A Roundtable on Moving Closer to Zero: Challenges and Opportunities for Reducing Children's Exposures to Toxic Elements from Foods

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ABSTRACT

Continual improvement in the safety of the food supply should be an ongoing goal for society. In 2021, the U.S. Food and Drug Administration announced Closer to Zero, an action plan to reduce exposures to lead, arsenic, cadmium, and mercury from foods commonly consumed by babies and young children to the lowest extent feasible. A roundtable presented at the International Association for Food Protection 2022 Annual Meeting brought together the collective knowledge and experience of panelists from industry, consumer advocacy, and government to discuss this complex and multifaceted initiative. Here, we summarize the panel's perspectives on the challenges and opportunities for reducing dietary exposures and the engaging dialogues between the audience and the panel on topics such as analytical methods, data sharing, building trust in the process, frequency of revisiting action levels, communication and outreach, addressing misconceptions, pros and cons of economic incentives, and setting different action levels for foods intended for children. Discussions included components of an iterative approach for continual improvement over time, including analytical methodology, reducing plant uptake, collecting data to better understand the distribution of toxic elements, finding common ground among all stakeholders, and communications that make a difference. The roundtable identified several paths forward for this effort at continual improvement.

OVERVIEW

The United States continues to have one of the safest food supplies in the world. Fresh produce is available throughout the year, and risk-based food safety management, including food preservation techniques, to protect safety and quality are commonplace. Continually advancing the safety of the food supply should always be the goal, and opportunities for improvement are constantly being considered.

Mitigating the presence of lead, arsenic, cadmium, and mercury in the food supply is complex and multifaceted. These contaminants are naturally occurring in the environment and are taken up by crops. The concentrations of these contaminants in the environment have increased because of human activities over decades or centuries, enhancing potential uptake by crops. The resulting dietary exposures to these contaminants can affect human health, including child development. Thus, reducing levels in foods, especially those consumed by babies and young children, presents an important public health opportunity yet can pose challenges for government, industry, and consumers.

In April 2021, the U.S. Food and Drug Administration (FDA) announced Closer to Zero (C2Z), an action plan to reduce exposures to these contaminants from foods commonly consumed by babies and young children to the lowest extent feasible *(7)*. C2Z implements a science-based, iterative approach for achieving continual improvement over time. The effort draws upon a range of scientific disciplines and gathers data and input from a range of stakeholder perspectives as it develops reference levels of dietary exposure to these contaminants from foods, proposes action levels for foods, and assesses achievability for meeting action levels and feasibility to further reduce levels of contaminants. Beyond food safety and toxicology, the C2Z approach considers nutritional needs during pregnancy and early childhood development, including those of the Dietary Guidelines for Americans *(4)*, to better understand the role of nutrition in protecting consumers from potentially risky exposures and modulating adverse health effects from children's exposures to toxic elements.

At the International Association for Food Protection (IAFP) 2022 Annual Meeting, we conducted a roundtable that brought our collective knowledge and experience from industry (both agriculture and manufacturing), consumer advocacy, and government to discuss the various aspects of the C2Z initiative to highlight the challenges and opportunities for reducing exposures among the very young. Here, as panel members and convenors, we

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summarize the panel's perspectives on the C2Z initiative and the impact on our respective organizations, as well as questions and comments from the audience and engaging dialogues and discussions during the session, on this complex, multifaceted issue.

KEY CHALLENGES AND OPPORTUNITIES PRESENTED BY THE PANEL: RESPONSES TO THE OVERARCHING DIRECTION

To start the roundtable, an overarching direction was given to each of the panelists:

While we all agree that reducing exposures to toxic elements from foods, especially for infants and young children, is an important initiative, please briefly discuss the challenges and opportunities from your perspective of the Closer to Zero initiative and impact on your respective organizations. Each panelist was asked to pick what they think are the biggest challenge and opportunity.

Each panelist took several minutes to share their thoughts from their respective perspectives. In the spirit of summary without attribution, this section summarizes the overall, and somewhat varied, approaches to this question.

