DOCKET NO. EPA–HQ–OA–2017–0190

BEFORE

THE UNITED STATES OF AMERICA

ENVIRONMENTAL PROTECTION AGENCY

COMMENTS OF THE

AMERICAN HERBAL PRODUCTS ASSOCIATION

ON

EPA's Request for Comments on Evaluation of Existing Regulations

May 15, 2017

Table of Contents

Prefatory remarks

The American Herbal Products Association (AHPA) is the national trade association and voice of the herbal products industry. AHPA members include domestic and foreign companies doing business as manufacturers and marketers of herbs and herbal products, as well as non-herbal products, including conventional foods and dietary supplements. AHPA serves its members by promoting the responsible commerce of herbal and non-herbal products including conventional human foods and dietary supplements.

On April 13, 2017, the Environmental Protection Agency (EPA or the Agency) published a Federal Register notice[1] in which the Agency invited input on EPA regulations that may be appropriate for repeal, replacement, or modification (the April 13 Notice). The April 13 Notice explains that the request for input was issued in accordance with Executive Order 13777, "Enforcing the Regulatory Reform Agenda," which established a federal policy "to alleviate unnecessary regulatory burdens" on the American people, and which, in its Section 3(a), directs federal agencies to establish a Regulatory Reform Task Force (Task Force) with duties to evaluate existing regulations, including by seeking input and other assistance, as permitted by law, from entities significantly affected by Federal regulations, and "make recommendations to the agency head regarding their repeal, replacement, or modification."

AHPA members manufacture and market conventional foods, dietary supplements and other consumer products that contain herbal ingredients. These ingredients are all potentially affected by EPA regulations on pesticide tolerances as established for all agricultural crops, including herbal crops, whether produced domestically or imported from foreign suppliers. These comments are submitted on behalf of AHPA and its members and address primarily, but not exclusively, those EPA regulations related to pesticides.

[1] 82 FR 17793; Docket No. EPA–HQ–OA–2017–0190.

Executive summary

1. AHPA supports EPA completion and expansion of Crop Group 19

   Virtually all herbal crops are specialty or minor crops for which it is economically unfeasible to develop the data necessary for crop-by-crop registration. EPA has efforts currently underway to review and revise existing crop groups and to add new crop groups as necessary, particularly with respect to Crop Group 19 (herbs and spices). EPA should prioritize completion of this work on Crop Group 19. Furthermore, EPA should consider adding to Crop Group 19 (or other appropriate crop group) each of the herbal crops identified by AHPA in its 2013 correspondence to EPA and IR-4, and additional herbal crops found through other sources to be commercially available in the U.S.

2. EPA should create exceptions for unavoidable, inadvertent pesticide residues

   Pesticide residues are currently ubiquitous in the environment and are routinely found at significant levels even in locations as remote as the Arctic circle. In addition, analytical technologies can now detect pesticides down to the 10 ppb level. As a result, traces of pesticides are commonly found in many food crops even when not the result of direct application, spray drift, or inappropriate crop rotation. EPA should use its authority under the Food Quality Protection Act (FQPA) to except trace levels of these substances from the definition of “pesticide chemical” or “pesticide chemical residue.”

   Rather than regulating these traces as adulterants under EPA’s “zero tolerance” policy, these traces should be controlled as contaminants regulated by FDA under good manufacturing practices for food. FDA should set appropriate action levels for these contaminants as it has done for other types of pesticides. In general, an action level of 0.1 ppm would be protective of public health and consistent with documented levels of unavoidable, inadvertent pesticide contamination. Lower action levels may be appropriate for substances of unusually high toxicity or whose toxicity is unknown.

3. EPA should create general tolerances for pesticides intentionally applied in foreign countries

With respect to pesticides that occur in a food because of intentional and legal application to the crop, whether in the U.S. or in a foreign country, EPA policies should establish a mechanism to create default tolerances which would apply to "all other crops" when (but only when) a pesticide is registered in the U.S. for use on one or more food crops or when an import tolerance has been established for that pesticide. The default tolerance for any food in the "all other crops" category should be calculated, based on the expected annual consumption of the food, to result in an exposure that is trivial (say, 100x lower) compared to the exposures that EPA knows will result from the use of the pesticide as registered in the U.S.

