Initial Statement of Reasons

Proposed Amendment to

Title 27, California Code of Regulations

Sections 25821(a) and (c)

Level of Exposure to Chemicals Causing Reproductive Toxicity:

Calculating the "Level in Question" for a Food Product and the Intake
by the Average Consumer of a Product

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California Environmental Protection Agency
Office of Environmental Health Hazard Assessment

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Summary

The Office of Environmental Health Hazard Assessment (OEHHA) is the lead agency that implements Proposition 65[1] and has the authority to promulgate and amend regulations to further the purposes of the Act. The Act requires businesses to provide a clear and reasonable warning before causing an exposure to a chemical listed as known to the state to cause cancer or reproductive toxicity.[2] Warnings are not required when exposures do not exceed a specific amount for a given chemical.[3]

For purposes of determining whether an exposure to a chemical listed as causing reproductive toxicity requires a warning, the level of exposure must be determined by multiplying the level in question (stated in terms of a concentration of a chemical in a given medium) times the reasonably anticipated rate of exposure for an individual to the given medium. For exposures to listed chemicals in consumer products, the level of exposure is calculated using the reasonably anticipated rate of intake or exposure for average users of the consumer product. This proposed action would amend Title 27, California Code of Regulations section 25821(a) [4] by adding the following limitation to the existing provision:

> For purposes of this section, where a business presents evidence for the "level in question" of a listed chemical in a food product based on the average of multiple samples of that food, the level in question may not be calculated by averaging the concentration of the chemical in food products from different manufacturers or producers, or that were manufactured in different manufacturing facilities from the product at issue.

In addition, the proposed action would modify Section 25821(c)(2) to clarify that the reasonably anticipated rate of intake or exposure from a consumer product to a chemical listed as causing reproductive toxicity "is calculated as the arithmetic mean of the rate of intake or exposure for users of the product".

Background/Problem to be Addressed by the Proposed Rulemaking

The Act and its existing implementing regulations are not sufficiently specific about how the intake or exposure of an average consumer to reproductive toxicants is to be determined. Lack of clarity can lead to incorrect or inconsistent determinations as to whether product-related exposures to these toxicants are exempt from Proposition 65's warning requirements pursuant to Health and Safety Code section 24549.10(c). The

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[1] Health and Safety Code section 25249.5 et seq., The Safe Drinking Water and Toxic Enforcement Act of 1986, commonly known as "Proposition 65". Hereafter referred to as "Proposition 65" or "the Act".
[2] Health and Safety Code section 25249.6
[3] Health and Safety Code sections 25249.10
[4] All further references are to sections of Title 27 California Code of Regulations, unless otherwise indicated.

proposed amendment to Section 25281(a) would provide specific parameters for measuring the concentration of a listed reproductive toxicant in a food product.

The proposed amendment to Section 25821(c)(2) would clarify how rates of intake and exposure are calculated for consumer product exposures, by specifying that the arithmetic mean of the intake or exposure level is to be used to calculate the rate of intake or exposure for users of the consumer product. Intakes or exposures to listed chemicals vary for different consumers of a given product, and can be represented by a distribution of values. Some consumers may use or consume a relatively large amount of a product, while other consumers may use the product in much smaller amounts. The existing regulation is not clear about whether an average consumer's intake is to be characterized by the geometric mean, the median level, some other percentile, or the arithmetic mean of consumer intakes. Clarifying that the arithmetic mean of the intake or exposure level for users of a consumer product is the appropriate approach helps the responsible business to correctly determine the rate of intake or exposure for average users of the consumer product and to decide whether a warning is required for a given exposure to a reproductive toxicant. This will ensure consistency in application of the regulations.

Purpose
The purpose of the proposed amendments is to clarify how a business should calculate exposures to listed reproductive toxicants. Each provision of the amendments is discussed below.

