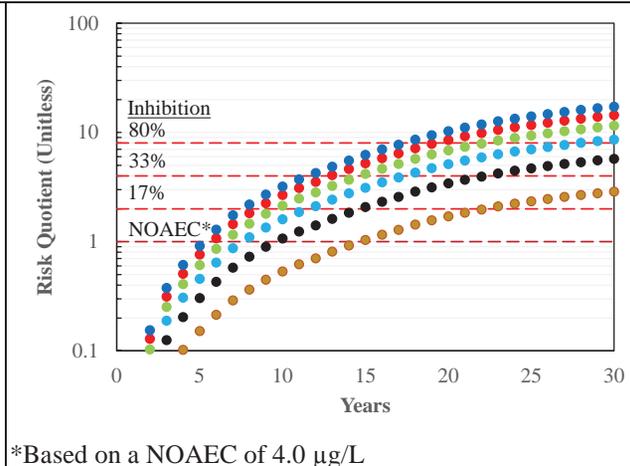
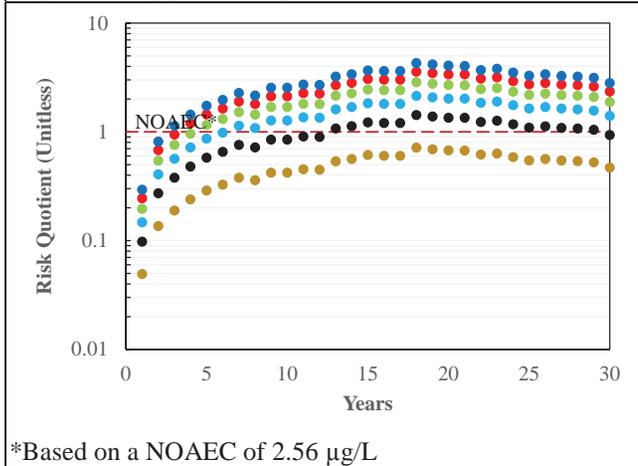
Flubendiamide	Des-iodo	
Benthic Pore Water	Overlying Water	Benthic Pore Water