4. General tolerances for foods that form a trivial part of the diet

As an alternative to 2 and 3 above, EPA can use existing residue monitoring data in conjunction with "worst-case" safety data to establish a single tolerance level that would safely cover numerous pesticides on a wide variety of foods that form a trivial part of the diet. For example, EPA could issue a regulation that sets a tolerance of 0.1 ppm for residues on all foods in Crop Group 19 (herbs and spices). If the Agency had risk concerns about some pesticides these substances could be excluded from the regulation.

5. Use of Codex Alimentarius Commission MRLs and scientific evaluations

EPA should consider utilizing FQPA Section 405 that directs EPA to consider harmonization of tolerances with Maximum Residue Levels (MRLs) established by the Codex Alimentarius Commission. The scientific evaluations to support these MRLs have already been conducted and should be available to the Agency. Utilizing these evaluations conducted by a peer scientific body would save both EPA and industry significant resources.

6. Regulations to protect the environment reduce costs and burdens on the food industry

> To comply with state and federal laws and regulations, food companies rely on the availability of raw agricultural commodities that are not contaminated with excessive levels of environmental pollutants. This in turn requires that clean air, water, and soil be available for the production of food crops. EPA should be cautious about relaxing regulations if doing so may increase environmental pollution with heavy metals, industrial contaminants, or other hazardous substances.

Detailed discussions of each of the points identified in this executive summary are provided below.

Use of Crop Groups should be expanded

A crop grouping system for purposes of pesticide regulation was established in 1962, and has been maintained and amended from time-to-time in the interim. The crop grouping regulations at 40 CFR §§ 180.40 and 180.41 enable the establishment of tolerances for specifically identified pesticides for a group of crops based on residue data for certain crops that are representative of the group, and establishes the maximum level of residue of the pesticide that could occur on any crop within the group. The system was established with the realization that the expense and time investment for fulfilling the residue data requirements established under EPA's regulations are limiting factors in making pesticide licensing and tolerance decisions for minor and specialty crops, and may preclude a registrant from petitioning the Agency for an individual tolerance for that use.

In AHPA's view, all or virtually all herbal crops are, in fact, specialty or minor crops. As such, they are seldom the subject of attempts by pesticide chemical producers to establish a pesticide tolerance solely and specifically for an individual herbal crop. Inclusion of herbal crops in EPA regulatory crop groups is therefore essential to ensure that pesticide use on herbal crops, when needed, is carried out in compliance with EPA's pesticide regulations.

AHPA understands and appreciates that EPA has an ongoing program, initiated in 2007 and in coordination with IR-4 (Interregional Research Project No. 4), to amend existing crop group regulations.[2] This process includes not only reorganization of existing crop groups but also creation of new crop groups and addition of crops not previously included in any crop group. Any regulatory amendment that adds new crops to a crop group ***reduces*** mandatory paperwork requirements under EPA's pesticide regulations, due to a reduction in required studies as compared to establishing pesticide tolerances for crops on an individual crop-by-crop basis, and provides regulatory relief and regulatory flexibility because the new or expanded crop groups ease the process for pesticide manufacturers to obtain pesticide tolerances on greater numbers of crops, particularly specialty crops.

Importantly, EPA asserts that revisions to crop groups result in no appreciable costs or negative impacts to consumers, minor crop producers, pesticide registrants, the environment, or human health. EPA has in fact identified each of its recent proposed regulatory amendments to crop groups as a "burden-reducing" regulation. AHPA agrees with EPA's view that each of these amendments has, in fact, been burden-reducing, and therefore encourages additional use by EPA of this amendment process to crop groups. AHPA also agrees, as EPA has stated in each of these recent proposed amendments to crop groups, that important beneficiaries of such amendments are minor crop producers, who benefit because lower registration costs will encourage more products to be registered on minor crops, and so providing additional tools for pest control; and consumers, who benefit by having more affordable and abundant food products available. AHPA notes, however, that food processors, importers, and distributors are additional beneficiaries, as these crop group expansions reduce the business disruptions that occur when foods are refused entry to the U.S. or are rejected from use or sale due to detections of pesticides that are not in fact unsafe.

[2] See for example the proposed rule at 72 FR 28920 (May 23, 2007) as finalized at 72 FR 69150 (December 7, 2007); the proposed rule at 75 FR 807 (January 6, 2010) as finalized at 75 FR 76284 (December 8, 2010); 76 FR 69693 (November 9, 2011) as finalized at 77 FR 50617 (August 22, 2012); and 79 FR 68153 (November 14, 2014) as finalized at 81 FR 26471 (May 3, 2016).