Section 25821(a)

Proposition 65 is focused on providing warnings for individual exposures to listed chemicals.[5] While the concentration of a given chemical in a non-food consumer product can often be controlled through product specifications and sourcing, the amounts of listed chemicals in food products can vary significantly[6,7,8] based on when

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[5] Health and Safety Code section 25249.6

[6] Food and Drug Administration (2017). Total Diet Study - Elements Results Summary Statistics. Market Baskets 2006-2013. US FDA, Center for Food Safety and Applied Nutrition, April 15, 2014, Revised April 2017. Available online at: https://www.fda.gov/downloads/food...totaldietstudy/ucm184301.pdf , accessed March 26, 2018.

[7] F Riddick, E Wallace, J Davis (2016). Managing risks due to ingredient variability in food production, Journal of Research of the National Institute of Standards and Technology, Volume 121, 17-32. http://dx.doi.org/10.6028/jres.121.002, accessed March 26, 2018.

[8] European Food Safety Authority (2012). Scientific Report of EFSA. Lead dietary exposure in the European population, EFSA, Parma Italy, EFSA Journal 10(7):2831.

and where the food was grown[9], processed or packaged[10]. Most of these chemicals are not intentionally added to the food. Calculations of the concentration of a chemical in a food product for purposes of determining whether a warning is required should reflect an exposure that a consumer might reasonably receive from a product purchased at a specific time and place in California. It is inconsistent with this purpose to average concentrations of a chemical in a food product based on samples of foods from different manufacturers or producers, or that were manufactured in different manufacturing facilities, because these are not necessarily representative of the products an actual California consumer would purchase or use. Where a business can show that averaging the concentration of a chemical in a given food product is appropriate, the proposed amendment would not allow the use of average concentrations of the chemical in food products from different manufacturers or producers or that were manufactured in different manufacturing facilities from the product at issue to be considered the "level in question", for purposes of Proposition 65. It may also be useful to consider the timing of when the product was manufactured as this can also affect the variability of chemicals in the product, though this issue is not directly discussed in the proposed amendments, as it does not lend itself to a rule of general application at this time.

The Act and its implementing regulations in Section 25821 do not specify procedures for determining the concentration of a listed reproductive toxicant, or "level in question", in a food product when the concentration in the product varies. Lack of clarity on this issue has led to the incorrect conclusion that the existing regulations allow averaging of the measured concentrations of a listed reproductive toxicant in a food product across similar products manufactured by different manufacturers, in different states and countries, and over extended periods of time.[11] For purposes of Proposition 65, the estimated concentration of a reproductive toxicant in a food product should reflect the exposure that an individual experiences from the particular food product when consumed. It is not consistent with the purposes of the Act to average across samples gathered from different locations. If the concentration of a listed reproductive toxicant is high in one sample and low in another sample taken from a different location, averaging those concentrations could produce exposure estimates that bear little resemblance to the actual exposure an individual would experience from consumption of a particular

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[9] Davis MA, Signes-Pastor AJ, Argos M, Slaughter F, Pendergrast C, Punshon T, Gossal A, Ahsan H, Karagas MR (2017). Assessment of human dietary exposure to arsenic through rice, Sci Total Environ 586:1237-1244. http://dx.doi.org/10.6028/jres.121.002 Available online at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5502079/pdf/nihms862521.pdf.

[10] Serrano SE, Braun J, Trasande L, Dills R, Sathyanarayana (2014). Phthalates and diet: A review of the food monitoring and epidemiology data. Environmental Health, 13:43. Available online: http://www.ehjournal.net/content/13/1/43

[11] *Environmental Law Foundation v Beechnut Nutrition Corp. et al.*, (2015) 235 Cal.App.4th 307

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food product at a given time. Thus, food-related exposures to a listed reproductive toxicant could occur without the required warning for reproductive toxicity even where the likely exposure to an individual consumer may be very high. OEHHA has concluded that the current regulations should be amended to provide limits on calculating chemical concentrations when multiple samples of a food product have been taken. As noted in the June 1989 Final Statement of Reasons for this subsection.[12]