Despite their significantly different backgrounds and experiences in chemicals and food safety, all panelists had similar comments in several areas. All panelists agreed that reducing exposures to toxic elements, especially lead and arsenic, given available information, is an important goal and applauded FDA for taking action. The panelists expressed similar rationale for considering this an important goal, but each panelist had various data points on which they based this conclusion. For example, one panelist noted the significant cost (in billions of dollars) from lost productivity that may be associated with reduced mental acuity because of exposure to lead, to which diet is a contributing factor. Other panelists focused on food security, affordability, and access to equally nutritious food across our population. Regardless of the perspective, panelists reported that this is an important initiative and supported the dedication of societal resources to move toward a solution. The panelists all recognized that this represents an important opportunity for all stakeholders in the food system to make a difference.

All panelists emphasized that this is a challenging situation that would not be easily solved but acknowledged that it needs to be tackled. Panelists also agreed that the goal is continual improvement, but they began to diverge on what could be achieved by when. Some panelists were confident that a focus by FDA on the subject will make a difference, whereas other panelists were more hesitant to suggest significant reduction is likely if we are to maintain access to affordable and nutritious food. Other panelists discussed the importance of more research, especially the importance of dependable methods resulting in a true baseline from which to measure success. Most panelists agreed that confidence in the data and methods to determine concentrations of toxic elements in food is critical. To that point, one panelist noted that a difference of 5 ppb of lead between two samples may be within the analytical variation of a method and that this should be considered when making decisions. Other panelists brought up the importance of research, including new processing and growing techniques, and ensuring we truly understand the challenges of the current situation to sufficiently approach new efforts at mitigating the presence of toxic compounds in food. Some panelists focused more on ensuring adequate understanding of potential unintended consequences before being too quick to implement mitigation strategies. For example, one panelist raised the possibility that efforts to reduce toxic elements could also reduce essential elements or create changes in food that reduce the absorption of nutrients. Other panelists focused on the importance of ensuring that mitigation strategies are practical and implementable and that they do not significantly affect the cost of food. Panelists generally agreed in their comments that making changes too quickly without understanding potential unintended consequences could negatively affect the availability and nutritional content of the food supply. Everyone acknowledged that the growers and producers want to produce the most nutritious and economical food available. Finally, an important theme throughout these discussions was the need for continual collaboration among all stakeholders.

Through these comments, it was clear that regardless of the background of the panelist, each was exceedingly knowledgeable about the issue of toxic elements in food, and no one took for granted that this issue could be resolved quickly. Several themes became apparent and quickly engaged the audience in discussions.

DIALOGUE BETWEEN THE IAFP 2022 AUDIENCE AND THE PANEL ON SPECIFIC TOPICS

Topic 1. Shoring up analytical methodology for testing toxic elements at very low levels

From the audience. Analytical methodology is an important issue. An audience member asked panelists to describe the best way to shore up confidence in testing toxic elements at incredibly low levels, such as 1 ppb or lower. Concern was expressed that it's not easy to find these things consistently and repeatably. The question as asked, "How might analytical methods be improved?"

From the panel. There is work that has been done with respect to testing lead in vegetable puree baby foods, which includes conducting proficiency studies sponsored by the Baby Food Council. Different laboratories participated, and there is a list of labs that can measure low levels with reliability. For example, in a study sponsored by the council, blinded samples were sent to 28 labs, and 26% of the labs were able to measure lead in the samples at a detection

limit of 1 ppb using a method certified by the International Organization for Standardization that is equivalent to the FDA method *(6)*. About half of the labs correctly reported the level at 6 ppb, and 80% reported it at 12 ppb. There are websites that provide a list of labs that demonstrated proficiency. It is important for a lab to report the limit of detection and the limit of quantification, which the lab may report as nondetect. For example, a nondetect result could mean undetected at 1 ppb, 6 ppb, or a higher limit (e.g., 20 or 50 ppb), and this is important context in understanding the nondetect result. It's important to use a quality lab for testing.