AHPA therefore strongly encourages EPA to continue its process of reviewing and revising existing crop groups and adding new crop groups as necessary. AHPA recommends this process be carried out in a way that expands the applicability of the crop groups to as many specialty and minor crops, including herbal crops, as possible, and believes such expansive utilization of the crop group regulations will maximize the potential burden-reducing effect of such regulatory amendments with no appreciable costs or negative impacts to consumers, minor crop producers, pesticide registrants, the environment, or human health.

AHPA has a more specific interest in Crop Group 19, “Herbs and Spices.” AHPA submitted information to EPA and IR-4 in May 2013 that identified just under two hundred commercially available herbal crops not currently included in Crop Group 19. AHPA understood at that time that IR-4 would be making recommendations to amend this crop group, and AHPA’s May 2013 correspondence requested that the identified herbal crops be recommended to be added to this crop group when it is next revised. AHPA continues to believe that Crop Group 19 should be revised to add many additional herb and spice crops, and believes amendment to this crop group, if done in a manner that adds a significant number of commercially available herb and spice crops, will result in a burden-reducing regulation. AHPA therefore requests EPA give prompt attention to reviewing and revising Crop Group 19, and give serious consideration to adding each of the herbal crops identified by AHPA in its 2013 correspondence to EPA and IR-4, and additional herbal crops found through other sources to be commercially available in the U.S.

Recently, EPA staff informed AHPA that a final regulation amending Crop Group 19 is slated for 2018. AHPA strongly believes that the amended crop grouping will reduce regulatory burdens and be economically beneficial. Accordingly, we urge the Agency to make issuance of the final regulation a priority.

EPA should streamline processes and use innovative approaches to relieve impractical regulatory burdens

Under current EPA policy, no detectable residue of a pesticide chemical is permitted on a food crop unless a tolerance or tolerance exemption has been established. As a result, any raw agricultural commodity or processed food is adulterated if it contains detectable traces of a pesticide for which no tolerance (or tolerance exemption) has been established by EPA for that crop or crop group; this is hereinafter referred to as the US "zero tolerance" policy for pesticides.

In the real world, however, it is becoming increasingly common that pesticide residues occur in or on foods for which there is no tolerance or tolerance exemption.[3] This is due in part to the increasingly internationalized food supply; foreign countries often have pesticides approved for use on food crops that are not approved in the U.S., either because the crop is not grown at all in the U.S. and hence has never been registered with EPA, or because the pests and other agricultural circumstances in the foreign country necessitate different controls from what is effective in the U.S. In addition, many detections of trace pesticides are due to the ubiquitous worldwide occurrence of pesticide contamination in soil, water, and air[4] and to dramatic improvements in analytical technologies, which can now routinely detect pesticide residues down to the 10 ppb range.

[3] For example, monitoring by the USDA in 2015 found that 73% of the tested samples contained traces of multiple pesticides, and hundreds of samples were found with pesticides for which no tolerance exists for the pesticide/crop combination. (USDA Pesticide Data Program Annual Summary, Calendar Year 2015.) In addition, AHPA members report that traces of pesticides can be found even in crops grown without chemical inputs in remote locations far from agricultural and industrial centers.

[4] Numerous studies have been conducted on ice core samples, plants, fish, etc. in locations as remote as the Arctic Circle or the Tibetan plateau, and these routinely detect measurable and sometimes quite significant levels of pesticide contamination. See for example, (a) Hoferkamp et al, "Current use pesticides in Arctic media: 2000-2007," *Sci. of the Total Environ.* 406 (2010) 2985-2994; (b) Yang et al, "Accumulation features of organochlorine pesticides and heavy metals in fish from high mountain lakes and Lhasa River in the Tibetan plateau," *Environ. Internat.* 33 (2007) 151-156; (c) Wang et al, "Passive air sampling of organochlorine pesticides, polychlorinated biphenyls, and polybrominated diphenyl ethers across the Tibetan plateau," *Environ. Sci. Technol*. 44 (2010) 2988-2993; (d) Yang et al, "Distribution of organochlorine pesticides (OCPs) in conifer needles in the southeast Tibetan plateau," *Environ. Pollut.* 153 (2008) 92-100; (e) Ruggirello et al, "Current use and legacy pesticide deposition to ice caps on Svalbard, Norway," *J. Geophys. Res. Atmosph.*115 (2010) D18308; etc.

