

**Transcript for FDA's Media Briefing:
FDA's Updated Interim Safety and Risk Assessment of Melamine and its
Analogues in Food for Humans
November 28, 2008**

Coordinator: Welcome and thank you for standing by. At this time, all participants are in a listen only mode. During the question and answer session, please press star one on your touchtone phone. Today's conference is being recorded. If anyone has any objections, you may disconnect at this time. Now I'd like to go ahead and turn today's call over to Judy Leon. You may begin.

Judy Leon: Thank you very much Operator. And thank you very much ladies and gentlemen for joining us this afternoon. We have called - I'm Judy Leon. I'm the Acting Director of the Office of Public Affairs for the Food and Drug Administration. We've called this teleconference this afternoon because we will be updating our interim risk assessment and posting it on our Web site shortly. And we wanted to give the news media the chance to ask questions and get some answers about that and its significance from our experts.

So we have joining us today, Dr. Stephen Sundlof who is the Director of FDA Center for Food Safety and Applied Nutrition. And I'm going to turn it over to Dr. Sundlof.

Stephen Sundlof: Thank you Judy. FDA's ongoing investigation continues to show that the domestic supply of infant formula is safe and that consumers can continue using US manufactured infant formula. FDA has concluded that the levels of melamine alone or cyanuric acid alone at one part per million in infant formula do not raise public health concern. FDA is updating its interim risk assessment issued in early October with the information that I'm going to be discussing today.

The FDA has been collecting and analyzing samples of domestically manufactured infant formula for the presence of melamine and melamine related compounds. To date FDA tests have found extremely low levels of melamine in one infant formula sample and extremely low levels of cyanuric acid in another. The levels were so low, and these are well below the one part per million level that we'll be talking about today, they are so low that they do not pose a health risk to infants.

Melamine is not naturally occurring and is not approved to be added directly into the food in the United States. However, melamine is approved for use as part of certain food contact substances such as packaging and equipment used to manufacture food. Low levels of melamine are present in the environment and trace amounts may occur in certain food commodities as the result of these approved uses.

Parents using infant formula should continue using US manufactured infant formula. Switching away from one of these infant formulas to alternate diets or homemade formulas could result in infants not receiving the complete nutrition required for proper growth and development. And that is my opening statement. I'll refer it back to you Judy.

Judy Leon: Okay. Thank you very much Dr. Sundlof. I also want to tell you that we have joining us this afternoon David Elder. He is the Director of the Office of Regional Operations for the Food and Drug Administration as well. So with that, what I would like to do is turn it to your questions.

Operator, we'll take the first question and we'll take a question and a follow-up. Ladies and gentlemen, please identify who you are by name and media outlet. Operator, we'll take the first question.

Coordinator: Thank you. We will now begin the question and answer session. If you'd like to ask a question on the phone press star one. Please un-mute your phone and record your name clearly when prompted. Your name is required to introduce your question. To withdraw your question, press star two. One moment please for the first question.

First question comes from Miriam Falco and state your affiliation.

Miriam Falco: Hi. Miriam Falco with CNN Medical News. I'm confused Dr. Sundlof. You're now saying one part per million does not raise public health concern. Then you're talking about 250 parts per million. We're getting numbers that are parts per billion. Very confusing especially when the FDA said I believe last week that you don't have any data on what's too much melamine for infants, you only have data on adults. So what's changed?

Stephen Sundlof: Okay. What we are saying today addresses part of the issue. We're talking about infant formula that contains either melamine or one of the melamine analogues but not present together. Our risk assessment of October 3 was based on the co-presence of melamine and melamine analogues and as we learned from the pet food case of last year, it was this combination that resulted in crystals in the urine.

We still do not have a - we're still reviewing the information on the co-presence of melamine and melamine related compounds. This specific - this risk assessment specifically addresses the issue when there is one or any other related compounds in infant formula but not both.

Judy Leon: Do you have a follow-up Miriam?

Miriam Falco: So in this particular case, you're talking about the melamine that was found in the one instant formula from Nestle and the cyanuric acid that was found in the infant formula from Mead, correct?