Achieving proficiency in an analytical method is an ongoing challenge without a simple solution. It takes a lab that is committed to achieving proficiency (not just a one-off) to obtain valid results for lead. That applies to testing other toxic elements, such as arsenic and cadmium. Another proficiency study was planned for later in 2022 that would be for heavy metals in grain products, because both cereals and extruded grain snacks are consumed by young children.

Another challenge moving forward is speciation. For example, there are no methods for speciation of arsenic in many food matrices, but the panelists agreed that inorganic arsenic is really what is of interest. Moreover, speciation methods are more expensive, for example, by an order of magnitude when testing for inorganic arsenic vs. arsenic.

Besides proficiency, it's challenging to address the issue of variability in the results: different numbers obtained by testing different samples of the same product by reliable, certified labs. In efforts aiming to move the needle (reducing exposure) or looking at a compliance situation, those differences matter. One panelist noted:

For example, if you are trying to meet a lead action level of 10 ppb, and you anticipate variability, you most likely must set your specification much lower than 10 ppb in order to account for the variability to have confidence that you are in compliance.

Topic 2. Data trust and what's needed to measure reduction in exposure

From the audience. The C2Z initiative seems to be an area ripe for a data trust. It is brilliant that FDA signals consideration of feasibility in the C2Z approach. It seems that this would be a tremendous opportunity to partner with industry, for industry stakeholders to come together to share their data. This raised several questions from an audience member, "Does industry have the data? If they do, how could this move forward? If they don't, how could we work together to get the data?"

From the panel. Industry does not have the data range needed, not from the grower's perspective. There are pockets of data. For example, there is a general understanding of soil, and depending on the state, there are programs that measure certain input to control heavy metal accumulation in things like compost. There is understanding of water, including well water and water from other sources. But the data available on finished products from a commodity standpoint are not adequate to assess reduction in exposure. Company-specific data exist for some commodities, which suggests high variability. It's necessary to understand the reasons for this variability, whether it is a laboratory issue or variability in different samples.

From the manufacturer's standpoint, some data exist *(3)*. One of the challenges is that overtime, the levels of detection and quantification have moved downward, for example from 11 or 8 ppb 5 years ago to 2 ppb nowadays. Some older data might not be as helpful as newer data because of the limit of detection issue.

A considerable amount remains unknown about the amount of data needed to make a determination about a baseline. The FDA Total Diet Study (TDS) *(9)* has 27 samples of many basic foods, including strawberries, bananas, and apples. One panelist noted, "The TDS data alone is probably not sufficient to determine baseline for the food supply, especially for crops like sweet potatoes, which are in and of themselves unique from a variability standpoint." Available data show dramatic differences in numbers, even in sweet potatoes harvested from the same field. There are numerous questions about data needs: what types of data, how much data, and what's behind the data? Where the crop was grown and under what conditions make a big difference. There is a lot to the data trust question that should be mapped out as a possible first step.

Trust is important, in terms of how to approach data collection to facilitate data sharing. Data discovery in potential litigation is a hurdle. It is important to have the U.S. Department of Agriculture (USDA) involved and have FDA promoting and encouraging more testing, especially through the research side, because incentive is needed to do more testing. One of those incentives is the establishment of action levels.

The USDA Agricultural Research Service has been doing a lot more work with big data, integrating data from areas such as heavy metals in products, nutrient quality, climate, growing location, and geography. With increased capability to integrate all these data, the data question can be better addressed through big data integration.

Topic 3. Communication and outreach to consumers and industry

From the audience. Field agents often work with recipients of the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) and the Supplemental Nutrition Assistance Program (SNAP), as well as farmers and processors. Audience members asked panelists about the kind of education or messaging they should share among those different groups and about what could be done to address misperceptions about growers and manufacturers and their efforts. It was suggested that a helpful approach could be looking for industry to help lead the conversations on mitigation strategies to reduce toxic elements in crops.

