December 16, 2013

Ms. Cynthia Oshita
Office of Environmental Health Hazard Assessment
P.O. Box 4010, MS-19B
Sacramento, California 95812-4010

Re: NOIL - emissions from high-temperature unrefined rapeseed oil

Dear Ms. Oshita:

The Institute of Shortening and Edible Oils, Inc. (ISEO) welcomes the opportunity to comment on the Notice of Intent to List (NOIL) issued on November 15, 2013 by the Office of Environmental Health Hazard Assessment (OEHHA) with respect to emissions from high-temperature unrefined rapeseed oil.

ISEO is a trade association representing the refiners of edible fats and oils in the United States. Its members represent approximately 90-95% of the edible fats and oils produced domestically (28 billion pounds) that are used in baking and frying fats (shortening), cooking and salad oils, margarines, spreads, confections and toppings, and ingredients in a wide variety of foods.

The NOIL proposes to list emissions from high-temperature unrefined rapeseed oil as known to the State of California to cause cancer for purposes of Proposition 65 under the authoritative bodies listing mechanism. The proposed listing is based on a 2010 monograph (the Monograph) of the International Agency for Research on Cancer (IARC).

The NOIL properly limits the proposed listing as following:

Emissions created by frying foods in unrefined rapeseed oil heated past its boiling point.
(Note: Most commercially available rapeseed oil, commonly known as canola oil, is refined. This notice does not pertain to emissions from refined rapeseed/canola oil.)

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1 The NOIL is available at http://oehha.ca.gov/prop65/CRNR_notices/admin_listing/intent_to_list/noilABpkg48b.html.
ISEO encourages OEHHA to continue to differentiate clearly between refined and unrefined rapeseed oil; between unrefined rapeseed oil from other kinds of oils; and between high-temperature frying and other kinds of cooking.

The Monograph recognized that there was not enough human evidence to implicate high-temperature frying of any particular kind of oil. Animal studies, on the other hand, only implicated high-temperature frying of unrefined rapeseed oil. The Monograph concluded:

There is limited evidence in humans for the carcinogenicity of emissions from high temperature frying.

There is sufficient evidence in experimental animals for the carcinogenicity of emissions from high-temperature unrefined rapeseed oil.

The rationale for these findings explained (emphasis added):

The epidemiological data are not detailed enough to distinguish between different cooking oils and fats and experimental animal data were available for unrefined rapeseed oil only, although data are available that indicate a higher mutagenic potency for unsaturated fats.

Under the authoritative body listing mechanism, OEHHA can only list unrefined rapeseed oil and cannot list refined rapeseed oil. The interpretive Proposition 65 regulations clarify the scope of the authoritative body listing mechanism. In particular,

a chemical is known to the state to cause cancer or reproductive toxicity if the lead agency determines that an authoritative body has formally identified the chemical as causing cancer or reproductive toxicity, as specified in this section.

The regulations define what is meant by the term “as causing cancer”:

For purposes of this section, “as causing cancer” means that either of the following criteria has been satisfied:

(1) Sufficient evidence of carcinogenicity exists from studies in humans. For purposes of this paragraph, “sufficient evidence” means studies in humans indicate that there is a causal relationship between the chemical and cancer.

(2) Sufficient evidence of carcinogenicity exists from studies in experimental animals. For purposes of this paragraph, “sufficient evidence” means studies in experimental animals indicate that there is an increased incidence of malignant tumors or combined malignant and benign tumors in multiple species or strains, in multiple experiments (e.g., with different routes of administration or using different dose levels), or, to an

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unusual degree, in a single experiment with regard to high incidence, site or type of tumor, or age at onset.

The Monograph shows that condition (1) is not met, because there is not sufficient evidence in humans. There is sufficient evidence in animals, but only for high-temperature frying of unrefined rapeseed oil. Accordingly, the NOIL appropriately limits the scope of the proposed listing to high-temperature frying of unrefined rapeseed oil.

It is important to distinguish between refined oil and unrefined rapeseed oil. The process of refining generally is performed on vegetable oils to reduce the free fatty acid content and to remove other impurities such as phosphatides, proteinaceous, and mucilaginous substances.

In addition, it is also important to note that there are different sources of rapeseed oil with substantial compositional differences. It is unclear which variety of rapeseed was used as the source oil examined in the studies reviewed in the IARC monograph. There are substantial differences between the low erucic acid rapeseed (LEAR) variety that is common to North America and high erucic acid rapeseed (HEAR) varieties found in other regions of the world. The oil refined for edible applications in the U.S. comes entirely from the LEAR variety more commonly known as “canola.”

The U.S. Department of Agriculture (USDA) defines “canola” in part as “seeds from the genus Brassica from which the oil shall contain less than 2 percent erucic acid in its fatty acid profile.” Similarly, FDA defines “low erucic acid rapeseed oil, also known as canola oil,” as having “an erucic acid content of no more than 2 percent of the component fatty acids.” FDA has noted that “high erucic acid rapeseed oil was never used as an edible oil in the United States.”

USDA has explained the history and use of canola oil as follows:

Initially, consumer demand for rapeseed oil was negligible because it naturally contains high amounts of erucic acid. Erucic acid was enough of a concern that in 1956, the U.S. Food and Drug Administration (FDA) banned rapeseed oil for human consumption …

By the early 1970s, plant breeders developed low-erucic acid rapeseed (LEAR) varieties that also had low glucosinolate content. In 1978, the Western Canadian Oilseed Crushers Association registered these varieties with the name “canola” …

Because of the higher palatability of LEAR varieties, FDA granted the oil produced from LEAR varieties Generally Recognized as Safe (GRAS) status on January 1, 1985. With its low level of saturated fat, LEAR oil appealed to health-conscious consumers, and production increased steadily …

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5 7 C.F.R. § 810.301.
6 21 C.F.R. § 184.1555(c).
Canola oil is the third largest source of vegetable oil in the world after soybean oil and palm oil, and use is continuing to grow. In the United States, canola oil is used in frying and baking applications, and is an ingredient in salad dressings, margarine, and a variety of other products. Canola oil appeals to health-conscious consumers because it has a low percentage of saturated fat and is free of artificial trans-fats. High-oleic canola varieties have been developed recently that are used in commercial high-temperature frying applications to replace partially hydrogenated oils.\(^8\)

OEHHA added an important note to the proposed listing for emissions from unrefined rapeseed oil:

(Note: Most commercially available rapeseed oil, commonly known as canola oil, is refined. This notice does not pertain to emissions from refined rapeseed/canola oil.)

In light of the many differences between refined and unrefined rapeseed oil, substantial compositional differences between canola (LEAR) and other rapeseed and the general absence of unrefined rapeseed oil from cooking in the U.S., OEHHA should certainly include in the final listing a note similar to that which appears in the proposed listing.

Respectfully submitted,

Robert L. Collette
President

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