Proposal to Translate Existing Residue Data for Residues of Propylene Oxide in Various Spice Commodities to Turmeric, Ginger, Sesame, and Capsicums

American Spice Trade Association, November 30, 2023

ChemSAC Issue

Guideline Waiver: To translate existing residue data for various spice commodities to establish tolerances for residues of propylene oxide (PPO) and its metabolites and degradates, on turmeric, ginger, sesame seed, and capsicum.

Question:

Does ChemSAC concur that the available residue data for propylene oxide residues on Crop Group 19 can be translated to establish tolerances for residues of PPO, including its metabolites and its degradates, including the reaction products propylene chlorohydrin and propylene bromohydrin, on the following commodities: turmeric, ginger, sesame seed, and capsicums?

Background

Facilitating the Spice Industry's Transition from EtO to PPO

Many spices are grown in tropical climates where they are subjected to excess heat, humidity, and minimal good agricultural practices, resulting in the potential presence of pathogenic bacteria in spice products. As such, spice companies are required under the FD&C Act 21 U.S.C 301 et seq. and Preventive Controls for Human Foods rule under the Food Safety Modernization Act regulations, 21 CFR Part 117, to establish validated treatments to control food safety hazards such as pathogens.

Fumigation with ethylene oxide (EtO) is one of three treatments that has been validated in spices to control microbiological hazards. EtO is leveraged by the spice industry during the processing and reconditioning of dried herbs and spices to control pathogens and reduce microbial activity. In fact, between 2015 and 2019, half of the reconditioning proposals for imported spices and herbs were for EtO treatment (EPA, 2023).

In April 2023, EPA published its proposed interim decision (PID) for EtO (EPA-HQ-OPP-2023-0244 / April 13, 2023) as part of registration review. Concurrently, EPA published proposed air emissions standards for EtO under the National Emission Standards for Hazardous Air Pollutants (NESHAP) under the Clean Air Act (EPA-HQ-OAR-2019-0178 / April 13, 2023). The PID proposes a phased cancellation of the registration of EtO for all spice commodities without documentation that alternative treatment methods are not viable and demonstration that the use of EtO is critical to food safety. Simultaneously, several states have considered legislation banning or restricting the use of EtO in the state (e.g., Maryland SB0916).

Together, these actions represent a concerted effort on both the federal and state levels to reduce occupational and bystander exposure to EtO. As a partner to EPA, the spice industry is committed to facilitating the availability of alternatives to ultimately lower national emissions of EtO. But, as ASTA indicated to EPA in its comments on the PID (ASTA, 2023), viable alternatives to EtO to treat spices are limited, and the spice industry has not had sufficient time to identify and evaluate the viability of alternative treatment methods for all spice commodities.

However, one viable alternative identified by the spice industry is propylene oxide (PPO). PPO is used as a fumigant to aid in the control of microbiological spoilage and to reduce bacterial and mold contamination in/on spices and dried herbs. The chemical has been leveraged by the spice industry for over 20 years as a key method to reduce microbiological hazards that may pose a public health concern. Similar to EtO, PPO can be used to treat spices in their final packaging, reducing the risk of post-process contamination. Furthermore, current EtO treatment chambers can be repurposed for PPO treatment fairly quickly.

The spice industry believes that the transition to PPO represents the most rapid and accessible pathway away from its reliance on EtO. However, because of current label limitations for PPO, the chemical cannot be used as an alternative for several key spice commodities for which EtO is currently used, including turmeric, capsicums, ginger, and sesame seeds. Sesame seed, ginger, and red pepper were among the top ten spices imported to the U.S. in terms of quantity in 2022 (USDA, 2022)

The expanded use of PPO to these missing commodities will aid in the industry's transition away from EtO and grant additional time for the industry to identify and evaluate the viability of other alternative treatment methods. Without the establishment of tolerances on these commodities, it may take the spice industry several additional years to identify viable alternative treatment methods and complete validation of the treatments.

