Public Meeting on the Development of an Enhanced Systematic Process for the FDA's Post-Market Assessment of Chemicals in Food
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>> Good morning, good afternoon. I'm Mike, program manager at FDA. We're going to get started in a few minutes. We're still going to allow our in-person people to filter into the room as well as to allow the online people as well. Just a few housekeeping notes today. Today's event is captioned. At the bottom of your screen, you can select captions. It is also being simulcast in Spanish. Couple reminders, there will be a Q&A session during today's meeting. Please note that if you do have any questions, please submit them early. We do know we're not going to get to all of them, but please get them in early so we do have time for that process. And we're- going to get to as many questions as possible. That being said, we're just going to give it a couple minutes. Today's webinar is also going to be recorded and will be posted on the website. Just a reminder to those in the room and those online, if we do have any technical issues, we will do our best to get the show back up and running. Also, please note that we do want to be respectful of everybody's time. Please avoid any distractions. Those making public comments, please note that your time is three minutes. And let's be -respectful of everybody who is making open public comments. We want to allow everybody to get through. -If there are any distractions or disruptions in the meeting, we will pause the meeting and allow security or anything to handle any of those distractions. So, thank you so much for joining us today. And we will get started in a few minutes.

Welcome to development of an enhanced systematic process for FDA's Post-Market Assessment chemicals in food. We're going to get started in a few minutes. But here's a few housekeeping rules. Those of you in the room right now, the sooner you can get settled in, the sooner we can get started. We are going to get started probably in a couple more minutes, but here's a few more housekeeping notes in the virtual environment. Today's event is being captioned. At the bottom of the screen please click captions if you need it. It's also being live interpreted into Spanish, so feel free to use that as well if you need it. We will have an open public comments section for today's event. Each of the open commentors, please note as you are joining the room in person, they'll be giving you instructions on how that will be identified.

Those virtually, we will identify you on the attendee list. When we get to that portion of the meeting, we're going to ask that all online open public commenters who signed up to raise your hand. And then we will call on you and unmute you. There will be a timer on your screen to help stay within the three-minute time frame. As the meeting goes along, if there's any disruptions, both technically or in person if we have any disruptions, we will pause the meeting at that time and then reconvene those issued are addressed. That being said, again, just give us a few more minutes as we allow the room to fill up and we'll get started shortly. Thank you much.

All right. It looks like we're getting settled in in the room and online. So, let's get this meeting started. Good afternoon and good morning, depending on where you're calling from. I'm Mike Kawczynski project manager here at FDA. I'd like to welcome you to the public meeting on development of an enhanced systematic process for FDA's Post-Market Assessment chemicals in food. Today's meeting is recorded and captioned. Also, it is available in Spanish as well. All those options are available at the bottom of your screen. There's a Q&A portion. So please at any time please use the Q&A pod. Submit your questions so we can get to as many as possible during that portion of the event. If at any time we have disruption technically or in the room, disruption of any type, we will stop the meeting, address the issue, and then come back. We will make sure that we have a good meeting for all that are attending. Those who are giving open public comments and signed up for that, please, a reminder that you do have three minutes. There will be a timer on the screen to help you keep track. Also, please note that those who are virtual, we have identified you in the attendee list. We'll be asking you to raise your hand at that time, and then we'll call your name and unmute you and you will see an option on the screen where you can select for your microphone to be activated. With that being said, I want to hand it off to my colleague in the room, Jessica], to take over some instructions for those in person. Jessica, take it away.

>> Thanks, Mike. Welcome everyone to this public meeting. As Mike noted, I'm here to help co moderate the meeting. I just wanted to share a few housekeeping items before we get started. The restrooms are out these doors on my right side down the hall on my right. There's also a kiosk for food and beverage if you do need that. It is cashless payment. Another note, the water fountains are nonfunctioning at the time. So, there is a table out in the lobby with bottled water for free. If you are a member of the media, please make sure to check in with the registration table. And lastly, I just wanted to note on the seats where you are, there are note cards and pencils. So, we'll be using these for questions from the audience during our Q&A with the FDA panel. So, you can write down those questions as you have them, and we'll be collecting those later. So with that, I am going to turn it over to our moderator today, Dr. Steve Musser, Deputy Center Director for Scientific Operations at CFSAN. Thank you.

>> Thank you, Jess. And thank you all for attending today. Just really nice to look out over a room full of people all here in person. Again, for showing up as we invite public comment on our proposal for enhancing our systematic process for FDA's Post-Market Assessment of

chemicals in food. As you heard, FDA and specifically the human foods program is developing the systematic process for conducting Post--Market Assessments of chemicals in foods. This includes ingredients generally recognized as safe, food additives, color additives, food substances and contaminants. This process that we're undergoing today is intended to guide our -Post-Market- Assessment. Going forward this includes the transparent process for identifying and prioritizing food chemicals currently in the market. Prior to this meeting, we shared a discuss paper which is really an outline of our thinking in this area; it is not complete and we're looking for comment. If you haven't seen it or would like to see it in your program, there is a QR code. You can simply use that to access the information. The discuss paper broadly outlines our general approach. It is not intended to be this is how we're going to do it. We're looking for input. And that's the purpose of today's meeting. We would like to share our thoughts on this paper and our process, and so there will be a panel of FDA folks speaking, as well as some invited guests who have their own perspectives that they would like to share. There will be an opportunity as mentioned before to ask questions. And we will also hear, the panel, will hear from the public in our public comments section of today's meeting. We really do believe that this will help advance our approach to chemical safety in our assessment of chemicals in general. -I- would like to note that it is intended to talk about the process we use, not specific chemicals or chemicals that might be before the agency at this time for review.

That said, I would again appreciate your participation and comments as we develop and refine this process. And I would now like to introduce Deputy Commissioner for Human Foods, Jim Jones to give a few opening comments.

>> JIM JONES: Thanks, Steve. It's great to be with all of you here this afternoon and thanks for all of you joining us virtually today.

Enhancing our food chemical safety is among our top priorities in the new human foods program, which if you aren't counting, I know I am, is six days away. Today's meeting marks a critical step forward to ensure food is safe. We have not had a robust Post-Market Assessment program here at FDA. This is largely because -there's- no statutory requirement for FDA's post-market review or safety testing to share that data with the FDA after a chemical is introduced into the market. As such, given our limited resources, the agency has not established a systematic process to ensure that our original determination of safety held up over time. Until now, we have taken an ad hoc approach to post-market safety by monitoring the literature and engaging with national and international counterparts to review emerging data as they become available. We have taken action to remove additives that no longer meet our safety standards. We are modernizing our approach because we have as a society we have learned much about chemical safety over the past several decades and in response to growing public demand for the FDA to do more to ensure the safety of chemicals currently in the US food supply. -You can say the two are related-.

Over the past few years, there have been an increasing number of state bills to ban certain additives and set limits for certain contaminants. While states are well under their rights under

the current regulatory system to do so, a strong national food safety system is not built state by state. The FDA must lead the way, but to do so, we need to do more. By instituting a systematic approach for chemical assessment, FDA is making the type of changes to our oversight program that will support equal access to safe foods, a resilient food supply and maintain consumer confidence. The proposal for a systematic and nimble process for identifying food chemicals in the US food supply for Post-Market Assessment will become a process that guides our office dedicated to post-market safety reviews. This will include previous authorized color additive, food contact materials, and GRAS substances as well as contaminants that entered the food supply through the growing and processing environment. While we have a strong commitment to do more in this space, the reality is our new human foods program did not come with increased budget, added authorities, or a change to the legal requirement for industry to conduct and share safety testing with the FDA. In FY 24 we sought to reduce the disparity between what is needed to advance the work and what has been historically allocated with the $19 million for the FY 23 budget.

Needless to say, the department did not see a budget increase. It was predicated on the FY 24 request which we did not receive, we are entering another year to meet our public mandate are greater than our resources. Simply put, prioritization drive can only take us so far and our budget constraints will limit the number of assessments. But you have to start somewhere. We are committed to do as much as we can with available data, current tools for surveillance, signal detection, and determining exposure. And we will continue to use our available resources to support the necessary toxicologist risk modelers and other scientific expertise for this complex work. While we are resource constrained, there are opportunities to better leverage the scientific work done by our federal partners and international partners and those in academia and research and we are exploring our options. This meeting in the public comment we hope to receive is a reflection of our commitment to stakeholder engagements early and often. We want your feedback about the proposal made public before we implement an approach. I expect that with continued engagement with our stakeholders and partners, we will make study progress toward our goal of enhancing food chemical safety. Thank you to my team for their hard work in preparing this proposal and arranging today's public meeting. And thank you to our guests for joining us. Speaking for myself and our entire HFP staff, we appreciate your commitment to food chemical safety, and we look forward to your continued engagement with us as we advance our goals to protect public health. Thanks. I'm looking forward to a great meeting.

[Applause].

>> Thank you, Jim. We're going to move into the part of the meeting now where we talk about- we- have presentations, one from FDA and one from Sarah Gallo, Melanie Benesh, Thomas Galligan, and Norbert Kaminski. We're going to start with the presentation from Dr. Kristi Muldoon Jacobs. Kristi is currently the director of FDA's office of food additive safety. That office, known as OFAS, is responsible for ensuring the safety of direct and indirect food

additives, color additives, and GRAS substances as well as supporting safety and innovation from new plant variety and made from cultured animal cells. She has extensive knowledge of regulatory statutes to ensure safety of products and has served as an expert to JECFA, OECD and ICH committees. She is an internationally recognized expert in expert in the application of new and alternative safety and risk assessment methods and she has served on 15 international working groups and has published over 30 peer reviewed journal articles. In her previous role before FDA, she was also at USP where she served as a toxicologist with expertise in the safety assessment of the FDA regulated products, including food ingredients, direct and indirect additives, dietary supplements, and drug impurities. Please welcome Dr. Muldoon Jacobs.

[Applause].

>> KRISTI MULDOON JACOBS: Good afternoon, everyone. Thank you, Dr. Musser. Thank you Deputy Commissioner Jones. Especially thanks to all you for joining today. We have been eagerly anticipating this public meeting. And I'm honored to be representing the team. The work I will be presenting today represents efforts of many people, so I just wanted to take a moment and acknowledge everyone that's contributed to the discussion paper and also preparing for this event. I also want to thank the meeting organizers who helped plan today. This is the first public meeting I've been involved in planning and I've just been amazed at how many small things take up a lot of people's time and energy to make it all go seamlessly. So thank you all so much. I also want to take a minute to remind everyone here and online why we're here today. And that's to hear your comments and input. We are at the early stages of this work. And as part of our commitment to increasing stakeholder input and engagement, this current proposal is being brought at an early stage with the express purpose of receiving your input and feedback from all interested stakeholders so that we can incorporate those suggestions as appropriate before we begin implementing a new program. Next slide, please.

Today's presentation will briefly touch on the current post-market approach that we have within OFAS and FDA.

Our proposed evolution of the current state, how we really took on this project and this work, really a discussion of our vision for what the future state should and could look like. And then a somewhat detailed discussion of our new envisioned and proposed process. Next slide.

But before we -- next slide, please. Thank you [chuckling].

Before we get into the details and focus for today's topic, it's worthwhile for us to mention where our authorities come from within the act related to food chemical safety. We're fortunate and we benefit from a clear definition within the FD and C act. That includes clear exclusions and expectation of safety for all chemicals used or found in food. The regulations direct both industry and FDA in their roles and responsibilities when seeking to use new substances or ingredients in food. The FDA has established premarket programs to ensure industry can meet its obligations to meet safety of ingredients and additives before going to market. These programs include petitions for food and color additives, food contact

notifications for substances used in packaging or processing of food, threshold of regulation exemptions, and GRAS notices. But we also have post-market authorities. And we're going to talk more about that today.

We can take regulatory action to ensure that food additive and ingredients continue to meet the safety standard over time. And under Section 402, we can take action when chemical hazards are present in food at unsafe levels or cause food to be adulterated. We have taken some notable actions, that I want to take a minute while I'm up here, to restrict authorized uses in PHOs and BVO recently. We took actions to remove or reduce harmful chemicals like PFAS from paper and paper packaging and lead in babies. One of the critical differences between our premarket work and post-market work is a lack of a systematic process directing the post-market work that we do. We think that a systematic process can help stakeholders have a process that they can look towards and expect to see the FDA is still playing an active role after substances come on to the market and are in the food supply. Next slide, please.

But that said, there actually is a significant amount of work that currently on goes in the space of food chemical safety. Within FDA in OFAS and other offices, our scientists are continuing to monitor the literature and keep up with emerging data and information through participation and international risk assessment bodies. I think we heard DC Jones talk about those. We engage in agency special projects and publish a lot of that work in -- at scientific meetings or in the public literature. But we do acknowledge the need for a more systematic approach and we took an evaluation of our work and identified several areas that are worth improving.

Our post-market work tends to be situational or ad hoc. It can often be reactive and not always prioritized towards issues of the greatest public health impact. We found that most of the post-market work, especially in cases of additives and ingredients is -- tended to occur under three different scenarios. We would take this work on when it was a subject of a petition or it was a substance that was included in a resubmission for a notification of petition or work of the like.

We would see the work in response to great public interest or inquiry. And then also, we would see it initiated by FDA experts when they were monitoring the literature or participating in a publication or at scientific meeting that they thought was worthy of additional review. We acknowledge we're living in an information age, and we are often under a deluge of information of varying reliability, and this is presenting a real challenge to our post-market work.

An additive ingredient, there have not been dedicated resources towards post-marketing. We heard DC Jones acknowledge that. This work has had to compete with our very critical premarket programs for that reason. We also observed an organizational separation between our contaminants work, our dietary supplements work, and our food chemicals work, and this inhibits the ability to share information across the organization. And lastly, we also noticed that unless this work that we were doing and I'm telling you about resulted in a regulatory action, our work would largely be not publicized, it may be presented at scientific meetings or as part

of a peer reviewed publication but this limited our ability to have stakeholder engagement and input and transparency. Next slide.

So we worked to consider an approach to evolve our program into what we think is a better future state. One of the things that we considered is we know that there are several other well respected authorities out there that have active post-market programs. And so we saw no need to recreate the wheel when those are offering good solutions. So we considered those. We looked at approaches taken in other organizations such as the EPA's TSCA program, the JECFA program, among others. We considered our current work stream, what we're observing, and we worked to come up with a proposed process that's especially designed to work within our US food system. Early on, we observed an express increased need for public input and transparency as part of our process, and so we worked to design a system to build these in. Next slide, please.

So I want to talk a bit about our vision. We really strove to design a process that was dedicated and reliable. I think that's an important feature of any regulatory program. But it also needs to be flexible and nimble. We recognized within the environment that we're in a one size- fits all approach is unlikely to fully address the need. We are a science-based organization also, and we wanted to ensure that we employed science and risk -based systems into our process. We wanted a system that primarily prioritizes substance based on public health needs but also acknowledge other factors such as stakeholder interests shouldn't be ignored and need to be incorporated as well. We certainly want -to - yeah, I know. We're- staying here. [Chuckling].

We want to improve our transparency and seek input. This is also a critical feature of our vision. As it relates to our science, we want to incorporate and consider other existing authoritative assessments. There's lots of good work that's going out there by other bodies, and we want to be able to consider that, incorporate it, evaluate it, and bring it in as a part of our work. We also want to use new technology, such as machine learning and AI, to support our work as well. Now we can go to the next slide.

So some general principles. The proposed process that we have in the discussion paper and we want to talk more about today is a science-based system that we think is impartial and incorporates the fundamental principles of dependable safety and risk assessment approaches. We are striving to create a process that's reproducible and reliable, and that will continue to contribute to our ongoing understanding of food chemical safety. For most of the chemicals in food, many of them, we do have some level of information, information that's coming out as new and have to contribute to that ongoing knowledge. The first step, therefore, in our process begins with identification of signals. We think it's really important that we're utilizing machine learning and AI data crawling technology to capture all the relevant information. Once we capture all this information, that information then needs to be triaged to identify the relevant and quality information that requires further consideration. This signal detection and triage steps are critical. Given the amount of information that's currently being created within the scientific community.

NIH pub med system which is one source of data information that we want to make sure that we're capturing and considering, publishes between 4,000 and 7,000 new scientific articles each day. To ensure that we are identifying all the relevant science, not just the information that captures the public attention, we need a system that can be trained to identify the information that's relevant for food chemical safety signal.

Once a signal is identified, all the relevant information needs to be gathered and identified that's going to inform that assessment. After that assessment is done, the outcome will inform whether regulatory action is needed, and we will need to consider what options we would identify from the various tools we have available that are targeted to the types of products where that chemical space -- where that chemical may need to be reduced in which product space.

When a risk assessment warns agency action, we'll consider all options under our authority as part of our risk management review. Hazard, public health impact, and risk reduction will all be taken into account when considering risk management, and all available tools under our authority will be considered. We are intently focused on making progress, but we also know that regulatory actions can take time and will include several layers of review. We want to prioritize our actions towards those with the greatest -- with the greatest risk and potential impacts. Our work overall will be focused on protecting public health, ensuring the safety of substances in the food supply, and strive to be transparent throughout the process. Next slide, please.