Stephen Sundlof: Well what we have found to date is that we have not found melamine and related compounds in any sample of infant formula. And so we are trying to address the current situation looking at the risk of the current situation as we have identified to date where we found melamine in one infant formula and cyanuric acid in another.

Miriam Falco: Right, I was just trying to confirm that. So of the 87 samples that you've taken since when, you have not found any other traces in any other samples?

Stephen Sundlof: That's correct. We still have, I think, ten samples to go. We've analyzed 74 domestic samples of infant formula and as indicated only those two have we found any evidence of melamine or its analogues.

Judy Leon: Okay. Thank you Miriam. Operator we'll take the next question.

Coordinator: Next question comes from Susan Heavy and state your affiliation. Your line is open.

Susan Heavy: Hi. I'm with Reuters. Dr. Sundlof, could you just clearly give us the exact numbers you found and of what chemical and in what product?

Stephen Sundlof: Yes and I want - just want to preface this by saying that these are very, very low numbers. These are what we consider to be trace amounts. There are two measurements - okay there's the Good Start Supreme Infant Formula with iron manufactured by Nestle Nutrition. In that product, there was melamine found at levels of 0.137 parts per million and 0.14 parts per million.

Susan Heavy: Million with an m?

Stephen Sundlof: With an m. So are you - that's the same as 137 parts per billion or 140 parts per billion. Those are equivalent.

In another sample we detected very low levels of cyanuric acid. This was a sample of Enfamil Lipil with iron, an infant formula powder manufactured by Mead Johnson. Three measurements were made on this sample and the results were 0.247 parts per million, 0.245 parts per million, and 0.249 parts per million. And I misspoke, I think there are 13 samples that are still being tested.

Judy Leon: And let me clarify. We will be posting a table on our Web site along with the updated interim risk assessment that has all of the latest test results along with numbers and manufacturer information so that should clear up some confusion.

Susan Heavy: Thanks.

Judy Leon: Did you have a follow-up Susan?

Susan Heavy: I did thanks. That table will help. I've gotten a lot of reaction from the industry and consumer groups and even members of Congress who are upset with the way the FDA has handled this. The news came out days ago. It's been trickling out but yet there's been nothing, you know, concrete from the agency and there's just been lots of confusion. Parents are confused. How have you handled this?

Stephen Sundlof: Well, one of the ways we're trying to be responsive is by having this media conference so that we can let the public know what we've learned and what information we have and how we view that information in terms of the health risk to infants.

Judy Leon: Okay. Thank you Susan. Operator, we'll take the next question.

Coordinator: As a reminder, if you would like to ask a question, please press star one. Please un-mute your phone and record your name. One moment please for the next question.

The next question comes from Elizabeth Weise and your line is open and state your affiliation.

Elizabeth Weise: Yeah hi. Thanks for taking my call. It's Beth Weise with USA Today. A question - so melamine and cyanuric acid clearly shouldn't be mixed in formulas if you've got them in both. So how - what mechanism do you know of by which these compounds might be getting into formula? And a follow-up question, do you think that there have always been trace amounts of this and we just weren't testing for it so we didn't realize?

Stephen Sundlof: To answer your questions, how did they get in here? Well melamine for certain is an approved food context substance. It's used in packaging materials.

Elizabeth Weise: What kind of packaging materials?

Stephen Sundlof: I don't have that information at hand. I think it is used in some can liners and there is the possibility of migrating - I think we've always said that we believed it would be there at some level until - during the pet food outbreak last year, we developed methods that would go down into the low parts per million. We could not detect melamine at the levels that we were reporting out in the infant formula with that method. And it's only been since last year that we have put a great deal of effort into improving the sensitivity of the analytical method so that to date we are able to detect it at these extremely low levels.

So whether or not it has been with us since several decades because melamine has been in food context processes for many decades, it's difficult to know but it certainly is possible.

Judy Leon: Could you restate your follow-up Beth?