From the panel. The USDA Food and Nutrition Service works with the state and local agencies to administer SNAP and WIC and interacts with extension specialists and other groups to share information with SNAP and WIC recipients. In the C2Z initiative, a workshop with an emphasis on communication is being planned to get the information out to the people who need it and to help the people who communicate the information to those who need it. Communication is incredibly important because advancing the science and making changes to dietary guidelines only constitute one step; further effort is necessary to make the science useful and accessible for consumers. A panelist noted that "if the consumer and the person who is supposed to receive the information is not choosing or getting it, then we can't achieve the goal of reducing exposures to toxic elements."

FDA is embarking on consumer research to better understand how consumers are reacting to information they are hearing. A panelist stated, "Many of the stories in the media have been a bit sensational and, sometimes, horrifying for parents." A challenge is how to cut through sensationalism to make sure that parents are still feeding their children nutritious foods. FDA has been relying on the Dietary Guidelines for Americans, which do provide advice—for the first time—for pregnant and lactating women, as well as children 0–24 months. For example, one of FDA's messages is stressing the importance of eating various nutritious foods to ensure nutrient adequacy. For children, if their diets follow these guidelines, they are less likely to have nutrient inadequacy. When FDA issued the draft guidance on action levels for lead in juice *(8)*, it pointed out that according to data from the National Health and Nutrition Examination Survey, 30% of children under the age of 12 months had consumed some juice within the last 2 days. However, the panelist noted, "The recommendation is zero, no juice under the age of 12 months." Juices can be a source of exposure to lead. Thus, trying to get Americans to be more aligned with the dietary guidelines will affect exposures.

From the consumer's perspective, homegrown foods cannot be ignored because "urban soils may have a higher level of lead in them than in farm soils," stated a panelist. People understand that lead is all around them, for example, from living in a pre-1960's home (which consumers deal with, accepting the presence of lead because they are informed). In some way, food is the same. What consumers get upset about is when they think they should have been informed or they don't feel the government and the industry are being transparent. The key to better engagement with consumers is to convey the message that government and industry are trying to do all they can to lower the level.

From a baby food manufacturer's perspective, there is a lot of feedback from consumers. To reinforce some comments from the other panelists, when there is reporting that there might be a heavy metal in food, some consumers' immediate reaction is often to buy organic or make their own foods, thinking those must be better and safer (even though they may not be). People want to take action, and it's a challenging situation. They want a clear message about what they can do so as to eliminate heavy metals; however, in many instances, zero heavy metals "is really not achievable no matter what they do," the panelist said. Moreover, there are many fruits and vegetables that don't have detectable lead or other heavy metals in them. Most crops are not sources of significant levels of exposure. Of all the dietary guidelines, a varied-diet message is the best one for good nutrition while minimizing heavy metal exposure. A challenge in communication is that such a message might not be what consumers necessarily want to hear. They want something specific and simple.

From the grower's perspective, communication not only needs to be clear for consumers but also should convey what the grower needs to do. It's important to consider feasibility—that growers' land is set, their inputs are fairly limited, and the growing conditions are what they are—in developing guidance and messages for growers. Growers and manufacturers are concerned about misperceptions, which present challenges for communication. From the government's perspective, FDA has held many meetings with stakeholders and learned that some industry groups have been proactive. For example, they started to test their own commodities to collect data. They are anxious to learn what can they do to reduce heavy metal exposures. FDA is working with USDA on outreach to growers because there are things that perhaps growers can control, such as amendments to the soil and modifications of pH and soil chemistry. FDA and USDA will hopefully have some workshops around mitigation strategies and hopefully partner with industry in those efforts.

Topic 4. Building trust in the C2Z process to ensure buy-in for action levels

From the audience. On the challenges related to perception and consumer perception, educating consumers about where toxic elements are coming from is one of the aspects of perception. Another major aspect is building a perception of trust in the C2Z process that stakeholders all participate in. If we get to the end of the C2Z process and consumers don't have trust in it, we are kind of at the same place we are at now. An audience member asked what can all stakeholders do to help build that consumer trust so that:

Whatever the action levels that were selected, consumers have trust that the process was followed, that there was logic and rationale behind the numbers, so that at the end of the day we are not all questioning the numbers that came out, losing that battle of consumer confidence?