So let's take a closer look. Our proposed process proposes two general types of assessments. One, focused. And the other, more comprehensive. Before we really dig into what makes the two unique, I want to start at the top and draw your attention to the top about what's going to be similar between each of them. The process will begin with signal identification. We talked about that in the last slide. A signal in this context is identified as any information, whether credible or not, from any source, that suggests a public health risk or the need for scientific evaluation. We anticipate signals to be multiple, varied, and frequent. Because of the sheer volumes of signals, it will be imperative to use technology to enhance the process of sorting them.

At the triage phase, we aim to utilize a combination of technology and human experts to assist us in identifying information of high quality and high relevance for use in regulatory safety assessments. These quality signals will then move into a fit for purpose decision.

This will determine whether or not that signal warrants are focused or a comprehensive evaluation. Rather than this one size fits all approach, we've designed a process that bins the assessment into one of these two categories. To determine fit for purpose, we will determine the scope and level of review needed based on the type and complexity of the information. We will consider whether the information is new to FDA. If so, does it suggest a newly identified hazard or potential risk, and whether the hazard occurs as relevant or anticipated exposure

levels? Based on our experience, some of these signals can be addressed quickly. These would follow the focused path. For example, studies released can at to our collective understanding on the chemical hazard profile, suggest changes in use due to consumer interest or industry practice. Some studies help explain the mechanism of action for chemicals with a long history of use. Or even suggest new toxicity at high or maybe even relevant levels of exposure. We want to evaluate these new data quickly to determine if there's a potential concern.

The focused evaluation can also determine if this is a situation that needs to be monitored. If there are data gaps that warrant more research, or if a more comprehensive assessment is warranted. It's also important, we think critically important, for us to document and share this information with the public to increase transparency and to ensure the public that FDA is considering new information relevant to food safety as it becomes available.

Now, in cases where the signal suggests a more complex and robust assessment is warranted, a comprehensive assessment can be directly recommended. These scenarios will likely take longer and be more resource intensive and may involve multiple experts across the human food program and may involve additional FDA or external review. These types of assessments will likely take more than a year to complete and may involve multiple opportunities for stakeholder engagement and input. Next slide, please.

So comprehensive assessments will be prioritized and listed on our website. In prioritization, it is our plan and our proposal to use a standardized multicriteria process that will emphasize science based public health factors but also include other decisional factors as well. -We are currently working on refining this criteria -no, the scoring directly. But we wanted to talk a bit about the criteria that we are taking into consideration for this scoring. The plan is, as this moves further along to make the scoring criteria publicly available for this work once that gets further along. But we do welcome your input on these factors and their weight. The scoring criteria will include the following science' based public health factors. Information on changes in exposure. For example we're thinking higher exposure, increases in exposure get a higher score, Decreases might get a lower score.

Scenarios where concerns for susceptible subpopulation exposure such as infants or people of childbearing age. The severity of the toxic end point. The identification of new scientific impact with the potential impact on chronic safety. Some of the other decisional factors that we want to take into account will include stakeholder interest, public interest, and actions or assessments of other regulatory agencies or international safety assessment bodies. Next slide, please.

So for a focused reassessment, just more detail on this. This will be aligned with the general safety and risk assessment principles that we discussed previously. Signals recommended for a focused evaluation will begin with scope and problem formulation. This is especially important for these assessments since they may be intended to evaluate a specific hazard end point or data type. The next phase would be the assessment. This assessment will be considered in the

context of the previous evaluated data and information to inform the risk management review and include both a safety and an exposure portion. We plan to communicate the outcome for these focused assessments. Likely, as part of a website update but this is still being determined, unless regulatory is recommended in which case existing processes would be followed.

And we expect that many of these reassessments may reaffirm the safety of the use of the substance or could result in the recommendation for a comprehensive assessment as well. Next slide, please.

Now, prioritized comprehensive assessments as I mentioned will be announced publicly. Similarly to focus assessments this will start with problem and scoping formulation and we envision a public engagement throughout this process. This could incur during scoping and problem formulation and sometimes during risk management and finally at the end of the assessment phase. These assessments may be similar or include elements of a systematic evaluation, a systematic system evaluation and be conducted by a team of SMEs across several FDA offices. We may additionally include consideration by the science board or other public peer review mechanisms on a case-by-case basis depending on the situation and what makes the most sense to make sure we've incorporated adequate review.

The resource needs for these assessments, we expect to be intensive, and they will need to be prioritized against other human food program issues, which could include microbial or nutritional risk. These comprehensive assessments are expected to take longer from many months to a year or years to complete.

So next slide. So as much as I would like to believe, I explained our intent and framework perfectly, we thought some examples might help show the signals and different types of evaluation. These examples are for illustrative purposes based on that. So the first example - next slide, please- is erythritol. In this -case - I'm sure many of you are -familiar -there was new data that pointed to specific cardiovascular effects in tests using erythritol. We had identified this paper internally, and it was also the topic of interest. It warranted additional review. While erythritol had been the subject of no question letters for the use of sugar alcohols and food and there existed high quality data supporting the safety, this study was found to warrant review based on several factors. To address this need, we assigned a small group of SMEs of experts within OFAS to review the relevant data and the information and discuss that data and information in the context of what is currently known about the safe uses of erythritol. Following a review of this information, FDA identified no concerns for the current safe uses of erythritol, but it's continuing to monitor the information in this area. This is an example of the type of situation where we would see could go through a focus review. It was completed relatively quickly, helped add to our knowledge and understanding of erythritol and identify this as an area to monitor but did not identify concerns for the continued safe use. -Next slide, please.

The next example we have is phthalates. Phthalates have been the topic of increased interest and information for several years. The term phthalates represents a large group of chemicals with similar but varied structures. Some have extensive safety information and others more limited. The term is used in papers and in several studies with varying quality and relevance. They have been the subject of several assessments by other bodies, resulting in some similar but also some dissimilar findings. This is a type of example that may have been a recommended for a comprehensive assessment in a systematic post-market assessment process. Such assessments are intended it be more resource intensive and take a longer time to complete. These assessments would involve additional opportunities for stakeholder input and may involve external peer review. Next slide.

Our final example is cadmium. Cadmium is a heavy metal that can occur in foods due to environmental contamination at levels that can vary in different food types and potentially be effected by pollution, geographic regions. Information in literature suggested an update in the toxic reference value or TRV and suggested a review could benefit from modelling to inform the assessment and the level. Here again is an example of the type of scenario that could be recommended for a comprehensive assessment. In this situation, FDA conducted a resource-intensive systematic review and derived a new TRV incorporating these modelling approaches. The science board reviewed these studies and they were subsequently published in a peer reviewed journal. Next slide, please.

So hopefully -- yup, last slide. Thank you. [Chuckling]. It was our intention here to develop a framework that would add value given the current need and aligned with our authorities under the FD and C act. With your input, we know that this can be adjusted and improved, and we thank you in advance for your comments. You know, while we believe that this is workable and can help improve our current post-market food chemicals work, we do know it will require additional resources to be fully realized. We are planning to utilize cross functional teams and assignments to optimize utilization of our current resources, but we also know it will not be enough. In order to get this work done, we will need additional scientists to do the review work and resources to optimize our AI and technology systems without this progress. Without this, we will make progress, it will be somewhat slow and limited. With that, I'd like to thank you for your attention. And again, thank the team that drafted the paper coming up with the framework and planning the meeting today and all of you in advance for your valuable and helpful comments. Thank you.

[Applause].

>> STEVE MUSSER Thank you, Kristi. Our next presentations will be from our consumer advocate representatives. It will be two people. Melanie Benesh is the Vice President at the environmental working group. And Thomas Galligan is principal scientist for food additives and supplements at the center for science in the public interest. Please welcome them in their presentations.

[Applause].

>> Thank you so much for the opportunity to be here today and for convening this public meeting. My name is Melanie Benesh and I'm with the environmental working group.

>> And I'm Thomas Galligan.

>> Next slide, please. But we are not here today just representing EWG and CFPI. We are part of chemical alliance that works with all of the groups represented on this slide and we're here today trying to offer a consumer perspective on behalf of all of these stakeholders. Next slide, please.

And we wanted to start by taking a step back and thinking about why this really matters and why this is important. These are just a couple of different headlines highlighting ways in which our food chemical regulatory system is broken. There are thousands of chemicals in food and food packaging. And many of those chemicals were proved decades ago and have never been meaningfully re-reviewed by FDA. And some of those chemicals had never been reviewed by the FDA at all because food companies had found a loophole to by-pass the review and sometimes not notifying the FDA that they're using those chemicals. And while the FDA has been doing some post -- ad hoc reassessments post-market reviews, those are largely happening outside of the public eye. And so it's very difficult for consumers to be able to understand what the FDA is doing and to know if those assessments are trustworthy. So it's really no surprise that recent data is showing that consumer confidence in food safety and falling. And it's no surprise that states have started to step in to ban some of the worst chemicals in food. And unless and until the FDA has a strong, credible systematic post-market review system, it's important that states continue to do that. Next slide.

>> Thomas: There is evidence that FDA is not adequately taking action to protect consumers from unsafe food chemicals. We could point to a number of examples. Red 3, methylene chloride, potassium (bromate). And I'll focus on that one here because it's a perfect example of why post-market review is valuable and improving to the existing system are needed. FDA as we all know banned BVO. And I say finally because that action came a decade after FDA began its own studies on BVO and 50 years after the agency had enough concern about the toxicity to move it from the GRAS list. This was a substance once deemed to be safe, then new evidence emerged, a post-market assessment occurred and finally removed from the food supply. Great example by post-market assessment is so important. But the fact that it took 50 years for that action to occur indicates that clearly the existing system needs improvement.

>> Melanie: Next slide, please. And these are our general principles of what an effective post-market chemical assessment program would look like. An effective post-market chemical program would be take weight of evidence using modern scientific principles. It would be systematic and objective where all principles, methods, processes, and criteria are established up front. It would be consistent and reproducible, transparent and public, unbiased, including peer review from unconflicted experts, and proactive, not just reactive to new information

that's coming in, but that takes stock of all of the existing information that's available and in addition to monitoring new information as it comes in. And most importantly, it has to be protective and has to center public health. So the FDA must take action if there are doubts about safety and shouldn't wait until it's proven that a harm has already occurred. Next slide, please.

>> Let me thank the FDA for the opportunity to review their discussion paper but we have some general concerns with the paper and the process out lined therein because it seems to deviate from the points that Melanie described. Our first concern is that throughout the paper there is insufficient detail about the methods and process and criteria that FDA will apply in performing this risk management process. Without those details, it precludes us from understanding what the FDA is doing and precludes us from being confident that the outcomes will be trustworthy. FDA will not begin this process with prioritizations of chemicals on existing information. Instead, this entire proposal is framed as one that looks forward, monitoring for new and emerging problems. It is more reactive. We would like the FDA to act on the existing information that's already out there. We already know there are some problems that need to be solved and this should begin by prioritizing chemicals based on that information. And we don't think it should come after focus assessments and be used as a step in the comprehensive assessment process. That should be the first step in the entire framework. Next slide, please.

We're also concerned about the focus assessments. And we're unclear on whether those assessments will consider the full body of evidence. And if not, we're worried that the focus assessments could miss key pieces of scientific information. The full scientific context is needed to assess the risk of these chemicals. We're also concerned about the level of public engagement and transparency at various points throughout the process, but most importantly, during that focused assessment process which seems to be largely occurring in house with limited public engagement and transparency. Further, there's a lack of clear criteria on when focus assessments will be used. And because that seems to ( ) the level of intensity and rigor and comprehensiveness of reviews, that decision point needs to be very clearly specified and scientific. And then finally our last concern is that there appears to be some blending of risk management and risk assessment. Next slide, please.

>> This is what an alternative might look like. This is a proactive process where the FDA is looking at the universe of chemicals of potential concern and prioritizing them based on existing information before conducting risk assessments and then finally moving on to risk management. The FDA can add or revise this priority list as new information emerges and comes in. And this is the process that is accountable, it's transparent, it includes peer review in multiple opportunities for public input. And the methods for prioritization and risk management are systematic, consistently applied, understood, and they reflect public input. Next slide, please.

>> So for that prioritization step, we believe chemicals should be prioritized based on risk, emphasizing those that are linked to the most severe outcomes, including carcinogens,

chemicals of concern for children, immunotoxins, endocrine disrupters, and linked to irreversible organ toxicity. Chemicals that are biopersistent should also be prioritized. Next slide, please.

>> And thankfully, these -- next slide, please. Yes. So thankfully, these chemical aren't typical. We included on the slide several authoritative lists that can be used to identify chemicals that may be linked to some of the health concerns listed on the previous slide. And then the FDA should also be looking at biomonitoring and exposure data from the total diet study, CDC information, NHANES. And the process should be quantitative, public process that can be modeled on approaches used by the EPA and other agencies. Next slide, please.

>> So when it comes to actually conducting these post-market risk assessments, we want to emphasize that it's impossible to establish a reasonable certainty of no harm, which is to say it's impossible to establish safety without high quality hazard and exposure data. It's also impossible without an evidence assessment that incorporates the whole body and not just individual studies. It should include in vitro, animal, and human studies. And consideration of cumulative effects. We are concerned that FDA would often lack high quality exposure data. And those situations, FDA should be take active steps to improve the quality of dataset available to them and not just using the poor quality data available to them. Next slide, please.

We also want to urge FDA to set concrete deadlines and hold themselves to them. That way, these assessments are conducted in a timely manner and don't drag on forever. We want to emphasize that each of these assessments should be subjected to peer review, preferably by a panel of external experts who are unconflicted and in a process that allows for public engagement and also these should be published publicly. And then lastly, these risk assessments should factor in only data that are relevant to health and safety and should not take into consideration factors like cost and feasibility.

>> The next step is risk management. And we want to emphasize that if the FDA finds there is no longer a reasonable certainty of no harm which is the legal standard, the FDA must take action, even if they can't prove that harm. And when managing range, the top priority needs to be protecting public health, not minimizing impact on industry. And for that reason, it's important that the risk assessment process determinations of safety be totally separate from the risk management process where other concerns and considerations may come in. And the FDA should be transparent about who makes the risk management decisions and how and should specify how FDA is going to enforce the risk management decisions. Next slide, please.

>> Finally, FDA should take this opportunity to reform its approach to GRAS. The current process reviews today heavily on post-market enforcement and puts consumers at risk. Often FDA only acts after consumers have already been harmed by unsafe GRAS substances. For example, the food has used the GRAS to terra flower and caffeinated alcoholic beverages without taking into consideration the harm. That is unacceptable. FDA cannot ensure the safety of our food supply if it does not know what is in our food and whether the substances

have been deemed safe through rigorous scientific process. At times even after FDA has raised concerns, companies have still used GRAS so overall FDA should take a new look at the entire GRAS process and make sure to take the burden off of the post-market review process. Next slide, please.

>> So just to conclude our presentation, we want to emphasize some of our key points. We want this framework to be proactive, not just reactive, addressing both existing and emerging information about food chemical safety concerns. This process should be systematic and transparent across the board. Prioritization of chemicals should the first step in this process. Risk assessments should be separated from risk management and risk management decisions need to be strictly enforced. And finally, we hope that the FDA will move swiftly to develop and implement this framework. And in this meantime we encourage states to continue to take action to protect consumers from unsafe food chemicals. And we look forward to continuing to work with the FDA on this process and thank you for the opportunity to be here. Thank you.

>> Thank you.

[Applause].

>> STEVE MUSSER Thank you, Melanie and Thomas. Our next presentation will be an industry representative, Sarah Gallo, who is senior Vice President, product policy, and federal affairs at Consumer Brands Association. Please welcome Sarah.

>> Sarah: Good afternoon. My name is Sarah Gallo, and I'm the senior Vice President of product policy and federal affairs at the Consumer Brands Association. First, I want to thank FDA for hosting this public meeting and providing me with the opportunity to provide testimony today, not only on behalf of consumer brands but also on behalf of various trade associations that represent many segments of the food and beverage industry and the supply chain. We collectively share FDA's commitment to providing consumers with safe and nutritious food and are supportive of the agency's efforts to launch a systematic process for the post-market assessment of chemicals in food, to in part maintain consumer confidence in the food supply and promote are more predictable regulatory landscape for industry. We're committed as stakeholders in the food supply chain to continuously monitor and support sound science and to assessment and evaluate new developments and information systematically in the context of the totality of the evidence. A proactive agenda for ensuring the safety of substances added directly or indirectly to food provides food companies with regulatory certainty, negates the ill advised and disruptive state by state patchwork legislation, strengthens areas of critical interstate commerce. And reaffirms FDA's federal authority and expertise in food safety. It also further empowers FDA to publicly defend ingredients that it has assessed and confirmed to remain safe for consumers.

I will now provide general comments regarding the discussion paper and then will address questions contained in it. We believe the launch of a more modernized systematic process for Post-Market Assessments will bring needed visibility and awareness to existing processes and

reviews undertaken by the FDA. It will also continue to further the agency's reputation as a leader on the global food stage, a reputation built and sustained by using sound, risk based, and validated science in its risk management decisions. As the agency is aware, the amount of information available on food substances has exploded in recent years. Both reflecting sound science and risk assessment by authoritative bodies, as well as information that is unfortunately much less reliable. This challenge presents a unique opportunity for FDA to provide confidence to public stakeholders regarding the regulation and management of food ingredients currently in commerce, as well as provide assurances to consumers that the food supply in the US is the most robust and safe in the world.