Elizabeth Weise: I'm just trying to get a sense of - I mean I think of melamine, you know, it's an ingredient in plastics and it's used to make hard dishware. So I'm trying to like what do we use it for? I mean so it's the liner in cans, I mean it sounds like it could be in plastic wrap, I'm trying to get a sense of how broadly this is used.

Stephen Sundlof: I don't have a good answer to that. It is, you know, it has many different uses in manufacturing, fermica countertops for instance, being largely composed of

melamine. And as you indicated, (unintelligible) type of dishware. So it is widely used in materials that do have direct contact with food.

Judy Leon: Okay. Thank you Beth. Operator, we will take the next question.

Coordinator: The next question comes from Jennifer Corbett. Your line is open and state your affiliation.

Jennifer Corbett: Yeah hi. I'm with Dow Jones News Journal. The question I have is on the Good Start formula. Is that the powder or -- well I have two questions -- is that the powder or the liquid form? And the other question I had on this cyanuric acid, is that a melamine related compound?

Stephen Sundlof: We're going to look up whether it's...

Judy Leon: What was - can you restate...

Jennifer Corbett: The first question was just on the Good Start formula. What type - was that powder or liquid, you know pre-mixed or?

Stephen Sundloff: We're going to look that up.

Judy Leon: We're checking right now.

Stephen Sundlof: And the second part of your question?

Jennifer Corbett: The second was just really a second question with these be -- I apologize I don't quite know how to pronounce this -- the cyanuric acid.

Stephen Sundlof: Cyanuric acid.

Jennifer Corbett: Cyanuric acid yeah. Is that considered a melamine related compound?

Stephen Sundlof: It is. It is and it's - where melamine is manufactured, one of the by products I believe is cyanuric acid. There is also some question about its use in different forms as sanitizers. And we are looking into that right now to determine whether or not cyanuric acid may be used in sanitizers or a related compound cyanuric acid may be used in sanitizers. But we are still looking into that.

Jennifer Corbett: Okay. Thank you.

Judy Leon: I can tell you that the spreadsheet just says Good Start Supreme Infant Formula with iron. It doesn't speak to the form. Some do, some say powder, some say liquid. We can check on that and get back to you if you'd like.

Jennifer Corbett: Okay yeah. That would be great.

Judy Leon: If you could send me an email. We'll make sure and close the loop with you.

Jennifer Corbett: Okay. That sounds good.

Judy Leon: Okay. Operator we'll take the next question please. The next question comes from Justin Pritchard. Your line is open and state your affiliation.

Justin Pritchard: Hi. It's Justin Pritchard from Associated Press. I have two questions. First of all, you know, on the October 3 guidance you said that you were unable to establish a level of melamine and melamine related compounds in infant formulas does not raise public health concern. And then since then you've made a point of saying that any changes or decisions have to be based on scientific evidence. So can you cite specific scientific evidence that allows

you to change it to one part per million if there is no co-presence? What specifically did you see that makes that a new piece of guidance?

Stephen Sundlof: Okay. Well and let me just tell you that this will all be very well stated in the update to the risk assessment so you can actually follow the numbers.

Justin Pritchard: Okay.

Stephen Sundlof: To get to that one part per million. Where we said in the October 3 risk assessment, we were having - we were unable to define what we considered to be a level below which we had no health concerns had largely to do with the fact that there are no good studies out there that we are aware of at this point where melamine and cyanuric acid or other related compounds have been fed and looked at from the stand point of the levels at which there is no concern.

So that part hasn't changed and we still are not able to establish a level - when both melamine and related compounds are present in infant formula. That hasn't changed. That is not to say that there is no level below which there is no concern. We believe that at very low levels, there should not be any health concern. But we don't have the information available today which will allow us to get to that particular point.

Where we do have good information, where there has been quite a few animal studies, is looking at melamine alone. And because of that, the level of the no-effect level that we talked about in our October 3 risk assessment of 63 milligrams per kilogram in a I think it was a rodent study, is the same level that we are basing this current risk assessment on. We make the assumption that melamine related compounds alone, such as cyanuric acid individually are - have approximately the same toxicology profile or potency as does melamine. So that's one of the assumptions in there, in the risk assessment.

