

PUBLIC HEARING
STATE OF CALIFORNIA
ENVIRONMENTAL PROTECTION AGENCY
OFFICE OF ENVIRONMENTAL HEALTH HAZARD ASSESSMENT

In the matter of:)
)
Center for Environmental Health's)
Petition Requesting Adoption of)
Regulations Setting a "Naturally)
Occurring" Lead Level in Candy)
Containing Chili and Tamarind)
-----)

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A P P E A R A N C E S

STAFF:

Mr. Allan Hirsch, Chief Deputy Director

Ms. Carol Monahan Cummings, Chief Counsel

Dr. Martha Sandy, Chief, Reproductive and Cancer Hazard
Assessment Branch

ALSO PRESENT:

Ms. Leticia Ayala, Environmental Health Coalition

Mr. Robert Falk, National Confectioners Association

Ms. Mario Pineda, Bqb Cert, LLC

Ms. Tayler Ward, Center for Environmental Health

Dr. Mark Starr, Department of Public Health

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1 P R O C E E D I N G S

2 CHIEF DEPUTY DIRECTOR HIRSCH: Okay. I think
3 we're going to go ahead and get started now.

4 Good morning. My name is Allan Hirsch. I am
5 Chief Deputy Director for the Office of Environmental
6 Health Hazard Assessment, also known as OEHHA, and with me
7 are Carol Monahan Cummings, OEHHA's Chief Counsel; Dr.
8 Martha Sandy, who is Chief of our Reproductive and Cancer
9 Assessment Branch; and Dr. Mark Starr, Deputy Director of
10 Environmental Health for the California Department of
11 Public Health.

12 So just need to go over some housekeeping items
13 first. If you need to use the restrooms during this
14 hearing, you would exit the doors in back, go to the left
15 at the end of the lobby, make another left and then the
16 restrooms are on your right.

17 In the unlikely event we have a fire drill or a
18 genuine emergency, you would go out the back doors, go to
19 the right, go down the stairs, and exit the building from
20 the main lobby.

21 Also, today's hearing is being webcast and the
22 entire proceeding is being recorded by a Certified Court
23 Reporter, who is on the right side of the room.

24 And if you want to alert a colleague about the
25 webcast, they can access it by going to

1 <https://video.calepa.ca.gov>.

2 So today's hearing was scheduled in response to a
3 petition submitted to us on March 14th, 2017 on behalf of
4 the Center for Environmental Health. And the Center has
5 requested that OEHHA commence the regulatory process to
6 issue a regulation pursuant to Health and Safety Code
7 Section 110552 setting a naturally occurring lead level in
8 candy containing chili and tamarind. A copy of that
9 petition and related materials, including today's
10 presentations, can be found on our website by clicking on
11 the link "Naturally Occurring Lead in Candy," which is
12 located on the right-hand side of our home page.

13 Under the provisions of the Administrative
14 Procedure Act, this is the time and place set for the
15 presentation of comments orally or in writing regarding
16 the petition for rulemaking. So please also be aware that
17 the written comment period -- the written public comment
18 period for this matter will close on July 20th, 2017. And
19 OEHHA will take under submission all written comments and
20 oral statements submitted or made during the hearing and
21 during the public comment period.

22 For organizational purposes, we request that
23 those of you wishing to speak at the hearing complete a
24 blue speaker's card and give it to Esther Barajas-Ochoa
25 who's waving her hand there, although you're not required

1 to do so in order to speak. After all the speakers who
2 have filled out blue cards have come up, I'll ask if
3 anyone else wants to speak.

4 So I have three points to go over to ensure that
5 the hearing today is as productive as possible, both for
6 you and for our departments. The first is a reminder that
7 today's hearing focuses on the question of whether we
8 should or should not proceed with a rulemaking identifying
9 a naturally occurring level of lead in specific kinds of
10 candy.

11 If you think we should, feel free to explain why,
12 and also any suggested approaches that you think we should
13 take. If you think we should not proceed with a
14 rulemaking, you can explain why not. And my three
15 colleagues will be giving short presentations to help
16 provide context to the subject of today's hearing.

17 The second point is that we ask -- well, we're --
18 we'll ask you to try to limit your comments to about five
19 minutes. We don't appear to have a large audience here,
20 so we can give speakers some leeway to go a little bit
21 longer, but we still reserve the right to ask you to
22 finish your comments if you go over five minutes.

23 Our experience is that if you have a lengthy or
24 a technical presentation that requires more than five
25 minutes, your comments would be most effective if made in

1 writing, and there is -- there's no maximum length to
2 written comments, and we'll be in a better position to
3 read your arguments carefully and give them the
4 consideration that they deserve.

5 And again, the written comment period is open for
6 two more weeks until July 20th, and if we decide to
7 formally propose a regulation, there will be an additional
8 opportunity for public comment.

9 So third, I just also want to be sure you're
10 aware that at today's hearing we will essentially be in
11 listening mode. Some of you perhaps have been to
12 pre-regulatory workshops we've had on regulatory items
13 where we often engage in back-and-forth discussions with
14 commenters. In this case, we may be able to answer
15 clarifying questions on today's presentation or we may ask
16 a simple clarifying question of -- of commenters, but
17 we're not really set up for a real back-and-forth
18 discussion as you might have seen in other meetings and
19 workshops. We're really here to simply listen.