We believe the FDA has a critical role to play in weeding out noise from true signals, assuring its evaluations and assessments of food substances are science and risk-based and communicating the results of the safety assessments and evaluations clearly. We appreciate FDA's focus on stakeholder engagement and transparency in the discussion paper and questions posed.

It's only through a transparent process that includes robust, public engagement that we can all have confidence that FDA's decisions are based on sound science and best available data and information. With that said, we have general alignment with FDA's proposed enhanced systematic process for Post-Market Assessment and would like to highlight a few areas where we have specific feedback.

We agree that the right first step is multi-sourced signal monitoring to drive decisions on identifying and selecting substances for Post-Market Assessment by the agency as well as FDA's approach of triaging chemicals identified for Post-Market Assessment through monitoring to ensure the FDA's resources are appropriately expended on chemicals where new information is deemed relevant to a human health risk assessment. FDA's monitoring should include scientific publications, global regulatory information and actions as well as other scientific publicly available information. We believe information sourced from general news reports, social media, or other sources that do not benefit from scientific peer review or well controlled data and assessment should be validated to determine their legitimacy. As opposed to social media or even mainstream media to drive decision making. Given this multistep screening process is the gateway phase in the process to Post-Market Assessment. We recommend FDA provide more detail on these initial steps and share the specific criteria it will use to base exclude or include food chemicals for Post-Market Assessment. We support the fit for purpose decision step and the use of two types of assessments focused and comprehensive to ensure the proper depth of assessment in chemicals and use of FDA's resources. We generally agree with the fit for purpose decision tree questions in Section 3 of the discussion paper and the prioritization of risk schemes for ranking food chemicals in Section 4.

We encourage the agency to present in detail to the public its methodology and criteria that will be used for both and seek comment on these approaches to ensure they are objective, comprehensive, of relevant risk factors, and scientifically sound. We believe the agency needs to address how it will manage uncertainty when weighing decisions around prioritization and

type of assessments to use. Such decisions are dependent on having enough data and -- if there's insufficient baseline, FDA should work with stakeholders to facilitate data collection and generation before initiating prioritization or assessment.

We also provide the following recommendations regarding FDA's proposal. While we believe FDA's two pronged approach of focused and comprehensive assessment is appropriate to assess public health risk of chemicals directly or indirectly added to food, it would be beneficial to create a separate process for unintentionally added and unavoidable environmental contaminants. We believe that the agency should foremost focus this framework on food chemicals that are tied to process linked to a premarket regulatory process. We recommend that FDA should focus the post-market program on food and color additive, food contact substances, and GRAS substances. As proposed FDA has embedded a prioritization step in the comprehensive process but there's not a similar step in the focused assessment process. We recommend the addition of a similar prioritization step to the focused assessment and that the results of each prioritization step be used to establish a public facing work plan, develop transparently with stakeholder engagement.

Through the risk prioritization process, we believe FDA needs to ensure a reasonable expectation for volume and throughput for a time frame for Post-Market Assessment to ensure a robust program, accountability and management of resources. FDA needs to communicate with stakeholders about where each substance currently resides in the process and be transparent about its work plan. The agency should ideally maintain an up to date summary on its website dealing where each substance currently resides in prioritization and assessment phases. Relatedly, FDA should communicate to the public about any Post-Market Assessment list it generates and what that signifies. The elevation of any food chemicals for post-market review has the potential to be misunderstood by the public as an adverse safety determination which can cause premature stigma in ingredients and negative market impacts. FDA needs to defend its conclusions and the ingredients it has assessed and confirm they remain safe for consumers.

For both focused and comprehensive assessments, we recommend FDA communicate to the public when it initiates either form of assessment and be open to direct engagement from stakeholders to identify and gather any available information that's to be considered. This can include relevant to the exposure assessment or can include a very focused request for specific data. Similarly, for both the focus and comprehensive assessments, where the publication of conclusions include specific risk management actions, public comment should be sought prior to initiation of these actions to ensure they can be implemented in a manner that protect public health and importantly, will not create shock or disruptions to critical parts of the food supply chain.

FDA should account for the time needed for manufacturers to engage in reformulation, relabeling, and clearance of products in retail circulation when considering whether to make changes to the regulatory status of a food substance. This is particularly important for any risk

management actions that are sought following the more limited focused assessment that may be subject to less public visibility during the assessment phase. Exceptions could be made where an acute public health risk has been identified that warrants rapid implementation. In closing, we value FDA's willingness to continue to engage with stakeholders on food chemical safety and the post-market regulatory landscape. We encourage the agency to share more information and seek public comment on its processes and scientific criteria that will be used to inform decision making around surveillance, prioritization and post-market CT reviews. The capacity of the agency to in a timely manner complete Post-Market Assessment including any risk management and communication activities is also extremely important to the success of the program. Thank you for your consideration of our comments.

[Applause].

>>STEVE MUSSER For our third and final presentation from our academic representative, Dr. Norbert Kaminski, department of pharmacology and toxicology, center for research on ingredient safety, institute for integrative toxicology at Michigan State University. Let's welcome Norbert.

>> Thank you, Doctor, for that introduction. Thank you for the FDA to give me the opportunity to provide a perspective from academia. And just an introduction here, I did share this document with other -the comments I'm going to make are intended to be constructed and hopefully help FDA in their efforts to further develop and implement this Post--Market Assessment. So if I could have the first slide, please. And the other thing I did want to say is I really enjoyed Dr. Jacobs' presentation because it added a lot more granularity to the discussion paper. -My comments are going to be based on the discussion paper.

So what I'd like to do is start with opening remarks, and then I'm going to address the question that FDA asked the stakeholders to address.

So in terms of opening remarks, my first remark is having an enhanced systematic process for Post-Market Assessment of chemicals in food is a good idea. What was not clear in the paper, discussion paper, is how is the new enhanced process different from the process that is currently in place. And specifically, why is the new process an improvement? Next slide.

Secondly, it would have been helpful in addressing the FDA's questions if a preamble were included where FDA stated their rationale for developing this new process. In other words, what is the problem being solved? Having such a preamble would also be important to allay any public concern that the FDA has developed this process because the current US food supply is unsafe. And I hope that there's another reiteration of this document, that such a preamble be included. Next slide.

It is important to emphasize that historically and currently, the vast majority of concerns about food safety are microbiological rather than chemical. Fourth, while the FDA uses a risk rather than hazard based approach in their scientific assessments, one of the key elements to

assessing risk is knowing exposure. Obtaining accurate exposure data are challenging, and how it will be obtained has not been discussed. And fifth, although it may be intentional, there is a noticeable absence of details throughout the current version of the proposed approach, which I think has also been mentioned by others. Next slide.

Probably also tells us the -but I want to address the questions posed to the stakeholders. When and how should the FDA engage the public on Post-Market Assessment. Transparency and engagement with the public throughout the process is important. -Focused -assessment -for- the focused assessment, publishing conclusions and any risk mitigation actions they be needed. - that nay be needed. So publish those. For comprehensive assessments, initially, the FDA should communicate to the public a concern has been raised and the FDA is investigating. Upon completion of the comprehensive assessment, FDA should provide a published final assessment and any risk mitigation action. Next slide. Second question was is the frequency and mechanisms of the envisioned public engagement described in Section 5 of this document appropriate-?

In addition to FDA's current methods of communication, the FDA should also consider posting information to a public friendly FDA website that is easy to find, easy to navigate, regularly updated, and written in a manner understandable by the public. Next slide.

In addition to the website, FDA should use Web Analytics to ensure that their communications are valuable and effective. So some of the criteria that should be evaluated are some things like traffic sources and channels, user behavior, audience location and device usage, and performance metrics. Next slide.

Three, the third question posed to us was should the FDA integrate an advisory committee review into our Post--Market Assessment process? From the academic side -- and this was unanimous - there's no need for advisory committees in the proposed Post--Market- Assessment process for the following reasons: Historically, the FDA has done a good job in ensuring food safety for the public and in large part without use of advisory committees; also, seating advisory committees is challenging, time consuming, and resource intensive; also, the broader the stakeholder representation, the greater the certainty that biases are introduced that decrease clarity of the recommendation; and last, we emphasize the advisory committees are only advisory. Next slide.

Fourth question was: Are the fit for purpose decision tree questions in Section 3 of this document appropriate? First of all, I am not sure that the questions in Section 3 really represent what would be qualified as a decision tree. Also, from the list of questions provided, it is unclear what specific criteria will be used to initiate an assessment, either focused or comprehensive. And in addition, it is unclear what specific criteria will be used to determine whether either a focused or comp -- versus comprehensive assessment will be undertaken. It will be important to be transparent about the criteria that will be used to make the above decisions so that they are fully understood by all stakeholders. Next slide.

Also in terms of some of those decision tree questions, for example, is this substance of significant public health interest? This should really be question No. 1. Because if it's not of public health interest, then there really is no reason to continue.

Second question I'd like to comment on is: Will the assessment require significant resources outside of the office of post-market assessment? What if the answer is yes? How will the FDA proceed?

Next question: Is there scientific consensus or strong weight of evidence about the substance suggesting its potential to impact the conclusion of reasonable certainty of now harm under the conditions used in food? I would say the academic perspective was that -- suggest that deleting scientific consensus as weight of evidence should be the primary criterion. Next slide.

Fifth question was: Is the prioritization of risks scheme the FDA outlines in this document appropriate for ranking food chemicals for post-market assessments? Overall, I think that prioritization of risk scheme is appropriate. But it is notable that in bullet No. 1, which says the toxicity of the chemical is severe with potentially life threatening adverse health effects, is it hazard or risk identification? Again, the importance here is exposure. What is the level of exposure? Next slide.

The last question posed was: Is the FDA's two pronged approach of focused assessments and comprehensive assessments appropriate to address public health risks of chemicals in food? The two pronged approach is fine. However, a single pronged approach with multiple decision or escalation points could also work and may give the public more comfort in the process. Also, has the FDA tried employing data from several recent case studies to do a trial run of the currently proposed evaluation scheme? Doing so could be highly informative in finetuning the process and verifying if the approach is practical. Next slide.

Also, there will be instances during some comprehensive assessments when critical data do not exist and additional research will be necessary to make an assessment. The flow chart should clearly identify where data gaps will be addressed in the process and should be separate from the risk management and mitigation steps. Last slide.

And now, just to summarize key points, how is the proposed process different and improved from the current process? Second, weight of evidence, good exposure data, and significant public health interest are all paramount criteria to the process. Third, transparent criteria for both initiating and the assessment process and for determining focused versus comprehensive assessment. This is very important. And last, communication to the public by current means and via an FDA website that's easy to find, easy to navigate, regularly updated, conveying information in a manner understandable to the public which is evaluated using quantitative metrics.

So again, thank you for this opportunity.

[Applause].

>> STEVE MUSSER Thank you, doctor, and all of our speakers to taking the time to prepare and give your remarks and help us in this process that we are currently undergoing. At this time, we're going to move into a two part panel session. It's two part because we are going to have our panelists come up and go over some questions that we received in advance. And then we'll take a short 15 minute break and reconvene for them to get questions LIVE from the public. So I'd like to invite our panelists to come up, and they will introduce themselves in a moment.

I'd just like to tell you how we arrived at the questions. We have quite a list. They were all submitted prior to the start of this meeting. We tried to pick the ones - that were most often asked. So, as you might imagine, we got several hundred questions maybe, -and we thought it would be helpful to the audience to at least hear what are the most topical. We have limited time here, so we may not get through the whole long list. But we'll certainly try. And then of course after the break, we will invite other questions. So I'd like to start by asking the panelists to introduce themselves. We'll- start with Dr. Arvidson.

>> KIRK ARVIDSON: I'm Kirk Arvidson, chief of the scientific development branch in the office of food additive safety.

>> And Dr. Jacobs?

>> KRISTI MULDOON JACOBS: Hi, everyone. I'm Kristi, director for the office of food additive safety.

>> And Dr. Robin?

>> LAUREN POSNICK ROBIN: Good afternoon, everyone. I'm Lauren Posnick Robin. I'm a branch chief in the office of food safety. Thank you.

>> Okay. Let's begin. The first question I'd like to ask is to Kristi. What's the timeline for implementing the new process and stakeholder engagement opportunities?

>> KRISTI MULDOON JACOBS: Thanks, Dr. Musser. So I mean, I think if you've been watching our work recently, you'll see we're already starting to implement gradually a lot of these processes or these approaches. We have included an updated website that lists some of the things that we have prioritized. And within that website, it indicates which stage of review the substances are. We mentioned that in one of the comments. So that's included. We are, though, planning to escalate this effort once the reorg is complete and are really hoping,- at least it is our aspiration,- --to be moving more fully towards full implementation by the end of calendar year 2025.

>> Thank you. And again, I'll just ask in the next session if you'd like clarification on any of these points or to ask more information about any of these questions, - please understand that you will have that opportunity. The next question is for Kirk. How does FDA plan to identify and evaluate the safety of substances that are determined to be GRAS by an industry entity about which FDA may not know post-market?

>> KIRK ARVIDSON: All right. Thank you, Steve. Well, we've actually begun developing a number of tools, both in information technology as AI and machine learning-based approaches such as the WILEE horizon scanning tool for signal detection and the FoodTrak food labels database. We can use those in our monitoring and surveillance of the food supply. These tools can be used to identify new ingredients through the signal detection tools that WILEE has and monitor for trends in the food supply.

>> Thank you. Our third question is - back to Kristi. How can the FDA justify that its current post-market surveillance for GRAS is adequate, timely, and appropriately staffed and resourced when it took 25 years from when meaningful evidence for health harms of industrial fats were first identified and 11 years from the first citizen petition to revoke GRAS status to remove PHOs from GRAS status?

>> KRISTI MULDOON JACOBS: Yeah. Thanks, Steve. So I want to start by saying we obviously think our post-market program needs improving. That's why we are here. We're putting together the discussion papers. These are things to improve upon. As it relates to the case of PHOs while they reference industrial fats they certainly were added. They also are naturally occurring. Certainly complicated the scientific review. After that scientific review was completed, we put out for public comment to receive comments from industry on whether or not they agreed with our determination that the use of added trans fats no longer met the generally recognized standard. It takes time. In addition to that, we engaged in rule making to remove references to PHOs within our regulations. This also provides opportunity for public comment which we - are talking about doing more of here and we want to, but we need to acknowledge that adds time-.

So when we are talking about our new process, we do want to continue to use those tools. Those are important tools that we have. We also want to leverage use of other tools like increased communication and other tools we have at our disposal so that we can move this and at least engage the public earlier, I should say, in our work. But I want to end with where I started. We do see a need to improve. That is why we are putting the proposed process forward and seeking to stand up a new process.

>> Okay. Thank you. Next question is back to Kirk. Will reassessing the GRAS status of chemicals be part of the FDA's post-market review?

>> KIRK ARVIDSON: That's an easy one. Yes. It is definitely within the scope of the post-market review program. As you know, some GRAS substances may not have been previously assessed by the FDA. But they may be - - assessed as a part of the post-market program if information becomes available suggesting that an FDA assessment is warranted.

>> Thank you. The next question, the fifth one, is for Kristi. And Lauren, I promise I'll get to you. These are just kind of in order of the most asked questions. Would FDA consider implementing discretionary review of self-affirmed GRAS dossiers? The prevalence of such dossiers attended by less than rigorous scrutiny warrants more oversight.

>> KRISTI MULDOON JACOBS: So I just want to reaffirm what Kirk said to the first question which was related to reviewing GRAS. That is part of this process. But in direct answer to this question, FDA already reviews GRAS conclusions as a part of our GRAS notification process. I did some calculation in preparation for the reorganization. On a rolling average of five years there are between 60 and 70 GRAS dossiers that we review and complete, that we file and complete, I should say, each year. So while we do continue to implement that important program and we are looking at GRAS ingredients as a part of this new process, -it is worth mentioning that Congress sets GRAS as a part of the law, and industry is not required to bring dossiers to us. It is our responsibility to administer the law. We do not in fact have the authority to make the laws. We can challenge a GRAS conclusion. And just this past year, I think it's still within this year, we started putting up some of our not GRAS memos and dossiers on work we have done which demonstrates the substance we have seen in food does not meet the determination of a generally recognized as safe use substance in food. And so that is a change that we're making as well-.

>> And the next question is also for you, Kristi. How does FDA intend to fund this work without additional budget appropriations?

>> KRISTI MULDOON JACOBS: Yes. So one good thing is that under the reorganization, we will have an office of post-market assessment within the new OFCSDSI, office of food chemical safety, dietary supplements, and innovation. I've been practicing that acronym. [Chuckling]. So we will have a new office. So we will have a process that we can put in place and people who are responsible to do it. That said, we did not get new resources with the reorganization. So we have reallocated some resources, a modest amount, to move into that program. And as I mentioned in my remarks, we are planning on utilizing cross assignments, but we will need additional resources to fully realize the program we outlined and to be successful and move as quickly as we really would like to.