From the panel. Building trust in the process is wholeheartedly agreeable and needs to include building trust among all stakeholders, not just with consumers. It cannot be overemphasized how complicated it will be to do outreach to the growers' community. A panelist said, "It's also important

not to vilify nutritious foods in the process." Bringing the growers along will only make whatever changes are necessary faster and more sustainable. Once established, action levels may stay in place for decades. Sustainable efforts are needed to ensure compliance because there will likely be fluctuation in contamination over time.

One panelist noted that "FDA has been trying to build that trust, but FDA alone can't do it all." One of the ways FDA is building better trust is with advocacy partners and other intermediaries so that they can then build that trust directly with consumers. Attending IAFP to have this dialogue is part of the effort of trying to make a difference. A panelist noted that "there is a misperception on the part of some in the advocacy community—a misunderstanding of what can actually be done to reduce the levels in products for infants and young children." There have been many FDA and stakeholder calls and meetings, which will continue for as long as necessary to get these messages out and to build that trust. In another FDA initiative, the agency has worked to build trust around biotech and the use of biotech in the food supply. FDA has done a lot of research with consumer focus groups to understand where the mistrust is and what is difficult for consumers to understand. As another panelist indicated, "Transparency is important." Consumers have felt that they never knew that sometimes biotech ingredients were in foods, and they have felt that they never had a role in the decision to use biotech. FDA has worked to regain trust regarding the biotech issue. Similarities about the relationship between transparency and trust exists for toxic elements, and there is a need to regain trust regarding the issue of lead and other toxic elements. The flurry of media attention on the issue, to the consumer, has felt a lot like the biotech issue: that they were not informed. There is a lot of work to do building trust in the C2Z process.

Topic 5. Anticipated frequency of revisiting action levels

From the audience. Panel members described C2Z as an iterative, incremental progress. This led to a series of questions from the audience:

From the perspective of action levels, do you anticipate revisiting those once every couple of years? How are you going to consider how action level revision is going to affect downstream stakeholders? How is it going to play out with so many consequences downstream for stakeholders?

From the panel. Making iterative, incremental progress is the goal. In the C2Z initiative, FDA identifies actions the agency will take to reduce toxic element exposure from foods eaten by babies and young children, with the goal for exposure to be as low as possible. The intention is to revise action levels periodically. FDA has not established a specific timeframe but will periodically revisit the science. For example, this will involve reviewing the science around exposure to understand whether a safe level for exposure can be identified with the new evidence or whether there is new evidence that might warrant reevaluating the reference level that had been established. If the reference level is updated, then reevaluating whether the action levels are still appropriate or need revision will ensue. Furthermore, action levels are not solely based upon reference level; also considered are factors such as the grower issue, manufacturing issue, and feasibility issue (whether there are actual steps that can be taken to further reduce exposure). For agricultural commodities, any types of mitigation techniques that are put in place will take time to manifest in actual reduction in the prevalence or quantity of these contaminants in crops. This is going to be a process longer than a 2-year timeframe.

Topic 6. Consumers questioning whether toxic elements are something new or have been present for a long time

From the audience. An educator brought up a question that consumers often asked about. The multi-part question is very interesting , whether you are working for a food company, for the government, or for an advocacy group:

Is this something new, or has this been happening for a long time? How are we discovering that leafy vegetables are accumulating toxic elements? What's changed: their occurrence in foods or our ability to detect them? The second part of the question is: what did we do before? Our children have always been eating foods. What did we do before and were there changes in recipes or the foods we give to our children?

From the panel. For the first part of the question, a panelist noted that the short answer is yes, there have always been heavy metals in the soil. Plant uptakes and phytoavailability have not changed. There have been some changes in urbanization that may have led to deposits in the soil, as well as changes in water and water routes that could have changed things. However, the panelist continued with an example: "The soils in Monterey County, where the majority of the U.S. summer spinach is grown, are tens of thousands of years old." Agronomic practices usually are not intended for managing heavy metal content unless there is awareness that a particular soil or condition could lead to a higher level of toxic elements in the crop. In general, the panelist noted that "agronomic practices are what they have been, even though they have been modernized."