20 So we don't have an agenda at the back of the
21 room, which we usually do. But really quickly, since I'm
22 wrapping up my opening comments, as I said, Carol Monahan
23 Cummings will give a quick legal overview of the petition
24 and today's hearing. Dr. Sandy will talk about the
25 approaches for developing naturally occurring levels of

1 lead in candy and summarize some of the past work we've
2 done in this area. And Dr. Starr will give an overview of
3 CDPH's lead in candy program and some of the trends that
4 they've seen over time.

5 So to enable the audience to hear you and to
6 ensure that your comments are recorded, when I call your
7 name, please come up to the microphone, and then it would
8 be helpful to the court reporter if you state your name
9 and the organization that you represent, if any.

10 However, you're not required to do so in order to
11 speak.

12 And so with that, our Chief Counsel, Carol
13 Monahan Cummings, will give a short presentation on the
14 background of this petition.

15 (Thereupon an overhead presentation was
16 presented as follows.)

17 CHIEF COUNSEL MONAHAN CUMMINGS: Good morning. I
18 think Mr. Hirsch just took all of my -- everything I had
19 to say, that -- no, not actually. But anyway, so just
20 as Mr. Hirsch said that we had received a petition from
21 the Center for Environmental Health asking us to adopt a
22 background level for naturally occurring lead in candy
23 that contains chili and tamarind. There's a provision of
24 the Administrative Procedure Act that allows any member of
25 the public to petition an agency to take a regulatory

1 action. And so that's what happened here.

2 Our office is required to either start the
3 regulatory action or set the petition for a hearing and so
4 we chose to set the petition for a hearing. We haven't
5 done work in this area for some time and we thought we'd
6 get some input from the public before we decide whether to
7 proceed with the rulemaking.

8 Under the APA, we have to either deny the
9 petition or grant it, in full or in part, and we will be
10 posting a notice announcing our decision whether or not to
11 proceed on our website. And as Mr. Hirsch mentioned, if
12 we decide to proceed, then there's -- will be additional
13 opportunities for public comment.

14 In terms of the statute that we're talking about
15 today, it addresses adulterated candy. And that is
16 actually -- those provisions are related to the Department
17 of Public Health. They do the enforcement under this
18 statute. That's why Dr. Starr is here to talk about their
19 program.

20 The statute itself identifies or describes what
21 candy is for purposes of the statute, and that's here on
22 the slide. It also defines adulterated candy, and that's
23 the issue that we're here to discuss today.

24 Adulterated candy is defined as candy that has
25 lead in excess of the naturally occurring level. So --

1 and that includes candy wrappers as well as the candy. So
2 the naturally occurring level in this particular statute
3 had two alternatives: One was a default level that would
4 be set by the Attorney General's Office, which basically
5 adopted a provision of a settlement that was entered into
6 by the AG several years ago with a number of candy
7 companies. And they established a particular level of
8 lead that would be considered naturally occurring for
9 purposes of that settlement.

10 That was incorporated by reference in the statute
11 as a temporary level until our office adopted a level
12 through a regular rulemaking. Dr. Sandy will talk about
13 our process that we went through in regard to that in a
14 minute. But in terms of the settlement that we're talking
15 with, it was People versus Alpro. I can't pronounce those
16 words. But in any event, the settlement established a
17 maximum lead level of 100 ppb, which is the level that is
18 currently being used by CDPH to determine whether or not
19 candy is adulterated for purposes of this -- the
20 enforcement of this statute.

21 So as I said, this was incorporated by reference
22 into the statute, and it is the current standard.

23 One thing I wanted to mention in terms of the
24 statute that we're talking about today, there was a
25 provision that was included in it that said that the

1 statute would only be implemented in any fiscal year when
2 there was sufficient funding available for that fiscal
3 year. And as you may know, back in 2005 and going
4 forward, the State was in not very good financial
5 situation, and so funding was not made available to the
6 level that it needed to be for each of the fiscal years
7 since the law was enacted. So we just wanted to point
8 that out and we'll go into a little more detail on that in
9 a minute.

10 So I -- that's basically the background on the
11 statute and why we're here. We're going to hear next from
12 Dr. Starr about the CDPH program that they currently have
13 in place to address adulterated candy.

14 DR. STARR: Good morning, everyone. Thanks,
15 Carol, for the introduction. Would you pass the clicker?

16 I'm waiting for it to switch over.

17 (Thereupon an overhead presentation was
18 presented as follows.)

19 DR. STARR: But anyway, I'm Mark Starr. I'm the
20 Deputy Director for Environmental Health, as Mr. Hirsch
21 mentioned, with Department of Public Health. In our
22 Center of Environmental Health, we have -- one program is
23 the Food and Drug Branch, which regulates and enforces the
24 safety of food manufacturing and processing drugs, medical
25 devices, and other related items.

1 And so it's natural for us to be involved with
2 candy, which of course is a food. And, in addition to the
3 Food and Drug Branch, we have a Food and Drug Laboratory
4 Branch in our center that does the testing, and I'll get
5 to that in a moment.

6 So you've heard about the legislation and Health
7 and Safety Code. Carol described that nicely, so I won't
8 go into that in any further detail, other than our role
9 is -- in the Department of Public Health, is to make sure
10 that candy is not adulterated under that part of the
11 statute.