>> Okay. The next question is for you, Lauren. Limited FDA resources constrain the extent to which it can conduct high quality reviews of the safety and health effects of the many chemicals in the food supply. Is there a mechanism by which industry can be required to fund reviews by either FDA or accredited private reviewers, especially with fee-based structure?

>> LAUREN POSNICK ROBIN: Thanks, Steve. FDA does not have the authority to charge user fees or other fees to cover review of new or existing food ingredients. So it would really be up to Congress to grant us that authority.

>> Okay. The next question is for you, Lauren. To what extent will the post-market assessment methods be harmonized with the European union?

>> LAUREN POSNICK ROBIN: Thanks again, Steve. Well, in terms of harmonization, I think there's a lot of harmonization in the science. FDA experts currently participate on European scientific panels, international panels, JECFA, and we participate in other US agencies' chemical assessment activities, but when it comes to our regulatory and risk management activities, we

have to work within the legal framework that's set forth by the US Congress, which of course differs from that of the European union.

>> Thank you, Lauren. Okay. 9th question is back to you, Kristi. We received a number of questions regarding cumulative exposure to chemicals. I'm guessing this is from this group or whoever submitted. We want to address that quickly. Response?

>> KRISTI MULDOON JACOBS: Okay. So I want to say- this is an important question, actually, that we're hearing more and more that's coming to us about this cumulative safety assessment. And so I would like to take this opportunity to say that when there is scientifically reliable information that demonstrates a cumulative assessment is warranted, we would conduct such an assessment. We recognize that after a substance is first approved, we expect that more data and information is going to be brought forward. That's the nature of food chemicals. I think in the work that I've done across different FDA regulated spaces, it's a little bit unique. -Once a new ingredient is on the market, there is a lot of interest within the scientific community to look more closely to do more research.

And as that research comes out, if that research suggests that a reassessment is warranted, this is what we're talking about. How will we identify and do that work?

Now, because we know that more research could be coming out when we do a premarket assessment based on the data and information that has been provided to make sure that we are accounting for uncertainty in the information as part of a safety assessment, we include a number of safety factors into the toxicity portion of that assessment. We include safety factors for interspecies diversity as well as other safety factors or uncertainty factors based on the size of the dataset. Another piece for calculation for those assessments the exposure side, we add additional redundancies and double counting and estimations to make sure that we're capturing an absolutely high upper estimate of what that exposure could account for. For instance, one of the things I like to say is that we assume industry will be overwhelmingly successful with every single new chemical and ingredient that they have developed and proposed, that it's going to overtake the market and be in every possible food ( ) at the maximum level despite the fact that we know there are other chemicals that have the same function and the same effect within that food. In that case, we are also adding - conservatism into our safety assessment approaches. -Thanks, Steve.

>> Thanks. The tenth question comes back to you, Kirk. With the new process, how can consumers submit concerns?

>> KIRK ARVIDSON: So that's one of the things that we want to hearing a little bit more about from you guys. What we're considering now is developing a web based portal. We have something called a CFSAN online module where folks come to us and submit food data submissions, notifications, et cetera. We may be able to leverage that type of a tool to allow you all to send in recommendations to us. If people are interested in submitting comments on a substance that is currently under evaluation, there are a number of ways to do that. Food

additives, color additive petition, there's a docket open and you can submit your petitions into the docket. There are other places you can call in, send in emails. We also have the CAERS data set, the adverse event reporting tool that we have at CFSAN. But in the meantime, consumers can report general complaints to FDA phone number as well as email. Someone will be assigned to assist you. Thanks.

>> Thank you. The next question we have for you, Lauren. Does -the reassessment, of all chemicals include pesticides?

>> LAUREN POSNICK ROBIN: Thanks, Steve. In the US, the safety of pesticides is evaluated by the Environmental Protection Agency and they set the tolerances for those pesticides. So this process will not include pesticides, but it will include all the chemicals that have been mentioned so far, food additive, food contact substances, GRAS substances, contaminants, and color additives. Thank you.

>> Thank you. The next question is also for you, Lauren. How will FDA prioritize chemicals used in regard to processing aids or are these excluded?

>> Lauren Posnick Robin: Processing aids are not excluded. Some people think of those as contaminants. But in the US they are regulated as food ingredients. And the assessments will be prioritized, and priority will be given to chemicals that have higher priority rankings. This is consistent with the overall approach being taken in the human foods program to prioritize work where it is most needed.

>> Thanks. So our last question-- I believe -- our last question for this particular session goes to you, Kirk. How will food color additives and dietary ingredients be prioritized for post-market assessment? Will this be based on any kind of adverse reports, or will it be based on the estimated volume used in the food supply?

>> KIRK ARVIDSON: Thanks, Steve. I have a long answer. As Kristi pointed out earlier in the presentation and in the discussion paper, we're looking at seven different sets of questions. So FDA experts will rank individual chemicals selected for those comprehensive - assessments. We talked about including some kind of a ranking system for the focused side as well and use these preestablished criteria to determine- a relative priority against other chemicals in the - queue. We envision using a multicriteria decision method, using this MCDA approach, the higher the score-, the higher the priority for that chemical for further review, with primary focus being risk to the public health. For public health ranking, we tentatively envision a chemical would receive a higher score based on severe toxicity, increases in exposure, presence in vulnerable populations and potential significant impact on conclusions of previous assessments. Note that this process is not intended for use with immediate public health threats. Those will be addressed and triaged, evaluated and responded to using our existing processes. Thanks.

>> Okay. So that concludes the formal part of our presentation today and our meeting today. The good news is that all of our panelists and invited presenters really kept to the time frame.

And in fact, some of them were very succinct and kept us under time. So it's good news for all of you since you'll have an opportunity both those present here as well as online to ask more questions in the public question part of the meeting. For you all, that just means more questions. I would like to just remind people before we take a short break that for our virtual audience, please enter your questions into the question and answer part of the meeting, electronic meeting presentation on Zoom. That way, we can not only capture them for the record but also, we'll be able to identify which ones -- who has questions. For in-person questions, please write your questions on the note cards that are provided there at your seats. And one of our staff members will come around to collect these, or you can give them to one of our staff folks.

Lastly, we won't be able to answer all of the questions, I suspect, today. But we do encourage you to submit your questions to the docket. Even if you get them answered, we encourage you to submit them so we have an appropriate record. I would now-- we're now scheduled for a 15-minute break. Why don't we try to be back here at 2:30, which is a slightly longer break, but please try and be back by 2:30. And there is -- there are refreshments in the lobby. Please take advantage of them. And I would ask that you be -- return here to start the meeting again at 2:30. Thank you all.

>> For those of you that are online, when we come back, we'll be coming into the additional Q&A. And right after that, we will go into the open public comments session. So when we come back, before open public comment, we will all those who are signed up to make a statement to -- we'll have you raise your hand and verify that you're in the room. And then we'll go through that process. With that being said, please be back by 2:30. We will reconvene. Thank you.

>> AUTOMATED VOICE: Recording stopped.

[Music playing].

[Break].

>> AUTOMATED VOICE: Recording in progress.

>> All right. Let's start getting back to the seats in the room. Those of you online, we'll get started shortly. Just a reminder, when we recoup, we will be taking the Q&A questions that were submitted by those in person and those of you online. We'll do our best to get through as many of those as we can in the allotted time. So again, this is just a call for everyone to get back to their seats. And let's get started as soon as possible. Whenever we're ready, I will hand it over to the podium. I'm going to ask that the panel be set back up as well.

>> I believe we're just about ready to get started with the next start of our presentation section, our question section for the panel. Thank you all for returning and for participating and for providing the questions. These are all questions that we received. I will read them, and we will get through as many of them as possible. It looks like I've got different hand writing

here, so I will try and do my best. Forgive me if I don't get it exactly right. So I'll read them and then the appropriate panelists will take the question. We are ready.

Do or will subject matter experts consider only one study that happens to catch the attention of the public? Or the FDA, e.g., the paper on erythritol seeing it may affect risk of CD outcomes or will it do literature and consider the entire body of literature entirely or similarly?

>> KRISTI MULDOON JACOBS: It's harder when you can't see the words on paper, Steve. But I'll try.

>> Sorry.

>> KRISTI MULDOON JACOBS: [Chuckling]. It's okay. But the idea is to have a repeatable and dependable process to identify signals, not just things that capture the public's attention. As it relates to the example that I gave, in that case, as a part of the consideration of that issue that came up, we didn't just look at one paper. There was an information gathering. But it was focused on all studies that are covered and have been conducted for erythritol. It was information and studies that were adequate and helpful to evaluate the concern that was raised in that initial paper that we identified, which was -potential- cardiovascular effects. It was more than one paper. There is an information gathering stage. When we identify something, we will need a review. We will gather all of the relevant information to inform that specific review. We expected that erythritol was going to be of interest, of course, since we were mentioning it today. So we went ahead and proactively posted that memo so that you could get a better sense of the type of evaluation that - at least with that as an example, thinking about it has been posted on our FDA sweeteners page, so you can find a link to the memo there. So I would invite you to take a look. But - a lot of this work is going to be on a -case -by case basis. It's going to depend on the amount of information, the questions raised. Just because that's the way we addressed erythritol, it's not necessarily going to be like that every single time. It's going to be on a -case-by--case- basis.

>> Next question: Will ingredients on which a focused assessment was completed be made public?

>> KIRK ARVIDSON: I'll take that one. Yes, actually. We're definitely making it public. We have a list right now, a select list for substances for post-market review, I don't remember the exact name. You can Google it and it will list off a variety of substances that we're looking at as well as the different stages we're in and summaries and links out to more in depth pages on those particular substances.

>> Thank you. It was mentioned that comprehensive assessment will be performed by a group of experts. Will the focused assessments be done by a single person? Who would make the decision to follow up or not?

>> KRISTI MULDOON JACOBS: I'll take that one. Being at the FDA, this is where there's a nice advantage. It's going to be case by case. Depending on the question, sometimes there may be

one expert that has the appropriate expertise that can review an answer, a situation. In other cases, there might be more than one expert. So for both comprehensive and for focus, we're going to bring the appropriate resources to bear to ensure that we're able to adequately address the issue that's been raised.

>> Does FDA intend to rely only on FDA staff to perform assessments for monitoring or if it is envisioned that qualified external resources will be needed to assist in the assessments?

>> KIRK ARVIDSON: I'll go for it. If I understand the question, it sounds like if we're going to do everything internally or if we set up something like a JECFA panel or something like that. The intention is to do it with our own internal staff as far as I know. And obviously there are certain cases such as PHOs where we had to go out and get data or generate data for ourselves. So we obviously have to work with folks outside to get some of those data. So we would do the assessments internal.

>> Okay. Thanks. And if anyone else on the panel wants to weigh in and provide additional information, please do so as well.

>> KRISTI MULDOON JACOBS: I'm going to weigh in because I can never resist the opportunity or opening to talk about the real scientific expertise that we have inhouse and the amount of scientific rigor. For a long time, especially within the office of food additive safety but other offices as well, we have a large chemical space to cover. That means we have to be able to have expertise inhouse to be able to cover a variety of different end points and have the expertise, knowledge, and experience to be able to evaluate reproductive or cancer end points or other chronic health end points. So I never want to miss the opportunity to talk about the excellent scientists that we have and the conflict of interest and independence that is required when you are in service in the federal government. And so the impartiality and expertise is something that we're proud to be able to have.

That said, it is, you know, we think bringing out the opinions to get, as I mentioned in my remarks, input from the science board when appropriate, a peer review when appropriate, we do think that that strengthens confidence. So we will -- and help us in our work. Although I think everybody's great, no human is perfect. And so bringing that to bear as part of what we plan to do, depending on the scenario, what that looks like, again, is going to be on a case-by-case basis.

>> Next question is two parts. Can you clarify the scope of the program? How many chemicals will you be able to review over a year, for example? I'm guessing this is current. And can a focused assessment result in regulatory action, or is it just a stepping back to comprehensive?

>> KRISTI MULDOON JACOBS: I'll take that one, too. [Chuckling]. I've been thinking a lot about these issues. So the second part of the question, I guess I'll take that first because - I really like the perspective of academia. I think you can think about this as a -two tiered process. You can think about it also as a process that can potentially build on itself. And so we do expect that if

there was a focused assessment, that based on that, identify that there was a need for the agency to take risk management actions to reduce exposure and ensure safety of substances in food, we don't need to go all the way to a comprehensive assessment to be able to do that. If the science and the record establishes that there is no longer reasonable certainty of no harm or that food is adulterated from contaminants, we can go straight to evaluating what our risk management options would be and taking the appropriate regulatory action. We can all envision, probably, a scenario in which a focused assessment can result in [a conclusion that] actually, we need to learn more. And that might look like a comprehensive assessment. From that perspective, you can say that this is a process, one process, that has off -ramps. Or it could be an on ramp of just starting at -that point.

>> Are there opportunities for external engagement within focused assessments?

>> KRISTI MULDOON JACOBS: So we hope that focused assessments in terms of how we express the findings, the FDA will be able to do internally. And I absolutely appreciate, and we absolutely appreciate, and we discussed earlier that there's a lot of value in having an external peer review. And comprehensive assessments, it's probably absolutely necessary as a part of that process. As it relates to expediency and being able to identify and address problems in an expedited way, I guess it's saying the same thing two different ways -we hope it will be done internally. And it might be that we might move to comprehensive. It might be the question that was raised didn't raise safety concerns. It might be there's significant data gaps, and we're going to seek to be able to get more data to fill those data gaps. But as it relates to focused assessments for the sake of expediency, we really are hoping that in order to be a focused- assessment, this is something that we think should be handled within the agency using our experts.

>> Okay. Next question: Are there any plans to work with other agencies, such as EPA, on chemicals in food ingredients and effects/cumulative effects on safety of foods produced?

>> KRISTI MULDOON JACOBS: We certainly would like to work with other agencies, especially in the hazard identification phase, whether they be US regulatory authorities or they be international partners where they're looking at questions that would be relevant to areas that are under our regulatory authority and responsibility. There are good scientists, good risk assessors and good work happening all over the globe, and we want to be able to leverage that work and work with partners that can contribute to helping us move the mission forward. So we certainly will. There may be some similarities in terms of the hazard part of that assessment. And then there might be some differences in terms of the exposure end of the assessment based on the different product spaces. But we would like to be able to leverage federal partners and international partners wherever we can.

>> Lauren, would you like to comment at all on contaminants?

>> LAUREN POSNICK ROBIN: Thanks, Steve. I mean, just echoing what Kristi said, there's already a lot of ongoing cooperation on contaminants between agencies, particularly EPA and

USDA, but other agencies like NOAA for seafood safety. And we frequently engage with international colleagues in JECFA and EFSA and a small group of international regulators to keep up on the current contaminant space and identify new risk management approaches. So I would see that being enhanced under this new program where we have chemicals in one office. And we also have a focus on prioritization to help us identify the most important contaminants.

>> Next question. There's a divide between public and private sector. Both may not listen to science, end quotes. How will you ensure FDA's decisions are science based and not driven by finance or fear?

>> LAUREN POSNICK ROBIN: That's clearly a little bit of a tough question. But I'm actually happy to take it on. You heard Kristi talk about the prioritization process. And so I think that will be key. There will be prioritization both in the chemical super office and in the larger human foods program. And I think that prioritization will be based on science. There will be points which public concerns and public interests are definitely considered because that is important to -- as a part of our stakeholder engagement. But we are all committed to bringing the best science into the prioritization process.

>> Okay. The next question: Will industry sponsored testing be excluded from consideration in reviewing scientific evidence?

>> KRISTI MULDOON JACOBS: FDA doesn't want to turn away good data. If data is good. We will review it. We will look to our independent analysts to do that. We will evaluate them impartially and fairly, regardless of their source.

>> How do we factor in the new exposure assessment for any chemical? What resources are we using and are they up to date?

>> KIRK ARVIDSON: Exposure guy. So yes. We have a number of tools with respect to assessing dietary exposure. And we are -- strive to have access to the most current dietary information. So we do partner with folks down at the USDA. We look at the total diet studies. At the NHANES information. All that information is brought in into one of our tools that we use to calculate dietary exposure. So we are bringing in- that new information that becomes available and using those in our assessments.

>> Thanks. Next question: With the limited budget, can we expect the Post-Market Assessment will be largely based on risk assessment of targeted items?

>> LAUREN POSNICK ROBIN: Steve, I think the answer to that question goes back to prioritization. So yes, we do have resource constraints. But we're committed to focusing on the chemicals that pose the most significant concerns based on our prioritization. I hope that addresses the question. If there's more to it that I didn't address, I'd be happy to take another swing at it.

>> Okay.

>> We have time for just one more question and then we have to move on to the open public comment.

>> Okay. Will FDA utilize its reinvigorated food advisory committee to assist with this work? If so, is there a plan on how that might be done?