> "One commenter recommended that the regulation provide guidance for determining the chemical concentration of a listed chemical, since the level of a listed chemical in a product may fluctuate from unit to unit of production, and specifically recommended that it refer to "level in question" as the mean or average level of a listed chemical unless exposure to the listed chemical produced acute adverse reproductive effects as the result of a brief period of exposure. (C-20, p. 13.) The Act does not appear to provide a basis for such a distinction. It does not appear to distinguish between reproductive toxicants on the basis of their acute or chronic toxicity. It simply provides that the "level in question" must be one thousand times less than the level which would produce no observable effect. A consistent interpretation of the words "level in question" appears to be much less confusing and more consistent with the Act. Accordingly, this recommendation was not adopted."

The proposed amendment furthers the purposes of the Act by helping to ensure that decisions concerning food warnings are based more closely on actual exposures to individuals consuming a food product containing a reproductive toxicant.

Section 25821(c)

Intake rates or chemical exposures of a population of consumers to a given product naturally have a range from low to high. For example, some consumers may use or consume a large amount of a certain product on a given day, while other consumers may use considerably less. The range can be characterized by a distribution from lowest to highest exposures with the use of histograms or frequency distribution curves indicating that some consumers use the product at much higher rates than others do. For food intake rates, the distribution is most often skewed to the right as discussed in OEHHA, 2012[13], Chapters 7 and 9. In right-skewed intake distributions, relatively

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[12] June 1989 Final Statement of Reasons, 22 California Code of Regulations Division 2, Sections 12701,m et seq., No Significant Risk Levels, Sections 12801, et seq., No Observable Effect Levels, at page 82. Available online at: https://oehha.ca.gov/media/downloads/crnr/art78fsrjune1989.pdf , accessed April 12, 2018.
[13] OEHHA (2012) Air Toxics Hot Spots Risk Assessment Guidelines. Technical Support Document for Exposure Assessment and Stochastic Analysis. Office of Environmental Health Hazard Assessment. Available at: http://www.oehha.ca.gov/air/hot_spots/tsd082712.html.

smaller numbers of people consume the product at higher amounts than other consumers of that product.

This proposed amendment identifies the arithmetic mean of measured intake rates or exposures as the method for identifying an average value, regardless of the shape of the distribution that best describes the sampling data.[14,15] This is because the arithmetic mean takes into account the magnitudes of all measured values and is an estimate of the expected (i.e., average) magnitude of intake or exposure. The anticipated rate of exposure for average users was adopted originally, in part, to avoid warnings based solely on occasional consumption at the highest levels.[16]

> See page 84 of the 1989 Final Statement of Reasons for this regulation:
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> "One commentator recommended that the regulation provide a means of dealing with variability and fluctuation of the "rate of exposure" term used to calculate the level of exposure, since some persons have a higher rate of exposure than others, though setting the anticipated rate at the highest rate may require a warning to all users of a product on the basis of occasional high consumption. (C-20, p. 11.) The Agency has attempted to provide a means of dealing with these variables in consumer products. Exposure assessment need only be based upon the reasonably anticipated rate of exposure. To further clarify the Agency's intent, the March 29 proposal provided that it is the reasonably anticipated rate of exposure for "average" users which must be assessed. Therefore, it appears that this concern has been resolved."

A single consistent measurement is used to calculate the average consumption amount of a food or usage of a consumer product. In the context of food, this would be the amount of a food product eaten on the day in question. Similarly, for a consumer product it would be the amount of a product used on a particular day. The use of the familiar arithmetic mean (calculated by adding the measurements and then dividing by the number of measurements that were added together) is the appropriate metric for identifying average consumption of a product by individuals consuming or using the product, and is being proposed to add clarity and consistency to the exposure calculation.

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[14] US EPA (1992), Supplemental Guidance to RAGS: Calculating the Concentration Term. Publication 9285.7-081. Washington, D.C.: Office of Solid Waste and Emergency Response. Available at https://nepis.epa.gov/Exe/ZyPDF.cgi/9100UGVL.PDF?Dockey=9100UGVL.PDF.