Overview of Propylene Oxide Use & Label Limitations

The current PPO label limits the application of the gas to only "Herbs and spices, group 19, dried", dried garlic, dried onion, and cocoa (bean and powder) which excludes several key commodities, including ginger, sesame seed, turmeric, and red pepper/capsicum (which is the most commercially traded spice worldwide). However, prior to 2006, the PPO label authorized application of the gas to spices and seasonings more broadly. The label read:

> "To aid in the control of microbiological spoilage and as an insecticidal fumigant for the control of stored products' insects. To reduce bacterial and mold contamination in **processed spices**, cocoa, cocoa beans, inshell and processed nut meats (except peanuts)." [Emphasis added]

Following EPA's registration review of PPO in 2006, the label was changed to cover crop group 19 commodities in an effort to provide more specificity. However, due to a lack of alignment between EPA's Crop Group 19, FDA's definition of spices, and ASTA's definition of spices, key seasoning commodities were excluded, including dried vegetables. In response to the August 2006 PPO RED, Keller and Heckman LLP submitted a public comment requesting that "vegetables, dried" be added to the tolerance expression in addition to "herbs and spices, group 19, dried." In EPA's response, labeled "HED Response to Public Comments on the Propylene Oxide (PPO) Reregistration Eligibility Decision (RED) PC Code 042501; DP Barcode D334250", EPA states that: "HED agrees with this comment and will revise the proposed tolerance expression accordingly." Despite EPA's indication that the label would be amended to include a tolerance for dried vegetables, this action was never fully executed.

In 2014, dried onion and garlic were added to the label based on the residue data originally submitted for the 2006 registration review (Blinne & Koch, 2001; MRID 45301901); however, other key dried vegetables integral to the spice industry, including turmeric, ginger, and capsicums, were notably excluded. As a result, the industry lost its ability to treat these key commodities with PPO despite the fact that it was apparently never the Agency's intention to formally revoke these applications.

The exclusion of dried vegetables from the PPO label in 2006 was inconsistent with other Agency actions at the time regarding ethylene oxide (EtO), which is a similar fumigant. In its 2006 "Report of the Food Quality Protection Act (FQPA) Tolerance Reassessment and Risk Management Decision (TRED) for Ethylene Oxide," EPA recommended revising 40 CFR 180.151(a)(2) to include tolerances for "herbs and spices, group 19, dried (except basil)" as well as "vegetables, dried" (EPA 730-06-032 / July 24, 2006). In 2008, EPA proposed to modify tolerances for residues of EtO, including establishing a tolerance of 7 ppm in "herb and spice, group 19, dried, except basil" as well as in "dried vegetables" (Federal Register/ Vol. 73, No. 251 / Wednesday, December 31, 2008 / [EPA-HQ-OPP-2008-0834; FRL-8394-7]). A final rule was issued in 2009 establishing the proposed EtO tolerances. Additionally, EPA clarified in the 2009 FR publication that the "vegetable, dried" tolerance encompassed key spices omitted from Crop Group 19, including capsicums, ginger, horseradish, paprika, garlic, onion, turmeric, and arrowroot (46694 Federal Register / Vol. 74, No. 175 / Friday, September 11, 2009 / [EPA–HQ–OPP–2008–0834; FRL–8426–2]).

Although the spice industry recognizes that the establishment of tolerances on additional dried vegetables may be useful, this petition is only requesting the establishment of PPO tolerances for commodities that are recognized as spices by ASTA (capsicums, ginger, turmeric) and sesame as these are the commodities which ASTA represents.

Overview of Available Residue Data

The tolerances established for residues of PPO by EPA in the 2006 reregistration were based on a series of residue studies in the following commodities: onion powder, black pepper, garlic powder, dried basil, celery seed, and chili powder (capsicums) (Blinne & Koch, 2001; MRID 45301901). These data were reviewed in 2005 Revised Residue Chemistry Chapter for Propylene Oxide Reregistration Eligibility Decision (RED) Document (EPA, 2005; D316571). Complementary residue data was subsequently provided on nutmeats and dried fruits (raisins, figs, and prunes) (Blinne, 2002, MRID 45813601; Schrier & Koch, 1998, MRID 44692801).