**Leafy Vegetables based on CAlettuceSTD Scenario (Ground Application)**

Agency Endpoints based on Time-weighted Average Concentrations

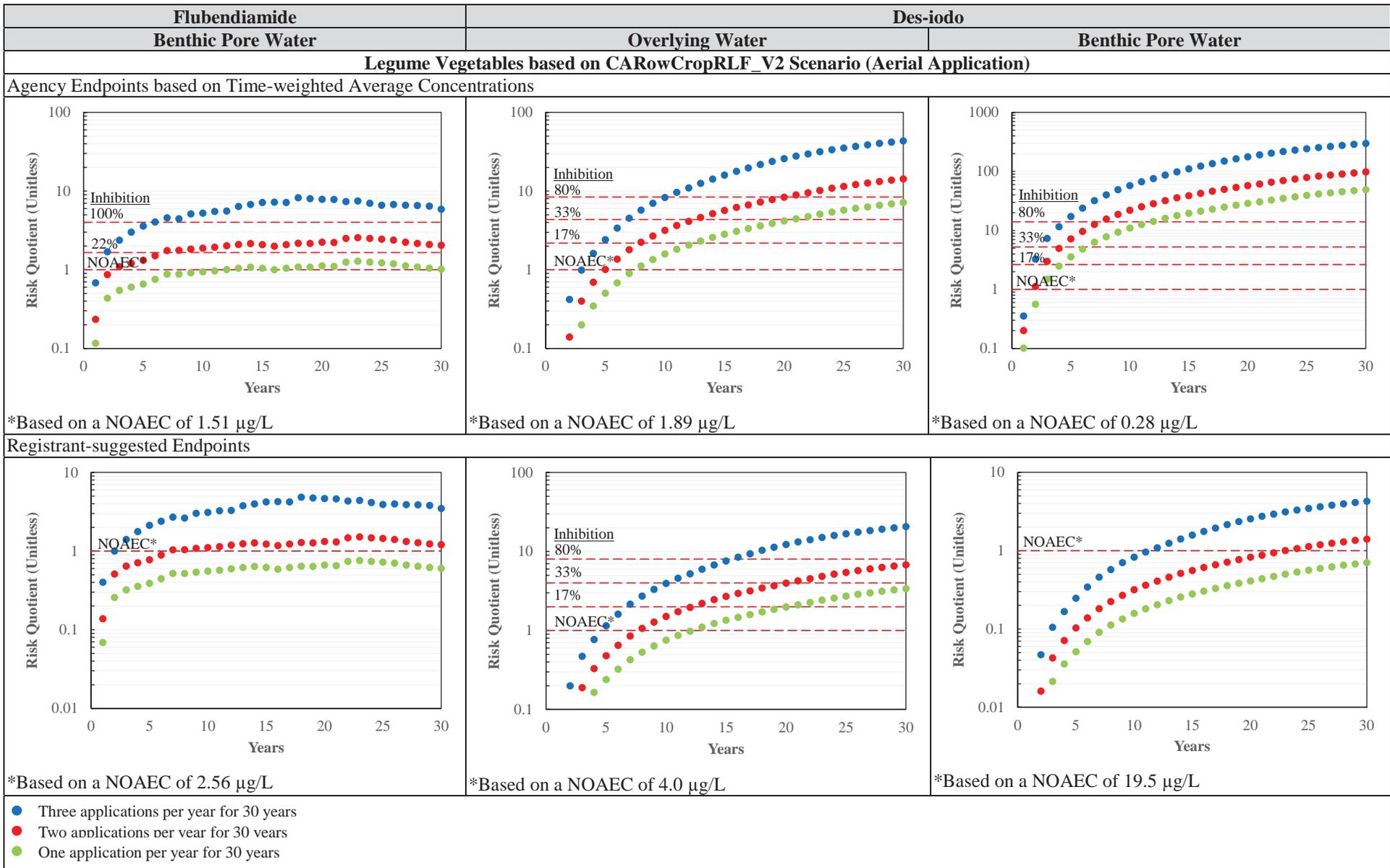


Registrant-suggested Endpoints

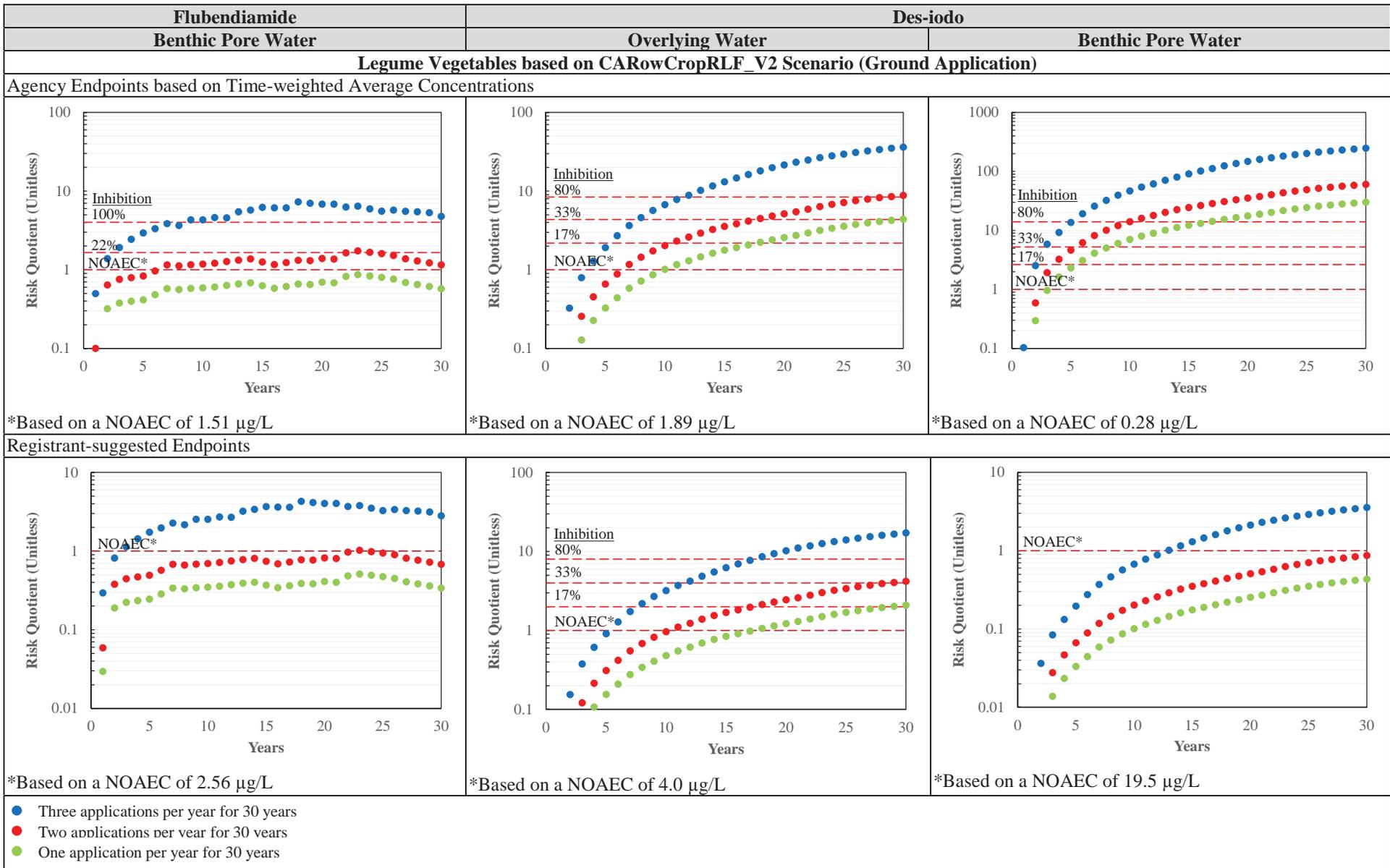


- Six applications per year for 30 years
- Five applications per year for 30 years
- Four applications per year for 30 years
- Three applications per year for 30 years
- Two applications per year for 30 years
- One application per year for 30 years

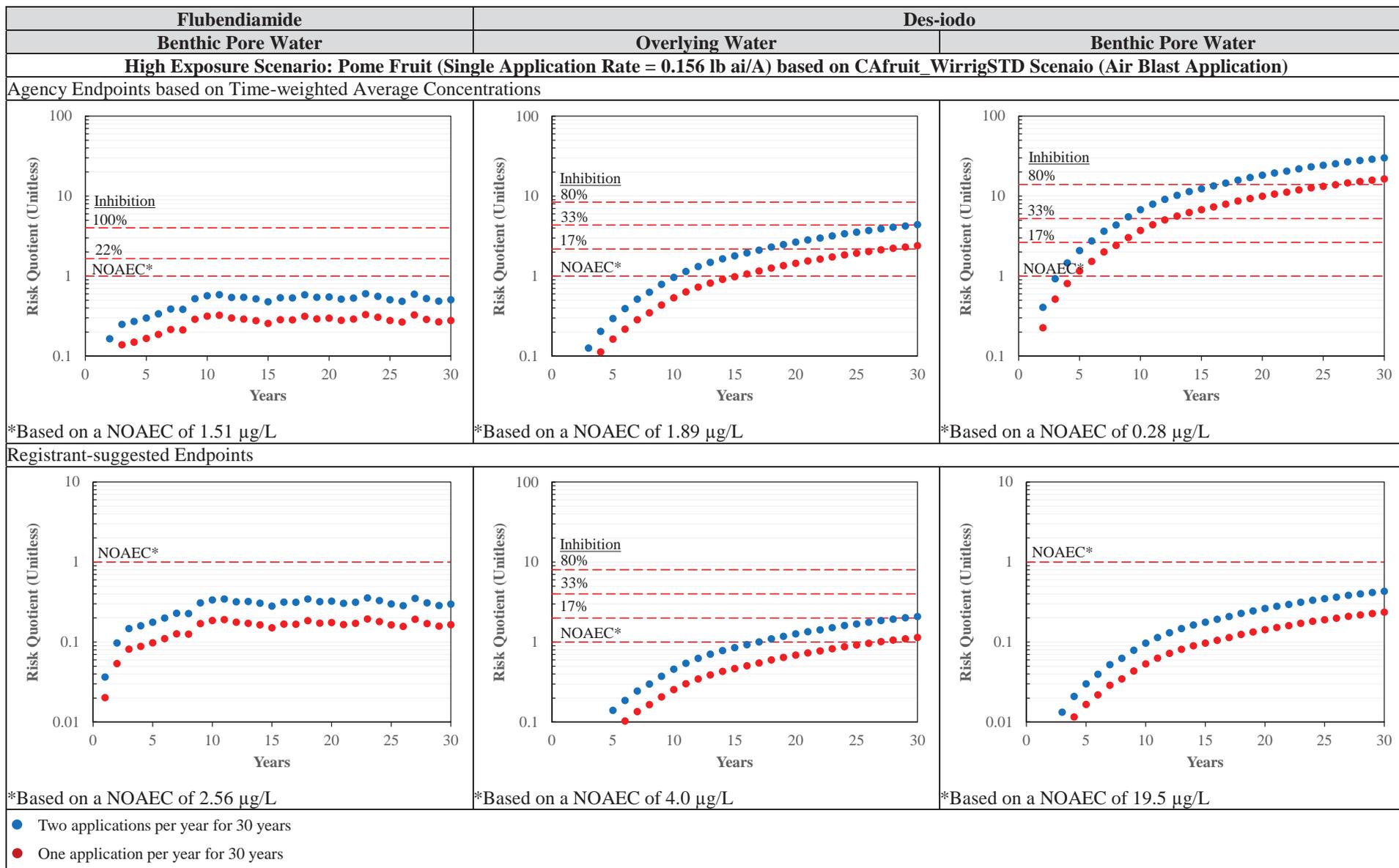
Appendix 2 Figure 1. Continued.