12 And this is focused on candy that contains chili
13 or tamarind or any other risky ingredient. So far, those
14 are the two that have been focused on. And as Carol
15 mentioned, based on the consent judgment, the maximum
16 level that we operate under is 100 parts per billion right
17 now, and that's based on that consent judgment. And
18 that's until a naturally occurring level is set in
19 regulation.

20 This is also consistent with the Food and Drug
21 Administration has provided a recommended maximum level
22 and guidance to the industry for any candy product
23 intended for small children, and they're -- they have the
24 same level of 100 parts per billion or 0.1 parts per
25 million.

1 So our role is to collect and analyze candy
2 samples, take enforcement actions when adulterated candies
3 are identified, and to basically monitor what's happening
4 out there with candy and lead. So that will be the focus
5 of what I'm going to talk about.

6 --o0o--

7 DR. STARR: So historically, we've been involved
8 with testing for lead in candy on -- before this
9 legislation was passed, but most of our testing has been
10 done since then. FDA has been involved as well for about
11 a decade before that. And when there were complaints or
12 it falls to the FDA. We would do that. And I'll talk
13 about some of the historical data we have on our website
14 in a moment. But really, I'm going to focus on what we've
15 been doing since we ramped up this program in 2007.

16 So early on, based on the history with candies
17 from Mexico being the primary ones that have been affected
18 with lead and other events, we focused on Mexican candies
19 for the first couple years.

20 But after that, we expanded the program to
21 include candies manufactured in other countries, as you'll
22 see in a moment, as well as the United States. We also
23 focused on products marketed to young children, because
24 that's where the primary public health purpose and
25 protection really is for this program.

1 So we get our samples from throughout the
2 industry as shown on this slide.

3 Have I gotten to that part yet?

4 Sorry, I should have. Someone set this up with
5 these lovely little transitions that I forgot to click.

6 So you can see at the bottom there, you know,
7 manufacturers, distributors, retailers, and so on. So we
8 collect samples from all those locations.

9 Our standard operating procedures are for our
10 field investigators to collect a kilogram sample, which
11 sounds like a lot of candy. But we need that much because
12 of the variability of the distribution of lead in the
13 product. And so our laboratory will take that sample and
14 homogenize it and test it for lead from a small aliquot
15 from the sample. I'll get to that in a moment.

16 We select a wide variety of candies. We've
17 learned that sugar-sweetened candies and chocolates have
18 not had lead, so we focus on others, trying to get the
19 most results for the sampling that we can do. We sample
20 from different communities and we try and represent
21 various cultures as well.

22 One side bar as I mentioned, that this only
23 applies to candies that have chili or tamarind, and so we
24 do have approaches for testing for lead in other candies
25 and other foods. It's not based on the parts per billion.

1 It's based on typical intake of those products and what's
2 in the products. So we're able to deal with that as well.

3 --o0o--

4 DR. STARR: So I mentioned our laboratory. They
5 get the samples that our field staff collect, and they --
6 this slide describes more than I'm going to talk about,
7 but as far as homogenizing and mixing the sample, using
8 various reagents to do that, and to extract a small
9 portion from that, that ultimately is an equivalent of one
10 gram from the source product. And that's what's tested in
11 ICP-MS is inductively-coupled plasma mass spectrometry for
12 those that are interested. And that's the equipment we
13 use. And then the results are reported back to the food
14 and drug branch, which is the -- our enforcement entity.

15 Currently, our lab is able to -- has a limit of
16 quantitation it's called down to 50 parts per billion.
17 And again the, regulatory level right now is 100. Through
18 differences in how we dilute the sample, we can get that
19 down to 10, if we need to.

20 --o0o--

21 DR. STARR: I'm going to skip these two, but will
22 go back to them. Don't panic. But I think I want to go
23 to what the actions we take when we do find elevated
24 specimens, and then I'll talk about the trends in a
25 moment.

1 So when we find adulterated candy, our Food and
2 Drug Branch notifies the responsible firm. They have to
3 -- well, it's a voluntary recall, but we have tools for
4 assuring that recalls happen. Most notably, we issue a
5 health alert and so firms initiate these voluntary
6 recalls.

7 We also will embargo the candy if there's any
8 left at the facility where we sampled it, so that they --
9 none of that can be distributed in the marketplace. And
10 then the manufacturer and/or importer are notified via a
11 formal letter with all the things listed on here.

12 In particular, the lead level in the product that
13 we discovered, that they cannot sell that candy for sale
14 any further. It's an illegal product in California at
15 that point in time. We are able to assess a nominal fee
16 for our costs of sampling and testing and for retesting.
17 And manufacturers are able to have their product
18 reevaluated, but they have to take specific steps that are
19 listed at the very bottom in parentheses on this slide.

20 They have to do a root cause analysis, basically
21 find out what the problem was, change their processes,
22 change their sources, whatever it takes to change that
23 product, so it's no longer a potential source of lead.
24 And then it can be retested, reintroduced in the
25 marketplace with a different label, and different

1 packaging, so there's no confusion with the original
2 product.

3 --o0o--

4 DR. STARR: Oops. I'm going to go back to those
5 trend things. Okay. So -- so how many recalls have there
6 been? About 72 since -- including 2007 up to the present.
7 And you can see they're spread relatively evenly from year
8 to year. Our sampling varies a little bit from year to
9 year, too, as I mentioned. Most notable on here is that
10 it's dropped notably in the last several years. And we
11 have not had any elevated levels detected, and therefore,
12 no recalls since 2013.

