

COMMENTS FOR PROPOSED REGULATION STABLISHING A NATURALLY OCURRING LEVEL OF LEAD IN CANDY

**ADDRESSED TO:
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**Clarification of lead concentration
(ppm) results in individual
ingredients and candies**



INTRODUCTION

- A group of candy manufacturers have worked very hard for several years to protect candy products from Lead and other heavy metals contamination to ensure safe and quality products for consumers.
- **In accordance with Office of Attorney General of California** requirements whether from settlements or from voluntary participation, the manufacturers of this group have **implemented the best control practices for several years.** **They have also opted to use our third-party auditing body (HACCP Registrar)** to assess, verify and ensure all stakeholders about our best efforts and good performance that goes beyond the basic requirement

INTRODUCTION – Data sources

- As **part of our certification program surveillance plan**, we have gathered **statistically sound data since 2010 year until now**, which we believe could **represent the best basis for establishing the Naturally Occurring Levels of Lead in Candy and seasoning products**, considering these data **represent a wide variety of ACTUAL, REAL** inbound materials and their suppliers, processes / products and their manufacturers, control measures, as well as sampling and testing laboratories and the corresponding results.

INTRODUCTION - Limitations

- In the other hand, we have also detected bad practices and weak elements in the supply chain that have been evaluated and addressed by ongoing action plans, some of them very complicated and beyond of our hands.
- The following charts represent data from 2010 to beginning of 2018 year that were considered in the report submitted for OEHHA evaluation after the 2017 public hearing.
- Data updated to April 2019 is available on your request.

Potential Impacts

In our [Opinion as a Third party auditor](#) we can share these potential impacts.

- Estimated levels of lead in raw material on certified raw materials (chili powder 0.01 ppm) seem unrealistic and never seen in our data since 2010. There will not be real offer of chili. In the market or prices will be significantly higher.
- Proposed naturally occurring level on candy products (0.020 ppm) seems unrealistic based on the available statistical data and observed practices of certified manufacturers applying the best control practices.
 - This could mean that some of the certified manufactures could lose their certification and potentially their settlements.
 - Several manufacturers have told us that they can not meet this level and the use of natural chili and fruits should be replaced with artificial ingredients.

Suggestions

- ✓ Consider the high variability of candy products:
 - Products known as tamarind candy are usually not made only of tamarind but by several types of natural fruits as (e.g. Mango, guava, pear, apple, tejocote, peach, etc.) with a potentially higher naturally occurring level.
 - Chocolate candies with chili???
- ✓ Consider the sound statistical data from certified manufacturers applying the best control practices that can represent the real naturally occurring level.
- ✓ Estimate different levels per major categories:
 - Traditional candies (e.g. based on sugar) can achieve the proposed level (0.020 ppm).
 - Candies with natural fruit or chili can have a different level (e.g. 0.05 ppm)
 - Candies or seasoning (e.g. high content natural Chile powder or salt (e.g. 0.07 ppm).
- ✓ Revise the proposed single limit that can covers all types of candy products.
- ✓ Let us collaborate with data or explanations that helps you on adequate estimates.

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**Individual data points (lead measurements ppm)
in 6 different ingredients compared with the
naturally occurring lead estimation (ppm) by the OEHHA**

Table 12, page 26, Technical Support Document



DATA ON RAW MATERIALS

- We do have information on raw materials and testing that could be relevant for your determination.
- We did not provided information in the 2018 report about raw materials since that was not asked for.
- See below some examples.