As a result, there is a significant disconnect between the occurrence of detectable pesticide residues on foods with no associated tolerance or tolerance exemption and the technical requirements of the existing enforcement policies. While regulators have taken a few steps to deal with this problem around the margins – for example, FDA has established "action levels" for certain persistent "unavoidable pesticide residues" in certain foods[5] – no comprehensive solution has been implemented.

The discrepancy between the requirements of the zero tolerance policy and the reality of widespread pesticide use and trace contamination has been causing problems in the food industry for decades. As long ago as 1988, farmers in California petitioned EPA to establish exemptions from tolerance requirements for pesticides occurring at trace levels due to inadvertent ambient contamination. The California Department of Food and Agriculture provided field study data supporting the petition, which showed that the trace levels were indeed unavoidable and inadvertent, due to widespread pesticide use in the San Joaquin Valley.[6] EPA has never acted on this petition.

Furthermore, FDA has for many years conducted pesticide monitoring of the food supply and routinely finds, in a variety of imported and domestic foods, traces of pesticides for which no tolerance exists. When found in food offered for import, the affected shipment is refused entry to the U.S.[7] and the responsible firm may be placed under an Import Alert; when found in domestic food, FDA has the authority to issue Warning Letters and to invoke other sanctions such as seizure to remove the food from commerce, or injunction to correct the cause of the violation. In addition, any person who introduces into interstate commerce a food adulterated with pesticides is subject to civil money penalties of up to $50,000 for individuals and

[5] Compliance Policy Guides Sec. 575.100 "Pesticide Residues in Food and Feed – Enforcement Criteria," FDA.

[6] Turner et al, "A field study of fog and dry deposition as sources of inadvertent pesticide residues on row crops," California Department of Food and Agriculture, Report No. 89-11, November 1989.

[7] Such refusal of shipments can cause significant disruptions to U.S. food processors and/or distributors, as well as their downstream customers, who were relying on successful importation of the food in question.

$250,000 for other persons, not to exceed $500,000 for all such violations adjudicated in a single proceeding.[8]

The food industry's pesticide-related difficulties are set to expand dramatically with the enforcement of new regulations under the Food Safety Modernization Act (FSMA). These regulations require food facility operators to conduct hazard analyses which must consider, among other things, chemical hazards including pesticide residues, whether intentionally or unintentionally introduced.[9] Other regulations require dietary supplement manufacturers to control for contaminants that may adulterate their products, which often includes pesticides.[10] U.S. food manufacturers and distributors report difficulties in finding needed raw agricultural commodities that meet the requirements of the zero tolerance policy.

In addition, EPA's current approach to pesticide regulation creates tremendous burdens both for the Agency and for pesticide manufacturers. Under the current framework, a tolerance is established for a single active ingredient on a specific crop or crop group. In addition, EPA's data requirements typically require that extensive and costly residue data from crop field trials be collected to support a tolerance. From a cost, timing and risk standpoint, this approach may be feasible and scientifically sound for major food crops, such as corn, soybeans, and alfalfa, that form a significant part of human or animal diets in the U.S. But for minor or specialty food crops, or for crops grown overseas that are not exported in high volumes to the U.S., the existing framework is simply cost-prohibitive and regulatory overkill. In many cases, residues are inadvertent so there is no incentive to conduct residue trials. Even in situations where residues occur through intentional use, the amount of use and the value of the food crop (or, for crops grown in foreign jurisdictions, the amount of the crop exported to the U.S.) cannot support the high cost of residue trials for EPA registration. Furthermore, the burden of submitting separate petitions for each pesticide residue is enormous.

[8] 21 U.S.C. 333 (f)(2)(A).

[9] 21 CFR 117.130.

[10] 21 CFR 111.70.

In light of the above, AHPA believes there are some practical, cost-effective and innovative approaches EPA can adopt to address the issue of inadvertent and intentional residues that may occur in or on foods.