But then when we do a very standard type of risk assessment in which there is a greater than a 1000 fold margin - or safety factor used in calculating what an infant might be exposed to. So it's based on animal studies and a 1000 plus fold safety factor.

Judy Leon: And Justin, do you have a follow-up?

Justin Pritchard: I do. Thank you for answering that. So if I'm understanding correctly, there is no new scientific evidence per say on this change in guidance. If that's the case, then why not just issue the one part per million on October 3?

Stephen Sundlof: Well on October 3 we still didn't really - we were looking at the potential of there being both melamine and related compounds in foods and we still do have that concern. And so remember that our - that the 2.5 parts per million for food other than infant formula is for melamine and related compounds. So that was the - the risk assessment was based on melamine plus related compounds.

When we started looking at the results of the testing of the infant formula and we found - what we found was that we didn't find the co-presence of melamine and the related compounds in any of the products tested to date. And therefore we could change the risk assessment to deal with that particular issue of melamine or melamine related compounds occurring alone in infant formula.

Judy Leon: Okay. Thank you Justin. Operator, we'll take the next reporter.

Coordinator: As a reminder, if you would like to ask a question over the phone please press star one. Please un-mute your phone and record your name. One moment

please for the next question. The next question comes from (Anna Shen).
Your line is open and please state your affiliation.

Annys Shin): Hi this is Annys Shin with the Washington Post. I had two questions. One is if the result of - if the trace amounts are the result of, you know, the line of the can or the can lining or some kind of chemical used to clean the equipment I guess, wouldn't it be wouldn't you find it more consistently in the samples? I mean why is it that it only shows up in these two samples if that's what you think a likely source is and can you really rule out contamination of an ingredient? That's my first question I guess.

Stephen Sundlof: I don't think we've ruled out anything. The reason that - I don't know the reason that it is appearing in some products and not others but, you know, different products are manufactured differently and that some are in cans and some are not in cans or in different kinds of containers. And certainly that may be an issue here. But I don't - I really don't want to speculate on why it is in some and not others because the real answer is, we don't know at this point.

Judy Leon: Annys did you have a follow-up?

Annys Shin: Sure. Initially, you know, when the situation in China was happening, I know one of the initial moves was to check with the infant formula makers and ask them where they get their milk product from and they told you that they didn't source it from China. But so I'm wondering when did you start testing? I mean why are we hearing about this now?

Stephen Sundlof: We actually started - we issued an assignment in September. Remember September 11 was the date that the Chinese announced that they had this problem with infant formula. And so within that month, and I can't tell you the exact date, but we did issue an assignment to our field to begin collecting

various samples of infant formula and other products that would be used in very young children or infants. And we began our testing program. Again we've collected I think 87 samples, that's 87 different products. And we are still in the process of analyzing all of those.

Judy Leon: Okay. Thank you (Anna). All right, Operator, we will take the next question please.

Coordinator: The next question comes from Miriam Falco. Your line is open and please state your affiliation.

Miriam Falco: Hi. It's Miriam Falco and I'm still with CNN. I've got a couple questions just to clarify because originally you had said ten samples still needed to be tested. You corrected that and you said it was 13 which is why you probably said there were 74 samples that you had gotten results on. Now you just said you collected samples from 87 different products. So you - do you have any way of knowing if this is a consistent problem in the two products that you did find traces of melamine and cyanuric acid respectively?

Stephen Sundlof: No. I mean those were single products and to my knowledge we haven't gone back and tested the, you know, retested that particular product made on a different date or whatever. We're still trying to get through the original 87 products that we've collected.

Miriam Falco: Okay. And if I can just make a request so that it's not just one reporter that's getting the info on this was it powder or liquid, maybe you can include that in the data you're posting later on? It would be helpful to all of us.

Judy Leon: Yeah we're going to do a posting and then we will be updating the data that we are posting as we have been updating our melamine Web site so...