>> KRISTI MULDOON JACOBS: So we mentioned the topic of external peer review and public engagement as a part of this process. And we are going to consider what resources we have available. I don't mean resources. What bodies are available to us, and we will use external peer review. There's a number of things. Also mentioned was the reinvigorated food advisory committee. We have external IQA, peer reviews, a number of ways which we can get our studies evaluated and reviewed, and we will consider all of those and choose the most appropriate.

>> Okay. So we will be now moving to the virtual questions. I have about 16 questions that we didn't get to. Thank you for submitting them. We will enter them into the record regardless of the fact that we didn't get to enter them specifically here. Thank you for contributing them. Michael, off to you.

>> Mike: Thank you. And let me pull up our next slide here with us. Yup. Here we go. For those of you who are virtual who did sign up to speak as an open public commenter, we ask that you now raise your hand in Zoom so that we can make sure you're ready to speak. So we'll give you all a moment to do that. Again, only those who have registered to sign up as an open public commenter. Just as a reminder, on screen, you will see a timer that we will give you three minutes to help keep everybody on track. Let's see. So once I see hands up, just a few little reminders as we're going through the process, those of you who are online, please note that we want to keep all comments professional. If at any time, if we have any profane language or something like that, we will have to remove the mic and move on to the next person. With that being said, I'm going to go with the first one. There will be a pop-up on your screen that says -- to allow you to talk. I'll do my best as I introduce people. We'll go with Alexi. You're going to be first. And please, when you are unmuted, please state your name, your company, organization, or if you're independent and if you have any financial interests. Please take it away.

Let's see. This is what I was afraid -- we'll try one more time. We're going to ask to unmute. Please make sure you see that pop up. There you go. You can unmute your microphone. That's why we're allowing that extra time. All right. Meantime, I'm going to move on to the next person. Representative Jan [Schakowsky]. I'm going to allow you to talk. Go ahead.

>> Thank you so much. Can you hear me?

>> Yes, we can.

>> Oh, thank you. I really want to thank the FDA for holding this public meeting. I thank you for that. It's very important. Of course, we're dealing with food chemical concerns. And I also

just want to say a thank you to Mr. Jim Jones who actually came to a hearing, the committee I was on, to talk about this important issue. He is the deputy Commissioner for human foods. So let me get right to it. So I want to urge you to consider and hopefully implement legislation that I have offered. The food chemical reassessment act, which I have introduced in Congress. And the bill would create the office of food safety reassessment at the FDA, which I think is very, very important. Also, it calls for 10, chemicals every three years to be reassessed because that really hasn't happened for a long time.

For example, BHA has been waiting 30 years after having asked for a reassessment of a legislation. That seems that too long a time to wait. We have also parabens which can cause cancer and BVO, which was banned by the FDA, at least it was put on being banned in July. But my question there is: Has there been federal monitoring of the efforts to get BVO out? I also just want to say pretty much in closing that it is very important that food safety is not left to the food industry to make the decisions. We need to do that. When I say that, I mean the FDA and the people need to be -- need to be protected. I do have one more question for -- and I don't know if Mr. Jones is there, but let me tell you when he spoke before our committee, he said that would really very much like to do more food safety work. But he said that there needs to be more money at the Food & Drug Administration to have the resources that are necessary. And so my final question would be: If we can be told what do we really need to do the work that will protect consumers to make sure that we are able to do the work to see what chemicals need to be addressed with and what order? So with that, that's all I really have. And I'm Congresswoman Jan from the ninth district of Illinois.

>> Thank you so much. Our next speaker is house representative Natalie [Mihalek]. I apologize for any names I mispronounce. On deck then will be Alexi -- senator -- I apologize -- Giannoulias. Hopefully, again, please state your name. So Natalie, are you ready?

>> It took a second to come up. Can you hear me okay?

>> Yes, we can.

>> Good afternoon, my name is Natalie, and I'm a member of the Pennsylvania house of representatives serving suburban Pittsburgh, and I'm also a mom of three young children who all loathe the fact that I'm on this meeting today advocating against their favorite junk foods. I have proposed legislation in Pennsylvania that targets a handful of chemical ingredients all of which have been found by the scientific community to adversely affect our health in a wide variety of ways, ranging from behavioral issues in children to immune system disruption and even cancer. I realize there was a lot of thought and effort and engage the public on this and I appreciate the thought that went in into resigning the program as well as developing a process to actually review the chemicals we are all eating. But these proposals are inadequate at this point in time. If we were having this conversation 30 years ago, I would applaud this proposal. But the reality we face with our food supply in this country calls for immediate and drastic changes to the system that we have.

Since the year 2000, we know that 99 percent of the new chemicals that have entered our food supply have done so through the GRAS loophole. This is in direct conflict with the reasonable certainty of no harm standard. I want to talk for a moment about legal standards and why I think the FDA has it backwards right now. As a former prosecutor, I'm very familiar with the proof beyond a reasonable doubt standard. Innocent until proven guilty. Defendants have the right to due process under the law. For some reason we are treating chemicals as if they are criminal defendants entitled to due process. Innocent until proven guilty, safe until proven otherwise. Chemicals made by companies whose only mission is to make more money. They are working on an honor system. History clearly shows that honor system doesn't work when it comes between a company and its profit. The proposed process allows for all thousand at least of these chemicals that we are ingesting to stay put while we sit around and wait for perfect science to 100 percent convince everyone beyond a reasonable doubt that it is in fact dangerous. Because our food review policies have been dormant for decades, we don't have the luxury of time. The kind of time that the proposed process allows for. Inaction has made this an emergency. Our food is literally killing us. We're spending over $4 trillion every year in this country on healthcare, and 85 percent of it is on preventable diseases.

The standard American diet may not kill you tomorrow, but just give it some time. We don't have time to waste. The clock has run out on our health. When you're down and the clock is ticking, you don't run the ball unless you're the Pittsburgh steelers. Throw a hail Mary and that is my plea to you today. To throw that hail Mary. This is the most important issue of our lifetime. It affects every single one of us. In till there's a process to remove toxic ingredients from our food supply, states like Pennsylvania will have to take up the fight themselves. Thank you.

>> Thank you. Next up, Alexis, the Illinois secretary of state. If you can please unmute. If not, we're going to go to Jim Krieger. And again, we're waiting for them to accept the unmute. You should have a pop up on your screen. Hmm. All right. Jenny Hopkinson, you're next. Again, some of the people are jumping off. Jenny, you want to take it away?

>> Yeah. Good afternoon, and thank you for the opportunity to -sorry, to provide feedback to assist the Food & Drug Administration as it considers the development of an enhanced systematic process for the FDA's Post--Market Assessment of chemicals in food. My name is Jenny. And I'm- providing remarks today on behalf of the Sustainable Food Policy Alliance which is comprised of the world's best known food companies. SFPA seeks to accelerate change through individual leadership and collective support for public policies that are innovative, raise the bar, and inspire further action by industry peers.

We recognize our responsibility to drive positive change for the people who use our products and the people who supply them and the planet. We welcome the opportunity to share insights, and we look forward to working with the agency moving forward for effective science based Post-Market Assessment of chemicals in our food that will support public health needs and ensure consumer confidence in the safety of the US food supply. Based on the pace of

emerging science, growing consumer interest in this area, and the number of states currently taking action via the passage of food and ingredient bans it's clear that we need a transparent process for conducting Post-Market Assessment of chemicals in food. FDA is clearly best positioned for the role, having the toxicological expertise to assess the safety of food ingredients consumed by the American population.

We appreciate FDA's commitment to proactively apply the latest scientific knowledge and make effective regulatory decisions. And we support many of the concept outlines in FDA's discussion paper, including the concepts of fit for purpose decision making, the use of multicriteria decision analysis tool to prioritize work and the recognition for the need for transparency and public engagement. As FDA works through this process, SFPA recommends the agency take the following actions. First, establish a regular cadence for when the prioritization is updated and clarify to the public what the agency's preferred mechanism would be to nominate or propose a substance for prioritization. Second, the agency should continue efforts to increase transparency. As this process evolves and is individual risk assessments take place, we think transparency will be key. For example, FDA should make public more details on the criteria it will use for prioritization. Efforts to be transparent on what reassessments is taking place and the timelines the assessments are on.

And third, FDA should development educational resources to help all stakeholders understand the changes FDA is making to keep pace with evolving science and be an effective regulator of food chemical safety. As food companies that reach millions of consumers SPFA believes that strong science based of food chemical safety will provide consumers with the confidence they deserve to have in our food system as well as offer industry regulatory predictability for producing safe and affordable foods for American consumers. SFPA looks forward to working with FDA and other stakeholders through this process and will submit more details comments to the docket.

>> Next up is Jim Krieger.

>> Thank you. I'm Jim Krieger, physician, clinical professor at the University of Washington, executive director of Healthy Food America. Thank you for considering this much needed Post-Market Assessment process. I'll use the example of nonsugar sweeteners as the context for my comments. They’re our poster child for the deficiencies and ensuring that a food ingredient causes no harm with reasonable certainty. Let's first consider Stevia, monk fruit and erythritol. Industry submitted GRAS letters about them and the FDA had no questions for any of them. The data in these notices does not reflect current knowledge. GRAS notice for erythritol before showing CVD. The last GRAS letter for monk fruit was 2018. And all the notices are based on animal tox data and inadequate human studies.

For example, monk fruit sites only two human studies with people aged 19 to 25 and only looked at glucose test 40 days after one exposure. Is it a way to ensure that a chemical is safe? Similar use for other ones like super low saccharin but there's a large growing evidence that

NSF is tied to type to diabetes. What should a robust and better process for Post-Market Assessment look like? Well, assessments should include multiple types of the total accumulated body of evidence like cohort studies and RCPs and tox data. Evidence on human outcome should be given the greatest weight. Data will have to come from prospective cohort of sample size. RCTs are less useful given their limited ability of health outcomes and ethical issues with human exposure. It's important to avoid conflicts of interest. Companies that benefit from a favorite safety determination should not be members of advisory review committees and must disclose their ( ) to the comments submitted to the FDA.

As noted before, user fees from industry are needed for robust and timely assessment process and Congress should act. The FDA should use the precautionary principal in deciding whether exposure is appropriate. This is taking preventative action in the face of scientific uncertainty. And while further scientific evidence is developed. It is used by the EPA and is with the - the public must be able to understand and review and offer feedback on assessments. There should be a transparent and timely process for individuals and organizations to request and get a response for a Post--Market Assessment and advisory committee are good ideas at the stages of prioritizing chemicals for review, reviewing the assessment protocols and reviewing draft findings. Thanks for this opportunity to offer comments. I look forward to seeing FDA move forward with this important work-.

>> Thank you. Next up is Paul Kirk. Again, just a reminder, just unmute your mike. Paul, take it away.

>> All right. Can you hear me?

>> Yes, we can.

>> My name is Paul Kirk, and I'm simply a concerned citizen. Imagine sitting down for dinner, only to realize that what you're eating may be contributing to cancer. As we gather for this open hearing, it's crucial to confront the uncomfortable truth. Why are we allowing substances linked to cancer to remain in our food supply? Today, we must demand transparency and accountability in our food safety regulations for the health of our families and future generations. The basic use of transparency by the FDA needs a complete overhaul due to the fact that food additives that cause cancer such as artificial sweeteners, nitrates, and ( ), BHA and BHT, propyl gallate, and caramel color are allowed in our food supply. Did you know that when E. Coli creates fecal matter, the actual defecation is what we know as asper tame? All the while, chemicals like brominated vegetable oil, ABA, potassium bromate, artificial food color such as red 40 and yellow 5 and recombinant growth hormone are not even allowed in other countries' foods. It is very transparent to me that the FDA simply does not care about the health or wellbeing of its own citizens.

Next, the flexibility of the FDA to allow 3600 different chemicals in food packaging is simply intolerable. About 100 of these chemicals are considered to be of high concern to human health, such as PFAS and biphenyl A. Furthermore, the multicriteria decision analysis needs to

determine why we allow around 14,000 food contact chemicals which are capable of migrating the food from packaging made of plastic, paper, glass, metal, or other materials. Also, a focused assessment needs to implement change. A change that does not allow a hormone disrupting chemical like biphenyl A or phthalates that have been linked to infertility. A comprehensive assessment has to be made as to why generally recognized as safe chemicals in our food packaging and our food supply that caused health problems are allowed to be served to our American citizens. In conclusion, while the FDA's efforts to ensure food safety and regulate harmful chemicals are commendable, there is a growing concern regarding the potential impact of these chemicals on public health and demographic trends. As the agency aims to support the rising birth rate and promote overall health among Americans, they must prioritize comprehensive evaluations and stricter regulations on harmful substances in the food supply. By addressing these critical issues, the FDA can help create a healthy environment that fosters well-being and encourages population growth, ultimately contributing to the vitality of future generations.

>> Thank you. Next up is Flor Linares. After that is Tiffany Lee.

>> Hi, everyone. Can you hear me?

>> Yes.

>> Awesome. Hi, everyone. My name is Maria, and I'm the head of strategy and business development at Talam. What we do is we found a way to reduce heavy metal out takes plants through naturally occurring micros and we are working to build solutions for ( ) in rice, spinach, wheat, and ( ). We are currently testing our technology across Ireland and the US and are planning to test in 2026. And I appreciate the opportunity to give some feedback here. Given the challenge of balancing contaminant risks and health benefits, we believe it's important to deal with added organic - environmental contaminants by adding a layer of testing on double finished goods. This should help limit the risks and monitor effectiveness on mediation strategies. When it comes to heavy metals with we are amazed by how little coordination there is between health, food, and agriculture. Lack of coordination in a Post-Market Assessment for environmental contaminants such as cadmium, lead, arsenic or mercury, which most times are intentionally added can make the stream worse. With that in mind, we believe it is equally important that FDA considers signal monitoring with other agency such as USDA and stakeholders across the food system from food companies to farmers. As we know better, we can do better. To conclude on behalf of my team at ( ) I would like to encourage the FDA to be as transparent as possible decision -making as we consider refining the refining the assessment process. -Thank you.

>> Thank you. Now up is Tiffany lee and following that will be Malavika Tampi.

>> My name is Tiffany lee. Oh, can you hear me?

>> Yes, we can.

>> My name is Tiffany lee, and I'm the executive director of Altagracia Faith and Justice Works, a nonprofit located in northern Manhattan, dedicated to putting faith into action, promoting social justice within our local immigrant community. We organize social justice community teams and have a youth service learning program which covers topics such as food justice. We are proud to partner with the interfaith public network and center for science to support campaigns to pass food safety legislation at the New York state level, two of which relate directly to today's hearing and we urge the FDA to take action on these issues for people across the country and hope this new Post-Market Assessment achieves this. In 1990, the FDA determined that food dye red 3 causes cancer when ingested by animals. However in spite of federal law prohibiting human or animal carcinogens being added to food, the FDA has taken no action to ban red 3 since it was determined to cause cancer. Our partners at CSPI filed a petition in November 2022 requesting immediate action to delete the die but the FDA still has not banned the dye. Where does that stand now?

The FDA banned brominated vegetable oil but only after decades of known safety issues and after California banned the sale of foods with ( ). The FDA should not wait until states like New York and California take the lead and should instead be a national leader for people across the country. Personally, I'm doily troubled to learn that some of these chemicals, the New York legislation seeks to ban are linked to other adverse effects including thyroid issues which I personally experience. I'm also deeply concerned by the FDA's permissiveness and process around substances, quote, generally recognized as safe, and apparent lack of accountability to the people these policies should protect and inform. Rather indifference to well funded food companies incentivized by profit, not health.

Recently, one of our community members came to me devastated by the recent death of her son after he ingested Neptune's fix, marketed as a dietary supplement which he believed would help him sleep and have overall improved health outcomes. The FDA determined that ( ) was unsafe years ago. And despite a warning in 2024, it is still available to consumers and harming even killing members of our community. Why? I read the FDA's discussion paper and questions to guide today's feedback and listened to all the presentations today and I support the model proposed by the consumer NGO representative. I would like to highlight the importance of engaging the public frequently and by multiple means, creating an advisory process, preferably including community members and timely action for the public health.

>> Thank you so much. Next up is Malavika Tampi. And following that will be Jayaraj Alappat.

>> Hi, can you hear me?

>> Yes, we can.

>> Perfect, thank you. My name is Malavika and I'm here as an individual systematic review and clinical methodology for regenerative agriculture. I also have a BS in food science. I have no intellectual or financial conflicts of interest. I'd like to emphasize that we are living in increasingly unpredictable times due to the complex intersection of ecological destruction, war,

destruction, and inequality. Positive changes smart mall and snow ball and to shift political will. We are dependent on that. Thank you FDA for your interest in engaging the public. To better understand the chemicals on our health, I attended the brain environment hosted by the University of Rochester and EPA. This highlighted how chemicals increases the risk of brain conditions as well as other health conditions like birth defects and cancers. Chemicals in foods start with what enter the soil, water and air not just what enters in our factories. These chemicals coupled with deforestation are causing decline in soil quality and mass extinction of wildlife, including pollinators.