CHILI POWDER- RAW MATERIAL

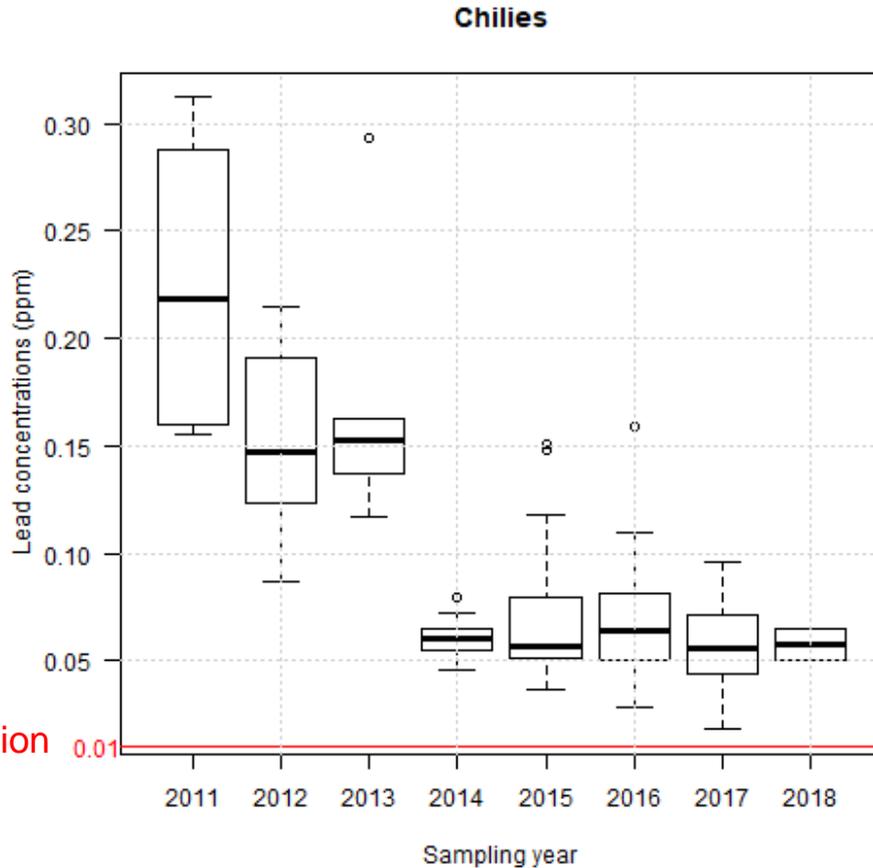
REMARKS

- Data from certified manufacturers
- Represent the results from application of the Good Manufacturing Practices
- This is a adequate basis for establishing the Naturally Occurring Level on chili as raw materials.
- OEHHA estimated level seems unrealistic.
- Any single result met this level since 2010 year.

Scatterplot of lead concentrations (ppm) in 4 different chilies by year



Boxplot of lead concentrations (ppm) in 4 different chilies by year



OEHHA estimation

0.01



SUGAR - RAW MATERIAL

REMARKS

- Some efforts from certified candy manufacturers about looking for vendor selection and pushing them to get the more accurate information.
- Actual data, not trying to represent the naturally occurring level.
- No significant efforts described or implemented by sugar manufacturers that we know
- There is no certified manufacturer.

