National Office
2717 Wentz Ave.
Saskatoon, Sask.
S7K 4B6
Tel (306) 652-9465
Fax (306) 664-6226
E-Mail: nfu@nfu.ca

national farmers union
In Union Is Strength

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Health Canada
Bureau of Chemical Safety
Food Directorate
Health Products and Food Branch
251 Sir Frederick Banting Driveway
Tunney's Pasture, PL: 2203B
Ottawa, Ontario K1A 0K9

Bcs-bipc@hc-sc.gc.ca

Comments by the National Farmers Union
Regarding: Health Canada's Proposal to Amend the Food and Drug Regulations to Permit the Use of a Second Source (Aspergillus niger ASP72) of the Enzyme Asparaginase in Certain Food Products – December 2009.

The National Farmers Union (NFU) welcomes the opportunity to comment on the proposal by Health Canada to amend the Food and Drug Regulations. Specifically, Health Canada seeks to permit the use of Asparaginase in the manufacture of certain wheat dough-based food products such as bread, crackers and cookies; and also cut potato products including French fries, sliced potato products and fabricated potato chips.

The NFU strongly opposes the proposal, and urges Health Canada to:

1. Extend the public consultation period beyond the February 21, 2010 cut-off date.
2. Expand the public consultation process beyond the internet-only vehicle to also include public meetings, advertisements in widely-distributed print and electronic media, and to allow telephone responses from the public.
3. Refrain from any approval of Asparaginase as a food additive.
4. Initiate independent, third-party testing by Health Canada scientists to determine the long-term health effects of Asparaginase as a food additive.

The stated purpose of amending the existing regulations to allow the injection of Asparaginase in food manufacture is to reduce the levels of asparagines in food, and thereby reduce the risk of formation of acrylamide. As the Health Canada document notes: "Acrylamide is formed as a reaction product between asparagines and reducing sugars, when certain foods are baked or fried at temperatures exceeding 120°C. Both asparagines and reducing sugars are commonly found in many raw food materials." The

Health Canada document also goes on to state that "dietary exposure to acrylamide has been identified as of potential concern" by the FAO/WHO Expert Committee on Food Additives.

Asparaginase is an enzyme that hydrolises an amino acid, asparagine, to aspartic acid by hydrolyzing the amide in free asparagines. Asparagine is a precursor of acrylamide. The injection of Asparaginase into the foodstuff prior to heating is claimed to lower the formation of acrylamide, according to Novozymes, the Denmark-based biotechnology company which manufactures "Acrylaway", one type of genetically-modified Asparaginase enzyme which is sold commercially to food manufacturers. The "Acrylaway" enzyme is obtained from a genetically-modified strain known as "*Aspergillus niger*".[1]

Aspergillus niger is also the source for another commercially-available form of Asparaginase, known by its trade name "PreventASe," This drug is manufactured by DSM Food Specialties of the Netherlands. In 2007, DSM Food Specialties signed an intellectual property rights agreement with Frito-Lay and Procter and Gamble to apply Asparaginase in food products in order to reduce acrylamide levels.[2]

The approval of genetically-modified Asparaginase as a food additive in the manufacture of processed foods represents a substantial profit centre for corporations that control the intellectual property rights on these products. It is, therefore, not surprising that these companies, and the trade associations which represent them, have put significant pressure to bear on regulatory agencies in many countries to approve the drug as a food additive.

However, there are many legitimate concerns that must be addressed before Health Canada is allowed to approve Asparaginase as a food additive.

1. Asparaginase is **not** a benign or harmless substance. Asparaginase is a protein and an enzyme which catalyzes, or facilitates, chemical reactions in a cell. Proteins are made up of amino acids. Asparagine is one of those amino acids. Aspartic acid is another. Asparaginase changes asparagine to aspartic acid, thereby substantially altering the functioning of cells. The order of all the amino acids, of which there are many, is very important to the functionality of an enzyme.[3] Asparaginase is an anti-cancer chemotherapy drug that is marketed under the trade name of Elspar