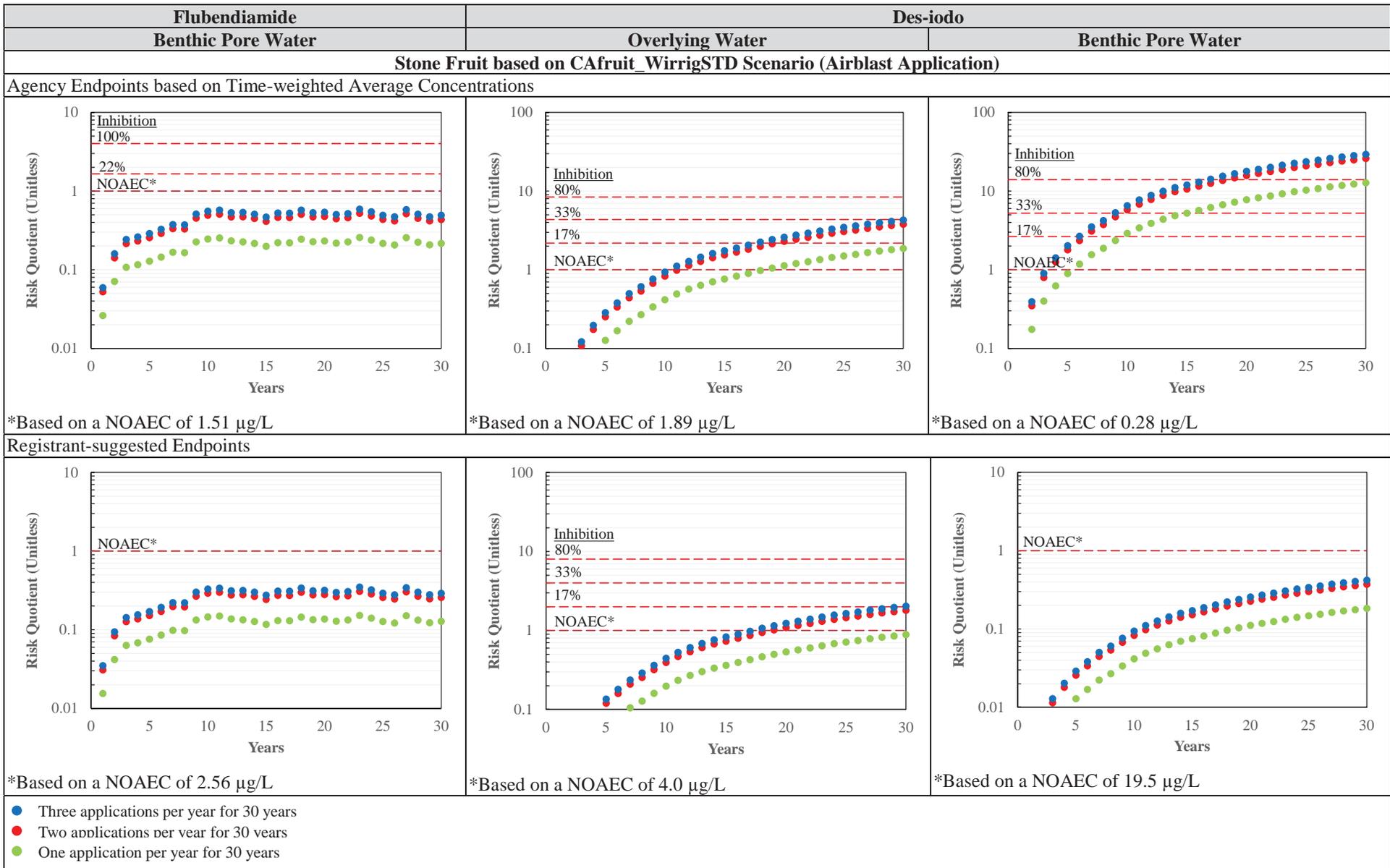
Appendix 2 Figure 1. Continued.



Appendix 2 Figure 1. Continued.



Appendix 2 Figure 1. Continued.