13 --o0o--

14 DR. STARR: The sources of these candies are
15 shown here. Most of them are from Mexico, India or China.
16 Some of that is the result of our sampling, because we do
17 tend to sample candies from certain areas, because we know
18 of the risk. But the proportion that are positive is also
19 higher for those countries. But you'll see there's
20 several other countries including the U.S.A. that have had
21 positive tests.

22 --o0o--

23 DR. STARR: Here's just a picture of some of the
24 candies. These happen to be products, I think mostly, if
25 not all, from Mexico, but there are many on our website

1 from multiple countries.

2 One thing you can see on these is that they are
3 marketed towards children and attractive to children, so
4 those are the ones, as I mentioned, that we tend to focus
5 on.

6 --o0o--

7 DR. STARR: So kind of wrapping things up -- I
8 missed a slide here. Oh, no. There it is. I'm sorry.

9 So wrapping things up, we have had just -- just a
10 little over 70 recalls, as I mentioned, in total since
11 2007, and none in the last several years.

12 They are based on the product having over 100
13 parts per billion, which is the current limit. The
14 majority of them are from foreign countries, but a few
15 from the U.S., as I mentioned. And some manufacturers
16 have addressed this and improved their product, changed
17 their product, and reduced lead content. And I think that
18 ultimately reflects in the decrease that we've seen since
19 2012 with no recalls.

20 --o0o--

21 DR. STARR: So this is just to demonstrate -- or,
22 I mean, it just shows some additional information on our
23 website. If you just go to cdph.ca.gov and type in the
24 search box "lead and candy," you'll find this page. And
25 so much more of the data and detail is posted there than

1 what I presented today. We also have some historic data
2 before this program began, when we were doing some lead
3 testing, and even some retest results are found there.
4 And many more photos of products, lots of other
5 information that will be helpful, if you're interested.

6 --o0o--

7 DR. STARR: So lastly, this is our email contact
8 information, as well as phone contact information, for our
9 Food and Drug Branch, if you need to reach them for any
10 reason.

11 Thank you.

12 DR. SANDY: Good morning. I'm Martha Sandy. And
13 Esther, if you can get our slides set up.

14 (Thereupon an overhead presentation was
15 presented as follows.)

16 DR. SANDY: I'm going to show you in the first
17 couple slides, once they show up, a brief timeline of
18 OEHHA's activities on lead in candy.

19 So the law went into effect in January of 2006.
20 And on July 1st, 2006, resources were allocated to OEHHA
21 to do this work, and we got one person year, one PY, for
22 two years. So in the summer, as soon as we got that, we
23 started recruitment and we managed to fill that one
24 position in December of 2006. And that fall, while we
25 were recruiting, we began initiation of our information

1 and data-gathering activities. It started some outreach
2 to stakeholders on this issue.

3 And in the spring of 2007, we initiated chili
4 sampling studies, because chili seemed to be a focus at
5 that time with high levels of lead -- or relatively high.

6 --o0o--

7 DR. SANDY: So then in July of 2007, the
8 Department of Public Health initia -- convened the
9 Interagency Collaborative on Lead in Candy. They had a
10 meeting and OEHHA was there and participated and
11 presented. And then in the winter of 2008, OEHHA
12 completed our chili sampling studies. And in
13 March -- February and March of 2008, we had a formal
14 request for information, relevant information, on lead in
15 candies flavored with chili and tamarind with a public
16 comment period.

17 At the end of that comment period or towards the
18 end in March, we had two different public workshops, one
19 in Los Angeles and one in San Diego, to receive input from
20 the public and other stakeholders.

21 And that spring and summer, we considered the
22 information we received, and we continued to analyze data
23 we had located or generated.

24 And then in July, July 1 2008, our funding for
25 that one PY ended.

1 --o0o--

2 DR. SANDY: So in terms of scope and problem
3 formulation, the key question was what candies are
4 covered -- and as you've heard many times, it's candies
5 containing chili and tamarind.

6 What is meant by naturally occurring lead?
7 Looking at the Health and Safety Code, it's defined as
8 lead that's not avoidable by good practices, such as
9 agricultural, manufacturing, and procurement practices or
10 other currently feasible practices.

11 And lead is not from -- naturally occurring lead
12 is not from agricultural equipment or fuels used on or
13 around soils or crops, or fertilizers, pesticides, or
14 other materials applied to soils or crops, or materials
15 added to water used to irrigate soils or crops.

16 --o0o--

17 DR. SANDY: So in approaching this project, OEHHA
18 reached out to diverse stakeholders including community
19 groups and the general public, county health agencies, the
20 California Department of Public Health, the U.S. Food and
21 Drug Administration, the California Office of the Attorney
22 General, and the candy industry. And as I had mentioned
23 in the timeline, in February of 2008, we issued a request
24 for relevant information with a public comment period. We
25 had specific areas and questions where we were looking for

1 input. And in March of 2008, we held stakeholder
2 workshops.

3 --o0o--

4 DR. SANDY: So some of the types of data and
5 information that we were seeking in that request for
6 relevant information are listed here. We wanted to know
7 what types of candy contained chili or tamarind that are
8 available and consumed in California. And what are the
9 ingredients in candies flavored with chili or tamarind and
10 consumed in California that contain lead at levels greater
11 than 10 parts per billion? We wanted to focus on the
12 important ingredients.