[1] "Acrylaway – a natural solution to a natural problem", http://www.novozymes.com
[2] "DSM agrees on asparaginase application rights with Frito-Lay and Procter and Gamble, August 30, 2007, http://www.dsm.com/en_US/html/dfs/news_items/30082007_preventase.htm
[3] http://www.pfeist.net/ALL/asparaginase.html "Asparaginase does not occur naturally in humans, but it is found in bacteria, plants, and many animals, including guinea pigs. Asparaginase for chemotherapy is usually isolated from cultures of E. Coli bacteria…Asparaginase was "discovered" about 35 years ago. They found that guinea pig serum suppressed the growth of lymphosarcomas in mice; asparaginase was later shown to be the active factor. It's not like the scientists knew that tumor cells have a low level of asparagines synthetase and designed the asparaginase treatment, rather, they found the treatment and worked backwards to find out why it worked…Many of the side effects of asparaginase are due to the fact that it is a protein. Its most important side effect is the possible occurrence of a severe (and occasionally fatal) allergic reaction…"

and manufactured by the pharmaceutical giant, Merck and Co. The drug is used to treat leukemia and works by starving tumor cells of needed nutrients and slowing tumor cell growth. According to information provided by the manufacturer, "this drug may have toxic properties and must be handled and administered with care…Allergic reactions to Asparaginase are frequent and may occur during the primary course of therapy…Anaphylaxis and death have occurred even in a hospital setting with experienced observers."[4]

2. Asparaginase is known to aggravate existing medical conditions, including kidney disease, liver disease, heart disease, diabetes, gout, infections, kidney stones and congestive heart failure. It can cause severe pancreatitis with bleeding. It may be linked to birth defects in pregnant women, and may interact negatively with certain foods or over-the-counter medicines.[5]
3. Common side effects of Asparaginase include joint pain, skin rashes, stomach pain with vomiting or nausea, headaches, breathing problems, loss of bladder control, muscle spasms, extreme thirst, unusual bruising and bleeding. Less common side effects are chills, fever, lower leg pain or paralysis of arms and legs.[6]

Clearly, Asparaginase is a drug which is intended for a specific purpose – namely to combat leukemia and other lymphatic cancers. The risks associated with this drug are many, and potentially very serious. The use of this drug, however, is justified when weighed against the far more serious effects of cancer. In this case, the treatment – administered under highly-controlled conditions - is preferable to the disease.

However, in the case of acrylamide formation caused by the heating of food through frying or baking, a far different equation emerges. Is the threat posed by acrylamide in food worth the risk of widespread application of Asparaginase? The evidence strongly suggests that the approval of Asparaginase as a food additive to combat acrylamide is not justified.

The initial confirmation of acrylamide as a "naturally-occurring" byproduct of the cooking process was made by Swedish researchers in 2002. The researchers found trace levels of the compound in some baked and fried foods. However, it is assumed the presence of acrylamide in foods is not new, and has been present for thousands of years, since people have been cooking food for uncounted generations.

The actual levels of acrylamide that have been documented in food are extremely low. In 2005, the California Office of Environmental Health Hazard Assessment (OEHHA) measured acrylamide levels in a wide array of common processed and unprocessed foods. The findings ranged from less than 5 parts per billion – which was "non-detectable". The OEHHA was obliged, under California law, to label potential carcinogenic substances on food. The OEHHA proposed to "remove the Proposition 65 warning requirement for most breads and cereals" because "a warning is not required when exposure to a listed

[4] http://www.merck.com/product/usa/pi_circulars/e/elspar/elspar_pi.pdf
[5] http://www.cancer.org/docroot/CDG/content/CDG_asparaginase.asp
[6] http://www.ehow.com/about_5345081_asparaginase-side-effects.html

substance is so low that it poses no significant health risk." The OEHHA suggested raising the maximum limits on acrylamide found in bread and cereals to a level that would effectively eliminate the requirement to post warning labels on such foods. The OEHHA justified the move by stating that "sound considerations of public health support encouraging, rather than discouraging, increased consumption of high-fiber foods, including breads and cereals…Increased intake of dietary fiber is associated with decreased risk for stroke and heart attack, decreased blood cholesterol levels, improved control of blood sugar levels in diabetics, and reduced risk of colorectal cancer. OEHHA believes that it is sound public health policy for warnings to reflect a careful balancing of the health risks and benefits of particular foods."[7]