There are concerns in the grower community, as mentioned before, about making sure that a balanced approach is taken for heavy metal management, which should consider the lands and agronomic practices to ensure these products will continue as a part of a healthy American diet in an affordable and accessible way. Changes may have a cascade of effects. For example, if mitigation strategies are too expensive for certain land, produce may not be grown on it anymore. If a certain level is required without appreciating that there is a diverse amount that could occur depending on factors such as the land, conditions, and season, the

panelist noted, "We need to ask the question, Is it a concern that occasionally a 10-fold higher level of lead occurs in some of the product? Does that matter in terms of adverse health effect?"

Over the last two decades, several things have changed. One is the view that there was a safe level for lead. In 2011, the Centers for Disease Control and Prevention determined that no safe level of lead in the blood had been identified. One of the main concerns is IQ decrement from childhood exposure to lead because it affects brain development. Other potential adverse effects in adults include an increased risk of heart disease and a slight increase in mortality in adults. A lot of the new understanding has emerged over the last 15 years.

FDA launched the C2Z Initiative in 2021. On lead, there is a clearer understanding of the risks than before. On inorganic arsenic, the evidence is emerging. When FDA initiated its risk assessment on inorganic arsenic in rice and rice products *(5)*, it acknowledged qualitatively that inorganic arsenic could have a neurological impact. The science has advanced and there are ways to quantify risks, which is important. For cadmium, most evidence is old and inconclusive. In the C2Z action plan, FDA is tiering its work and the setting of action levels: lead first, then inorganic arsenic, then cadmium (for which hopefully the evidence will become clearer), and then mercury.

A major change that drove a general reduction in lead exposure was the removal of lead from gasoline in the 1980s. There was a concurrent decrease in lead exposure from foods from the removal of lead-soldered cans (FDA banned such cans in the early 1990s). Removing lead from gasoline and lead from cans resulted in huge reductions in lead exposure.

As society made progress in reducing nondietary sources such as paint, pipes, and gasoline, food becomes a more significant source of exposure. The effort to move the needle in the realm of foods is going to take some time. When you take mitigation steps in a field, you won't know whether you are successful until the crop is harvested and tested. It's an iterative process that will take some time because it involves activities in the field.

Topic 7. Many voices and different views in candid dialogues and debates between the audience and the panel

7a. Whether moving closer to zero might be perceived as "chasing zero": Misconception about hazard vs. risk

From the audience. An issue that has not been discussed is the idea of hazard vs. risk. Building on the discussion earlier on data trust, one of the main concerns is the lack of clarity on hazard vs. risk when data are being presented to the public. The public sees exposure as hazard. A misconception with moving closer to zero is that some people perceive this as only chasing zero. Analytical methods can detect down to part per billion, part per trillion, and even lower level for many compounds. When a report describes arsenic at 20,000 ppt in one brand and 10,000 ppt in another brand, consumers see "20,000 and 10,000 arsenics." We need to do a better job of explaining risk; this must be pertinent to this conversation.

When the heavy metal issue came out, Congress was surprised there were heavy metals in baby foods—heavy metals are in Earth's crust. Even Congress doesn't get this. We are losing the battle unless we start talking about risk vs. hazard and why there are plethora of hazards associated with foods but not many risks associated with foods. Furthermore, the Joint Food and Agriculture Organization of the United Nations and World Health Organization Expert Committee on Food Additives rescinded a reference level for lead *(10)*. However, this does not mean that a reference level won't be established in the future, as the panel alluded to earlier. We cannot assess risk in a vacuum without considering feasibility of mitigation and nutrient content of these particular foods. We need to have some types of direction, so that 5 or 10 years down the road, when analytical methods get to even lower detection limits, that does not automatically mean that action limits would need to be lowered. We can't look at just the heavy metals. We must take a wholistic approach.