The Food Quality Protection Act (FQPA) of 1996 provided EPA with a variety of tools to remedy these difficulties. For example, FQPA Section 402 gives EPA the authority to except substances from the definition of "pesticide chemical" or "pesticide chemical residue" under certain circumstances. In addition, FQPA Section 405 gives EPA the authority to take the initiative in establishing or modifying tolerances for pesticide chemical residues in or on a food, as well as in establishing or modifying exemptions from the requirement for a tolerance for a pesticide chemical residue on or in a food.[11]

FQPA requires EPA to evaluate the safety risks associated with each pesticide chemical and to ensure that tolerances and exemptions will, with reasonable certainty, not result in any harm from the aggregate exposure to the pesticide in question. EPA has adopted the concept of a "risk cup" which represents the total level of acceptable risk from a pesticide and corresponds to the pesticide's "Reference Dose," which is the level of exposure a person could receive every day without significant health risk. The risk cup evaluation considers both dietary exposures (based on data from U.S. pesticide registrations and from monitoring by USDA and FDA) and certain non-dietary exposures.

However, EPA's risk cup evaluations ignore the existence of dietary exposures for which EPA does not have reliable data, as may occur with pesticides not registered in the U.S. or any pesticide/crop combination that is not well represented in USDA and FDA pesticide monitoring programs.

AHPA notes that, whether or not EPA has data about these dietary exposures and whether or not EPA includes these exposures in its risk assessments, the exposures nevertheless currently occur and in fact have occurred for decades. It is unreasonable and illogical to pretend that such exposures either do not exist or can

[11] FQPA Section 405, which created 21 U.S.C. 346a (b) and (c).

be eliminated by an arbitrary requirement for the food industry to avoid any food ingredient contaminated with traces of pesticides.

Furthermore, AHPA notes that an incremental exposure due to trace contamination in the food supply presents extremely low safety risks, because trace exposures are much smaller than exposures for common foods consumed in much larger daily quantities. In addition, the risk assessments conducted by EPA are necessarily rife with assumptions, many of which serve to overestimate the risk; for example, EPA routinely includes a 10x safety factor based on the requirements of FQPA with respect to infants and children, even though many foods are not consumed by infants or children.[12]

AHPA therefore urges EPA to avail itself of the full range of its authority and to create rational policies for trace levels of pesticide residues in foods.

a. Exceptions for unavoidable pesticide traces

With respect to pesticide traces caused by the ubiquitous distribution of pesticides in the environment, AHPA understands the difficulty EPA faces to account for these types of exposures in the context of its "risk cup" paradigm. However, Congress in passing FQPA provided EPA with the tools necessary to solve this problem. Specifically, Section 402 of FQPA provides that EPA may by regulation except a substance from the definition of "pesticide chemical" or "pesticide chemical residue" if (a) its occurrence in a raw agricultural commodity or processed food is attributable primarily to natural causes or to human activities not involving the use of any substances for a pesticidal purpose in the production, storage, processing, or transportation of any raw agricultural commodity or processed food, and (b) EPA consults with FDA and determines that the substance more appropriately should be regulated under a different provision of food law.[13]

[12] For example, many dietary supplements are labeled for adult use only, and many conventional foods are not fed to children due to taste, expense, and other factors.

[13] 21 U.S.C. 321 (q)(3).

AHPA believes that *de minimis* levels of pesticide residues resulting from the globally ubiquitous presence of pesticides in the environment qualify as "naturally occurring" insofar as they are widely distributed by natural atmospheric and hydrologic activities. Furthermore, insofar as they are not the result of direct application to the crop in question, careless spray drift, or inappropriate crop rotation, they are not the result of human activity using the substance for a pesticidal purpose in the production, storage, processing, or transportation of any raw agricultural commodity or processed food. Therefore, EPA has the authority to exclude these substances from the definition of "pesticide chemical" or "pesticide chemical residue."

This will formalize in regulation what is already EPA's existing practice, which is to largely ignore the contribution of these pesticide traces in EPA's risk assessment activities, particularly for the wide range of pesticide/crop combinations that are not registered in the U.S. and are not picked up through USDA and FDA monitoring. Rather than regulating these substances as adulterants under EPA's zero tolerance policy, they should be regulated by FDA as contaminants and controlled through enforcement of 21 CFR Parts 117 and 111. As with other forms of unavoidable pesticide contaminants, FDA can set an appropriate general action level that is both practical for industry and protective of public health; AHPA suggests the 0.1 ppm default tolerance used in Canada.[14]

AHPA believes a threshold of 0.1 ppm would be appropriate for two reasons.