13 What processes are there that introduce lead into
14 these ingredients? And what's the level of naturally
15 occurring lead in soil and agricultural areas where chili
16 peppers are used to make the candies and where they're
17 grown?

18 --o0o--

19 DR. SANDY: Continuing on, we had questions about
20 good agricultural manufacturing and procurement practices
21 with respect to the production of these candies. What are
22 the methods that minimize the amount of soil, dirt, or
23 dust that comes into contact with or remains on chili
24 peppers used to flavor candies? And also, what types of
25 candy wrappers contain lead?

1 --o0o--

2 DR. SANDY: So specifically, the types of candies
3 we focused on, we wanted to focus on candies with chili or
4 tamarind that are available in California and most
5 commonly consumed in California. We wanted to know that.
6 And we also wanted to know where the manufacturing
7 locations were of those candies, and their ingredients
8 that are consumed by Californians.

9 --o0o--

10 DR. SANDY: So as is evident from these questions
11 that we asked, our approach has been to look -- to take an
12 ingredients-based approach for candies that are flavored
13 with chili and tamarind. And our aim was to identify the
14 fraction of lead that is naturally occurring in chili
15 ingredients, tamarind ingredients, and other candy
16 ingredients.

17 --o0o--

18 CHIEF DEPUTY DIRECTOR HIRSCH: Okay. Thank you
19 very much.

20 So that completes the presentations overview part
21 of our hearing. And now, we proceed with the public
22 comments.

23 I have two blue cards up here so, again if,
24 you're interested in speaking, we recommend -- looks like
25 now we have three. Okay. Great.

1 So if you haven't filled out a blue card and
2 you're interested in speaking, I recommend that you do so
3 and Esther can hand it to me.

4 So the first speaker -- and I'm just doing these
5 in the order that I have them -- will be Robert Falk,
6 representing the National Confectioners Association.

7 MR. FALK: Actually, I would like to speak --

8 CHIEF COUNSEL MONAHAN CUMMINGS: Sorry. You
9 can't speak from back there. If you want to come up, you
10 can do that. There's people on the webcast that can't
11 hear you.

12 MR. FALK: There we go. Hi. I'm Bob Falk. And
13 I'm here today on behalf of the National Confectioners
14 Association. I'm happy to go forward now, but
15 traditionally, I believe the petitioner is accorded the
16 first opportunity to speak.

17 CHIEF DEPUTY DIRECTOR HIRSCH: And that was the
18 third card that I got just now, I noticed, is a
19 representative of Center for Environmental Health. So I
20 don't disagree with you that's typically what we do. So
21 Tayler Ward, the Center for Environmental Health.

22 MS. WARD: Good morning. The Center for
23 Environmental Health would like to thank OEHHA for the
24 opportunity to comment during this hearing.

25 The Center for Environmental Health would like to

1 emphasize the importance of setting a naturally occurring
2 level of lead in candy lower than 100 ppb. Lead is a
3 carcinogen, a neurotoxin, and causes reproductive harm.
4 There is no safe blood lead level, and children are
5 especially susceptible to its negative side effects.

6 Eleven years ago, CEH spearheaded the creation of
7 the Health and Safety Code 110552. We realize the levels
8 of lead in candy containing chili or tamarind was a
9 problem that required intervention and expected a
10 naturally occurring level of lead to be determined.
11 Although, 100 parts per billion has become the de facto
12 level of lead used by the Department of Health Services,
13 we believe the actual level of lead that's naturally
14 occurring is much lower than 100 parts per billion.

15 The Health and Safety Code Section 110552 sets
16 the maximum level of lead in chili and tamarind candy. It
17 is easy to imagine a child consuming multiple pieces of
18 candy in one sitting. If each piece of candy contains 100
19 ppb of lead, their lead exposure would be much higher than
20 the current Proposition 65 threshold.

21 Last year, Mondelez International, Inc.,
22 formerly Kraft Foods, agreed to limit lead in their ginger
23 candy -- ginger snap cookies to no more than 300 parts --
24 30 parts per billion per serving, a significantly more
25 health-protective standard.

1 If this organization can limit lead to no more
2 than 30 parts per billion per serving, candy makers should
3 be able to make candy containing chili or tamarind with
4 lead levels much lower than 100 ppb. OEHHA has proposed
5 to set naturally occurring lead levels 10 times lower than
6 100 ppb for vegetables, fruit, meat, and seafood. There
7 is no reason candy containing chili or tamarind should be
8 an exception to this proposal.

9 Consumers should not be exposed to 100 ppb of
10 lead in candy when manufacturers have shown much lower
11 limits are feasible. It is OEHHA's duty to protect
12 consumers from high exposure to toxic chemicals, and lead
13 in chili and tamarind candy is no exception. To continue
14 using 100 parts per billion as a standard for what is
15 naturally occurring would be willful blindness.

16 Thank you.

17 CHIEF DEPUTY DIRECTOR HIRSCH: Okay. Thank you.
18 So with that, I'll take the remaining two in the order
19 that we received them. So Robert Falk representing the
20 National Confectioners Association.

21 MR. FALK: I'm back.

22 (Laughter.)

23 MR. FALK: So I haven't been at many hearings
24 where the agency has been accused of being willfully
25 blind. And I think that is hardly true in this case,

1 especially given what Dr. Sandy covered. The agency
2 actually has spent a lot of resources over time looking at
3 this issue. And this is a rare issue where the program
4 enacted on both by the legislature, as well as in the Prop
5 65 arena, as well as at the federal level has been largely
6 successful, and I think that the Department of Public
7 Health's testimony and results reflect that. And I don't
8 think anyone needs to be ashamed of success.