From the panel. At the beginning of the session, the panel discussed risk and the differences between hazard and risk. For consumers, not everybody perceives risks or receive messages the same way. In recent peer-reviewed papers *(1, 2)*, FDA scientists state that "despite the smaller contribution of dietary lead to BLLs [blood lead levels] compared to other sources, no safe level of lead exposure has been identified for lead-induced neurodevelopmental effects, and therefore, reducing lead exposure from food is still relevant to public health" *(2)*. If one takes the amount of FDA's estimated exposure in the diets for children and translates that using common mechanisms for lifetime loss in earnings, one panelist noted that "it's estimated [to be] 17 billion dollars. It might be undesirable to put children's brains in terms of dollars, but that's a risk estimate."

Another panelist noted that "the intention is not to be 'chasing zero'; that phrase has been assiduously avoided." The misconception on this is a challenge. Efforts are under way to establish an interim reference level for lead. For arsenic, the level is largely unknown regarding impacts on childhood development, so action levels will not be established until after the science has been evaluated to determine whether an interim reference level can be identified.

For toxic elements, the goal is not to keep on driving it to zero but rather to find a point at which exposure no longer poses a significant risk. Among these efforts, the role of nutrition is an important piece of evidence being considered. Hopefully there will be more research on the competition between nutrients and contaminants that occurs within a plant and within the human body. For example, an assumption is made currently about the 100% bioavailability of these contaminants, but maybe new scientific evidence

will show that heavy metals from foods are not 100% bioavailable. More information along those lines will help establish action levels.

7b. Whether to set different action levels for foods intended for children vs. the general population

From the audience. The agricultural community has a lot of data and knowledge, for example, on what's in the soil, what the plant will pick up if the right amendments aren't in the soil, and that cadmium is present in the second cutting instead of first cutting of spinach. Growers rotate crops and deal with a toxic element before it becomes an issue. FDA has resolved to reduce exposure as low as possible, but FDA alone cannot solve the problem, including education. It takes everybody together, more partnership, and industry to help lead the conversations. There is mistrust of FDA in the industry, as indicated by experience with microbial sampling of produce in the Salinas or Yuma regions (e.g., FDA had limited access to growers' land). However, consumers may have misconceptions about industry's efforts: where the industry puts mitigations in place to control toxic elements, whether the produce is healthy, and whether it is safe.

For setting action levels, we can look at how another industry and consumers manage the risk for children from airbags: there is a sticker in the car asking drivers not to put a car seat for infants and children in the front seat. Audience members asked whether limits could be set for toxic elements in foods for infants and children (e.g., in foods that go into the school lunch program). Setting action levels that are protective of children based on available data is one way to proceed. This is not an easy task, and a lot of the data are still missing. For the rest of the population, a set of values that is a safety range could be explored based on the science and data.

From the panel. As far as creating a separate market for foods that are for children and foods that are not, there are a lot of challenges in that approach. To some degree, some firms already have limits for baby foods they produce. However, there will be challenges with the approach of establishing action levels for baby foods, and only baby foods. What about those children who don't eat those baby foods? What about families that share the same foods with infants and young children (to get their infants off baby foods as soon as possible)? From a practical standpoint, what implications will it have on the cost if in the produce aisle, there are specialty carrots, for instance, that would be suitable for children? Why can't the rest of the consumers have those specialty carrots? Those are some of the issues and potential unintended consequences that should be considered to not have huge market disruptions moving forward.

7c. Pros and cons of economic incentives for growers to grow specialty crops for children

From the audience. For the economic aspect of the issue, we need to consider not only the time it takes to adapt interventions but also the costs. There would be costs to growers from growing specialty crops (for children) or implementing special mitigations on the fields, which ultimately would be passed on to customers. Audience members asked for the panel's perspective on government support, whether subsidies or other economic incentives, to help reduce the burdens on the growers' community, for example, for them to grow crops with lower levels of lead.