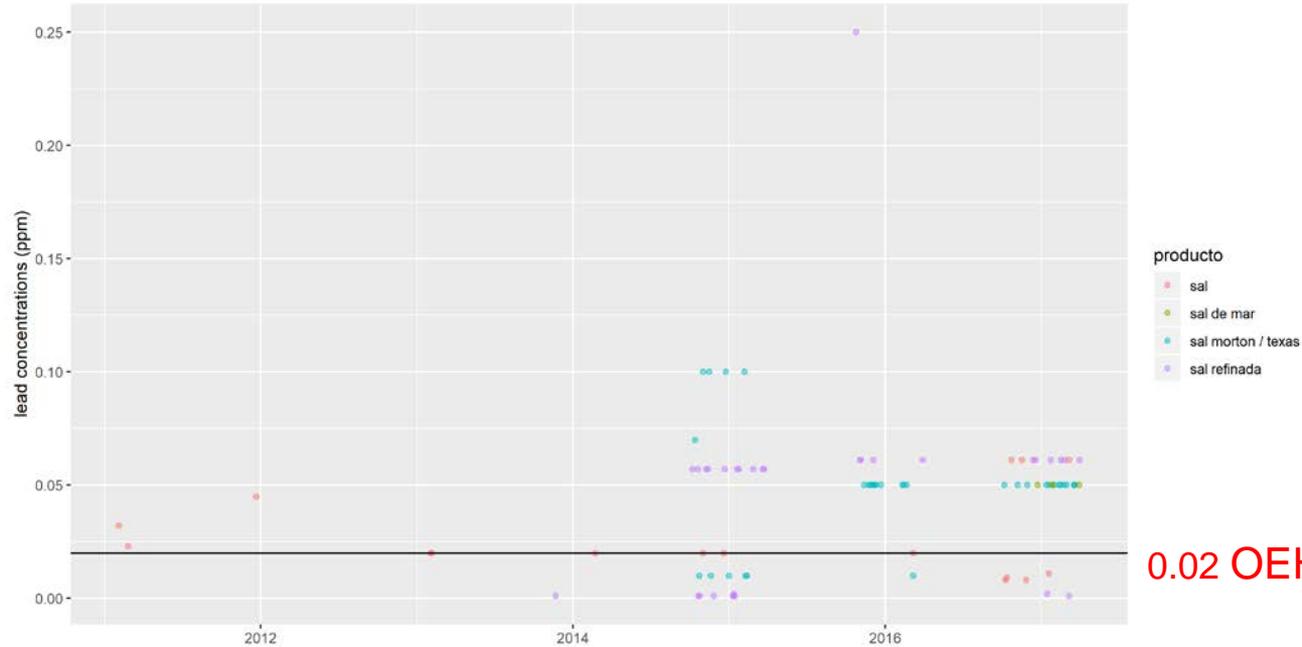


SALT - RAW MATERIAL

REMARKS

- Some efforts from certified candy manufacturers about looking for vendor selection and pushing them to get the more accurate information.
- Actual data, not trying to represent the naturally occurring level.
- Examples of salt that met OEHHA estimated level.
- No significant efforts described or implemented by sugar manufacturers that we know
- There is no certified manufacturer.

Scatterplot of lead concentrations (ppm) in salt by year



0.02 OEHHA ESTIMATE



SiO₂ and TiO₂- Raw material

- Some efforts from certified candy manufacturers about looking for vendor selection and pushing them to get the more accurate information.
- Actual data, not trying to represent the naturally occurring level.
- OEHHA estimated level much lower than our statistical real data.
- No significant efforts described or implemented by sugar manufacturers that we know
- There is no certified manufacturer.



CANDIES FINISHED PRODUCTS

REMARKS

- Data from certified manufacturers
- Represent the results from application of the Good Manufacturing Practices
- This is a adequate basis for establishing the Naturally Occurring Level on Candies as finished products.
- OEHHA estimated level seems unrealistic.



INTRODUCTION- DATA SOURCES

- After the last Public Hearing in Sacramento July 20th -17 we provided data about the specific questions OEHHA asked at that time (e.g. about finished product testing): however, the proposed level for finished products and **references on the supporting document do not correspond to our data and our proposed conclusions.**
- The use of 0.01 and 0.02 percentiles from our charts seems to be an under representation of provided certified manufacturers and products results that are a potentially better interpretation of the naturally occurring level.