[15] DPR (California Department of Pesticide Regulation, 2003). Memorandum: Why Worker Health and Safety Branch uses Arithmetic Means in Exposure Assessment. Worker Health and Safety Branch, DPR, September 22, 2003.

[16] June 1989 Final Statement of Reasons, pages 84-85. Available at: https://oehha.ca.gov/media/downloads/crnr/art78fsrjune1989.pdf.

The geometric mean (calculated by multiplying the measurements together and then taking the nth root of the product, where "n" equals the number of measurements that were multiplied together) is often used for determining the central tendency for very different types of measurements. The geometric mean is often applied in the case of percentage growth values, such as annual interest rates, where amounts are compounded and use of the arithmetic mean leads to incorrect results.[17] It is also used in estimating growth rates of populations[18], and generally for data that increase exponentially over time. For example, the geometric mean is used for a rating system that scores products based on two or more criteria, such as price, availability and sales data. However, the geometric mean is not typically used for identifying average consumption or usage levels of a food or consumer product. For example, the single measurement may be the amount of a food product eaten, the ounces of a consumer product used on the day it is used, or the amount of contact with a durable product used on an ongoing basis. In addition, the more variable the measurements, the more the geometric mean underestimates the expected exposure.[19,20]

The median, also called the 50th percentile, represents the middle value of a distribution, with 50% of the measurements falling below the median and 50% falling above. It is sometimes used to describe the central value of a skewed distribution because it is not impacted by high or low values. The median does not take into account exposures of those people who consume more or less of a food or product than typical consumers. This is because the median falls at the midpoint of the distribution where 50 percent of individuals surveyed have higher levels of consumption of a particular food or product and 50 percent have lower levels of consumption, without regard to actual consumption levels above or below the midpoint. Similar to the geometric mean, the median does not provide a measure of expected consumption levels for a food or consumer product except where the distribution is symmetrical.

Because Proposition 65 is intended to warn Californians of significant exposures to listed chemicals, a determination of the exposures to a chemical in a food or consumer product should be based on the full range of exposures experienced by Californians. It is appropriate to weigh all individual consumers equally for purposes of calculating intakes or exposures. The arithmetic mean accounts for consumption levels at both the low and the high end of the range, weighing the intake of each consumer equally. Thus,

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[17] MJ de Smith (2015). Statistical Analysis Handbook, A Comprehensive Handbook of Statistical Concepts, Techniques and Software Tools, Section 4.2 Measures of Central Tendency, available at: http://www.statsref.com/HTML/index.html?averages.html
[18] Ibid.
[19] US EPA, Supplemental Guidance to RAGS, *supra* note 14.
[20] DPR (California Department of Pesticide Regulation, 2003). Memorandum: Why Worker Health and Safety Branch uses Arithmetic Means in Exposure Assessment. Worker Health and Safety Branch, DPR, September 22, 2003.

OEHHA proposes to amend the regulation so that the reasonably anticipated rate of exposure for purposes of Proposition 65 is calculated as the arithmetic mean.

Necessity

The existing regulations are not sufficiently specific regarding how exposures to a given product by an average consumer are to be calculated. It is inconsistent with the purposes of the statute to average concentrations of a reproductive toxicant in a food product that is based on concentrations measured in samples of foods from different manufacturers or producers, or from different manufacturing facilities, because these are not necessarily representative of the levels of the chemical in products an individual would typically be exposed to when consuming a particular product in California. The proposed amendment would not allow the use of average concentrations calculated in those ways to be considered the "level in question", for purposes of Proposition 65. Allowing averaging of concentrations over geographic locations could allow food-related exposures to a listed chemical to occur without the required warning for reproductive toxicity even where the likely concentration, and hence exposure, to an individual California consumer may be very high. The results of such averaging can bear little resemblance to the actual exposure an individual incurs from consumption of food purchased at a given time and location. OEHHA has thus concluded that the current regulations should be clarified as to the limits for calculating chemical concentrations should they occur in a food to further the purposes of the Act.