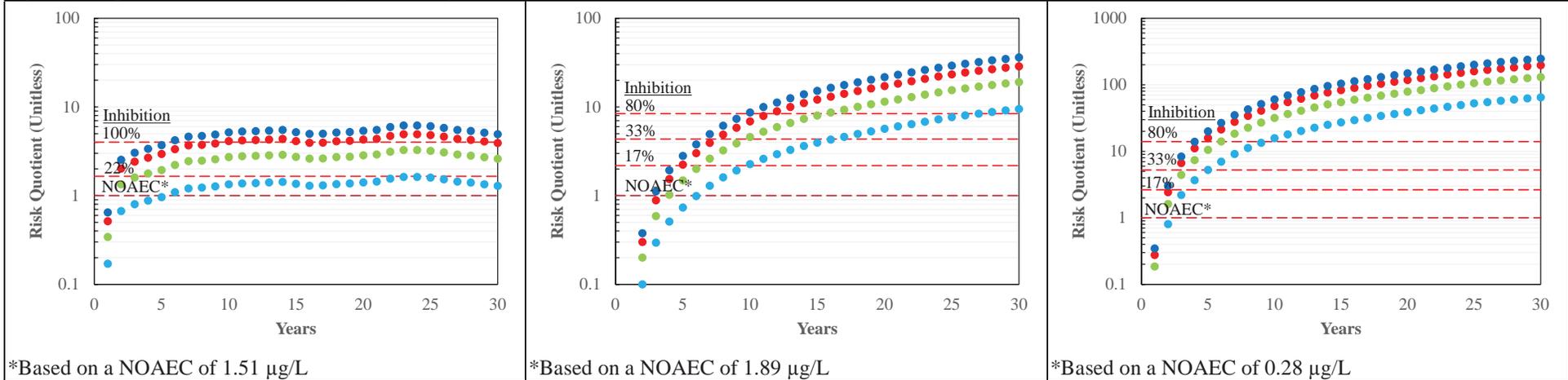


Appendix 2 Figure 1. Continued.

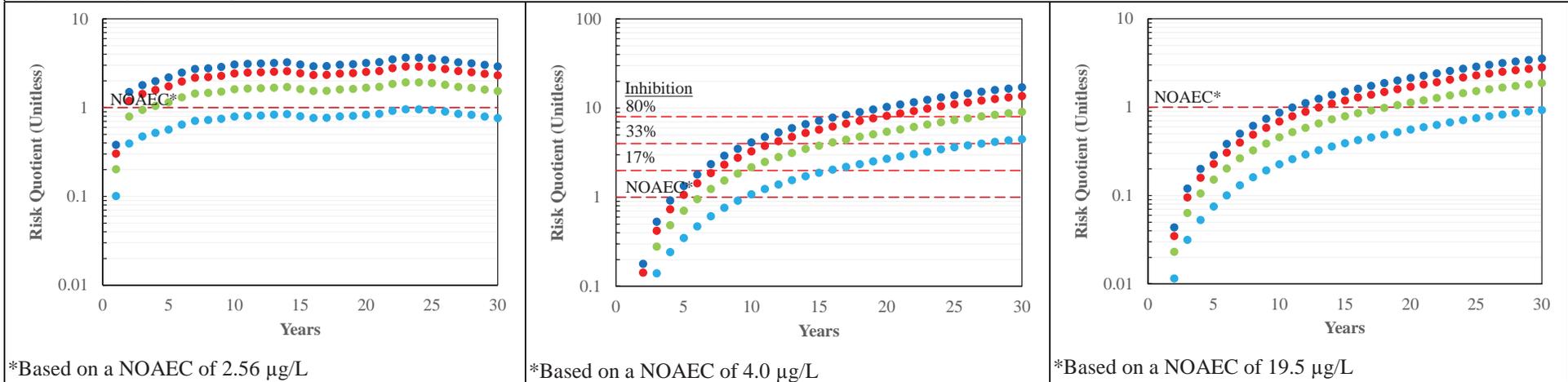
Flubendiamide	Des-iodo	
Benthic Pore Water	Overlying Water	Benthic Pore Water