From the panel. From the grower's perspective, and to reiterate an important point, it is not feasible to ask a grower to grow carrots in one field that are safe for babies and children and to grow carrots in another field that are safe only for adults. This is not an economically feasible or a practical approach. Growers grow for all generations and their families. One of the biggest concerns is going down a path of deciding that one carrot is better than another just based on heavy metal content, when in reality, stakeholders are still trying to understand the risk from the amount of lead in carrots in the context of the American diet and whether the risk is unacceptable. It's a complicated conversation to discuss and try to predict a specific time within a child's development when carrots are a portion of the diet. From the grower's perspective, mitigation strategies should aim to lower lead in all carrots. That's not an easy proposition, because it will cost money and resources. It will take time for growers to figure out how to grow new varieties well, and there will be certain soils that the new varieties won't work in. Therefore, it takes careful consideration of the pros and cons of setting limits for children vs. adults, because it is not desirable to limit the amount of carrots available for the American diet.

A panelist noted that "FDA does not have the power to subsidize farmers; Congress does." Another panelist added that, from USDA's perspective, there are cost implications for the federal feeding programs. The government offers a lot of subsidies in terms of feeding programs for specific populations that are not available to the overall population. Although the USDA does not provide a subsidy, the USDA Agricultural Research Service is set up specifically to direct funding from the federal government to conducting the research that supports what the producers and growers need to know. Growers cannot afford to make significant untested changes in their crop production, because if it doesn't work, they are out of the crop or field for a whole season. The intramural and extramural research programs at USDA support research to test strategies for improving crop quality and quantity. The USDA feeding programs are supported by a significant proportion of the USDA budget. Changing what's in the food supply for these programs could significantly alter the ability for these programs to ensure the overall eating patterns for the recipients are safe, are cost effective, and provide nutrition security.

CONCLUSIONS

The panel and the audience had an engaged and collaborative discussion, sharing their thoughts on the

C2Z initiative and addressing a lot of thought-provoking questions. Key takeaways are as follows:

- Everyone agrees C2Z is an important topic but that the process is a marathon, not a sprint.
- We all want a science-based, data-driven solution.
- We don't want to undermine overall nutrition or food security.
- The concepts of trust and accurate and effective communication are important.
- We don't want to scare consumers from food that provides good nutrition. Consumers should be provided guidance on the best way to manage risk from toxic elements, including consuming various nutritious foods and ensuring a diet that is adequate in nutrition (e.g., iron and zinc).
- There are many components of a solution to this issue, including analytical methodology, research on ways to reduce plant uptake, collecting data to better understand the distribution of toxic elements, finding common ground among all stakeholders, and communication methods that make a difference.

At the end of the discussion, each panel member had an opportunity to summarize their thoughts in a brief closing statement. In general, all panel members acknowledged that this was a complicated subject. Solutions are not intuitive and will take engagement from all stakeholders. The discussions clearly demonstrated the broad-based support for efforts to make a difference. Solutions must be evidence based and data driven. Working at such low levels of contaminants makes it important to trust the data and understand the limits of the analytical methods. Thus, an important area of focus must be accurate, consistent, and repeatable test methods. This will not be solved all at once, and a stepwise effort toward making incremental improvement over time is the best approach. As we make strides to improve this issue, communication is going to be critical. It is important that we don't make mistakes that scare people from good nutrition or lead to unintended consequences, such as significantly increased cost. We need to set goals and establish priorities, considering, as stated by one panelist as an example, that "reducing lead exposure in children by 6% could increase lifetime earnings for society by substantial dollars." We won't all agree throughout the process. We may not agree on the amount of reduction or the time to get there, but achieving these goals could have a major impact on increasing lifetime earnings across society. Because of the potential benefits of these efforts, we should recognize our differences and work to set them aside. In the end, all panelists recognized the importance of this issue and continued to agree this was a worthwhile effort for society. Discussions at this roundtable show that there is a huge opportunity for collaboration among all stakeholders to tackle what once was thought of as an intractable problem.

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