Additionally, intakes or exposures from consumer products vary for different consumers, and can be represented by a distribution of values. The existing regulation is not clear about whether an average consumer's intake is to be characterized by the geometric mean, the median level, some other percentile, or the arithmetic mean of the consumer intakes. Clarifying that the arithmetic mean of the intake or exposure level for users of a consumer product is the appropriate approach will help businesses to determine the correct rate of intake or exposure for average users of the consumer product so they can decide whether a warning is required under Proposition 65.

Technical, Theoretical, and/or Empirical Study, Reports, or Documents Relied Upon

Documents relied on include:

- OEHHA (2012) Air Toxics Hot Spots Risk Assessment Guidelines. Technical Support Document for Exposure Assessment and Stochastic Analysis. Office of Environmental Health Hazard Assessment.

- OEHHA (1989) Final Statement of Reasons for Title 22, California Code of Regulations for Sections 12801, et seq., No Observable Effect Levels.

- US EPA (1992), Supplemental Guidance to RAGS [Risk Assessment Guidance for Superfund]: Calculating the Concentration Term. Publication 9285.7-081. Washington, D.C.: Office of Solid Waste and Emergency Response.

- DPR (California Department of Pesticide Regulation, 2003). Memorandum: Why Worker Health and Safety Branch uses Arithmetic Means in Exposure Assessment. Worker Health and Safety Branch, DPR, September 22, 2003.

- Food and Drug Administration (2017). Total Diet Study - Elements Results Summary Statistics. Market Baskets 2006-2013. US FDA, Center for Food Safety and Applied Nutrition, April 15, 2014, Revised April 2017.

- F Riddick, E Wallace, J Davis (2016). Managing risks due to ingredient variability in food production, Journal of Research of the National Institute of Standards and Technology, Volume 121, pages 17-32.

- European Food Safety Authority (2012). Scientific Report of EFSA. Lead dietary exposure in the European population, EFSA, Parma Italy, EFSA Journal 10(7):2831.

- MJ de Smith, (2015). Statistical Analysis Handbook, A Comprehensive Handbook of Statistical Concepts, Techniques and Software Tools, Section 4.2 Measures of Central Tendency.

- Davis MA, Signes-Pastor AJ, Argos M, Slaughter F, Pendergrast C, Punshon T, Gossal A, Ahsan H, Karagas MR (2017). Assessment of human dietary exposure to arsenic through rice, Sci Total Environ 586:1237-1244.

- Serrano SE, Braun J, Trasande L, Dills R, Sathyanarayana (2014). Phthalates and diet: A review of the food monitoring and epidemiology data. Environmental Health, 13:43.

Copies of these documents are included in the rulemaking record for this regulatory proposal.

Reasonable Alternatives to the Regulation and the Agency's Reasons for Rejecting Those Alternatives

The proposed regulatory action clarifies the existing regulations regarding the appropriate methods for calculating exposures from food products to a chemical listed as causing reproductive toxicity. Eliminating inconsistency in the application of the regulation furthers the purposes of the Act. It is inconsistent with the Act to average concentrations of a listed chemical in food product samples that were manufactured in different facilities because these are not representative of the products an individual would typically be exposed to when purchasing and consuming a product in California.

In addition, clarifying the use of the arithmetic mean to calculate the intake level for users of a consumer product will provide guidance to businesses determining the

average rate of intake or exposure for product users, thus providing necessary compliance assistance and certainty for the regulated community and those who enforce the law.

An alternative to the proposed amendments would be not to adopt them. However, as can be seen by the court's decision in the *Environmental Law Foundation v Beechnut Nutrition Corp. et al.*[21], the existing provision of the regulations was interpreted to allow both the use of average concentrations of lead in products produced over significant time periods, geographic locations and producers; and to allow use of the geometric mean when calculating individual exposures to the chemical. Neither finding is consistent with the intent of OEHHA's regulations or Proposition 65, which is focused on an individual exposure from a specific product. Therefore, OEHHA believes that the regulations should be clarified so that businesses and courts can apply the correct analysis in the future. It should be noted that it is also inconsistent with the purposes of the Act to average concentrations of chemicals in products manufactured over extended periods. OEHHA considered including a time element in this regulation. However, given the diversity of food products and manufacturing methods, we were unable at this time to develop a rule of general application that would address this issue. It may be that this issue must be resolved on a case-by-case basis. OEHHA may revisit this issue in a future rulemaking.