We are on track to be a planet of physically, mentally unwell humans and farm animals in the coming decade. Human survival is dependent on environment which makes me wonder why. The FDA in collaboration with other players can be a part of this required change. I reviewed the document shared by the FDA, thank you for sharing that with us. I would be interested in more details about, one, the criteria for prioritization and scoping process. Two, robustness of methodology quality of evidence and move from evidence to decisions. Three, plan for updated - I would like to understand the plan for updated decisions based on emerging evidence. Four, what are the internal systems which helped minimize delayed action? 5, expertise and conflicts of interest of decision makers at the FDA and beyond. How these conflicts were managed during the decision- making- process.

And seven, peer reviewed processes. And eight, effort to improve methodologies for synthesis and decision making. I suggest that FDA use language or plain language summaries suitable for the average citizen and relevant materials. For example the document with the questions for the public that was shared with us was quite technical and not easily understood even by a researcher like me. This could all be supported by having a panel of citizens engage in your scoping, decision making, and public making process. This is similar to what I use for clinical practice guidelines for big agencies across the nation. FDA should publicize how and why public comments were incorporated into decision or not. Public should be made away how FDA is collaborating with other agencies. The results of this collaboration and if collaboration is not haptic, why not. This also includes political influence and corporate lobbying and its impact on decision making. And finally, I want to encourage the FDA to look into and provide guidance on regenerative agricultural practices and incorporate those practices as a part of the larger community building that the FDA is responsible for. Thank you so much.

>> Thank you. Next up is Jayaraj Alappat. And after that will be JD Hanson.

>> Hello, my name is Jayaraj Alappat for Merieux nutrisciences in Chicago. The previous panelist Lauren mentioned that pesticides are not included in this safety evaluation. As a consumer I'm concerned about it because it's a chemical. The globalization of supply chine and new material and finished products from various parts of the world and the climate change, changes the residues contaminants in foods and are proactive. Looks like it is not. It is time to include the original material, the processes as well as the climate change situations and the problems due to climate change in this evaluation. The second point I want to make sure FDA

addresses, recently California legislature passed a bill in 2024 to ban 7 dyes from school foods. It was signed into law and enacted December 31st, 2027. Blue 1, 2, green will be banned because of the connection between this to the dyes with children's neural behavior problems such as ADHD. Now the question we ask is these and other molecules have not been evaluated for decades. Why are we taking that much time? Why we are not proactive? The question I have for FDA is: How are the new program is going to be different from the one we are using to become more proactive? And these are a few suggestions for FDA to adopt in this plan. No. 1, adopt more risk based approach. No. 2, identify data gaps and fill them and adopt a more modern technologies ( ) and enhanced stakeholder participation. And more interagency collaboration. And rapid reaction to new food safety alerts. Hopefully, with all this in action and the indent to be -- intent to be more proactive hopefully we will see the food we are consuming more safe in the future. Thank you.

>> Thank you. Next up is Jaydee Hanson. And on deck will be Jennifer.

>> This is Jaydee. I am the policy director for the Center For Food Safety. I have no known financial conflicts of interest, and we appreciate the work that the FDA is doing to gear up a more robust food safety program when it comes to chemicals. The FDA must now give higher priority chemicals which, one, cause cancer; two, have disrupting effects; three, have reproductive and developmental health effects, especially on children. Chemicals that cause damage to organs, for example, liver and kidneys. Having had to have a liver biopsy because of a chemical exposure I had, it's not fun for anybody. I can't imagine a child. And finally, we need to look carefully at the chemicals that are biopersistent. Now, data on all of these can be assessed using the databases of other countries and states that have been more proactive than FDA has been thus far. I would note that we and some other groups already have legal petition with the FDA on PFAS. And we've been in discussion on other chemicals. But the list of banned chemicals must include substances like phenyls or phthalates and PFAS, which are not going to be the normal food additives, but they become food additives by virtue of being food contact substances.

We also think that the FDA needs to look more carefully at the nanoscale of chemicals. One thing the FDA has not been doing in a way that is obvious is assessing the nanoscale chemicals. 18 years ago, the FDA was beginning to make good progress, but it has seemingly not looked at the effects of nanoscale titanium dioxide in its review of titanium dioxide as a food additive. Okay. I think I am at the end of my talk.

>> Thank you. Next up is Jennifer Pomeranz and on deck will be Michael Levin.

>> Thank you very much for the opportunity to speak. I'm Jennifer. I'm at the NYU school of global public health. I don't have financial interest related to this. Thank you for all the work you do at the FDA. My colleagues and I recently published a paper in the American journal of public health demonstrating exactly what the environmental working group represents --

>> Jennifer could you please try to speak up a little bit. We want to make sure we hear you.

>> Industry self regulation for GRAS substances and FDA's lack of a formal approach for reviewing substances already in our food supply are inadequate to -protect - those are questionable safety and those that are unknown to the FDA and the public, which I have not heard clearly addressed today on how the FDA intends to identify these self- GRAS substances. Some of the current situation is due to lack of premarket authority and resources that is clearly Congress's job and I do appreciate that representatives joined today. But other issues are due to the need for a more rigorous attention to the food supply with the FDA's current authorities as identified today, the ( )- report. A meaningful post-market review process must leverage premarket authorities, pursuant to the food additives amendment and/or ( ) to prevent more unknowns from entering our food supply. Post-market, we know FDA is not able to keep up with problematic ingredients. Reliance on industry information or food labeling loan will be highly misplaced. Previously big terms to include things like spices, flavorings, colorings, chemical preservatives. The current state of the situation highlights the need for objective, conflict free science and human experts with the precautionary principle in mind.

Moreover, a robust market framework must include reevaluation of GRAS current use and levels of added sodium, sugar, and caffeine. For these substances, there is wide spread agreement that current levels in many products are not recognized as safe. These violate good manufacturing practices as empirically demonstrated by widely varying added sodium, sugar, and caffeine content. This can be addressed through post-market recategorizing of excess levels for GRAS. FDA does not regulate caffeine levels that explicitly exceed tolerance levels set in 1977 for cola type beverages, energy drinks far exceed these levels at a cost. I've spoken to a father who lost his son from a heart arrythmia due to an energy drink. The quantifiable harps of excess sodium and added sugar or even greater are estimated to kill hundreds of thousands of Americans annually. We are glad FDA recognizes it's time to fix the post-market review framework by emphasizing the need for enhanced premarket in addition to the post-market review of all substances in our food supply. Thank you.

[Switching captioners].

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>> [Michael Levin, Health Business Strategies, LLC] One of my clients, 501(c)(3) that includes an FDA Center of excellence is a client of mine because they published on the need to continuously update analytical methods to detect fraud regarding effective assessments as I mentioned we live in a dirty world. We can now detect and quantify chemicals in food ingredients at the par petroleum level. This may result in new FDA rules that would not meaningfully enhance food protection but instead add new cost to the supply chain and benefit only the plaintiffs' bar while wasting precious enforcement resources. To conclude, low hanging fruit, please consider an effective rapid response program to bring enforcement action against any legal and highly addictive drug masquerading as a dietary supplement required years, that's unacceptable to

consider building a response team with online portal gated enforcement process. The time is now. Big stuff, big dangerous can't wait.

>> [Jannah Tauheed, CSPI] Step scientific, thank you for the opportunity to speak today. I have no financial interest. The FDI is an independent nonprofit public health and consumer advocacy organization. While a step in the right direction, we believe the FDA can make major improvements to the post-market framework outlined in its discussion paper to increase scientific rigor and provide greater transparency. I would like to highlight a few points, first, the FDA needs to proactively gather more high-quality hazard and exposure data figure reliance on the status quo is insufficient. While the discussion paper states the FDA may request new data from industry or other stakeholders, collect new analytical or exposure information, or conduct exposure and safety studies, we believe obtaining new high-quality data is essential to this process. Decisions based on underlying data that is of insufficient quantity and quality would at best do nothing to protect public health and at worst do harm. Second, the paper states transparency and external engagement are important parts of the planning process. That the FDA envisions engaging public with two important parts of the comprehensive assessment process and that there may also be instances where they seek external peer review of focus assessments at an ad hoc basis. We believe transparency should be maintained throughout the entire process from prioritization of chemicals and preliminary screenings to risk assessment and management. Is critical that the FDA obtain external feedback and additional key steps at the process with opportunity for comments at each point of public engagement.

Finally, risk management decisions, including setting limits on contaminants should be driven by protection of public health, not achievability as is done by the Codex commission and partially adopted under FDA's closer to zero program. Setting standards based primarily on industries accountability to achieve the standard using current practices and methods fails to maximize public health protection and is not capitalized on important opportunities to promote innovation. While achievability can be used as a secondary consideration, the protection of public health must be the number one priority. Thank you for the opportunity to speak today and we look forward to submitting detailed written comments.

>> Thank you. Next is Eric Hendrick and following that is Abigail Junge.

>> Can you hear me?

>> Yes.

>> Thank you for this opportunity. I am Eric Hendrick, Dir. of toxicology and toxicologist and regulatory consultant in the food industry and more than 35 years of experience in the business and we are based in Orlando, Florida. To assess the population is wanting to know how much the substance to which the population is exposed. This is a basic lesson and toxicology, mixed a poison. But we need to establish to call something a food chemical is a misnomer as the chemicals are now also used in dietary supplements, vapors, tobacco products, drugs, aromatherapy, therapy products and ingested cosmetics.

Further, the functionality of many chemicals has changed. An extract of the herb rosemary once used sparingly as a flavoring ingredient is now also used in much greater amounts as an antioxidant and human and animal food. These increased applications and use levels resulted in increased consumer exposure over what was originally envisioned as a safe level when the ingredients was approved in the 1970s. At one time, FDA underwrote surveys of production volume and manufacture these and the National Academy of Sciences with the promise of anonymity to the manufacturer's, the service captured 60% of the total production. The data gathered was adequate to determine a mean prepacked -- from which is possible for how close the percentile was to be allowable intake and in addition to the substance of grass or food additive a petition would have a significant impact on exposure. The last of it was published in 1987. The surveys were valuable resources bearing on consumer safety and if the FDA doesn't have the budget to reinitiate the surveys and Junior manufacturers and associations can step up to the plate for not only the post-market assessment but in support of the substances in 21 code of regulation 182 and 184 whose continued use was largely based contingent on a low level of use reported 1970s in the absence of adverse data. Moreover, the inclusion of many ingredients from 21 CFR 182, 184 were based on lack of adverse effects being reported from safety studies conducted before the laboratory practices that were established in 1979. Many of the experiments that lacked GLP lacks necessary controls, testing environment and examination of critical toxicological parameters. Is also significant increase talks logical studies including examination of changes in thyroid hormones morphology, organ weight and miss apology associate with high-fat oil consumption that can have unknown adverse events associate with the grandfathered ingredients. We need to have qualified toxicological experts evaluate the rigor and quality of the test conducted prior to GLP and propose what studies and research need to be conducted to address the safety gaps. Thank you very much.

>> Thank you. Next is Abigail Junge.

>> Thank you, Eric, for mentioning the toxicology. I am actually baby 47 weeks from Camp Lejeune and hold the record for the longest birth and just thankful to still have my mother. The reason this was so important to me, when you dip people in benzene and Paphos we developed a benzoate allergy called (). The development of enhanced system process for FDA post-market assessment and chemicals and for as long overdue and unnecessary and why we require breakdowns at every aspect of foods manufacturing from the preventers of which the derivative enrichments and other adulteration's and the products have encountered during the manufacturing and processing. A large amount of the adulteration's come back to a known allergy that is legislated into our diets via the wood-based enrichment legislation as well as the press -- GRAS. Requires abstaining from fava and peanuts and citrus and grow mold for citric acid. Grasses and Hayes like microbes that make the vitamin basis and gums and warms that's in nearly every cream cheese on the market and others that cause brain fog swelling and pain. They come into nearly every aspect of our lives from food and beverage enrichments, soaps and lotions make up eyedrops toothpaste shampoo and all medications. It's innate in the artificial colors and preservatives and long known that there are benzoate's and byproducts cause swelling and growth yet we allow them instead of utilizing other processes available. Extending shelf life over the cost of human life is unacceptable. As of generations pay the price showing the allergies through their skins affected psoriasis in ear canals or spikes in ADHD and autism diagnosis is becoming nearly half of all children, brain fog, a fit of a cancer, congestive heart failure, glaucoma and all cause dementia becoming prevalent and more importantly allergy based conditions that we allow big business to continue to propagate against our citizens. While other countries won't allow US foods in their countries unless they take the steps that indeed have been defined in the EU, and it's a great start to make the producers responsible for knowing that what they put in their products as well as informing the consumers that they very much do harm. That when they don't acknowledge and clearly defined where the products are derived from or what it encounters in the packaging alone. Thank you.

>> Thank you. That concludes those that signed up to be an open public comment or and now we will take a short 15 minute break and then we will come back and go to the open public comments for those in the room. Thank you and at this time we will take a 15 minute break.

(Break)

>> We will get started in about 30 seconds. I would like to invite our panelists back up.

JESSICA ROWDEN: Welcome back everyone. We will now start are in person portion of our public comments. We have about 18 in person comments. Everyone will have three minutes.

If you are here, I will call your name off in the order that you registered in person. We have a microphone to my right of the room. You can use that. You will have three minutes and I will give you a one-minute warning and let you know when the time is up. We did receive many requests for public comments. If you are unable to get your comments in, some had to leave and some online that were not able to do that, but we encourage you to submit your full comments to the docket that way we make sure we have them. I think that's all I have for reminders. Our panelists are up here. I will call our first commenter to please come up to the microphone. We need some tech in the room. The microphone is not working. Here he comes.

>> Always the first person, right?

>> Hi, I am Jensen Jose center for science and public interest, no financial conflicts of interest. At CSPI we believe a successful reassessment program must compel companies to provide safety data for GRAS substances on the market and for premarket review echo and must systematically reassess dietary ingredients on the market. While the scope of FDA's plan explicitly includes GRAS, the agency can assess the substances without knowing what GRAS substances are on the market, which foods they appear in, and the information companies used to establish safety. FDA's previous post-market assessments have determined several presumably GRAS substances were unsafe but only after they caused harm to the public. Some of the substances include caffeinated alcoholic beverages, (Indiscernible) and trans-fat. But there are potentially many more unsafe substances that the agency doesn't know about because the vast majority of chemical since 2000 were introduced without FDA loophole. These have to be assessed to remove unsafe ingredients. To adequately reassess GRAS under the current plan, FDA would have to face the impossible task first identifying risks associated with unknown GRAS substances, gathering all available information industry used to establish GRAS and, third, gathering safety data produced after the GRAS substances were introduced. Theoretically, industry already has the information. It would be more effective and efficient to require companies to provide the information to FDA rather than agency trying to find it on its own. Reassessment program can't be successful unless companies are compelled to provide data on substances already on the market and close the GRAS loophole.

With supplements, reassessment plan should systematically assess the diet ingredients used in supplements. New dietary ingredients are often introduced through the GRAS loophole without FDA knowledge. Often the dietary ingredients are introduced even when FDA as previously question safety without review. FDA has multiple safety questions for that tonight -- to new dietary notifications. The company continued to market ingredients with both conventional foods and dietary supplements. Another example is EGCG, the substances often innocuously labeled as green tea extract and often marketed as a weight loss supplement. Evidence indicates it may cause leukemia.

>> One minute.

>> A GRAS notice was submitted and then withdrawn. EGCG has been found in over 25 foods and sold as a supplement by retailers currently including Amazon, GNC and Walmart. I urge the agency to ensure reassessment plants addresses the dangers GRAS substances in conventional foods and dietary supplements. Thank you.

JESSICA ROWDEN: Thank you. Our next public commenter is Todd Wagner. As a reminder, please state your name, organization and any financial interest. And also our panel is here taking notes on remarks.

>> I know it's 4 PM, hang in there. My name is Todd Wagner, born in the Midwest attorney by education and a technology and media entrepreneur and philanthropist, that's my business career. Most importantly for today's purposes a concerned citizen, parent and cofounder of food fight USA.com, a nonprofit whose mission is in part to help clean up America's tainted food supply that's making us sick. We have a health problem in this country. 11% of the country has diabetes and that number is rising big approximately four to $500 billion each year of our $5 trillion annual budget is spent just on that. Not to mention 75% of our country is overweight or obese, which leads to a whole plethora of chronic diseases that are also part of it because estimated 22% of all deaths deemed worldwide can be attributed to ultra processed foods. UPS, are the straw that stirs the obesity, cancer and diabetes drink. In large part, created by the GRAS loophole. How many people in this room avoid many foods due to their ingredients? People are fed by the food industry that has no attention to health and are healed by the health industry which pays no attention to food. These are like ships passing in the night but need to move lockstep. The four toxic chemicals at food fight USA help to get banned in California last Tober Lake red dye three are like getting the FBI's 10 most wanted off the streets. It's a start, but not enough to keep the streets safe. There are hundreds if not thousands more, no one knows what -- what I do know, you're only as 400 approved chemicals and we have over 10,000. Closing the GRAS loophole takes us away from the game of workable where we can't keep up. We have an entire food industry taking these tainted raw ingredients and use of pesticides and insecticides and then creating the entire UPS industry created in large part by exploiting the GRAS loophole. Post-market testing and analysis of at least 10,000 chemicals is probably the single most important thing, the F part of the FDA needs to focus on. Is the cumulative effects and dosing, say with these products.