AND TABLES TO COMPARE DATA

Figure 3. Distribution of Lead Concentrations in Candies Tested 2012-2017¹⁹

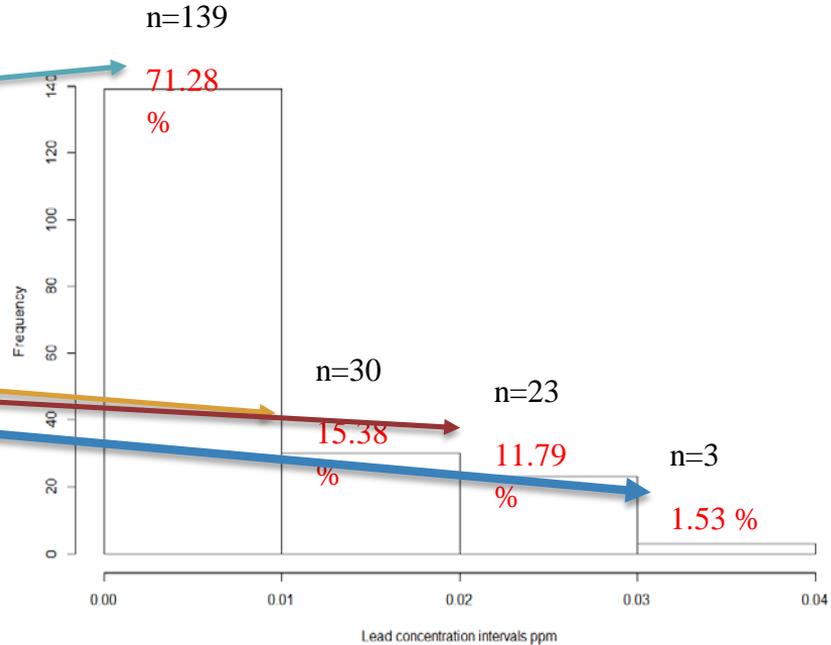
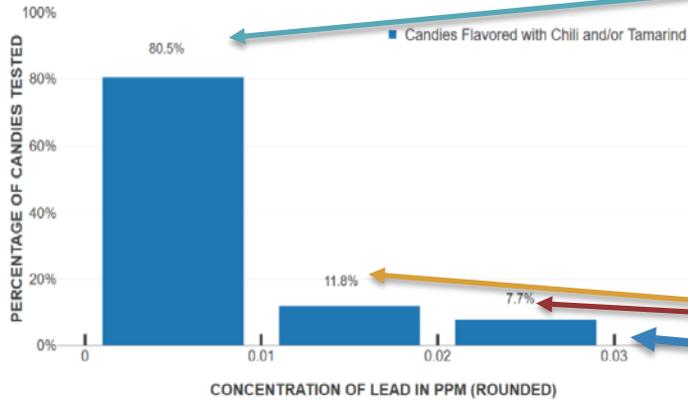
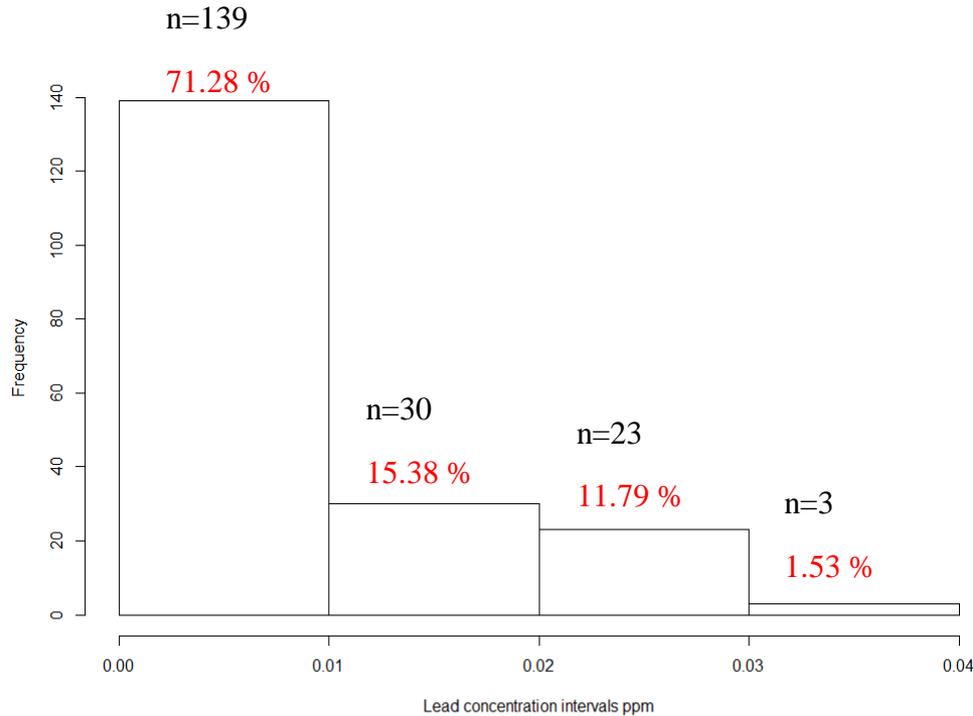


Figure 4 shows the distribution of lead concentrations by candy type in comparison to the naturally occurring level of 0.02 ppm.

We consider pertinent to clarify that the report presented by the OEHHA does not show our original data, more importantly 3 candies (Chili and fruit candy, fruit candy, and traditional candy) have been excluded (c.f. next figure)



Histogram of lead concentration intervals (ppm) from 3 different candies (chili candy, tamarind candy, and chili and tamarind candy)



