Hexane extraction in soyfood processing

The selection of hexane as the solvent of choice for extraction of oils, other nonpolar constituents of plant foods, or removal of undesirable constituents from plant foods is one of the most common practices in the food industry. The solvent extraction process generally involves solubilization and partitioning in hexane, separation of the extract, and solvent volatilization and removal to recover the extracted constituents. Hexane extraction of oilseeds was introduced in the 1930s and there is no evidence to substantiate any risk or danger to consumer health when foods containing trace residual concentrations of hexane are ingested. Hexane extraction of oil from soybeans is established as a safe and efficient process. No evidence exists to associate health risks or dangers from eating soyfoods exposed to hexane extraction processes.

Vegetable Oil Processing. Processing of soybeans traditionally consists of five unit operations: 1) oilseed harvesting, elevator handling, and storage; 2) preparation (flaking) of soybeans for solvent extraction; 3) solvent extraction, oil/solvent separation and volatilization of solvent; 4) volatilization of residual solvent from flakes; and 5) oil refining. The extraction process separates the oil from the flakes by “washing” with hexane in a countercurrent extractor. Volatile hexane is removed from the separated oil and flakes by increasing the temperature through direct or indirect contact with steam. Residual hexane is very susceptible to volatilization during heating of the oil or flakes under high vacuums and temperatures in selected processes designed to produce soyfoods or soy ingredients for human consumption with negligible hexane residual.

Commercial Hexane Extraction Solvent. An extraction solvent is defined as an organic solvent selected to extract constituents or components of raw materials, efficiently removed after separation, yet may result in the presence of unavoidable residues or reactants in the extract or raw material. The selection of an extraction solvent under conditions of Good Manufacturing Practices will result in the removal of all but negligible solvent residues from the food or food ingredient. Under selected extraction and processing conditions, the presence of residues or reactants in the final food or food ingredient is unintentional and technically unavoidable. 

n-Hexane has chemical properties that provide ideal functionality as a solvent for extraction of vegetable oils. n-Hexane is a compound of specific molecular structure chosen for use as a pure (0.5 to 5.0% hexane isomers and other impurities) solvent or reagent in laboratory research settings. Commercial hexane selected as a solvent for extraction of soyfoods refers to a broad range of volatile compounds that consists of hexane isomers including n-hexane, related six carbon compounds, and possibly small quantities of volatile five carbon and seven carbon hydrocarbons. Concentrations of n-hexane in commercial hexane may range from 20 to 80% with allowable concentrations less than 0.4% of pentane and heptane isomers, acetone, methyl ethyl ketone, dichloromethane, or trichloroethylene. n-Hexane and the other compounds in commercial hexane are highly volatile, with volatilization temperatures ranging from 49.7 to
80.7°C (116 to 178°F), providing for adequate volatilization and removal of the solvents from soyfoods.

*n*-Hexane residual concentrations of 19.1 to 95.3 mg/L in extra virgin olive oil, 0.9 mg/kg in peanut oil, and 1.5 mg/kg in sunflower oil are reported. Based on concentrations of residual *n*-hexane typically observed in refined vegetable oils of 0.8 mg/kg, the greatest daily intake of *n*-hexane from foods is estimated at 1.45 mg/kg-bw per day for the 6 to 8 year old age group. This estimate indicates that the contribution of *n*-hexane from food sources in the worst case is 1.95% of the estimated total daily intake from inhalation and other environmental exposure. The contribution from food sources is considered an overestimate because of the assumption that an *n*-hexane residual concentration of 0.8 mg/kg occurred in the oil component of all foods containing vegetable oils as an ingredient. However, processed foods that contain vegetable oil are in many instances exposed to processing temperatures that exceed the volatilization temperatures of *n*-hexane (68.7°C) or the other compounds identified as commercial hexane. It is therefore expected that *n*-hexane residues in the oil component of processed foods will be further reduced during processing or preparation.

**Hexane, Health Risk and the Environment.** *n*-Hexane is not acutely toxic to mammalian species. Exposure of consumers to *n*-hexane is less than the concentration at which critical health risks are likely. Inhalation of ambient and indoor air was declared the major route of human exposure to hexane in Canada. Since gasoline contains hexane, exposure to hexane in the air from volatilized gasoline and automobile exhaust at service stations may be the most common source. Exposure from other sources such as drinking water, food and soil did not contribute significantly to total exposure. Examination of hexane as an ecological hazard “concluded that hexane is not entering the environment in a quantity or concentration or under conditions that have or may have an immediate or long-term harmful effect on the environment or its biological diversity, or that constitute or may constitute a danger to the environment on which life depends.” *n*-Hexane does not have the potential to bioconcentrate nor biomagnify in the environment. *n*-Hexane is unlikely to cause ecological harm in Canada.

**Conclusions.** The critical health effects from exposure to *n*-hexane will result from exposures to large concentrations over long periods of time. Determinations of *n*-hexane in both indoor and ambient air, the source of long term exposures, were not at concentrations that pose a risk to human health. Further, **assessment concludes that exposure to the broad range of identified uses of *n*-hexane in foods, drinking water, soil, skin moisturizers, or health care products in the screening assessment, will not pose a risk to human health as they are intermittent.** Given the extensive range of existing uses, and the large volumes of *n*-hexane currently in commerce, it is considered unlikely that any new use could significantly change the existing exposure profile.
Acceptable specified hexane residues in selected foods

1) 10 mg/kg in food containing defatted protein products and defatted flours\(^1\);
2) 30 mg/kg in defatted soya products as sold to the final consumer\(^1\);
3) 25 mg/kg in spice oleoresins\(^2\);
4) 2.2% by weight in hops extract\(^2\), provided that hops extract is added to the wort before or during cooking in the manufacture of beer;


### Composition of Commercial Hexanes.

<table>
<thead>
<tr>
<th>Compound</th>
<th>Volatilization Temperature (°C)</th>
</tr>
</thead>
<tbody>
<tr>
<td>(n)-hexane</td>
<td>68.7</td>
</tr>
<tr>
<td>2,2-dimethyl butane</td>
<td>49.7</td>
</tr>
<tr>
<td>2,3-dimethyl butane</td>
<td>58.0</td>
</tr>
<tr>
<td>2-methyl pentane (isohexane)</td>
<td>60.3</td>
</tr>
<tr>
<td>3-methyl pentane</td>
<td>63.3</td>
</tr>
<tr>
<td>methylcyclopentane</td>
<td>71.8</td>
</tr>
<tr>
<td>cyclohexane</td>
<td>80.7</td>
</tr>
</tbody>
</table>

permissible at less than 0.4% concentration

pentane                     36.1
dichloromethane             40.0
acetone                     56.2
methyl ethyl ketone         79.6
trichloroethylene           87.0
heptane                     98.4