I suggest and food fight USA can make recommendations on expertise available now like the center for human technology to analyze the chemicals in mass and find patterns to at least

create a starting point of which chemicals at molecular overlap with known carcinogens and disruptors. It should be another arrow in the quiver similar --

>> JESSICA ROWDEN: Time.

>> Todd Wagner: Without using these types of tools the well-intentioned FDA human foods program will not be responsive or quick enough. When you publicly state it might take years to complete a single analysis we had 10,000 chemicals --

>> We need urgency and answers. And arguments over arranging deck chairs. The joke of all this is that food companies are already reformulating chemicals in dozens of countries around the world. It's not you, it's the food. Thank you.

JESSICA ROWDEN: Thank you. Next, Steven Gendel.

>> That's a long walk. Thank you for the opportunity to speak here. I'm Steve Gendel currently an independent consultant, but my remarks are also based on my experiences as a scientist in the FDA. Thank you my three minutes of fame I would like to address two issues. When I prepared the comments they would be things that nobody else would talk about, but turns out they been popular subjects so I want to add my two cents. The first one is to address the question of integrating advisory committees. I think if the food program were to actively disentangle assessment from regulation they could effectively leverage this valuable resource and bring the assessment process more into the open bingo other FDA centers make extensive use of advisory panels for assessments and input without compromising the regulatory processes and authorities or timelines. And foods should do the same.

The human foods program could use advisory panel, I emphasize the plural, as part of many of its non-decision-making activities, including in today's context signal monitoring and answering most of the so-called for purpose questions in section 3 of the outline. Second, concerning the question on so-called fit for purpose decision, I would like to suggest an increased emphasis on changes in dietary exposure. Both for that specific substances and to the contaminants that come along with those substances. An industry where places pop into existence and merge and divest him and no one is being held responsible for looking at the reality of the assumptions made during assessments that may have been made several decades ago. This includes failure to look at changes in contaminants caused by differences in manufacturing processes --

JESSICA ROWDEN: One minute.

>> Productions by new manufacturers that may not be aware of limits in the original assessment, new contaminants and substances that are now sourced through complex international supply chains that didn't exist back then.

To increase the emphasis put on that factor I suggest we make a part of the review of information at the very top of the flowchart rather than postponing the consideration until other signals have triggered an assessment.

Finally, I want to acknowledge the perennial album a resource limitation which has come up several times. However, the transition that will happen next week is a rare opportunity for the agency of this program to be creative rather than cautious. Start with what needs to be done, not what you think you can afford. And then boldly go on your public health mission. Thank you.

JESSICA ROWDEN: Thank you. We have a timer clock by the microphone so you can see how much time is left and I will give you reminders. Next is Sydni Arnone.

>> Good afternoon, I am speaking today on behalf of the international food additive counsel. I would like to begin by recognizing the FDA's commitment to improving post-market oversight and express our appreciation the FDA has divided the opportunity for the public and stakeholders to provide comment. Transparency to the process and activities helps further public confidence. In the interest of brevity I will focus on two key points. First, transparency, we've heard a lot about it today. If the FDA is seeking to model the post-market review process after EPA's framework we feel there's notable differences that should be considered. Include structured approach for public engagement starting from the selection of chemicals for review because the EPA uses a well-documented process for stakeholder input and extensive pre-prioritization data collection with clear opportunities for public involvement at key stages. Including a 90 day mandatory 90 day comment period after chemicals are identified. The structure allows for transparency and give stakeholders a chance to participate early on before important decisions are made. We are concerned the current FDA proposal does not offer similar opportunities for early public input. Particularly during the ingredient selection phase. We believe increase engagement would foster greater transparency and build trust among stakeholders. Second, the inclusion of contaminants alongside ingredients. Contaminants and food are different yet FDA proposes gripping them under one risk prioritization process. Contaminants and overtly have different risk management strategies. We urge the FDA to separate the categories to ensure appropriate assessment and resource allocation. Thank you

for the opportunity for public engagement on this critical issue and we look forward to submitting additional feedback in the written comments.

JESSICA ROWDEN: Thank you. Next Mona Calvo and then Tom Neltner.

>> Good afternoon. I am Mona Calvo, an adjunct professor in the division of nephrology at the Icahn school of medicine at Mount Sinai --

JESSICA ROWDEN: Can you speak into the microphone?

>> Shall I repeat it?

JESSICA ROWDEN: Yes, please. We will start over.

>> Good afternoon my name is Mona Calvo and I am an adjunct professor in the division of nephrology at the Icahn school of medicine at Mount Sinai in Manhattan, New York. I have no conflict of interest financially. What I am going to talk about today is I would like to submit a candidate for reassessment. And that is a GRAS substance group that received its GRAS approval between 1970 and 1975. It's been on the market for a long time with a lot of approved functions. Ultra process food consumption keeps rising and at the same time and increasing number of studies are linking hi ultra process foods intake with serious health outcomes including all mortality -- in the general population. Widespread use of phosphate additives and processing is considered a contributing factor to the negative health effects of high process food consumption. Phosphate additives are more rapidly and efficiently absorbed the naturally occurring dietary phosphate in protein and other unprocessed foods. Phosphate additives, excuse me, are not always accounted for in nutrient database, despite their greater contribution to dietary intake. Total phosphorus intake is underestimated in national surveys such as () yet phosphate intake is shown to be excessive, twofold higher than the RDA for most US adults. Health effects of excess phosphate additives intake relate to the ability to elevate zero phosphate which leads to tissue vessel calcification and to disrupt the release of mineral regulating hormones and poor vitamin D maintenance of calcium and phosphorus homeostasis. Chronic kidney disease patients must restrict dietary phosphate additives intake to slow disease progression through dialysis and death. Therefore they need knowledge.

JESSICA ROWDEN: Time.

>> They need knowledge of the total quantity and forms of phosphate and films that is not currently required in US food labels. Is the key motive intake for phosphate additive from

processed foods that are the health concerns in the general population. The first step for FDA to assess this should be to determine estimates of population exposure to phosphate additives in the US food supply. Exposure estimates and correction of phosphate content in nutrient databases can be facilitated by FDA requiring total phosphate content listed on the nutrient facts label and clear identification of phosphate additives on a company ingredients labeled of process and food and beverages.

JESSICA ROWDEN: We ask that you conclude your remarks because…

>> Mona Calvo: This action would provide all tools to make healthy food choices. Thank you.

JESSICA ROWDEN: Thank you as a reminder of everyone can submit full comments to the docket. Tom Neltner followed by Maricel Maffini.

>> I am Todd Neltner and I have a conflict of interest big like all of you, I eat food and care about it not impacting my health. That is a conflict of interest because not everyone here has all the same interests. What I want to do is talk about something that has not been raised before. You heard a great many comments but I want to raise a concern with the proposal that it doesn't address the clear, statutory directives to FDA when it comes to post-market assessments. Congress was crystal clear in the law on three aspects. One, food and color additives including those asking to remove approval of which there are seven pending, one for 34 years, those have to have a final decision within 180 days. That a statutory duty your grade can't come up with another system that ignores that statutory duty. And yes, people don't sue you when you miss the deadline and Glenn Scott from 1990 isn't here to defend that, but you can't ignore the statute quickly come up with a process that ignores it is wrong. At the back end the statute is crystal clear and you cannot have food additives that are found to induce cancer in man or animal. Red dye number three should have been a slam-dunk. Is not in the priority system because it should have an immediate offramp that is found to induce cancer in animals, out. Same with methylene chloride and for ethylene. There's a number of chemicals where you can't just ignore the statute for sake of your own internal bias hierarchy. Third, this is not easy, but Tom Wegner got added and is a cumulative effect not exposure. Cumulative effect of chemically and biologically related or pharmacologically FDA says meeting biologic related chemicals in the diet. What I see is an effort to take each chemical or maybe the related chemicals and look at them, and isolation to reality. Congress in 1958 was explicit, you have to consider the cumulative effect of related substances, biologically related substances in the diet. That means you don't start with the chemical and say how convinced can I be that it is bad? You start with asking what are all the chemicals that are going after my brain or thyroid or kidney? Thank you to the prior presenter bigger or which ones are affecting the biology and make sure we think of them together and not in isolation bigger because that's how we want people to care about it not so --

>> That is time

>> You need to look at the function. If you emulsify need to look at all and oils, not just parse them out to go thank you.

JESSICA ROWDEN: Thank you. Next up is Maricel Maffini and then Karyn Schmidt.

>> Hello I am a scientist independent consultant. Food chemicals have been a big focus of mine for more than 14 years. I make the comment on my behalf only. The reassessment and safety and health of food chemicals is urgently needed. I am encouraged by the decision for and implemented robust post-market process. The lack of comprehensive transparent process has the wrote -- eroded the public's trust. Less than 22% of almost 4000 chemicals directly added to food have information necessary to estimate a safe level of exposure. Less than 7% of those don't have developmental or reproductive data. Evidence only has 7%. Evidence of human health concerns have been mounting for many chemicals have been approved decades ago. These are the three things that I think is a successful reassessment should be on. The office of reassessment is risk assessment of risk management and transparency. The office of reassessment should be independent from the office of premarket review and it's important that those involved in the reassessment have not participated in premarket approvals and authorization to minimize biases towards their own prior decisions. And the experts doing reassessment should have expertise with analysis and integration of evidence with the streams from human data to molecular pathways. Having a clear separation between risk assessment and management is crucial because the role of risk is to objectively review all the evidence to conclude whether there is a reasonable certainty the use of the chemical would cause no harm bigger the outcome of the risk assessment and forms the risk management decision may also consider non-risk related issues such as cost and availability of substitute societal values and political meals. Other agencies here in the states and internationally are a few examples of separated systems of risk management assessment vehicle lastly, transparency is the key word today, the key to restore the trust in the system and it should include stakeholder input in every step of the process, a feature that so common and other federal and state agencies. Thank you for the opportunity to present.

JESSICA ROWDEN: Thank you. Next, Karyn Schmidt followed by Shelby Furman.

>> Thanks. Karyn Schmidt American chemistry Council, Senior Dir. of regulatory and science affairs, no financial interest. Would like to thank FDA for convening the form today and we see based on the turnout there is broad interest in this topic. Importantly, we have one big take

away today and that's that everyone in the room is invested in having a high functioning, high-quality, science-based set of reviews both premarket and of course where necessary post-market for chemicals. It's in all of our interest to see that the program works and efficient and effective and that FDA is held up internationally as the paragon for food safety review. We hope we can all work together to make that happen.

A couple quick observations. We really encourage FDA to continue as indicated it would facing its reviews on high-quality science including best available science and weight of the evidence reviews. Peer review should continue to be populated by relevant experts in the field in addition to the other very important criteria for selecting the peer review panel. Were FDA concludes it would like to proceed with additional review of a particular chemical 's prioritization criteria should include risk and that means it includes consideration of exposure and that should be as early in the process as possible.

We want to point out that EPA is also undertaking post-market reviews of chemicals. This is under existing chemical program and in some cases there is overlap. The same chemical may be undergoing post-market review by FDA at the same time it's with APA. We encourage FDA and EPA to continue to work together to share information and think about regulatory outputs as well as underlying risk assessment and hazard-based review.

We want to encourage FDA as it moves forward with some novel AI technology to make it publicly available, ask for stakeholder input and provide a degree of transparency about the algorithms being selected and how they are being applied. Thank you for the opportunity to comment and we look forward to submitting written comments.

JESSICA ROWDEN: Thank you. Next is Shelby Furman followed by Nichole LaPado.

>> Good afternoon I'm Dr. Shelby Furman, the food industry Association. FMI works with and behalf of the entire industry to advance a safer and more healthier and more efficient consumer food supply chain. We appreciate FDA holding today's public meeting and for the opportunity for oral comments. Also will be providing detailed written comments on FDA's discussion paper and the process it as outlined but wanted to provide a high-level overview of our perspective. FMI and members are committed to ensure safe food supply and welcome FDA's effort to engage in post-market assessment of chemicals and food through science and transparency. We believe as the agency is charged with protecting public health there is scientific expertise undertake this work because agency as the authority to carefully evaluate scientific data and information on particular substance allowing for it to make risk-based

decisions and communicate those to consumers and industry alike. Second, FMI applauds the FDA for outlining the general approach to post-market assessment and food. We believe transparency is key and the visibility the FDA undertakes. Encourage FDA to look for additional ways to make stakeholders aware of the work is conducting in the area. At a minimum the status of decision process should be made available to the public. Timely communication of FDA's efforts will remind the public both of the FDA leadership and the safety of the food supply. FMI applauds FDA for considering a multitiered approach and assessment that's warranted. FDA notes that the agency is developing processes for conducting post-market assessment for a wide range of potential food components from direct additives to food contact substances in environmental -- a one-size-fits-all will not be practical for the highly varied categories and we encourage FDA to consider what difference in the assessment process night best for each category. As an example the unique challenges and considerations for environmental contaminants like heavy metal and metal Lloyd's that should be taken into consideration during the assessment process. FMI supports FDA's willingness to incorporate external engagement into post-market assessment, through peer review. Our goal is to support FDA and making science-based policy decisions in a clear and transparent form for all stakeholders to follow and participate as appropriate in order to protect public health and gain the trust of consumers. I want to thank FDA for its leadership on this important matter and for the openness and willingness to receive input on the proposed approach. Thank you for your consideration.

JESSICA ROWDEN: Thank you, Nichole LaPado followed by Anna Rosales.

>> Nicole LaPado. As a mom, nutrition close and health advocate I cannot stand by and watch what is happening to our country's health to the food that's available to us. We have already heard that 74% of Americans are overweight or obese bigger 60% of adults and 33% of teens have prediabetes. 25% of teens Avenue fatty liver disease that in the past has only been seen in elderly alcoholic will alter process food makes up 58% of our calories. There are numerous studies in the BMJ and NIH that show direct association between exposure to alter process food and 32 adverse health conditions. It should shock you that our food industry needs reform and change. The FDA's process also needs change. GRAS, generally recognized as safe is not a failsafe for protecting us. Under GRAS they can deny a product and ingredient manufacture can hire their own experts to claim under reasonable certainty in the minds of competent scientists that the substance is not harmful for the intended condition of use. This process is broken. In addition to the paint manufacturer expert your process allows a manufacturer to withdraw notice of any product still in question and still use the ingredient. It shameful. Let's not dismiss the fact that 47% of your funding comes directly from Pharma and food industry piglets hard to be objective to companies poisoning our citizens that are also funding you. The food companies fund many other scientific studies bigger the number of studies in favor of the food and beverage companies are staggering compared to those with no industry funding.

Before we can even address what is in our food that is causing the adverse health conditions we need to fix the system that causes it in the first place. The FDA can no longer allow a broken system to kill us. The FDA must tighten the reins on the GRAS process because they must crackdown on the rapid chemicals being introduced into our food system bigger than the FDA must not allow food companies to decide if the food is safe based on studies paid by their deep pockets. And Maya Angelou said, do the best you can until you know better. Than when you know better, do better. FDA, you must now do better for us citizens. Thank you.

JESSICA ROWDEN: Thank you. Next is Anna Rosales.

>> Registered dietitian government affairs at the Institute of the technology. We are a non-prophet individual member Institute with over 11,000 members whose mission is to advance the science of food and its application across the global food systems to ensure sustainable, safe, nutritious food for all. We appreciate the opportunity to share our perspective. The pre- and post-market assessments including reassessing the current GRAS system should improve transparency to strengthen consumer confidence and ensure and to and transparency and approval of ingredients in foods. The FDA's updated systematic process for post-market assessment of chemicals and food should ensure transparency for all stakeholders including in the process, prioritization, responses and scientific references bigger transparency is critical in building public trust and ensuring consumer confidence in the US food supply. While transparency brings visibility to the process of science, education and risk communication help the public interpret and understand the regulatory decision. The updated process the FDA must continue to be grounded in science and transparent and risk assessment and analysis and clear communication to the public. As a food system continues to resolve the innovation disruption in public health concern it's essential for FDA to build capacity for pre-and post-market assessment and act in a timely manner with limited resources, prioritization grounded in science and the processes created to identify which materials are reviewed as a critical element bigger to further support this work the FDA should avoid duplication and delay by leveraging global processes and existing engagements as you notice the standard bodies across the world such as () which will simultaneously accelerate the responsiveness of post-market assessment and reduce duplicative work stream and break forward food standards.

As development of the post-market IST will continue to engage membership and provide feedback to the FDA bigger IST and members are committed to helping ensure we have an adequate safe and nutritious food supply for everyone. In closing, we believe it is imperative that the FDA create a review system that incorporate the elements of science, timely responses, efficiency, risk communication, stakeholder engagement and transparency to help build consumers trust in a more resilient food system for the future. Thank you.

JESSICA ROWDEN: Thank you. Caroline Murton followed by R.D. Cathey.