Reasonable Alternatives to the Proposed Regulatory Action that Would Lessen Any Adverse Impact on Small Business and the Agency's Reasons for Rejecting Those Alternatives

The proposed regulatory action will not adversely impact small business because it is simply a clarification of the intent of the existing regulation. The alternative would be not to make these clarifications, thus allowing inconsistent and inappropriate calculations of exposure. OEHHA has determined that there is no reasonable alternative considered by OEHHA, or that has otherwise been identified and brought to the attention of OEHHA, including alternatives that would lessen any adverse impact on small business or would be as effective and less burdensome on small business. In addition, OEHHA has determined that the proposed regulatory action will not impose any mandatory requirements on very small businesses because Proposition 65 expressly exempts businesses with less than 10 employees[22] from the requirements of the Act.

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[21] *Environmental Law Foundation v Beechnut Nutrition Corp. et al.*, (2015) 235 Cal.App.4th 307
[22] Health and Safety Code section 25249.11(b)

Evidence Supporting Finding of No Significant Adverse Economic Impact on Business

The proposed regulatory action will not have a significant statewide adverse economic impact directly affecting businesses, including the ability of California businesses to compete with businesses in other states because the proposed amendments to the regulation do not impose any new requirements upon private persons or business beyond those that are already required by Proposition 65. The proposed action simply provides clarification concerning the appropriate methods for calculating those exposures that require a warning and does not cause any significant economic impact on private persons or businesses.

Efforts to Avoid Unnecessary Duplication or Conflicts with Federal Regulations Contained in the Code of Federal Regulations Addressing the Same Issues

Proposition 65 is a California law that has no federal counterpart. There are no federal regulations addressing the same issues and thus OEHHA has determined that the proposed regulatory action does not duplicate and will not conflict with federal regulations.

Economic Impact Assessment Required by Gov. Code section 11346.3(b)

OEHHA finds that there will be no significant economic impact related to the proposed clarifying amendments. The proposed amendments will not impose any significant costs because businesses are already subject to the warning requirement of Proposition 65. The proposed amendments do not impose any mandatory requirements that would significantly increase costs for businesses. The proposed amendments provide guidance for the person or business responsible for determining whether a warning should be given, and will provide additional clarification for courts as they interpret the regulations as they apply to a given case.

Creation or Elimination of Jobs within the State of California

The proposed regulatory action will not impact the creation or elimination of jobs within California. The proposed regulatory action will provide more specific guidance in Section 25821 for calculating the concentration of a chemical in a food, and the intake level of average users of a consumer product.

Creation of New Businesses or Elimination of Existing Businesses within the State of California

The proposed regulatory action will not impact the creation of new businesses or the elimination of existing businesses within California. The proposed amendments would

provide safe harbor guidance for the person or business responsible for determining whether a warning should be given.

Expansion of Businesses Currently Doing Business within the State of California

The proposed regulatory action will not impact the expansion of businesses currently doing business within California. The proposed amendments would provide safe harbor guidance for the person or business responsible for determining whether a warning should be given.

Benefits of the Proposed Regulation to the Health and Welfare of California Residents, Worker Safety, and the State's Environment

The proposed amendments to Section 25821 will benefit the health and welfare of California residents and the safety of workers. The additional guidance provided to businesses regarding how to determine whether a warning is required will increase the likelihood that residents and workers will receive appropriate warnings when required under the Act. This furthers the purposes of Proposition 65 by providing more certainty in assessing whether chemicals in a consumer product result in exposures that require a warning under Proposition 65, and which product exposures are exempt from the warning requirements.