in focus

Biopesticides for food crops

What to submit in a tolerance exemption petition (USA)

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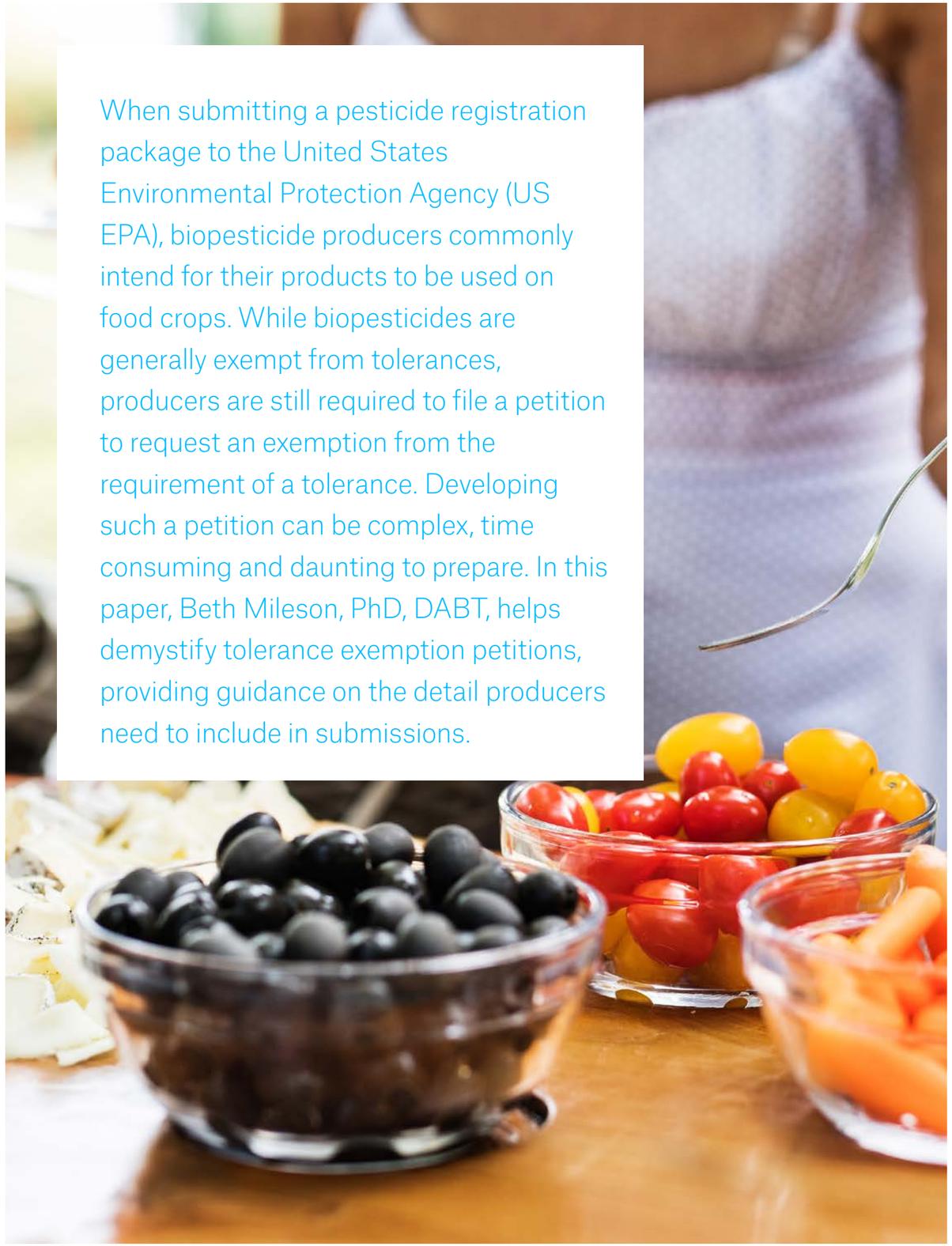

When submitting a pesticide registration package to the United States Environmental Protection Agency (US EPA), biopesticide producers commonly intend for their products to be used on food crops. While biopesticides are generally exempt from tolerances, producers are still required to file a petition to request an exemption from the requirement of a tolerance. Developing such a petition can be complex, time consuming and daunting to prepare. In this paper, Beth Mileson, PhD, DABT, helps demystify tolerance exemption petitions, providing guidance on the detail producers need to include in submissions.

Biopesticides are pesticides that are derived from natural materials including plants, microbes and minerals. Indeed, everyday ingredients such as baking soda and garlic oil are considered biopesticides due to their pesticidal activity.

Even though biopesticides are generally less toxic than conventional pesticides, they are still regulated under the Federal Food, Drug, and Cosmetic Act (FFDCA) when applied to food crops.

One of the regulatory requirements that must be met relates to the amount of residue that can lawfully be present on the food or animal feed treated with the biopesticide, otherwise known as a tolerance. As part of the EPA submission package, the registrant must prepare a petition to either request the establishment of a tolerance or, generally in the case of biopesticides, to request an exemption from the requirement of a tolerance.