9 The success is attributable to really a very
10 collaborative effort between government and citizens'
11 organizations and the industry. As the Department's
12 testimony this morning indicated, in terms of U.S.
13 companies, there really haven't been any incidents of
14 adulterated candy being found in the market. And even in
15 terms of candy coming in from overseas, and particularly
16 from Mexico, the program has been very successful in terms
17 of what we see currently, which is, over the past three
18 years, no adulterated candy being found on the market.

19 When OEHHA held its public data call-in and
20 workshops back in 2008, it gathered a great deal of
21 evidence on the question of naturally occurring levels in
22 Mexican candies. That testimony included information
23 about the levels of lead found in soils in Mexico where
24 chili peppers are grown. It included isotopic analysis
25 showing that the isotopic signature of the lead in the

1 candies matched up with lead in Mexican rock and soil as
2 opposed to gasoline.

3 In terms of the feasibility prongs of the
4 statute, and the lowest level of feasible prong of the
5 statute, OEHHA heard testimony about a joint investigative
6 committee that the Attorney General had formed using
7 experts from the Department, from FDA, their own food
8 safety consultant, as well as a couple members of the
9 industry who looked at the feasibility question very
10 carefully, determined the set of good practices or best
11 practices, required their implementation through the Prop
12 65 settlement.

13 The key practice was, of course, insisting that
14 companies that made chili candy make sure they use chili
15 powder that had been made from chilis that were washed
16 before they were ground up to eliminate as much soil-based
17 lead as possible.

18 They also found that with respect to tamarind
19 candies, the key practice there that needed to be
20 eliminated was the use of clay pots as containers for the
21 tamarind-based candy. That was the source of route on the
22 tamarind side.

23 So the 0.1 PPM level that the AG identified was
24 not pulled out of the sky. It was based on a feasibility
25 analysis. It was based on naturally occurring

1 considerations, and it was also based on FDA's exposure
2 assessment of the level protective of young children who
3 frequently consume candy. There's been nothing that I'm
4 aware of, or I think the agency is aware of, that has
5 changed that in the ensuing decade.

6 One other point I want to emphasize is that I
7 think CEH is confusing the Proposition 65 scheme and its
8 unique definition of naturally occurring with that imposed
9 by this legislation. They are not identical. There are
10 significant differences in them. The agency does not have
11 the burden that defendants face under Prop 65 to prove a
12 series of negatives. The definition of naturally
13 occurring is narrower under the statute than it is under
14 Proposition 65. And those differences are quite
15 significant with respect to the issue before the agency.

16 Finally, I want to make two concluding points.
17 One is that the agency is under no legal obligation to act
18 at this point. As Carol's presentation indicated, when
19 the legislature adopted this bill, it adopted it with a
20 provision that said that the agency's implementation
21 obligations were limited by funding provided to the
22 agency. Since the need for the agency action has largely
23 gone away, if not entirely, the legislature has not chosen
24 to appropriate more money for implementation of this
25 program.

1 Secondly, and I think a very important point, is
2 that in trying to implement this program, the biggest
3 challenge faced was to educate smaller Mexican candy
4 companies on the standard, on the best management
5 practices that were needed to achieve the standard, and to
6 bring them from an unregulated community into being part
7 of the regulated community. That was quite challenging.
8 I think the agency, through the collaborative, got input
9 from the Attorney General's Office on the challenges it
10 faced in that educational process. It would be very
11 daunting to upset the apple cart and have to reeducate
12 those kinds of companies, and they may well come out of
13 compliance if they do so.

14 I think the focus on Mexican candies when it
15 arose was timely. There were real adulterated products in
16 the market with lead levels of 1, 2, and 3 parts per
17 million. They also had insect fragments in them. Those
18 problems have been eliminated, at least with respect to
19 the Mexican candy sector. I think some of the attention
20 has now shifted to candies from Asia.

21 So with all of that, I think that, in short,
22 OEHHA doesn't have the resources to redo this program now.
23 It's a successful program, and that it should move on to
24 other priorities.

25 Thank you very much.

1 CHIEF DEPUTY DIRECTOR HIRSCH: Okay. Thank you.

2 And then the next speaker, Leticia Ayala with the
3 Environmental Health Coalition.

4 MS. AYALA: Good morning. Buenos dias. My name
5 is Leticia Ayala representing Environmental Health
6 Coalition. It's a community-based organization. We work
7 on social and environmental justice in the San
8 Diego/Tijuana region. Dedicated to protecting human
9 health and the environment from the impacts of toxic
10 chemicals in low-income communities of color.

11 And as many of you may know, we have successfully
12 defended families and children from the health threats of
13 lead poisoning, including advocating for the passage of
14 AB 121 back in 2005. We named it the Children's Right to
15 Lead Safe Candy Bill.

16 In recent years, the CDC has finally caught up
17 with the science by affirming that there is no safe level
18 of lead exposure. Brave, bravo, bravo. And now we're
19 thrilled to be here with OEHHA as they consider taking
20 action in setting a strong health-protective standard for
21 lead in candy. We know that the current standard is too
22 high, because of the -- all the years that we've been
23 working with the candy manufacturers, that has been a
24 successful program and they have proven to reduce the
25 levels. Obviously, you -- we've seen the charts where we

1 have no recalls in the past three years. So that shows
2 that the lead can get out of candies and it is achievable.

