



**NATIONAL CHICKEN COUNCIL**

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May 8, 2014

***SUBMITTED ELECTRONICALLY***

Ms. Cynthia Oshita  
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**Re: NOIL – Nitrite in Combination with Amines or Amides**

Dear Sir or Madam:

The National Chicken Council (NCC) is pleased to submit these comments on the California Environmental Protection Agency's Office of Environmental Health Hazard Assessment's (OEHHA's) proposal to list "nitrite in combination with amines or amides" as a chemical known to the state of California to cause cancer under the Safe Drinking Water and Toxic Enforcement Act of 1985 (Proposition 65). NCC represents vertically integrated companies that produce and process more than 95 percent of the chicken marketed in the United States. NCC's members would be directly affected by the proposed listing, as many of our members produce products containing nitrites. NCC and our member companies are deeply committed to the safety of the food we produce.

Nitrite is a critically important food ingredient used in certain chicken products to protect food safety. Nitrite is used as a curing agent and is very effective at inhibiting the growth of bacteria capable of causing serious food-safety illness, including *Clostridium botulinum*, *Listeria monocytogenes*, and *Clostridium perfringens*. Nitrites are therefore a vital component of many product formulations. Various forms of nitrite are approved for use in food and recognized as safe by the U.S. Food and Drug Administration (FDA) and the U.S. Food Safety and Inspection Service (FSIS).

We are greatly concerned that the proposed listing is based on an incomplete and outdated view of the relevant science and is inconsistent with the requirements of Proposition 65. We accordingly urge OEHHA not to add "nitrite in combination with amines or amides" to the list of substances known the state to cause cancer.

NCC appreciates the importance of reducing food-safety risks, including those posed by long-term exposure to substances found in a food. We do not believe, however, that the International Agency for Research on Cancer (IARC) report cited by OEHHA supports listing “nitrite in combination with amines or amides” as a chemical known to the state to cause cancer. We fully support the comments submitted by the American Meat Institute in this regard. In particular, we have the following concerns with the agency’s proposal:

- The IARC report does not identify a single, well-defined chemical. Proposition 65 requires providing a warning before exposing “any individual to a chemical known to the state to cause cancer” and that the authoritative body on which the listing is based “specifically and accurately identif[y] the chemical.” The proposal would list not a chemical, but rather the product of the mechanism of endogenous nitrosation that occurs only under certain circumstances. This is not a specific chemical, and the proposal does not satisfy the requirements of Proposition 65.
- The proposal inaccurately interprets the IARC report’s conclusions. Under the conclusions reached in the IARC report, “nitrite in combination with amines or amides” does not necessarily lead to an increased risk of cancer. The report’s “overall evaluation” states that “[i]ngested nitrate or nitrite under conditions that result in endogenous nitrosation is probably carcinogenic to humans.” The report’s findings therefore apply only “*under conditions that result in endogenous nitrosation.*” Endogenous nitrosation requires more than the mere presence of nitrite, amines, and amides. The proposal’s listing is therefore overly broad and inaccurate in light of the IARC report.
- Subsequent research has called into question the conclusions reached in the IARC report. A 2012 review article found that more recent epidemiological evidence shows no association between dietary nitrite and stomach cancer (the only organ for which IARC concluded nitrite increased the risk of cancer).<sup>1</sup> Epidemiological studies published since the IARC report have found no association between nitrite and stomach cancer. Based on this and other information, we believe IARC would now likely conclude that nitrite under conditions that result in endogenous nitrosation is not classifiable as to its carcinogenicity to humans.
- The National Toxicology Program (NTP), which is also an authoritative body for Proposition 65 determinations, studied potential cancer risk posed by nitrite with great rigor.<sup>2</sup> The NTP study reached only one adverse finding, noting “equivocal evidence” of increased cancer risk in the forestomach in female mice. Because humans do not have forestomachs, this organ is not an appropriate organ for assessing human health hazards. The NTP report therefore found no increased risk of cancer in humans. OEHHA should consider this authoritative body’s reports in reaching any listing determination.

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<sup>1</sup> Bryan, N., Alexander, D., Coughlin, J., Milkowski, A. and Boffetta, P. (2012a). Ingested nitrate and nitrite and stomach cancer risk: an updated review. *Food Chem Tox.* 50:3646-3665.

<sup>2</sup> National Toxicology Program. (2001). Toxicology and Carcinogenesis Studies of Sodium Nitrite (CAS NO. 7632–00-0) in F344/N Rats and B6C3F1 Mice (Drinking Water Studies), Natl. Toxicol. Program. Tech. Rep. Ser., No. 495, United States, pp. 7–273.

- Because nitrites, amines and amides are found widely in nature, the proposal could lead to wide over-labeling of products, diluting the value of cautionary labeling and confusing consumers.

## **Conclusion**

NCC appreciates the opportunity to comment on this proposal to add “nitrite in combination with amines or amides” to the list of chemicals known to the state of California to cause cancer under Proposition 65. We strongly believe that the IARC report, the NTP study, and subsequent studies do not support the conclusion that nitrite in combination with amines or amides has been identified as a specific chemical known to cause cancer. We therefore urge OEHHA not to finalize the proposed listing.

Thank you for your consideration. Please do not hesitate to contact me if I can provide additional information.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Ashley B. Peterson". The signature is written in a cursive, flowing style.

Ashley B. Peterson, Ph.D.  
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National Chicken Council