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May 7, 2014

VIA U.S. MAIL AND ELECTRONIC MAIL:
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Ms. Cynthia Oshita
Office of Environmental Health Hazard Assessment
P.O. Box 4010, MS 19B
Sacramento, California 95812-4010

Re: Notice of Intent to List: Nitrite in Combination with Amines or Amides

Dear Ms. Oshita:

We are writing on behalf of numerous clients that grow, distribute and sell agricultural commodities and who process agricultural commodities to produce food products and ingredients for food products (referred to collectively as “food products”), regarding the above-referenced Notice of Intent to List a chemical substance or group of chemical substances referred to as “Nitrite in Combination with Amines or Amides” as a chemical “known to the State to cause cancer” for purposes of the Safe Drinking Water and Toxic Enforcement Act of 1986,” also referred to as “Proposition 65” or “the Act.”

By this letter and the agency’s response, we seek to clarify certain understandings regarding the identity of the chemical substance that OEHHA intends to list under Proposition 65, and to confirm that the presence of certain chemical substances that are present in the aforementioned food products will not give rise to a requirement for Proposition 65 cancer warnings pursuant to Section 25249.6 of the Act.

Designation of Listed Substances. As background for this request, we note that the document that serves as the basis for this proposed listing, Volume 94 in the series of “IARC Monographs on the Evaluation of Carcinogenic Risks to Humans, entitled Ingested Nitrate and Nitrite, and Cyanobacterial Peptide Toxins (IARC 2010)” (hereinafter, “IARC Monograph”) appears not to identify any single, discrete chemical moiety as carcinogenic. Rather, as the Notice quotes, the reference in the IARC Monograph is to “ingested nitrite in combination with amines or amides.” This is the reason, we understand, that the chemical identified for listing in the Notice is referred to as “Nitrite in combination with amines or amides.” Accordingly, the substance that will be listed is a collection of substances to be referred to as “nitrite in combination with amines or amides,” and not, for example, “nitrite,” or “amines” or “amides.”

While this may appear obvious, the designation of the listed substance as a combination of substances has important implications for the application of warning requirements under Section 25249.6 of the Act and the Proposition 65 implementing regulations. Specifically, it appears to us, and we request that OEHHA confirm, that Section 25249.6 will prohibit a person

subject to the Act from “exposing” an individual in California (without a Proposition 65 warning) to the above-quoted combination of substances together, and not to “nitrite” or “amides” or “amides,” even in instances where those substances may be or become present in a food product.

This distinction is important to persons who grow or process or sell food products, because so many food products contain nitrite or amides or amines or some combination of these substances in their natural state, and neither the food products nor the combination of nitrite and amides or amines in them are thought to present a risk of cancer, in part because the same food products contain antioxidants that are thought to diminish the risk of cancer. Indeed, the Monograph notes that fruit and vegetable sources of nitrite, amides or amines also “contain vitamin C and other compounds such as polyphenols” that diminish the risk of cancer. [IARC Monograph, Section 2]

In this regard, the Notice indicates that the proposal for listing is based on OEHHA’s observation that the IARC Monograph satisfies the “formal identification and sufficiency of evidence criteria in the Proposition 65 regulations for *nitrite in combination with amines or amides*,” (emphasis in original), and goes on to recite that “[i]n many studies in rats, *when sodium nitrite and specific secondary or tertiary amines or amides* (emphasis added) . . . were mixed in the diet or given in the drinking-water or by gastric intubation, an increased number of malignant tumors . . . was observed.” Thus, it is only when a person subject to the Act exposes an individual to a requisite *combination* of these substances, *i.e.*, by adding this combination of substances to a food product, that the warning requirement under Section 25249.6 would be invoked.

Route of Exposure. It further is clear, both from the title of the Monograph and from the discussion throughout, that the only relevant route of exposure is by ingestion of this combination of substances. We thus suggest that it would be appropriate to clarify that in the listing itself, pursuant to Section 25707(a) of the Proposition 65 regulations. In other words, the listing should indicate that inhalation exposure and dermal exposure are outside the scope of the listing.

Exemption for Exposure to a Naturally Occurring Substance in a Food. The importance of the designation of the listed substance as a combination of substances, rather than as three separate substances, further is manifested in the application Section 25501 of the Proposition 65 implementing regulations, entitled “Exposure to a Naturally Occurring Substance in a Food,” which provides in pertinent part as follows:

“(a) Human consumption of a food shall not constitute an ‘exposure’ for purposes of Section 25249.6 of the Act to a listed chemical in the food to the extent that the person responsible for the exposure can show that the chemical is naturally occurring in the food.

(1) For the purposes of this section, a chemical is ‘naturally occurring’
[a] if it *is a natural constituent of a food*, or

[b] if it is present in food solely as a result of absorption or accumulation of the chemical which is naturally present in the environment in which the food is raised, or grown, or obtained”

(Emphasis added; reformatted for clarity.)