2

**Individual data points
(lead measurements ppm) in 6
different candies**

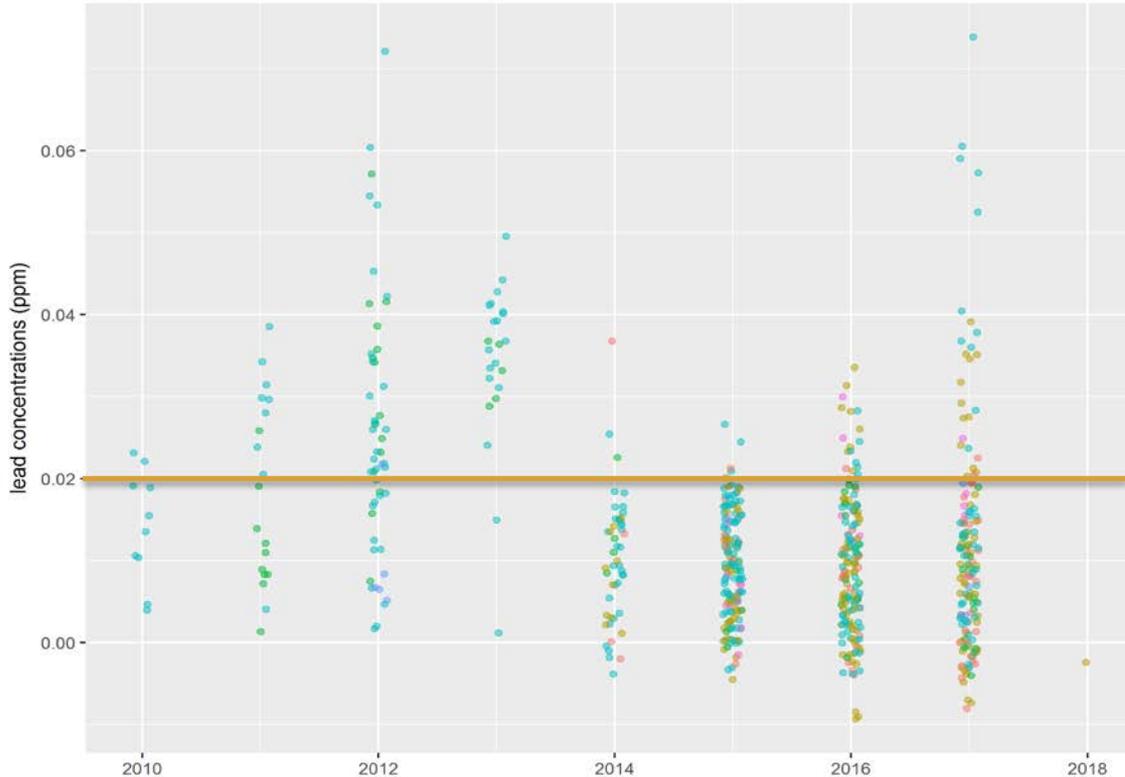


CANDIES FINISHED PRODUCTS

- The following data shows the testing results of products from Certified manufacturers following the best control practices.
- A clear trend of reduction to below limit of detection (e.g. <math><0.020</math> ppm currently).
- Fewer results between 0.020 and 0.070 that represent less frequent formulas , particularly with higher content of natural ingredients (e.g. chili and Fruits). But still from the best control practices.
- **The distribution of statistical data IS NOT trying to represent all kind of manufacturers and products (e.g. good and bad ones in the market).**



Scatterplot of lead concentrations (ppm) in 6 different candies by year



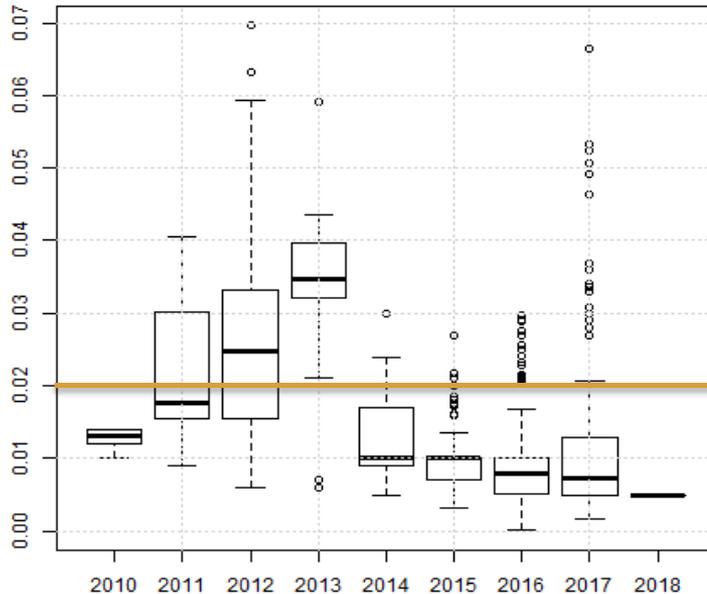
CLASSIFICATION

	candy	n= 67
	chili candy	n= 161
	fruit candy	n= 70
	chili and fruit	n=296
	tamarind candy	n=9
	chili and tamarind candy	n=25

0.02 naturally occurring lead level proposed by the OEHHHA in candies flavored with chili and/or tamarind.