**Strawberry based on CA Strawberry-noplasticRLF\_V2 Scenario (Aerial Application)**

Agency Endpoints based on Time-weighted Average Concentrations

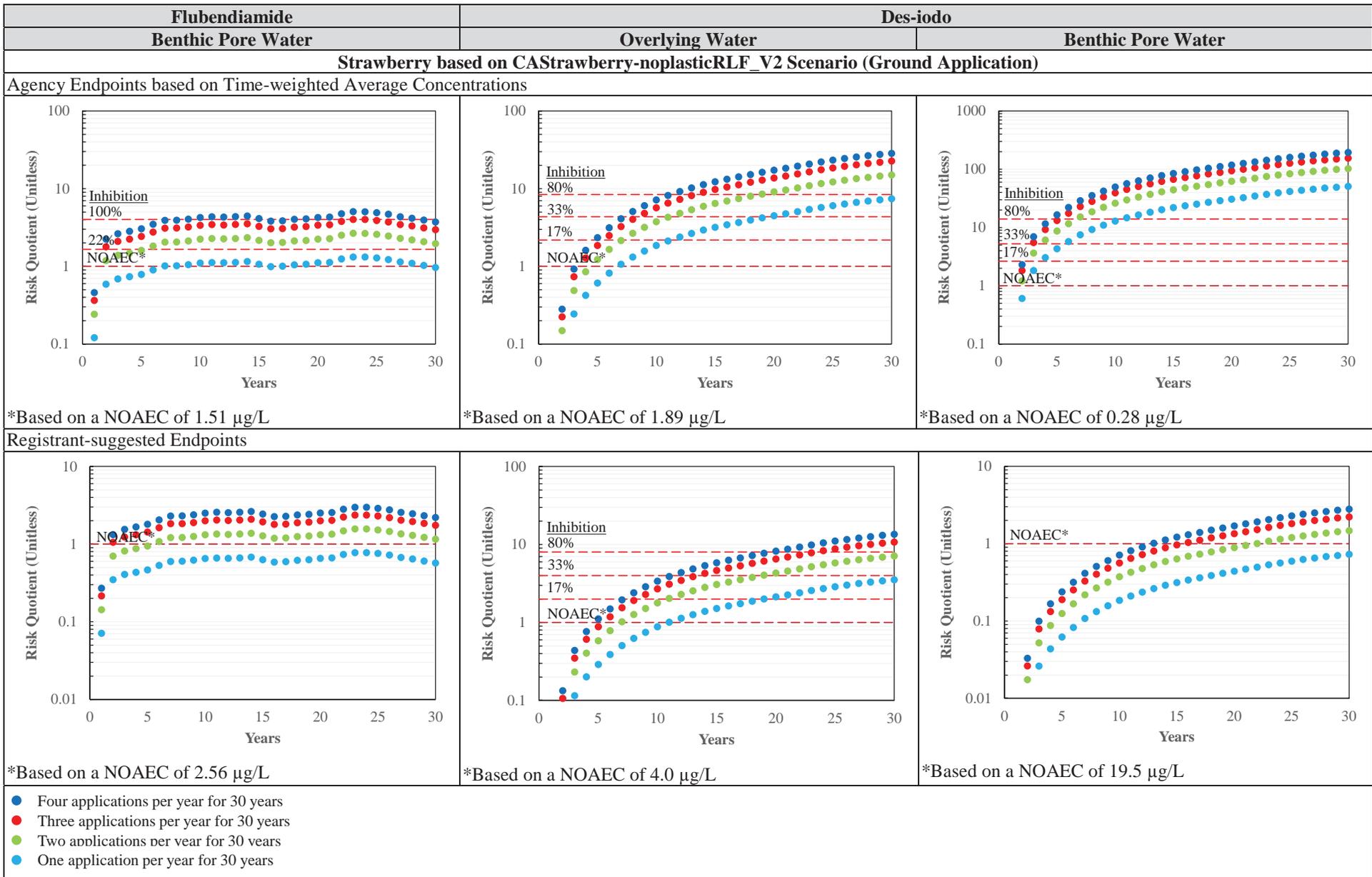


Registrant-suggested Endpoints



- Four applications per year for 30 years
- Three applications per year for 30 years
- Two applications per year for 30 years
- One application per year for 30 years

**Appendix 2 Figure 1. Continued.**

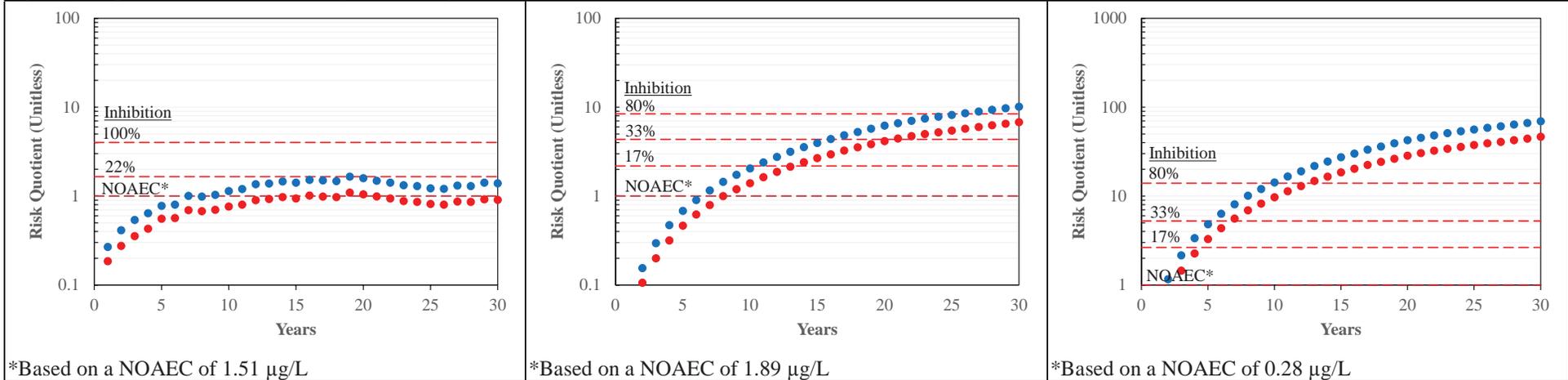


Appendix 2 Figure 1. Continued.

Flubendiamide	Des-iodo	
Benthic Pore Water	Overlying Water	Benthic Pore Water

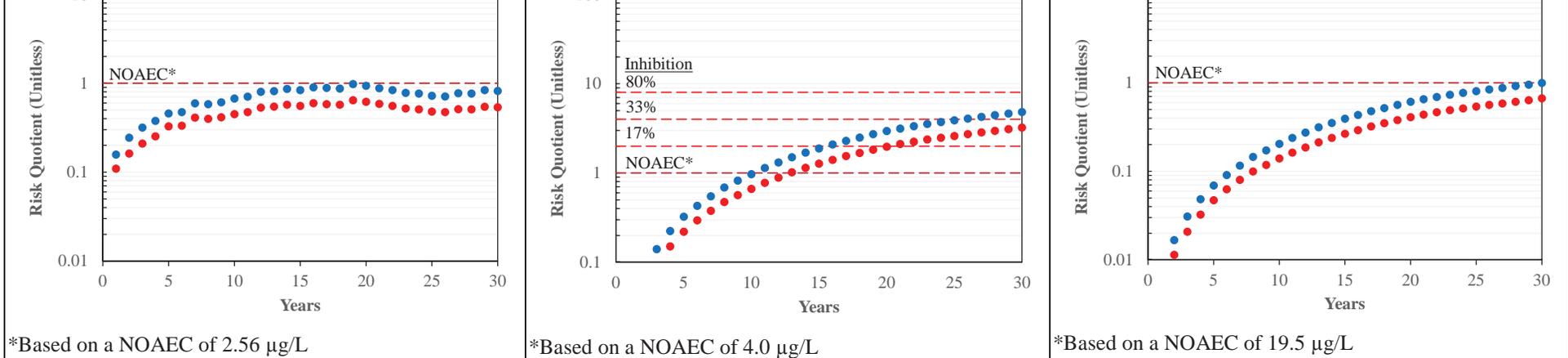
Tobacco based on NctobaccoSTD Scenario using a TN Weather File (W13882.dvf; Aerial Application)

Agency Endpoints based on Time-weighted Average Concentrations



\*Based on a NOAEC of 1.51 µg/L      \*Based on a NOAEC of 1.89 µg/L      \*Based on a NOAEC of 0.28 µg/L