The commodities studied are representative of different spice types: spices derived from fruits and berries (black pepper), seed spices (celery seed), dried vegetables (onion powder, garlic powder, chili powder), and dried herbs (basil).

The studies evaluated the magnitude of residues of PPO in/on dried herbs and spices after treatment with a single application of PPO at the then maximum label rate of 2.4 oz PPO/ft^3

(maximum is now 2.0 oz PPO ft^3). The treated commodities were sampled at nominal intervals of 3, 6, 12 21, and 30 days after fumigation treatment. A summary of analyzed PPO residues as prepared by EPA in its 2005 RED is available in Table 1.

The study concluded that PPO is poorly absorbed by dried herbs and spices, resulting in rapid loss of PPO from the matrix during air off-gassing. The study noted that "the consistency of the short half-lives across the representative herb and spice matrices demonstrate that propylene oxide is not significantly retained by this crop group once it is exposed to fresh air." EPA determined that the data was sufficiently representative to be extrapolated across individual spice matrices to establish a tolerance of 300 ppm on crop group 19.

Moreover, EPA indicated in 2006 (D334250) that it believed the submitted spice residue data to be sufficient to establish a tolerance in/on dried vegetables. In EPA's response to Keller and Heckman LLP, the Agency states:

> "Based on the registrant's request, EPA will propose tolerances for PPO and PCH in/on dried vegetables. Residue data are not available for either PPO residues in/on dried vegetables per se. Therefore, proposed tolerances for PPO residues in/on dried vegetables will be based on the 300 ppm tolerance for dried herbs and spices and proposed tolerances for PCH residues[1] in/on dried vegetables will be based on the 6000 ppm tolerance for basil."

Since the original tolerances were established using residue data on one of the dried vegetables being requested (capsicums), and EPA had previously indicated that these data were sufficient to establish a tolerance on "dried vegetables" more broadly, ASTA proposes that tolerances for PPO and its reaction products and metabolites be established in turmeric, ginger, capsicum, and sesame seed based on the available residue data. The use patterns (application rate, holding time, etc.) in these commodities would be consistent with those outlined on the existing label for Crop Group 19, garlic powder, and onion powder, which would also result in similar residue levels as those observed in the Blinne & Koch (2001) study.

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[1] Although tolerances have previously been established for the reaction product propylene chlorohydrin, EPA notes in its 2021 Interim Decision for PPO that it plans to "remove PCH tolerances and revise the PPO tolerance expression to include reaction products; hence, covering PCH residues due to the use of PPO." As such, this proposal requests tolerances for residues of PPO, including its metabolites and its degrades, including the reaction products propylene chlorohydrin and propylene bromohydrin.

Table 1. Results of Blinne & Koch (2001) as summarized by EPA (2005; D316571)

TABLE 8. Propylene oxide/Propylene chlorohydrins/Propylene bromohydrins Residues in Treated Commodities (ave of 2 samples) (after off gassing at 25 C)