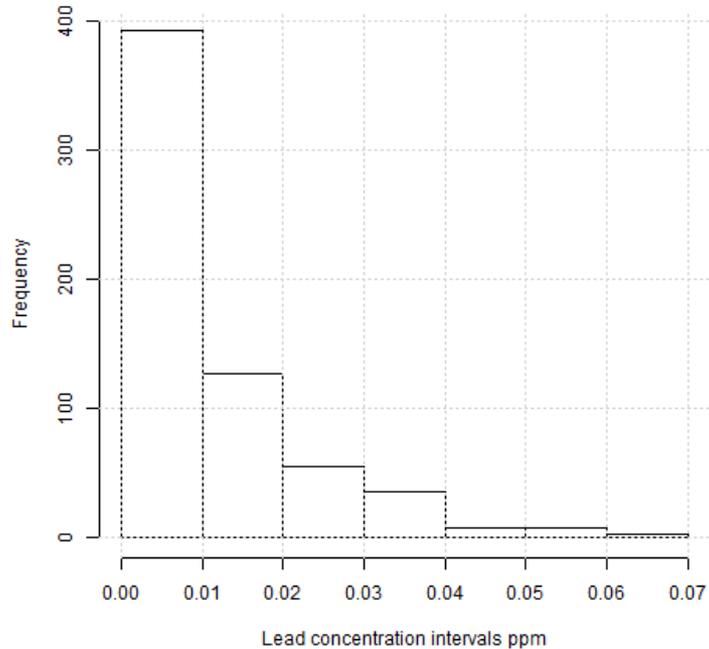
Boxplot of lead concentrations (ppm) in 6 different candies by year



0.02 naturally occurring lead level proposed by the OEHHA in candies flavored with chili and/or tamarind.



Histogram of lead concentration intervals (ppm) including 6 different candies (chili candy, tamarind candy, and chili and tamarind candy, chili and fruit candy, fruit candy, and traditional candy)





Fitting a theoretical log-normal probability distribution to 6 different candies

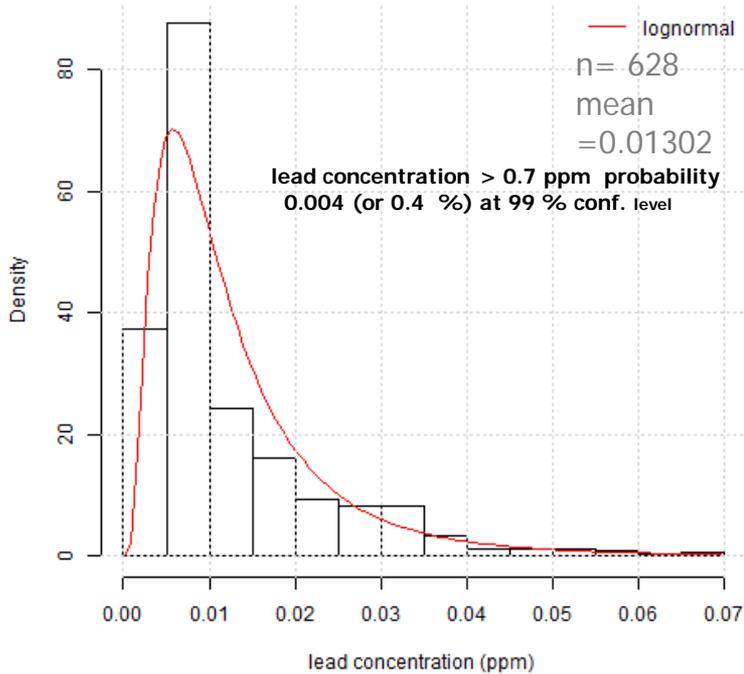


Table 1. Probabilities of finding different lead concentrations in 6 different candies (ppm)

Lead	Probability of occurrence %	Probability of non-occurrence %
0	100	0
0.01	50.30	49.70
0.02	17.81	82.19
0.03	7.12	92.88
0.04	3.19	96.81
<u>0.05</u>	<u>1.57</u>	<u>98.43</u>
<u>0.06</u>	<u>0.83</u>	<u>99.17</u>
<u>0.07</u>	<u>0.46</u>	<u>99.54</u>
0.08	0.27	99.73
0.09	0.16	99.84
0.1	0.10	99.90

OEHHA DETAILS

Proposition 65 office: (916) 445-6900 or email p65.questions@oehha.ca.gov.

Written public comments are due by 5pm on May 22, 2019:

<https://oehha.ca.gov/proposition-65/comments/comment-submissions-proposed-adoption-new-chapter-and-section-chapter-3>



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