Registrant-suggested Endpoints



\*Based on a NOAEC of 2.56 µg/L      \*Based on a NOAEC of 4.0 µg/L      \*Based on a NOAEC of 19.5 µg/L

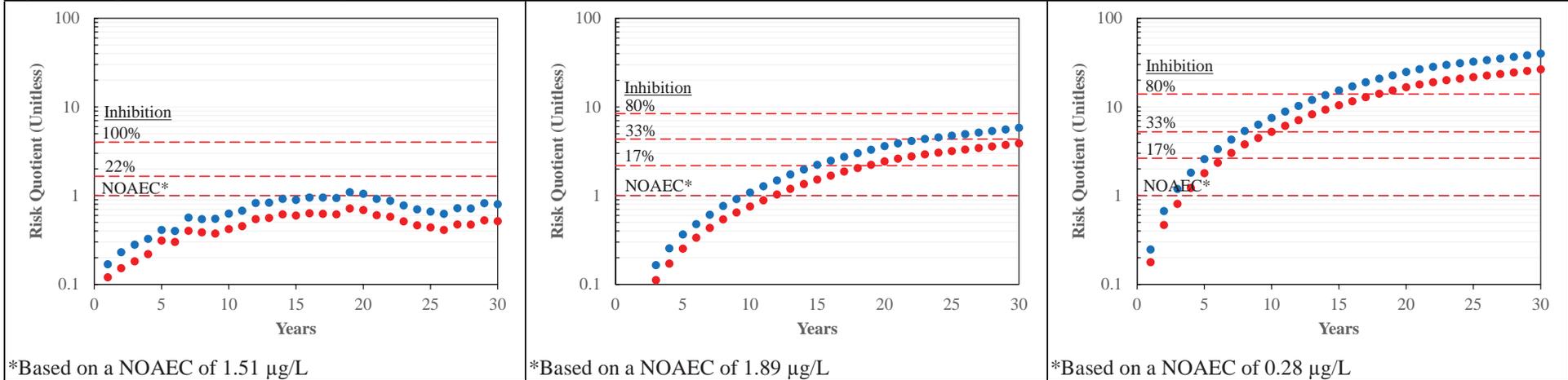
● Two applications per year for 30 years  
● One application per year for 30 years

Appendix 2 Figure 1. Continued.

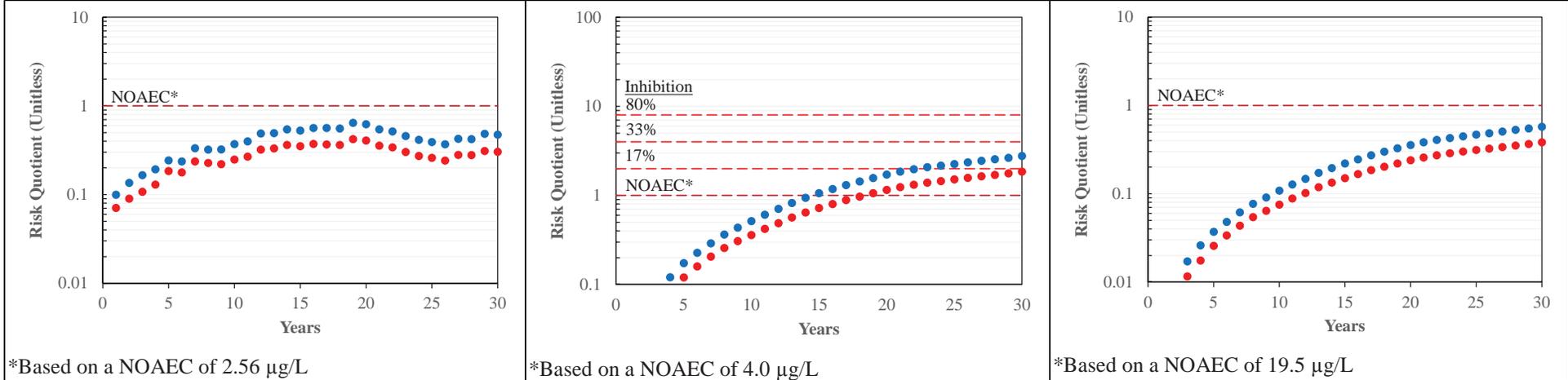
Flubendiamide	Des-iodo	
Benthic Pore Water	Overlying Water	Benthic Pore Water

Tobacco based on NCTobaccoSTD Scenario using a TN Weather File (W13882.dvf; Ground Application)