>> My name is Carrie Murton a legislative analyst at the environmental Defense fund for going place to have this opportunity to comment on the FDA's post-market assessment process for food chemicals book of the FDA's convening of this meeting is a promising step towards improved post-market review system. My comments I will have two key principles the FDA must consider as it refines its process. Community engagement and cumulative effects. We appreciate FDA's outreach and other stakeholders as it seeks feedback on the proposed post-market review process. But in all instances where the FDA seeks public comment agent closely consider ways to promote equitable and meaningful participation by a broader range of relative groups including underserved communities. Stakeholder groups invited today come with a wealth of experience in trust and knowledge such as my own and we hope to see the FDA proactively seek more input from underserved communities on post-market review moving forward. Equitable opportunities for public input with proactive outreach to underserved communities should be provided at least once during all post-market reviews. As a discussion paper is been written, and entire focus assessment goes without public input to the decision whether to perform a focus or comprehensive assessment on a chemical should be open for public comment, especially since one of the proposed determinants is whether a chemical is a significant public health interest. The two-pronged approach is only acceptable if the FDA uses comprehensive assessment for the majority of chemicals and reserve focus assessment for extremely specific and rare cases break up the discussion paper proposes the FDA draw upon processes similar to those outlined in the existing chemicals program to conduct its own post-market review. However, consideration of hazard and exposure is a key component of the existing chemicals program. Able only be a suggestion in the FDA's proposed assessment process and not at all mentioned in the outline for focus reviews of the FDA must establish clear uniform criteria for reviews that enter hazard and exposure are fully considered for every chemical. The criteria must include consideration of cumulative effects.

Individuals are exposed to the same chemicals, many of the same chemicals through food, air and water but many of which pose similar health effects including cancer and endocrine disruption figure the FDA should look at the real world exposures to the chemicals during rather than examining each chemical in isolation assessments that failed to consider commutative effects will underestimate the risk and curb the effectiveness of the post-market review process. Thank you.

>> Next is R.D. Cathey followed by Shakeera Springs.

>> My name is R.D. Cathey with FDF laboratory on behalf of the American Council of Independent laboratories. I think FDA for the opportunity to comment on the FDA's development of enhanced systematic process for post-market assessment of chemicals and

food bigger ACL is a trade association representing independent commercial scientific engineering firms with over 1000 facilities in the United States engage in testing, product certification, consulting and research and development to enhance public health and safety. The members of the food science section perform microbiological, chemical and physical services to characterized composition, purity, residue content and contamination in the areas of food, pharmaceuticals, cosmetic related manufacturing facilities. Also researches the safety and efficacy of drugs, food additives, medical devices, pesticides and other chemical products regulated by federal state and local authorities including FDA, the USDA and the EPA bigger ACL fully supports FDA's efforts to protect public health. We are very encouraged by the meeting on this important topic and the food science section as a long working relationship with the FDA in the form of memorandums of understanding regarding method development of a laboratory accreditation for the analysis of food accreditation, dietary supplement, test food for importation alerts and other initiatives require membership includes FDA lab accredited laboratories, accrediting bodies and other stakeholders the scientific community bigger we wish to remind the public and FDA the accredited independent laboratory community is an important food safety asset that has and will continue to support the mission of FDA and ensuring safe food bigger and the Independent laboratories are available to assist in FDA's effort in the post-market assessment chemicals and food. Additionally, we support international accreditation standards in which FDA labs have been accredited. That should apply to all private laboratories and the only private laboratories authorized to be independent for growth FDA is looking for standards to emulate protesting and reporting the standard tell by the Consumer Product Safety Commission outline the general requirements for confidence of testing and collaboration. They are successful and efficient examples bigger we have been consistent in urging FDA to adopt and recognize international accreditation standards as a baseline and national sector specific technical standards as the primary basis for qualification of laboratories and sampling organization to sample and submit analytical data to the FDA for any purpose bigger ACL as long advocated for the need to establish uniformity in private package review and standardize analytical data requirements about which the FDA may rely to make better and more efficient imported food, pharmaceutical and cosmetic admissibility decisions. We also content a critical component to improving the process is to develop standards that will establish uniformity among FDA district offices and laboratory and reviewing private laboratory data bigger we thank you for your attention moving forward, please call upon ACL is a valuable resource.

JESSICA ROWDEN: Thank you. Next Shakeera Springs followed by Brian Ronholm

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Thank you for having me. I am completing my doctoral at Walden University and no financial interest. I would like to take the opportunity to say thank you to the panel as well. I'm standing here with () at 42 years of age I'm unable to pinpoint what food ingredients are causing continuous inflammation in my small intestine. After years of genetic testing I have been diagnosed with anemia due to malabsorption from unknown food ingredients. I have suffered from anemia for over 30 years despite efforts to manage through my diet and costs about $17,000 per treatment and I usually get one to two per year. This highlights a potential gap in the FDA's regulation of chemicals and additives in food that may interfere with nutrient absorption. This has driven me to write my doctoral study on persistent dietary diets and safety. After obtaining my doctorate degree next year I plan to continue this journey by retiring my counting practices and become a research scientist to help identify gaps in current regulations bigger my concern is that chemicals in food may be contributing to conditions like anemia by interfering with nutrient absorption. Thank you.

JESSICA ROWDEN: Thank you. Brian Ronholm followed by Daniel Fabricant.

>> Hello, we reach the point where everything has been set and not everyone has said it some happy to be part of the last part of the process. I am Brian Reinhold and consumer policy reports. I wish I was someone that high financial conflicts of interest but I do not to go independent nonprofit. I want to think the FDA for convening this meeting and Deputy Commissioner Jones for having been here for a vast majority of the meeting. He smartly left the room before it was my turn, but he has been here for the majority of the day and that sense an important signal to everyone. This meeting does represent an exciting opportunity for the FDA and all stakeholder groups. We are excited that you have undertaken this effort. I would only say we are hoping that the FDA follows through with this promise to move forward quickly with this process bigger the agency as may these types of promises in the past but hasn't been able to follow through. Preferred examples today, a couple speakers brought up the red dye three where in 1990 the agency promised that they would review it but never did. Understanding that sometimes it's a lack of resources that impacts the agencies, but it's also part of a culture which I know is being addressed.

I would say that even the industry now as a vested interest in seeing the agency follow through with this work. Perhaps in a way that they didn't before. Hello Sacramento bigger to the representative of state government that may be listening, I would emphasize that no action is being taken today but no decisions are being made and no process is being implemented. Your work will continue to be important in pushing the agency and pushing this process forward.

The public meeting represents a good progress and first step and to rebuild consumer trust, the FDA needs to ultimately establish a post-market review process that is consistent, predictable, transparent, and scientifically credible bigger the process that allows for self-regulated GRAS without notification should end bigger ultimately this meeting will be irrelevant if the agency doesn't follow through in a meaningful way towards that goal. Thank you.

JESSICA ROWDEN: Thank you. Next, Daniel fabricant followed by Liora Fiksel.

>> Hopefully everything hasn't been said. Daniel Fabricant, CEO of natural product Association and represent about 500 companies with 10,000 locations throughout the world, predominantly dietary but also natural organic foods and other natural products. As a reformed regulator and everyone here is a citizen and public I think it's important to understand the agency's job in the agency's authority comes from risk-benefit. A lot of talk about precautionary principle and premarket and all these wishes and things like that. That's really nice and it's good to want things but the clarity needs a comp what authorities are available and the other systems -- at the enemy of any process to make things. The goal of a regulator of any good regulator is to address specific important regulatory problems. I understand the focus is to set up an umbrella system. It's not necessarily to ask a question what is it we are doing and what are we trying to do? Everyone says we are trying to do things better, what does that mean you have been looking at toxicology, organ systems are different, acute is different than chronic and long-term use. What specific questions are we asking and trying to solve? I was encouraged by Dr. Jacobs presentation bigger as we talk about the public and everyone is part of it, they looked at a wreath with all, how many here have seen there was a hearing on CBD? A lot more Americans in public at been exposed to CBD get the agency has never rendered an opinion. Similarly, I was at the agency when Dr. always found heavy metals and applesauce and apple juice 10+ years ago. It's important to note and you hear from that nature pours a vacuum. What they have been looking for is for the agency to authoritatively have a level on those things of what should be the daily intake for all Americans, not just Californians or New Yorkers. These are important issues that need to be tackled. When we hear about different stakeholders and some stakeholders matter more than others and I understand the industry will never be a stakeholder but it begs the question of why we need advisory groups with everyone at the table because realistically the science will always be done by industry and there has to be an interface figure otherwise people just go to their corners and nothing gets solved regards tough to see eye to eye when you don't meet face-to-face. With that I'm hopefully the last one of the day and I appreciate the time and look forward to public comments.

JESSICA ROWDEN: Thank you, two more. Liora Fiksel I am probably mispronouncing your name followed by Danielle Quist.

>> Good afternoon I'm here on behalf of environmental Defense fund that no financial conflicts. I like to express my sincere thanks to the FDA for this opportunity to provide comments and optimizing FDA's post-market assessment on chemicals and food. And providing two recommendations to establish an advisory committee for food chemical safety and to enhance the peer review process. Expertise and scientific rigor are essential especially as FDA faces challenges with increasing complexity of chemicals and evolving the cumulative effects. FDA needs access to specialized scientific expertise now more than ever. Advisory committee focus on food chemical safety would provide FDA with critical independent expert guidance in evaluating the chemicals ensuring the agency's decisions are based on the most up-to-date scientific evidence. We believe there is an urgent need to establish an advisory committee focus on food chemical safety to guide FDA's regulatory decisions. The establishment of a scientific advisory committee should be mirrored by the establishment of a transparent and coherent peer review strategy that includes public involvement and inclusive () the letter review is inadequate for evaluating the complex scientific information that underpins regulatory decisions without food additives. Letter and Journal reviews while less expensive do not provide in-depth discussion and scrutiny comes from panel review where experts can deliberate together, challenge assumption and arrive at more informed conclusions by the lack of public engagement in the letter reviews further weakens the process. Establishing a peer review process to ensure the regulatory decisions are based on the most thorough and inclusive scientific evaluation through transparent process. You can look to other agencies as a model like EPA's office of pollution prevention which uses the science advisory committee on chemicals also known -- for panel peer review but to hold public meetings for open discussions among experts and input from the public ensuring all perspectives are considered before decisions are made bigger this is a type of rigorous open process that we believe should be replicated within the FDA. The human foods program we encourage you to lean in under leadership expertise and experience in setting up the program. In conclusion establishing a scientific advisory committee and the peer review process would greatly enhance FDA's ability to make informed scientific decisions that reflect a diversity of perspectives and these steps are essential for upholding the FDA's mission to protect public health and reinforce trust in the regulatory process. Thank you for your consideration.

JESSICA ROWDEN: Thank you. Danielle Quist.

>> Thank you. This is what happens when you are late, you are last. My name is Danielle Quist, vice president of regulatory affairs and counsel at the international dairy foods Association. I don't have any conflicts of interest. I want to thank you for holding this public meeting and for taking the need for transparency and public input into this post enhance post-market assessment program seriously. I hope I say something or some nuance that hasn't already been said several times over today. I just want to share that the international dairy foods administration, a member strongly support the robust science-based proactive and transparent

post-market assessment program with strong regulatory oversight. We believe that consumers must have confidence in the safety of our food supply. At the same time there are processors need sufficient regulatory certainty to support product innovation and a manageable environment. The draft document and discussion document we think is having in the right direction and we have the following recommendations for today for consideration. Given the number of substances used in food and the pace of innovation is critical the FDA prioritize which substances would be subject to a post-market assessment with a single prioritization process set at a regular cadence for both focused and comprehensive assessment that set forth the public work plans. And to increase accountability we -- for concluding focus assessment and both timelines and milestones for comprehensive assessment in the public work plan. This provides predictability at the completion of the assessment steps and while considering the agencies immense mandate and potential need to alter the work plan to adjust emerging public health and avoid consumer confusion and premature market disruptions we urge the FDA to inform the public about the prioritization process and its purpose and that prioritization is a substance for assessment does not signal the substance is unsafe for human consumption. Equally importantly at the FDA we urge the FDA to defend substances it has assessed and confirms they remain safe for consumers and communicate clearly how such decisions were made. Only with full transparency will the public regain confidence in FDA in the assessment process and its outcomes. Finally, we urge FDA to establish separate process for addressing unintentionally added and unavoidable environmental contaminants which are not subject to premarket review and are not GRAS. Environmental contaminants will likely require surveillance and data collection strategies and processes that differ from a post-market assessment program. FDA's tools for responding to and communicating about contaminants will be different than that of a post-market assessment for food substances that have undergone a premarket safety review. We urge FDA to exclude environmental contaminants from its post-market assessment program. Thank you and we will expand on the highlights in written comments. We are done.

JESSICA ROWDEN: Thank you. Thank you to all of our public commenters. This concludes the section of our meeting. If you are online or in person and didn't have a moment to give, suite ask you to do the docket. Now we will wrap up the date with Dr. Kristi Muldoon Jacobs.

KRISTI MULDOON JACOBS: What a day! Thank you everyone for hanging in there.

We do this we will but the microphone in the middle. Thank you to all of you who attended both in person and online. I think you can see we have been hard at work developing a framework that we believe will help improve our oversight. Today's meeting represents a critical step in our step forward to ensure chemicals in foods remain safe and our discussion paper describing at a high level the systematic process was intended to inform at a high level, our thinking and hopefully today we provided a little bit more detail and clarity around the way we were thinking. We can start to implement such a process when ready. We did hear feedback from an impressively wide amount of stakeholders. Industry, public citizen, NGOs,

academia. All of these really brought good, thoughtful suggestions which we truly appreciate. And as I reflected on the day, I am impressed and also grateful about the amount of similarities that I am actually seeing and what largely seems to be a process that people are looking to see. Some of the themes we saw where we saw a lot of agreement was the need for transparency. If there was a person that didn't talk about transparency, I almost want you to ask you to raise your hand to ask who didn't care? It seemed like almost everyone was in alignment with transparency being important. And not just transparency but a desire to increase for public engagement. And I want to pair that against another theme that I saw was an interest in acting quickly. There was a reflection, especially in our current process on how long things can take. And I think we are committed to both of those things as well but would raise that as a little bit of opposing forces. As we seek public comments it does result in a longer process. But yet, still we see consensus for interest in both of those. Consensus in the importance of the science-based approach. I was trained as a scientist, for those of you that don't know my background I have a PhD in molecular biology and toxicology and spent years at the NIH studying mechanisms carcinogenesis in human cells and in animals. Looked at the effects of radiation on the possibility of forming and preventing cancer in humans. Science and the scientific process is incredibly important to me as a regulator and person.

I appreciate hearing from all of you that the science here is critically important and we don't lose sight on that.

More clarity, there is consensus we heard and feedback that I want to make sure we bring home. Is more clarity about our priorities and criteria as it relates to how we will identify substances, how we will prioritize them and how we will determine which are fit for purpose. Will this be focused or comprehensive? It's important feedback. We are thinking about and have ideas but this is an important piece of this group is looking for more clarity that's important for us to know.

We heard a lot about the importance of quality data and information in making our determinations based on quality information and the need that we will have to utilize new tools and AI machine learning. There is so much information coming out and it's our responsibility to be able to make decisions and recommendations based on the best available quality of science and it's our job to find that out and that will require the systems to help.

Another thing I was struck with is there is general consensus that everyone wants us to come up with something that will work. Everyone sees a need for this. We see a need for this and everyone wants to come up with something and bring forward their ideas with something that will work. We truly appreciate that and I think that will be critical. Hearing your comments and reading your comments, having time to digest and adjust which we certainly plan to do based on what we heard today is going to help us get there. We greatly appreciate the insight shared. There was a lot of valuable suggestions today big we know this is not the end of the conversation. We do invite you to provide additional feedback into the docket, especially related to the questions we identified, the public docket will remain open until December 6 of

this year. Looking ahead, the FDA's human food program, including the creation of a new office of post-market assessment is set to be implemented on October 1. And, of course, the systematic post-market we have been discussing today will begin right away to go over the next few months we will consider the comments and refine the plans and going to engage in additional stakeholder feedback if we don't have questions I would be amazed.

And we would plan to be able to implement this process by the end of 2025. But I would be remiss, and I'm struck because I'm remembering a stakeholder that I forgot to mention and I will go back will be actually heard from legislators both federal and state. This was truly important for all of us to see the level of interest and engagement in the process. We had FDA were looking back at how often does that happen? It is not typical, I will say that for sure. In addition to that, as we have heard today, safety and risk assessment does take significant resources. Both our premarket and post-market work. It is especially relevant that we have good data to base decisions on, especially exposure data that we will seek. Well, unfortunately, this takes a significant amount of resources, our FY 2024 budget request for additional $19 million for this work did not get funded. As you can see that didn't stop us, we are still here today. We continue to plan and suggest and make some changes. And we do hope to increase the current amount of review. But we will need adequate resources to achieve the stated goals that we were discussing today. enhancing our approach to food chemical safety is among our top priority in the new human foods program. As Deputy Commissioner Jones stated earlier we are committed to doing as much as we can with our current resources. We will be excited to share more as this progresses. We will continue to engage our stakeholders and refine our approach, enhance our food chemical safety program. We thank you for your interest and your participation to the very end of the day. Thank you all for being here and for those that stayed online. (Applause)

>> That does conclude our meeting. Thank you for your participation and interest and have a good evening.