The text in the table that appears in the Notice, under the heading “Occurrence and Uses,” is intended to illustrate this distinction, as we understand it. Thus, the sentence providing that “[n]itrite is a natural constituent of fresh produce, including spinach and celery, and of fresh uncured meats,”¹ and other text in the table indicating that certain amines are the “building blocks of protein” and that amides can be formed from amines and may include proteins,² all acknowledge that these substances are “natural constituents” of many food products, in particular produce such as fruits, vegetables, cereals and grains, soya, meats and meat products.

The IARC Monograph itself confirms this, at Section 1.4: “Nitrate and nitrite are naturally occurring ions that are part of the nitrogen cycle and are ubiquitous in the environment The content of nitrate and nitrite in vegetables depends on the type of vegetable, the method of production, the use of fertilizer, the season and light.” The Monograph specifically acknowledges the presence of nitrate in all vegetables and fruit, cereal grains and their products, milk and dairy products, and eggs and that the presence of nitrite in these items of produce is a result of natural conversion of the nitrates to nitrite. “Evidence from studies . . . support[s] the contention that nitrate contained in vegetables is converted to nitrite before consumption”

On the basis of these statements in the Monograph, we request that OEHHA confirm that produce of the types described above is anticipated to contain naturally occurring nitrite, and that nitrite formed in produce after harvest and before consumption, including during transit, display and storage, is not included within the proposed listing. Thus, persons subject to the Act who grow, distribute, process or sell such food products need not determine how the levels of nitrite in their food products might have been affected by factors such as methods of production, fertilizers, season and light conditions because, in the final analysis, any nitrite that is present arises from the natural conversion of nitrates to nitrite, which is a natural constituent of the food products within the meaning of Section 25501(a)(1), rather than a contaminant within the meaning of Section 25501(a)(3) or (4).

Returning to the text in the “Occurrence and Uses” table referred to above, OEHHA specifically acknowledges there that certain amines are the “building blocks of protein” and that

¹ We understand that this sentence in the table is intended to be illustrative, and not restrictive, in its application. For example, the observation that “nitrite is a natural constituent of fresh produce” is not intended to indicate that nitrite is not a natural constituent of processed produce or other foods, or that the term “produce” is to be restricted only to spinach and celery. Rather, the term naturally applies to other forms of produce, such as fruits, vegetables, cereals and grains, soya, meats and meat products, as the Monograph indeed reflects.

² As noted above, we believe it would be helpful to supplement these comments in the Notice to acknowledge affirmatively and expressly that amines and amides are natural constituents of all green plants and many types of produce, such as fruits, vegetables, cereals and grains, soya, meats and meat products, as the agency has acknowledged regarding nitrite.

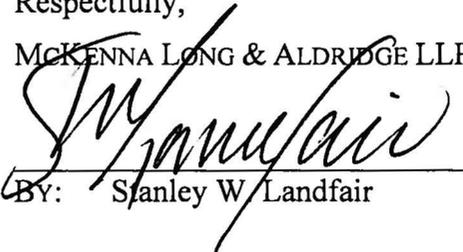
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amides can be formed from amines and may include proteins.” Thus, similarly to the discussion above regarding nitrates and nitrite, we ask OEHHA to confirm that all green plants and many types of produce also contain amines and amides, including enzymes, receptors and other proteins; that such amines and amides are naturally occurring constituents of produce, whether they are taken up from soil as part of the natural carbon cycle, from irrigation water, or other sources; and that persons subject to the Act who grow, distribute, process or sell such food products similarly need not determine how the levels of amines or amides in their products might have been affected by factors such as methods of production, fertilizers, season and light conditions, *etc.*

Because the food products referred to above contain naturally occurring “nitrite in combination with amines or amides” under Section 25501 of the regulations, Section 25249.6 of the Act would apply only if the combination of nitrite or amides or amines were present in the food and the individual “responsible” for exposure to the combination added both the nitrite and an amine or amide as a combination (*e.g.*, as a curing brine containing both nitrites and amides or amines). Conversely, if either the nitrite or the amine or the amide were a “natural constituent” of the food, then consumption of the food would not result in “exposure” to the combination for purposes of Section 25249.6.

Conclusions. As we understand the Notice, per the discussion above, the production and sale of fresh and processed produce (including uncured meats) for consumption in California would not result in “exposure” to “nitrite in combination with amines or amides” for purposes of Section 25249.6 of the Act, in part because nitrite, amides or amines all are “natural constituents” of food products within the meaning of Section 25501(a)(1) of the regulations. Unless the processing activity were to result in the addition of the requisite combination of these substances to a food product, there would be no “exposure” to this combination for purposes of Section 25249.6. In other words, human intervention to add the *combination* of nitrite and amides or amines would be required in order for Section 25249.6 to be invoked.

Thank you for the opportunity to submit these comments, and for the Agency’s confirmation.

Respectfully,
MCKENNA LONG & ALDRIDGE LLP

BY: Stanley W. Landfair