Agency Endpoints based on Time-weighted Average Concentrations

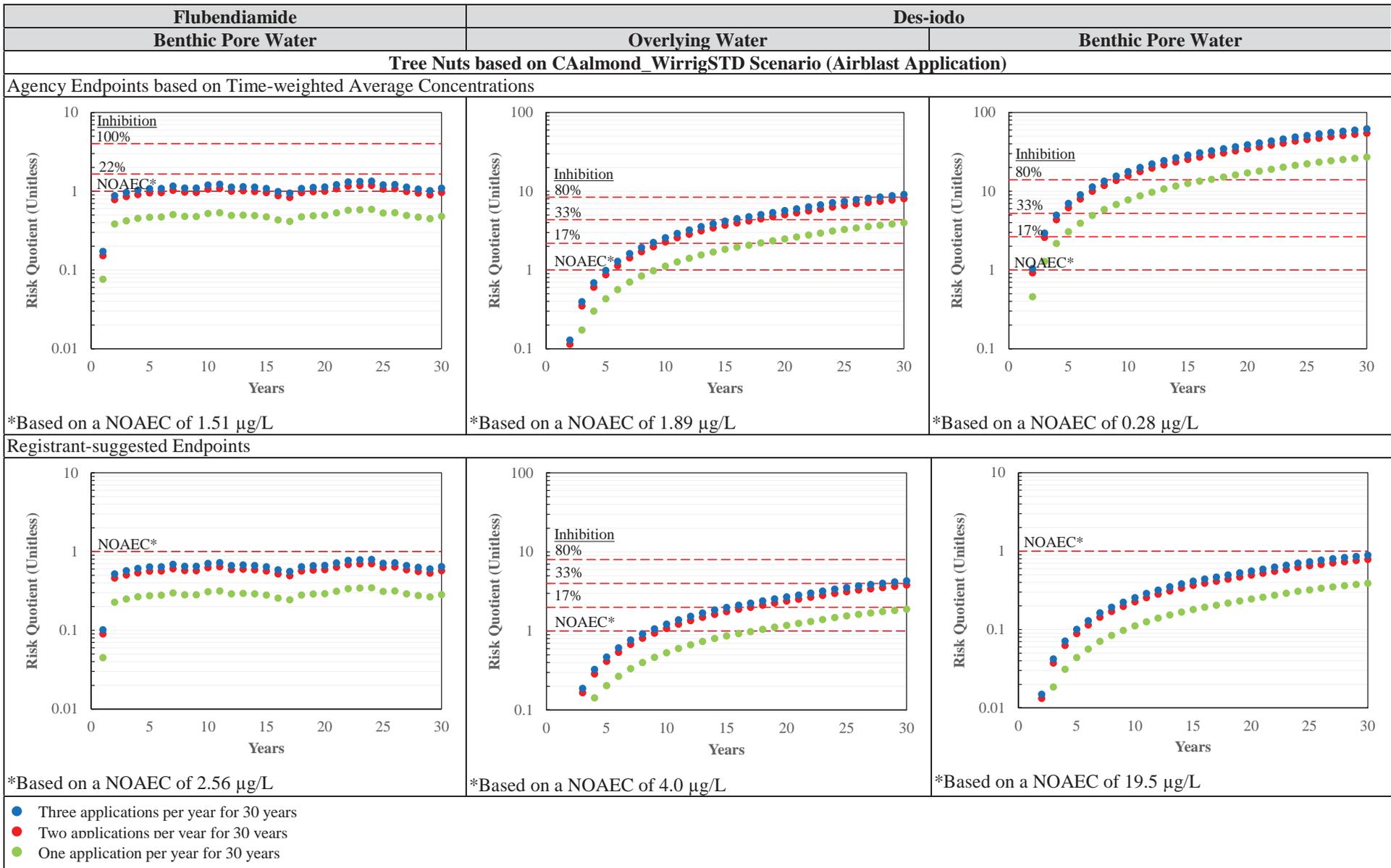


Registrant-suggested Endpoints



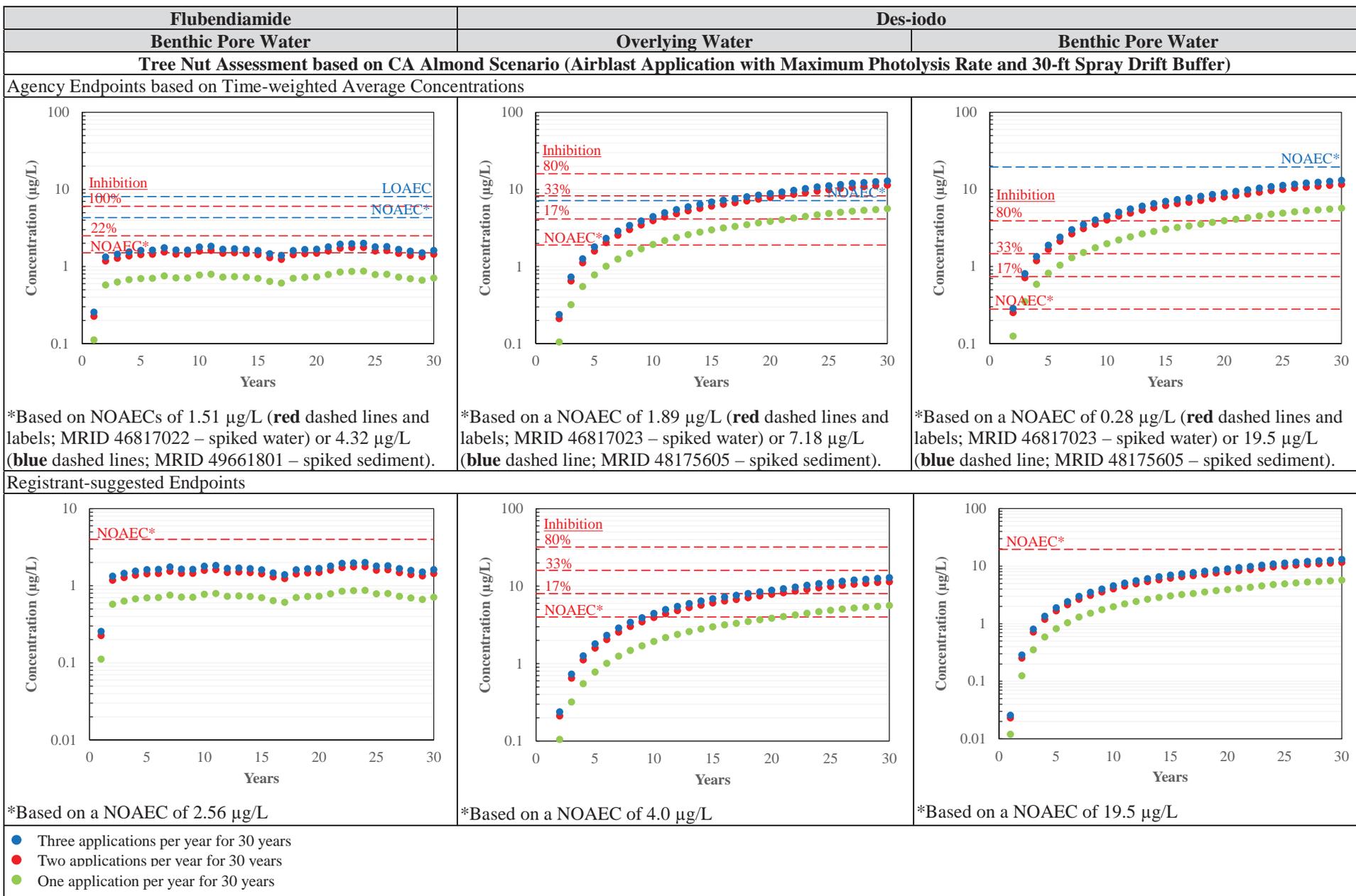
- Two applications per year for 30 years
- One application per year for 30 years

Appendix 2 Figure 1. Continued.