What is a tolerance exemption petition?

Under the FFDCA, a 'tolerance' is the maximum residue level of a pesticide that legally can be present in food or animal feed. The EPA is responsible for regulating tolerances and granting exemptions from the requirement of a tolerance in the US.

An exemption from the requirement of a tolerance for a biopesticide means that there is a reasonable certainty of no harm to the general US population, including infants and children, from exposure to residues of the biopesticide under conditions of prevailing or proposed use.

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What needs to be included in a tolerance exemption petition?

The formal petition is composed of prescribed sections, but how to address these sections can be mystifying because the US EPA's instructions are geared towards tolerance petitions for conventional pesticides. A reasonable outline for a tolerance exemption petition for a biopesticide will contain nine sections, detailed opposite.

Section A:
Active ingredient, product names and proposed use practice

The identity of the Technical Grade Active Ingredient (TGAI), and the name of the end use product (EP) must be provided. The proposed use practice should be summarized in the detail necessary. For example if the biopesticide is intended for use on only a few crops, those can be listed. If the product is proposed for non-food uses in addition to food uses, the non-food uses can be specified as well.

Section B:
Product identity/chemistry, including identity of the pesticide and relevant metabolites, magnitude of residues and analytical method

The TGAI name and Chemical Abstract Service (CAS) number should be identified in this section as well as additional information from the product chemistry studies conducted and submitted to support registration. A brief summary of the metabolism resulting in any metabolite(s) of interest should be presented as well. It is important that a rationale for not submitting an analytical method to detect the TGAI and metabolite(s) be presented in the petition. Example rationales may include: the TGAI degrades rapidly to the innocuous components, carbon dioxide and water, or the TGAI was of minimal toxicity and is readily degradable with a short half-life.

Section C:
Mammalian toxicological profile

A brief summary of every mammalian toxicity test that supports registration of the TGAI and EP should be presented in this section. This includes genetic toxicity tests.

Section D:
Aggregate exposure

The aggregate exposure to the TGAI for assessment of a potential tolerance exemption includes exposure from use as a pesticide, and all other exposures that might occur through non-pesticidal applications of the active ingredient. Aggregate exposure to the TGAI includes information on dietary exposure, drinking water exposure and non-dietary exposure from use of the ingredient in cosmetics or consumer products. These three types of exposures may be discussed separately in this section of the petition.

Section E:
Cumulative effects

The cumulative effects section is required to consider the available information concerning the potential cumulative effects of exposure to residues of the biopesticide of interest and other substances that share a common mechanism of toxicity with that biopesticide. If there are no other substances known to share a common mechanism of toxicity with the biopesticide of interest, this information is provided.

Section F:
Safety determination

The safety determination includes an assessment of the potential exposure and risk from use of the biopesticide to the US general population, and infants and children. The goal is to present a qualitative summary that demonstrates a reasonable certainty of no harm to all populations from exposure to the biopesticide under conditions of prevailing or proposed use.

Section G:
Effects on the immune and endocrine systems

Often there is no evidence to suggest that particular biopesticides function in a manner similar to known hormones, or that they act as endocrine disruptors. If this is true, it can be stated in this section, otherwise a summary of these endpoints must be included in Section G.

Section H:
Existing tolerances

If there are any existing tolerances that are in the Code of Federal Regulations (40 CFR) for the biopesticide, the tolerance(s) should be included in this section.

Section I:
International tolerances

Identify any Codex Alimentarius Commission Maximum Residue Levels (MRLs), or any other international tolerances in this section. If there are no known International MRLs, state that there are none, but check Codex to be certain.

Notice of Filing

Once the petition is complete, a Notice of Filing must be prepared. The Notice of Filing is a brief summary of the petition input on a Microsoft Word template that is intended for publication in the US Federal Register. The template is specific for biopesticide petitions and is available on the EPA website. The Notice of Filing announcing the filing of the pesticide tolerance petition is published early in the review process and public comments are solicited.

Timeline

The timeline for EPA review of a biopesticide tolerance exemption petition is associated with the primary action of the submission (i.e. product approval). For example, if the petition is submitted in conjunction with a product under the category 'New active ingredient; food use; petition to establish a tolerance exemption,' the decision review time is 18 months. If the petition is submitted in conjunction with the category described as a 'New food use; petition to establish a tolerance exemption,' the decision review time is 13 months. The EPA review timelines may change slightly from year to year.