Commodity	Application Rate	Temperature Treatment time, # Air washings	PPO Residues, ppm							PCHs Residues, ppm						PBHs Residues, ppm					
		Day	0	2	7	12/13	21	29/30	40	0	6/7	12/13	21	30	40	0	6/7	12/13	21	30	40
SPICES/HERBS																					
black pepper	2.4 oz PPO/ft^3	125 F, 4 hours, 4	250	93.3	55.1	42.9	23.7	12.9	NA	910	322	215	168	200	112	11.8	3.82	1.08	<1	NA	NA
chili powder	2.4 oz PPO/ft^3	125 F, 4 hours, 4	18.7	NA	0.628	0.437	NA	NA	NA	2860	1690	1110	800	357	239	22.9	14.1	10.7	7.8	3.4	2.5
chili powder	0.5 oz PPO/ft^3 (20% label rate)	125 F, 4 hours, 4	1.52	0.202 day 4	0.149	NA	NA	NA	NA	572	254	223	112	86.5	NA	6.41	3.97	3.76	2.01	1.80	NA
onion powder	2.4 oz PPO/ft^3	125 F, 4 hours, 4	32.1	15.2	9.05	7.60	4.54	3.63	NA	107	42.4	38.8	NA	31.2	NA	1.03	<1	<1	NA	NA	NA
garlic powder	2.4 oz PPO/ft^3	125 F, 4 hours, 4	218	147	117	72.4	35.8	20.7	NA	500	338	192	384	126	192	1.14	<1	<1	NA	NA	NA
basil (dried)	2.4 oz PPO/ft^3	125 F, 4 hours, 4	372	164 day 4	107	60.2	31.5	19.4	NA	6670	1860	1080	627	384	359	14.6	4.5	2.15	1.46	<1	NA
celery seed	2.4 oz PPO/ft^3	125 F, 4 hours, 4	126	68.8 day 4	45.5	43.3	28.5	21.4	NA	474	161	124	62.5	NA	NA	15.7	6.36	4.67	NA	NA	NA
NUTMEATS																					
		Day	0	6	12/13	17/18	22	27	41/44	0	7	12/13	18	27/28	41/44	0	7	12/13	18	27/28	41/44
Almond	2.4 oz PPO/ft^3	52 C, 6 hours, 4	3580	1150	759	542	379	273	125	6.25	5.38	4.02	NA	3.04	4.88	11.9	9.24	4.26	NA	1.66	2.03
Pecan	2.4 oz PPO/ft^3	52 C, 6 hours, 4	3720	373	171	71.2	45.0	36.7	NA	22.8	NA	11.6	NA	8.22	NA	<1	<1	<1	<1	<1	<1
Walnut	2.4 oz PPO/ft^3	52 C, 6 hours, 4	1670	876	542	392	254	209	90.5	6.12	NA	9.42	8.43	7.42	7.79	4.73	NA	5.57	6.36	7.89	5.74
COCOA																					
		Day	0	2	6	12	22	30	40	0	2	6	12	22	40	0	2	6	12	22	40
cocoa powder		80 F, 48 hours, 1	221	136	69.2	27.7	9.55	5.86	3.84	13.4	12.5	9.41	4.93	6.16	4.68	10.5	9.62	8.53	4.27	4.84	3.11

Similar Spice Physiochemical Properties Allow for the Extrapolation of Available Data to Turmeric, Ginger, Capsicums, and Sesame

Spices and herbs share intrinsic properties that support the extrapolation of results from one commodity to another. Key intrinsic properties often shared amongst spice commodities include particle size, density, physical shape, water activity, type of plant, and product form. The physical parameters of a spice, namely density, water activity, and part of plant, are known to influence the efficacy of a microbial treatment modality and subsequent residues (where applicable). ASTA has published a guidance document on how the intrinsic physical factors of spices and process-related considerations can be extrapolated across spice types for the purpose of validating spice process controls, as well as available scientific literature (ASTA, 2022). On this basis, it is anticipated that the application of PPO to turmeric, ginger, capsicums, and sesame result in similar efficacy and residues as those outlined in Blinne & Koch (2001) and those expected for Crop Group 19 commodities.

The physical parameters and intrinsic properties of spices influence the penetration of PPO gas into the spice matrix, the uniformity of treatment, and contact time. The following tables demonstrate that the water activities and densities of the requested commodities are comparable to those commodities tested in Blinne & Koch (2001), as well as other spice commodities in Crop Group 19 for which PPO and PCH tolerances have been established.

The water activity of spices typically ranges from 0.3 to 0.65, as shown in Table 2, but can vary based on moisture content of the spice, temperature, humidity, and age.

The bulk density of spices typically ranges from 0.300-0.600 g/cm^3 (Table 3) but can vary based on moisture level, particle size (finely ground spices will have a higher bulk density compared to coarsely ground or whole spices), packing method, temperature, and age.