3 So we hope that in setting the standard, if OEHHA
4 chooses to move forward with this, that you look at
5 what -- what the candy manufacturers are already doing, so
6 that the standard reflects what is achievable. In other
7 words, we wouldn't want OEHHA to set up a standard that's
8 higher than what is currently being done -- achieved. And
9 we also know that the candy manufacturers, you know, took
10 a long time for them to -- as Robert indicated, to switch
11 over to like the non-lead basings in the wrappers, and
12 establish good practices, due diligence in washing those
13 can -- the chilis. And they learn that doing those two
14 things, that combination, that significantly dropped the
15 levels of lead in the candy.

16 So we hope that this -- if there is a new
17 standard, that it will continue to promote those types of
18 practices. It took us a long time, a lot of years to get
19 to this, and we don't want to move forward -- or
20 backwards, sorry.

21 And we would hope that this would actually
22 continue to motivate even others in other industries to do
23 the same for children.

24 Thank you.

25 CHIEF DEPUTY DIRECTOR HIRSCH: Okay. Thanks.

1 Yes, I saw a blue card being handed over here. So Mario
2 Pineda. You can give your organization. Bqb Cert, LLC?

3 MR. PINEDA: My name is Mario Pineda. I represent
4 a certification body -- a third-party certification body
5 working on this topic since -- I don't know, maybe five
6 years ago. The company is Bqb Cert. We have been working
7 with the candy manufacturers since a long time, and
8 particularly, in Mexico, in other places, Guatemala, even
9 in the States. I think my position is neutral. We do a
10 certification process. So whatever the limit is
11 established by the science, technical or whatever the
12 basis is, I think it will help us to do a better work in
13 terms of the certification that is, in some cases,
14 required for candy manufacturers.

15 So at this point, sometimes it's difficult for us
16 to do the best evaluations, since we don't have this
17 limit. Sometimes we -- of course, at this time, we work
18 on the general attorney recommended level. But sometimes
19 the manufacturers, the ingredients, or other stakeholders
20 ask us what is the basis for this limit, or the good
21 practices, or other parts of this certification process?
22 And sometimes we cannot answer to give a good answer. So
23 I think establishing the limit, it could be very useful
24 for everybody, so that's one point.

25 Another point that I want to highlight is the

1 results from the health department that shows very good
2 performance in the last years. I think is -- it has
3 support. I think it's not just coincidence. The
4 manufacturers, particularly in Mexico where I work, have
5 been working very, very hard aside -- in the industry.
6 But some of the companies that actually were sued in the
7 past, have been working very hard. Some of them have
8 maintained not only the practices, but also a
9 certification for some of them more than five years. And
10 the results that I have known are very good. So as the
11 process to face this problem, I think the industry have
12 worked a lot, and other stakeholders also.

13 We have -- in the papers, we have been working
14 with -- we have focused on tamarind and chili. But in my
15 knowledge, there is some other ingredients that are maybe
16 more important now. There are other ingredients that the
17 manufacturers are using that could cause more problems to
18 solve.

19 I raise maybe a question in the packaging
20 material. We have, under the guidance for ceramic
21 packaging, that it's really -- not really used commonly.
22 But we have, if I remember well, it's 100 ppb, the limit.

23 But for elastic wrappers, that is the most common
24 now, we have 20 parts per million. So it's a big, big
25 difference, and there is no reason for that in the real

1 world. We have companies that are certified now that have
2 results much lower than that. So I think there is a lot
3 of work to do, and to refocus the work on new concerns
4 that could help also the manufacturers to do better work
5 or maybe not necessarily to do a better work, maybe to
6 show they have been doing very good work by now.

7 So, in my opinion, I think that this limit, if we
8 take the science, if we take this -- the real
9 experience -- the opinion from the industry, and the other
10 stakeholders, of course, could help everybody to improve.
11 Okay.

12 Thank you very much.

13 CHIEF DEPUTY DIRECTOR HIRSCH: Thank you. So
14 those are all the blue cards we have.

15 Is there anyone else who'd like to speak? This
16 is your chance to do so.

17 Okay. Well, hearing none, okay. If not, I will
18 declare this hearing to be closed.

19 Now again, our written comment period will remain
20 open until July 20th. So if you'd like to submit written
21 comments, we encourage you to submit them electronically
22 to us at this email address: [leadincandy.comments -- lead](mailto:leadincandy.comments--leadincandy.comments@oehha.co.gov)
23 [in candy, all one word, leadincandy.comments@oehha.co.gov.](mailto:leadincandy.comments@oehha.co.gov)

24 You can also snail mail comments to us postmarked
25 by 5:00 p.m., July 20th to Monet Vela, M-o-n-e-t, V-e-l-a,

1 Regulations Coordinator, at the Office of Environmental
2 Health Hazard Assessment, 1001 I Street, Sacramento,
3 California 95812. And that address is on our -- is on our
4 website as well.

5 So the process from there is after the close of
6 the written comment period, we will consider all comments,
7 those that we have received here today, as well as written
8 comments.

9 And then we will decide on whether or not to
10 proceed with a rulemaking. And we'll publish our decision
11 in the California Regulatory Notice Register, which is a
12 kind of a newsletter that's known to inside Sacramento
13 types, but we will also post that same decision on our
14 website.