Miriam Falco: Well I'm just making that request because you said you'd sent it an email and I'm just trying to speak on behalf of everyone here. And I have a question about the cyanuric acid because you didn't really specify how - you said it might be used for cleaning purposes so why do, how do you think it got into this particular product and how do you know there is not an opportunity for both melamine in the liner and cyanuric acid from sanitizing machinery that it can't get into one product which could then lead to the prompt that we saw in pets the kidney stones etc. which would be very bad for a little baby.

Stephen Lundlof: Right. We are concerned and that's why we're looking for all compounds. Again of all the samples we've tested so far, none have contained melamine plus one of the other analogues. So that is something that obviously we will continue to look for and take the appropriate action if we find levels of both melamine and cyanuric acid. My - just to reiterate though, even though we still are not able with the information that we have, with the scientific information that is available to us, able to set that particular a particular level in infant formula when you have a combination of melamine plus related compounds.

I don't want to give the impression that that means that any level is unsafe because we are now down at extremely low levels of melamine over I think it's somewhere on the order of 10,000 fold less than the amounts associated with the Chinese infant formula contamination. So this - so we're again, these are extremely low levels. And as we learn more about the combination of the two, we hopefully will be able at some point to set a level below which we do not have health concern.

Judy Leon: Great. Thank you very much. Operator, we will take the next call.

Coordinator: The next question comes from Joan Lowy. Your line is open and please state your affiliation.

Joan Lowy: Associated Press. I was just wondering if you could just describe to us I mean I've seen descriptions of it elsewhere but why it is you feel that you can set a level for melamine alone but not a level for melamine and related compounds?

Stephen Sundlof: Okay. It's because what appears to be happening and we know this from the pet food incident last year, we assume that is similar with the Chinese infant formula this year although we don't have confirmation on that. The problem that was seen is that these crystals that develop in the kidneys are not pure melamine. They are a combination of melamine and the related compound cyanuric acid or other related compounds.

And that all of the studies that have been produced to date, they are limited but there have been some animal studies that have been published in which when they fed melamine alone at relatively high levels and for - or cyanuric acid alone at relatively high levels did not see any of these kinds of lesions that we've seen in the past with the pets.

But when melamine and cyanuric acid were co-administered, even at very low doses, they found the precipitation of crystals in the kidney. So it appears to be a, you know, a very different type of syndrome that is seen once the co-presence of melamine and their related compounds are in the diet.

Miriam Falco: Can I ask you why you didn't make that clear in October that you were talking about when you said that you couldn't find - set any level that would be safe that you were only talking about the presence of melamine with something else rather than just melamine by itself?

Stephen Sundlof: Yeah throughout the whole risk assessment we talked about melamine and melamine analogues. So I thought it was relatively clear that that's what we were talking about. And again we're still not able to - let me also go back and say we were able to define a level below which we had no health concern for all foods except for infant formula with melamine and melamine related compounds and melamine analogues. And that's what that 2.5 parts per million represents.

It represents melamine and all melamine related compounds. What we said in the October risk assessment was that we were not able, based on the fact that infant formula is the sole source of nutrition for infants and the fact that infants probably do not have as well developed kidney function which is the target of the poisoning, that we did not have sufficient information nor do we today to define a specific level below which we have no concern.

Judy Leon: Okay. Thank you very much. We are out of time so I'd like to thank Dr. Sundlof and thank all of you for joining us this afternoon. Just a reminder, we will be posting the interim risk assessment and the testing results to date. We will endeavor to update all of these documents as we have been updating our melamine Web site from the beginning of this and we will endeavor to do - in fact I just have been told that it is up live right now. So there you go. And we will be updating the information as it becomes available.

Also I'm getting a note that the Good Start formula is liquid. So that means I don't have to send any follow-up emails. With that again, I will thank you all for joining us this afternoon and have a nice holiday weekend, what's left of it. Thank you very much.

Coordinator: Thank you so much for participating in today's conference call. You may disconnect at this time.

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