Table 2. Example water activity ranges of spices

Water Activity (a_w) Range	Spices
0.3 to 0.4	**Garlic, onion**, cumin, coriander, oregano powder, parsley
0.4 to 0.5	**Basil leaves,** basil powder, rosemary powder, **chili powder**, mustard, *paprika*, curry powder, allspice, oregano powder
0.5 to 0.6	**Black pepper**, cinnamon, nutmeg, *cayenne*, oregano leaves, mace, *turmeric, ginger*
0.6 to 0.65	Cloves

Bold: Commodities tested in PPO residue study (Blinne & Koch, 2001)
Italics: Commodities requested.

Table 3. Example densities of spices

Spice	Bulk Density (g/cm^3)	Particle Density (g/cm^3)	Data Source
White pepper	0.539	1.01	Ozturk et al., 2018
Black pepper	0.487	1.27	

Red pepper (capsicums)	0.423	1.07	
Paprika powder (capsicums)	0.438	1.21	
Curry powder	0.401	1.15	
Sesame Seed	0.481	-	ASTA, Personal Communication (September 26, 2023)
Turmeric Powder	0.352-0.400	-	
Ginger Powder	0.352-0.400	-	
Garlic Powder	0.481-0.545	-	
Onion Powder	0.481-0.545	-	
Celery Seed	0.529	-	

Bold: Commodities tested in PPO residue study (Blinne & Koch, 2001)
Italics: Commodities requested.

Capsicums

Capsicums (red pepper) generally refer to a variety of common pepper commodities, including cayenne pepper, paprika, chipotle pepper, jalapeno, and serrano pepper. Red pepper is derived from the fruit of *Capsicum* species. Capsicums are classified under Crop Group 8: Fruiting Vegetables. However, in their dehydrated forms, capsicums are used as spices similar to other dehydrated vegetables, including garlic powder, onion powder, turmeric powder, and ginger powder.

Different types of capsicums have relatively similar physiochemical properties. Bulk density can range from 0.423-0.438 (red pepper – paprika powder) (Table 3). Meanwhile, the water activities of capsicum commodities typically range from 0.4 to 0.6 (Table 2).

Chili powder (which is made from capsicums) was tested in the Blinne & Koch (2001) PPO residue study that served as the basis of the current PPO and PCH tolerances established for Crop Group 19. The study demonstrated that average PPO rapidly off-gassed from chili powder, resulting in a half-life of only 1.5 days. Provided that a capsicum commodity was directly examined in the original study that served as the basis for the establishment of tolerances on Crop Group 19, garlic powder, and onion powder, it would be appropriate to extrapolate the tolerances of 300 ppm for PPO, as well as the revised tolerances for the reaction products of PPO such as PCH per the 2021 interim decision, to capsicums.

Turmeric

Turmeric powder is made from the dehydrated rhizome of a flowering plant. Turmeric is classified under Crop Group 1: Root and Tuber Vegetables. In its dehydrated form, turmeric is utilized as a spice, similar to garlic powder and onion powder (Crop Group 3: Dehydrated Vegetables), ginger powder (Crop Group 1: Root and Tuber Vegetables), and capsicums (Crop Group 8: Fruiting Vegetables).

Turmeric powder has a water activity range similar to that of black pepper, cinnamon, nutmeg, cayenne, oregano, and mace (Table 2). Turmeric powder typically has a lower density (0.352-0.400 g/cm^3) than some other spices, which is conducive to penetration by PPO throughout the spice matrix, ensuring thorough treatment.

In Blinne and Koch (2001), three dehydrated vegetable products were tested – onion powder, garlic powder, and chili powder. It was concluded that PPO rapidly off-gassed from these products, with calculated half-lives of 4.5, 8.1, and 1.5 days, respectively.

Provided that the intrinsic properties of turmeric are in line with those of other spices and that two dehydrated vegetable commodities were included in the study that served as the basis of the tolerances for Crop Group 19, it would be appropriate to extrapolate the tolerances of 300 ppm for PPO, as well as the revised tolerances for the reaction products of PPO such as PCH per the 2021 interim decision, to turmeric.