In 2005, the California OEHHA proposed several options regarding the posting of warning labels for food items in which acrylamide was detected. In 2006, in response to lobbying by the food industry, the state ruled that food manufacturers were not required to place acrylamide warning labels on certain products.[8] In late 2009, a scientific study funded by the Grocery Manufacturers Association in the US determined that "tolerable intakes of acrylamide should be set at 2.6 micrograms per kilogram of body weight to avoid the risk of cancer. This would be equivalent to 182 micrograms for a 70 kg human as a tolerable daily intake (TDI) for carcinogenic levels. The TDI for neurotoxicity was found to be higher, at 40 micrograms per kg per day, or 2,800 micrograms per day for a 70 kilogram human."[9]

Health Canada concluded that studies done in 2007 and 2008 revealed "an association between dietary acrylamide intake and endometrial and ovarian cancers, but it is not conclusive of a cause-effect relationship." While there appeared to be a link with those two types of cancer, there did not appear to be any link between dietary acrylamide and breast cancer.[10] Health Canada estimates the average exposure of adults to acrylamide in food is between 0.3 and 0.4 micrograms per kilogram of body weight per day. A microgram is one-millionth of a gram. For young children 6-11 years of age, the average exposure is roughly twice the adult exposure. This is largely due to the fact that children consume more food than adults on a per-body weight basis. These estimates of Canadian exposure to acrylamide are consistent with exposures that have been calculated in other countries. For example, the average daily intake of acrylamide in Sweden has been estimated to be 0.5 micrograms per kilogram of body weight per day.[11] The Food and

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[7] Acrylamide and Proposition 65, Questions and Answers, Office of Environmental Health Hazard Assessment, May 2005, http://www..oehha.org/Prop65/acrylamideqa.html

[8] "California withdraws proposed acrylamide warning rules" by Lorraine Heller, April 3, 2006. http://www.foodnavigator-usa.com/Legislation/California-withdraws-proposed-acrylamide-warning-rules

[9] "Scientists determine safe acrylamide levels" by Stephen Daniells, December 8, 2009, citing "Estimation of Safe Dietary Intake Levels of Acrylamide for Humans" by R.G. Tardiff et al, in Food and Chemical Toxicology journal, http://www.foodnavigator.com/Science-Nutrition/Scientists-determine-safe-acrylamide-levels

[10] Health Canada, Acrylamide, "What is Health Canada Doing to Protect Canadians?" http://www.hc-sc.gc.ca/fn-an/securit/chem-chim/food-aliment/acrylamide/index-eng.php

[11] Health Canada, ibid.

Drug Administration in the United States estimates the average intake of acrylamide in the US to be about 0.4 micrograms per kilogram of body weight per day.[12]

There are many ongoing studies around the world focusing on determining links between dietary acrylamide and various cancers. Several of these studies are due in the very near future. For example, the US National Toxicology Program will release data from its systematic animal study on the health effects of acrylamide. This study is part of the FDA's Action Plan for Acrylamide in Food, which was initiated in March 2004. Health Canada itself is expected to update its Risk Assessment of Dietary Acrylamide to include recent monitoring data on dietary acrylamide among Canadians and more details on which foods contribute to dietary acrylamide exposure. And the Joint FAO-WHO Expert Committee on Food Additives (JEFCA) is slated to update its previous risk assessment of dietary acrylamide, to take into consideration the hundreds of studies that have advanced understanding of acrylamide in the past five years.[13] It would be inappropriate for Health Canada to approve Asparaginase before the results of these studies are released.

The ongoing studies illustrate that there is, at the present time, inconclusive evidence that dietary acrylamide at the low levels so far detected, contribute significantly to certain types of cancers.

There is no such uncertainty, however, regarding the toxicity of the synthetic acrylamide used in industrial processes. The California OEHHA added acrylamide to its list of suspected carcinogens in 1990. At that time, the primary concern was with the synthetic chemical's potential health effects on workers who handle the chemical." The OEHHA noted that "Acrylamide is widely used in grouts and cements, pulp and paper production, ore processing, permanent-press fabrics, and dye manufacture. It is also used to produce polyacrylamide, which is used in water and wastewater treatment, soil conditioning and oil drilling. Acrylamide is present in tobacco smoke."