(1) It is protective of public health because it is far below the tolerances established for many pesticides in many foods. For example, carbaryl, 1-naphthyl *N*-methylcarbamate has established tolerances of up to 10 ppm in pome fruits, 10-22 ppm in leafy greens, cabbage, and spinach, and up to 215 ppm in animal foods such as alfalfa hay or corn stover;[15] and malathion has established tolerances for up to 8 ppm in many foods and up to 135 ppm in

[14] "Pesticides and MRLs in Canada," USDA Foreign Agricultural Service, 2015.

[15] 40 CFR § 180.169.

animal foods.[16] If certain pesticides are significantly more toxic than most, or have toxicological properties unknown to EPA, a lower general action level could be established for those pesticides.

(2) It is consistent with the lower end of the levels of unavoidable, inadvertent contamination found in the 1989 California field study. For example, that study found unavoidable, inadvertent levels of parathion, diazinon, chlorpyrifos, and methidathion in food crops that were generally under 0.5 ppm (with a few much higher data points), but the majority of data points were approximately 0.1 ppm or less. Thus, a threshold of 0.1 ppm should enable food firms to source ingredients that comply with the requirements.

b. General tolerances for intentionally applied pesticides

With respect to pesticides that occur in a food because of intentional and legal application to the crop, whether in the U.S. or in a foreign country, EPA policies should establish a mechanism to create default tolerances which would apply to "all other crops" whenever a pesticide is registered in the U.S. for use on one or more food crops or when an import tolerance has been established. The default tolerance for any food in the "all other crops" category should be calculated, based on the expected annual consumption of the food, to result in an exposure that is trivial (say, 100x lower) compared to the exposures that EPA knows will result from the use of the pesticide as registered in the U.S.[17]

Although this would mean many foods will still be illegal for sale in the U.S. due to the presence of pesticides which have no U.S. registration (i.e., no registration or tolerance established for any use on any crop in domestic cultivation), at least foods would not be precluded from import, use, or sale merely due to the

[16] 40 CFR § 180.111.

[17] In other words, the default tolerance would not be a single number applicable to all foods, but rather would be calculated for each food depending on the expected consumption of that food, as determined either by the directions for use in the food labeling or on other data such as USDA dietary surveys.

presence of trivial levels of those pesticides for which tolerances have been established and that Americans may therefore already consume in much larger quantities from other sources. This will make it easier for food firms to source compliant raw materials, especially for specialty or minor crops which are the most likely to lack an established U.S. tolerance on a crop-specific basis, while also protecting the public health.

c. General tolerances for foods that form a trivial part of the diet

As an alternative to (a) and (b) above, AHPA believes EPA can use existing residue monitoring data in conjunction with "worst-case" safety data to establish a single tolerance level that would safely cover numerous pesticides on a wide variety of foods that form a trivial part of the diet.[18] For example, EPA could issue a regulation that sets a tolerance of 0.1 ppm for residues on all foods in Crop Group 19 (herbs and spices). If the Agency had special risk concerns about some pesticides these substances could be excluded from the regulation.

d. Use of Codex Alimentarius Commission MRLs and scientific evaluations

EPA should also consider utilizing FQPA Section 405 that directs EPA to consider harmonization of tolerances with Maximum Residue Levels (MRLs) established by the Codex Alimentarius Commission. The scientific evaluations to support these MRLs have already been conducted and should be available to the Agency.

[18] For example, EPA has informed AHPA and its advisors that the Agency has on several occasions developed "back of the envelope" risk assessments of the safety of consuming foods that are consumed only in small quantities and contain pesticide residues above the zero tolerance threshold. EPA's risk assessments assumed that the highest residue of a pesticide found in any analyzed sample was present on all of that food in commerce, a conservative assumption that previous experience indicates may overstate risk significantly - by an order of magnitude and often more. Nevertheless, these assessments have always found that the dietary risks from consuming the food in question were very low, as a result of the fact that the food represents only a small portion of the diet for the large percentage of the population.

Utilizing these evaluations conducted by a peer scientific body would save EPA and industry significant resources.