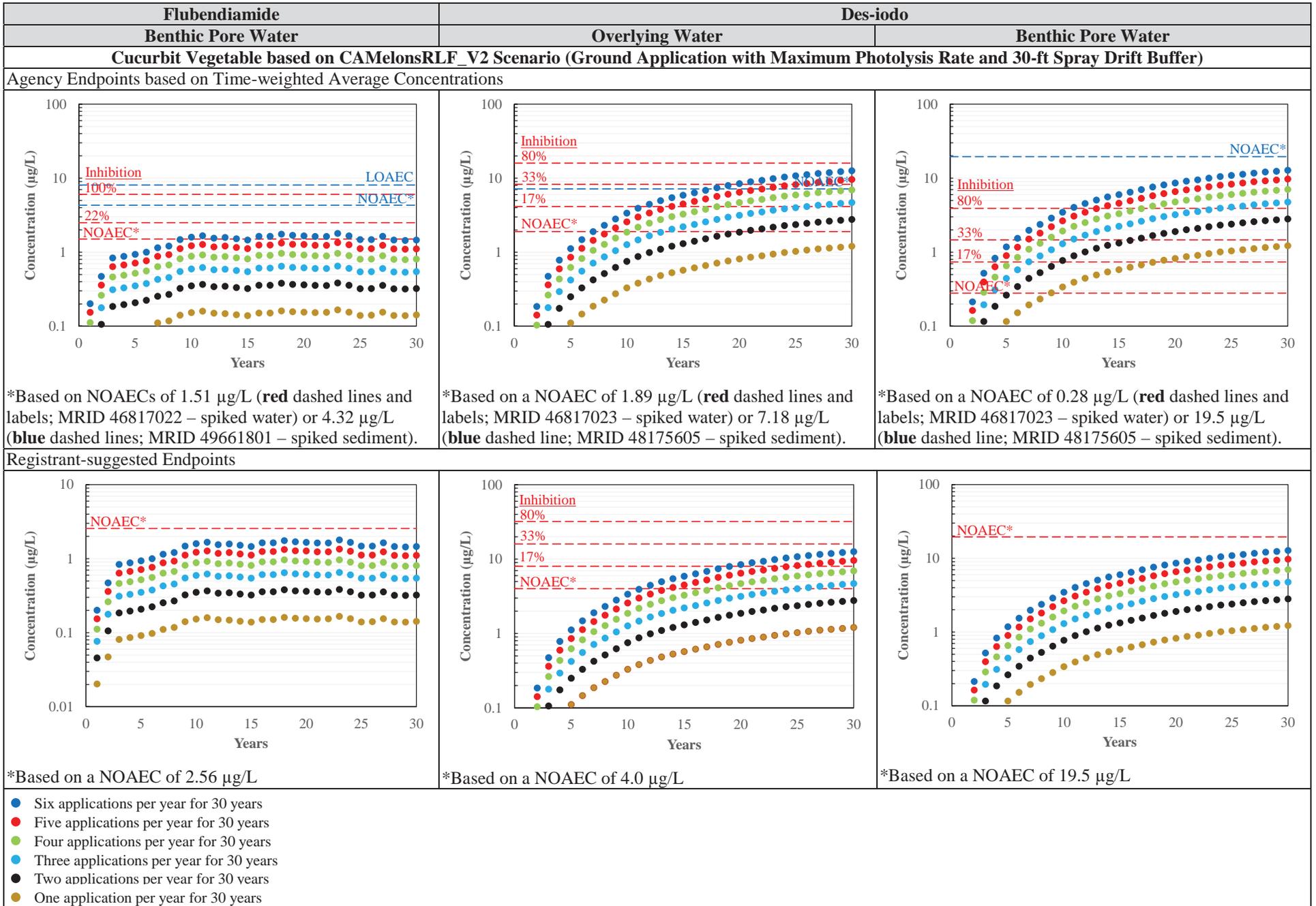


Appendix 2 Figure 1. Continued.

Appendix 3. Results of the Tree Nut and Cucurbit vegetable Use Assessments with the Des-iodo Aqueous Photolysis Half-life Included.



Appendix 3 Figure 1. Comparison of Time-weighted Average Concentration Endpoints and Registrant-suggested Endpoints for the Tree Nut Scenario



Appendix 3 Figure 2. Comparison of Time-weighted Average Concentration Endpoints and Registrant-suggested Endpoints for the Cucurbit Vegetable Scenario.

## Appendix 4. Flubendiamide Chemical Parameter Inputs to the Surface Water Concentration Calculator

SW Surface Water Concentration Calculator (SWCC Version 1.106)

File Scenario Help

Chemical Applications Crop/Land Runoff Watershed Batch Runs Out: Pond Out: Reservoir Out: Custom TBA Advanced

Chemical ID (optional) Flubendiamide

	Parent	<input checked="" type="checkbox"/> Degradate 1	<input type="checkbox"/> Degradate 2
<input checked="" type="radio"/> Koc <input type="radio"/> Kd Sorption Coeff (mL/g)	1954	334	
Water Column Metabolism Halflife (day)	0	0	
Water Reference Temperature (°C)	25	25	
Benthic Metabolism Halflife (day)	855	0	
Benthic Reference Temperature (°C)	25	25	
Aqueous Photolysis Halflife (day)	11.58	78	
Photolysis Ref Latitude (°)	40	33.26	
Hydrolysis Halflife (day)	0	0	
Soil Halflife (day)	0	0	
soil ref (°C)	25	same	
Foliar Halflife (day)	0	0	
MWT	682.4	556.5	
Vapor Pressure (torr)	2.85e-1	1.59e-1	
Solubility (mg/L)	.0293	.187	
<b>Molar Conversion Factors</b>			
Water Column Metabolism	0		
Benthic Metabolism	1		
Photolysis	1		
Hydrolysis	0		
Soil	0		
Foliar	0		

Q10 2

Ready...

Working Directory: C:\Projects\Flubendiamide\Water Monitoring\Year 3\SWCC  
 \ChangeAppRate\CA Airblast Almonds with Max Des-iodo Aqueous

IO Family Name: FluAlmAB

Run