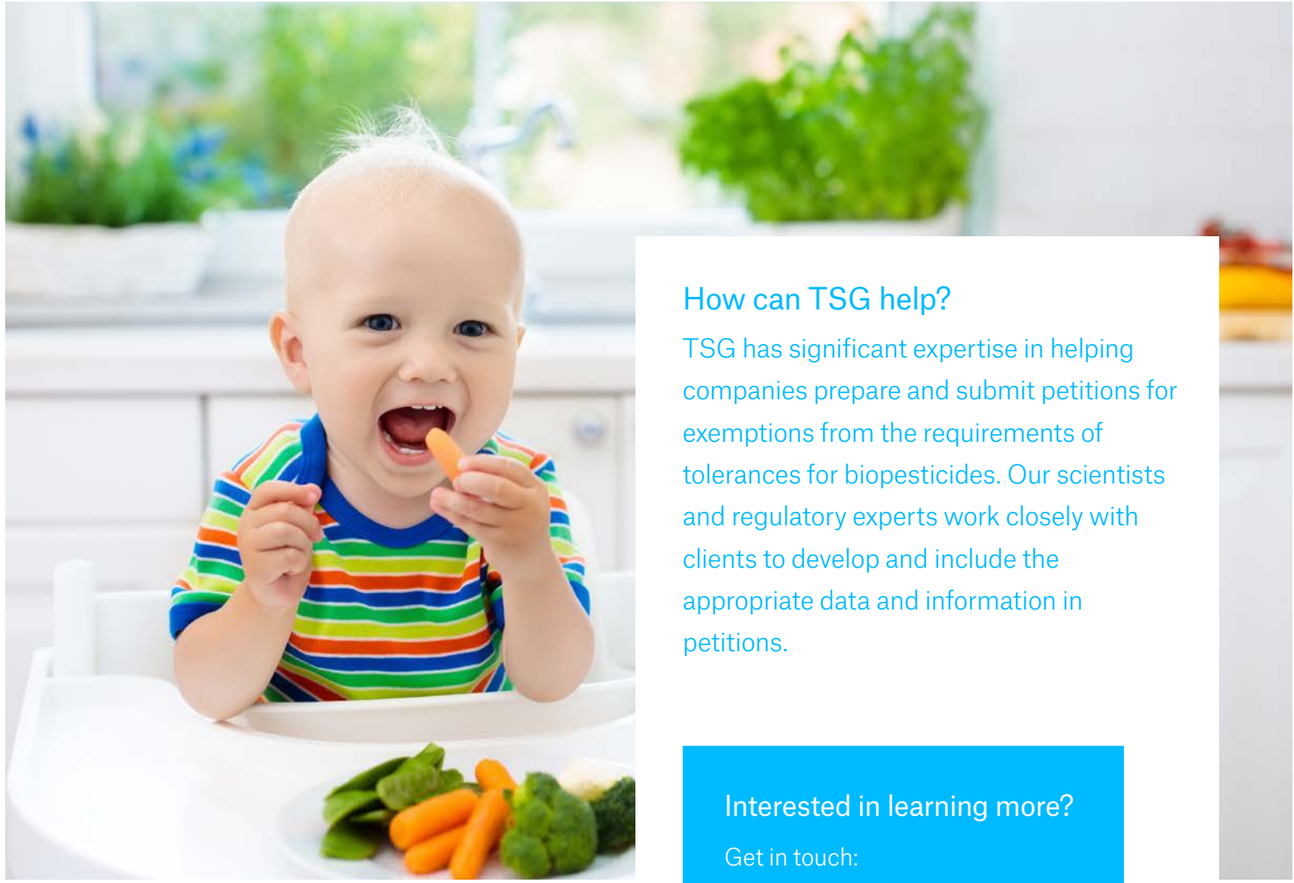
Fees

The fee for review and publication of the tolerance exemption petition and the Notice of Filing is covered in the application fee for EPA review of the new active ingredient or the new use. These fees are updated each fiscal year and are provided on the Fee Schedule for Registration Applications page of the EPA website.

Check EPA guidance

This quick guide is aimed at helping biopesticide registrants understand how to develop a petition for an exemption from the requirement of a tolerance. However, it is important to check EPA guidance to make sure that every detail required is covered.

The tolerance exemption document may seem daunting to prepare, but the task is not insurmountable, especially if the biopesticide is of minimal toxicity and the data are available to support the required sections, detailed on pages 3 and 4.



How can TSG help?

TSG has significant expertise in helping companies prepare and submit petitions for exemptions from the requirements of tolerances for biopesticides. Our scientists and regulatory experts work closely with clients to develop and include the appropriate data and information in petitions.

Interested in learning more?

Get in touch:
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About the author

Beth Mileson, PhD, DABT, Principal Scientific Consultant, Team Leader

Beth Mileson is a Board Certified Toxicologist with over 20 years of experience in neurotoxicology and regulatory toxicology. Beth specializes in providing scientific support for pesticides, industrial chemicals, and consumer products. She has particular expertise in understanding and characterizing the modes of action of xenobiotic substances.

Beth conducts risk assessments to assist companies with business decisions, monitors human health studies, develops protocols for testing in cooperation with contract research organizations (CROs), serves as an expert witness in ongoing legal cases, and implements strategies to support new and existing product registrations. She also meets with federal and state officials on behalf of companies to discuss and resolve various compliance issues related to toxicity.

Beth has a BA in Biology and an MS in Biology and Zoology from George Washington University. She has an MBA from George Mason University and a PhD in toxicology from the University of North Carolina at Chapel Hill.

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