The approaches outlined above would significantly reduce burdens on the food industry as well as costs and review times borne by EPA and pesticide manufacturers, and would not involve any significant increase in risks to consumers. Under these approaches, EPA would often need to issue only one or a few regulations instead of the multitude of regulations necessary under the current framework. By adopting these approaches, the regulatory savings would be immense.

EPA environmental regulations reduce certain business expenses

AHPA assumes EPA will receive comments in response to the April 13 Notice to request or recommend the Agency repeal, replace or modify certain regulations relevant to controlling sources of environmental pollution. For example, some of the regulations targeted by comments may currently limit release into the environment of heavy metals, such as lead and mercury; industrial waste or by products; or other contaminants that are likely to become widely dispersed in the environment and thereby make their way into the food supply.

Food companies are required by law and regulation to ensure the foods they process and distribute are safe for consumption and to prevent, control, or minimize the occurrence of hazards and potential adulterants.[19] As such, food companies rely on the availability of raw agricultural commodities that are not contaminated with excessive levels of environmental pollutants. This in turn requires that clean air, water, and soil be available for the production of food crops.

AHPA is supportive of regulatory agencies, including EPA, establishing regulations that are reasonable and that seek to minimize economic burdens on U.S. domestic businesses while simultaneously achieving regulatory goals or statutory

[19] Food Safety Modernization Act; 21 CFR Part 117; 21 CFR Part 111; etc.

requirements. However, AHPA is simultaneously concerned that appropriate regulations be maintained to minimize environmental contamination and avoid disruptions to food companies, as well as to preserve environmental and human health generally.

Food companies already experience significant burdens and costs associated with environmental contamination. In the context of good manufacturing practices under 21 CFR Parts 117 and 111, the costs associated with testing for contaminants such as pesticides, heavy metals, and radiation run to at least hundreds and sometimes thousands of dollars per shipment or batch. These costs multiply quickly whenever noncompliant test results are found; for example, if a manufacturing raw material does not meet its specifications it must be rejected (with corresponding cost to the grower or vendor) and production must be delayed (which often results in lost sales both to the manufacturer and to downstream distributors and retailers) while new material is sourced and tested.

But even once the food product is manufactured, the costs and burdens can mount after the product reaches the marketplace. For example, California's Proposition 65 (formally the Safe Drinking Water and Toxic Enforcement Act of 1986) requires warnings to be provided for exposure to any of the chemicals identified by the state as carcinogens of reproductive toxins, and lead, mercury and other heavy metals, as well as other environmental contaminants, are included in the state's list of such chemicals. Because enforcement of this law is allowed by "private" enforcers, an industry has arisen in the state over the last 30 years made up of organizations that seek to identify purported exposures that lack warnings and that then proceed to file legal complaints and to exact payment of penalties and other settlements to resolve these.[20]

There are some private enforcers of Proposition 65 that specialize in bringing legal actions against companies that sell foods, based in particular on allegations of exposure to lead and sometimes mercury and other heavy metals. According to records maintained by the state, settlement costs were recorded in the two-year

[20] Most companies choose to settle with the plaintiffs, even if the firm does not agree that the suit has a legitimate basis, rather than face the extremely high expenses of a court battle.

period 2015-2016 in excess of $11 million to resolve legal actions brought by just one of these private enforcers. This amount includes only publicly available information, and so does not include whatever costs were incurred by settling companies for their own legal expenses.

Most of these millions of dollars have been paid by small companies, and none of these were alleged to have deliberately included or added lead or other heavy metals in their manufacturing processes. Rather, these compounds can be assumed to have been present in the relevant products due to their presence in the environment – i.e., in the air, soil, or water in which the raw agricultural commodities were grown. Thus, any reduction in EPA's controls on heavy metal pollution can be reasonably assumed to be liable to cause economic harm to companies that sell foods in California.

AHPA therefore requests EPA give attention to the potential negative and direct economic harm that may be incurred by industry, especially small businesses, as it considers any comments received in response to the April 13 Notice that suggest any reduction in the Agency's regulations that may increase environmental pollution with heavy metals, industrial contaminants, or other hazardous substances.

Closing

AHPA greatly appreciates the opportunity to present comments on this matter. AHPA staff and counsel will make themselves available at any mutually convenient time to further address any of the topics addressed herein. Please feel free to contact us if clarification or additional discussion is needed on the issues raised in these comments.

Respectfully submitted,

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