<u>Ginger</u>

Ginger powder is made from the dehydrated rhizome of a flowering plant. Ginger is classified under Crop Group 1: Root and Tuber Vegetables. In its dehydrated form, ginger is utilized as a spice, similar to garlic powder and onion powder (Crop Group 3: Dehydrated Vegetables), turmeric powder (Crop Group 1: Root and Tuber Vegetables), and capsicums (Crop Group 8: Fruiting Vegetables).

Ginger is characterized by a water activity range similar to that of black pepper, cinnamon, nutmeg, cayenne, oregano, and mace (Table 2). Ginger powder typically has a lower density (0.352-0.400 g/cm^3) which is conducive to penetration by PPO throughout the spice matrix, ensuring thorough treatment.

In Blinne and Koch (2001), three dehydrated vegetable products were tested – onion powder, garlic powder, and chili powder. It was concluded that PPO rapidly off-gassed from these products, with calculated half-lives of 4.5, 8.1, and 1.5 days, respectively.

Provided that the intrinsic properties of ginger are in line with those of other spices and that two dehydrated vegetable commodities were included in the study that served as the basis of the tolerances for Crop Group 19, it would be appropriate to extrapolate the tolerances of 300 ppm for PPO, as well as the revised tolerances for the reaction products of PPO such as PCH per the 2021 interim decision, to ginger.

<u>Sesame</u>

Sesame seed is an oilseed that has a high essential oil content. Seed spices vary in size and shape, essential oil content, and physical appearance. However, they are typically relatively dense compared to some other spices such as ground cinnamon or paprika. Other seed spices for which a PPO tolerance has been established include anise seed, celery seed, dill seed, fennel seed, lovage seed, mustard seed, and poppy seed. Although these commodities are distinct, spices derived from the same part of plant are likely to have similar characteristics, such as density.

In Blinne & Koch (2001), residues of PPO in celery seed were examined. It was concluded that PPO rapidly off-gassed from celery seed, with a calculated half-life of 7.1 days. This data was considered sufficient to support the establishment of a tolerance in a variety of seed spices contained within Crop Group 19. Given that sesame is also a seed that is likely to share similar intrinsic properties, it would also be appropriate to extrapolate the data and subsequent tolerance of 300 ppm for PPO, as well as the revised tolerances for the reaction products of PPO such as PCH per the 2021 interim decision, to sesame.

It is important to note that this proposal is limited to sesame seed used as a spice/seasoning. Sesame seeds used for the production of sesame oil undergo separate processing that does not require microbial reduction. As such, the application of PPO to sesame used in oil production is not necessary.

Dietary Risk Assessment Implications

In EPA's 2021 interim decision for PPO, no dietary assessment was conducted for PPO as residues are not expected in surface water or groundwater based on its registered uses. However, a quantitative risk assessment was conducted for PCH, a reaction product between PPO and chloride ions present in treated commodities. Acute and chronic exposure estimates were below 100% of their respective population adjusted doses; as such, no dietary risks of concern were identified for PCH. Moreover, no dietary cancer risks of concern were identified for PPO or PCH (EPA, 2021). It is not anticipated that the establishment of tolerances on turmeric, ginger, capsicums, or sesame will result in significant changes to the exposure or dietary risk assessments.

Proposed Solution

Based on (1) EPA's previous precedent allowing for the establishment of EtO tolerances on dried vegetables to cover key spices excluded from crop group 19 and (2) existing tolerance data on commodities that share similar intrinsic physical parameters that support the extrapolation of results to the highlighted commodities, we are proposing to translate the aforementioned residue data to establish tolerances of 300 ppm for residues of PPO in turmeric, ginger, capsicums, and sesame seed.

Deviation from Guideline

A waiver is requested from OCSPP Residue Chemical Test Guideline 860.1500 to allow use of existing residue data on various spice commodities to establish tolerances for residues of propylene oxide in turmeric, ginger, capsicum, and sesame seed.

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