15 So that's the way you can track what we're doing
16 here.

17 So we have one quick informal question, if you
18 can...

19 MS. AYALA: Yes. I heard Dr. Starr mention that
20 the -- and let me see if I understood you correctly --
21 that there's the chili and tamarind-based candies, and
22 this is about that, the standard for that. But that for
23 the others that are non-chili and tamarind, that the --
24 that the Department has another set of guidelines,
25 protocols, or standards, is that correct?

1 DR. STARR: See if I can get the exact name for
2 it. There's a level that's set by FDA that's called the
3 Provisional Total Tolerable Intake Level of Lead. And so,
4 for example, for a child age zero to six, that's six
5 micrograms per day. And that level is established as
6 something that would raise the blood lead level, if they
7 consumed that much every day, by one microgram per
8 deciliter. So that -- that's what we use for other foods,
9 other commodities, so we would --

10 MS. AYALA: Oh, other foods, not other candies?

11 DR. STARR: Well, other candies as well, I
12 believe. I'd have to double check.

13 MS. AYALA: So like the ones coming from China
14 and India and all the other ones in the U.S., you're using
15 a different standard, and you would continue to use a
16 different standard than this?

17 DR. STARR: It's -- there's not a -- it's not a
18 numeric number as in this legislation, and maybe Carol can
19 explain better. But our understanding, this legislation
20 applies primarily to candies with chili and tamarinds or
21 another substance that has a similar risk. So what I was
22 just noting that for other foods, we have a way of
23 enforcing lead levels, even though this may not apply to
24 those.

25 MS. AYALA: Um-hmm.

1 DR. STARR: So -- and it's based on what the
2 average, you know, say, a child would consume, you know,
3 for another product and how much lead is in that and make
4 sure that their total daily level is below that
5 recommended --

6 MS. AYALA: It seems like there's an
7 inconsistency there. And also, that the bill, when it was
8 crafted, it was for candy products. You know, we did
9 focus on the Mexican chili and tamarind, because that was
10 the number one problem at the time, but it was really so
11 that you all could capture and look at other candies as
12 they come through the market.

13 CHIEF COUNSEL MONAHAN CUMMINGS: Hold on, Bob.

14 So I think that what I want to say about that is
15 that this current hearing is about the petition to adopt a
16 number for chili and tamarind. The statute does have some
17 provisions where we could look at other ingredients, other
18 than chili and tamarind, but that wasn't what the petition
19 was for. So our focus today is on what the petition asked
20 for. And in the event that there's another ingredient or
21 another type of material that needs to be looked at, we
22 can do that separately. But I don't know that we want to
23 get into a back and forth right now on whether or not the
24 standard should be the same for all types of foods or
25 whatever.

1 So just saying that. I don't know if you want to
2 still add something, Bob.

3 MR. FALK: I do, and I have a question, also.
4 So, Leticia, the federal government's guideline for any
5 candy frequently consumed by children is 0.1 ppm. It's
6 the same level the State set specifically for the chili
7 and tamarind candy, so there is a standard that governs
8 all sale imported or domestic candy in the United States.

9 With respect to other ingredients, there are
10 provisions in this legislation that would allow OEHHA to
11 look into them if, A), they had the funding; and B),
12 there's evidence of an actual health threat being posed by
13 some other ingredient.

14 Thirdly, I want to say with respect to other
15 ingredients, the fact that lower Prop 65 limits may have
16 been set for another ingredient like ginger really has
17 nothing to do with the issue of what the level under this
18 bill should be for chili and tamarind.

19 And then lastly, my question is simply, is there
20 a listserve for this matter?

21 CHIEF DEPUTY DIRECTOR HIRSCH: We have a general
22 OEHHA listserve. So that's a good point. If you wanted
23 to make sure you became -- that you're notified when we do
24 make a decision, you can go to our website and sign up for
25 our general OEHHA listserve, and that will -- you'll get a

1 listserve when we do announce that decision.

2 MR. FALK: Thank you.

3 CHIEF DEPUTY DIRECTOR HIRSCH: Yeah, and a lot of
4 others.

5 (Laughter.)

6 CHIEF DEPUTY DIRECTOR HIRSCH: Okay. So again,
7 thank you very much. The public hearing is closed. We
8 appreciate you coming and appreciate the interest and the
9 comments. It's been very, very helpful.

10 Thank you.

11 (Thereupon the California Office of Environmental
12 Health Hazard Assessment public hearing adjourned
13 at 11:04 a.m.)

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1 C E R T I F I C A T E O F R E P O R T E R

2 I, JAMES F. PETERS, a Certified Shorthand
3 Reporter of the State of California, do hereby certify:

4 That I am a disinterested person herein; that the
5 foregoing California Office of Environmental Health Hazard
6 Assessment public hearing was reported in shorthand by me,
7 James F. Peters, a Certified Shorthand Reporter of the
8 State of California;

9 That the said proceedings was taken before me, in
10 shorthand writing, and was thereafter transcribed, under
11 my direction, by computer-assisted transcription.

12 I further certify that I am not of counsel or
13 attorney for any of the parties to said hearing nor in any
14 way interested in the outcome of said hearing.

15 IN WITNESS WHEREOF, I have hereunto set my hand
16 this 19th day of July, 2017.

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20 

21
22
23 JAMES F. PETERS, CSR
24 Certified Shorthand Reporter
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