Acrylamide is also a building block for the polymer, polyacrylamide. Polyacrylamide is a well-known additive to commercial herbicide mixtures (35% to 30% solutions) to reduce spray drift and to act as a surfactant.[14] Polyacrylamide is known to interact with glyphosate, a widely-used herbicide. The most popular glyphosate herbicide is Roundup, manufactured by Monsanto. Experiments have shown that heat and light contribute to the release of acrylamide from polyacrylamide. Glyphosate was found to influence the solubility of polyacrylamide.

It is possible that acrylamide is being released from polyacrylamide in the environment, and that a major source of that polyacrylamide is glyphosate herbicide formulations. Cooking vegetables that had been exposed to the glyphosate herbicide used with herbicide-tolerant crops, or used during soil preparation for normal crops, would result in

[12] "Scientists determine safe acrylamide levels", http://www.foodnavigator.com/Science-Nutrition/Scientists-determine-safe-acrylamide-levels
[13] "CDC Releases Acrylamide Exposure Study, December 2, 2009, http://www.acrylamidefacts.org
[14] "Is Monsanto Poisoning Consumers with Pesticide Residues?" by Prof. Joe Cummins, August 2002, Organic Consumers Association, http://www.organicconsumers.org/monsanto/Acrylamide.cfm

the release of more acrylamide. The relationship between acrylamide, polyacrylamide, and glyphosate herbicides has not been adequately studied, and research needs to be done in this area to determine whether a causal link exists.

Clearly, the presence of acrylamide in food that appears "naturally" as a result of exposure to heat in excess of 120 degrees Celsius, is disturbing. However, a realistic assessment of this source of acrylamide reveals that the actual risk to consumers is likely very low. Consequently, there is very little evidence to suggest any need for Asparaginase as a food additive that would be widely used by industry. The risks from Asparaginase could well outweigh the risks from so-called "naturally-occurring" acrylamide.

The pressure to approve Asparaginase as a food additive appears to be coming from the biotechnology companies, namely DSM and Novozymes, that stand to benefit from the widespread commercial application of their genetically-modified products. The discovery of "naturally-occurring" acrylamide is being used by these companies to opportunity to market their expensive, and highly-profitable, "solution". But this "solution" – with its dangerous toxic characteristics - may carry more risks than the problem it is supposedly intended to solve.

In addition, the origin of the "naturally-occurring" acylamide that appears during the cooking process for foods needs to be further studied. The possibility of a link between the release of acrylamide and the widespread application of polyacrylamide mixed with glyphosates in the environment must be taken into account.

The potential for creating increased risk to consumers through the approval of genetically-modified Asparaginase as a food additive is serious. Health Canada, therefore, should refrain from any such approval until it can be proven that Asparaginase is absolutely safe for such a use.

The National Farmers Union adopted a comprehensive policy on genetically-modified food at its national convention in November, 2000. Three important elements of that policy deal specifically with "health effects" and can be summarized as follows:

1. "The Precautionary Principle must be the basis for assessing the human health effects of GM food. Where human health and safety are concerned, mere "risk assessment" is not acceptable."
2. "Independent scientists at publicly-funded and operated labs under the jurisdiction of the Federal Minister of Health must conduct exhaustive long-term human health testing on GM foods. The assumption that GM foods are "substantially equivalent" to their non-GM analogs is unproven."
3. Food – genetically-modified and non-modified alike – must be adequately tested, regulated, and inspected. These critical tasks must be performed by a sufficient number of adequately-funded, independent, publicly-paid inspectors."

The Health Canada proposal falls short on all counts.

As noted earlier, the NFU calls on Health Canada to refrain from granting approval to these genetically-modified strains of Asparaginase.

There is insufficient evidence at this time that this drug is safe for widespread application in manufactured foodstuffs. The Precautionary Principle stipulates that approval for any drug or food additive should only be given after the safety of that drug or food additive is proven. The onus of proof should not fall on the public to prove that the drug or food additive being considered is dangerous or harmful. All too often, experience has shown that drugs approved for market release are later recalled after the true health effects begin to show up in the public over a period of months or even years. Given the wide-ranging application of this food additive, tracing the negative effects back to the source may well prove difficult, if not impossible.

Finally, any genetically-modified enzyme that is added to foods which are manufactured in Canada could have severe negative consequences in markets, both domestic and abroad, that are sensitive to GM technology.

All of which is respectfully submitted
By the
National Farmers Union