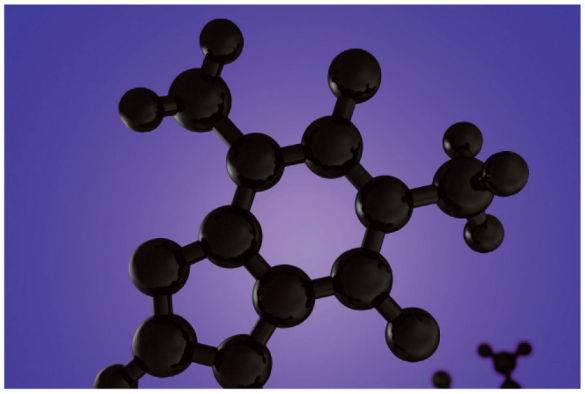
Canadian Food Inspection Agency
Agence canadienne d'inspection des aliments

Food Safety Action Plan

REPORT

2010-2011 Targeted Surveys

Chemistry



Propylene Oxide in Foods

TS-CHEM-10/11-19

Canada

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Executive Summary

The Food Safety Action Plan (FSAP) aims to modernize and enhance Canada's food safety system. As a part of the FSAP enhanced surveillance initiative, targeted surveys are used to test various foods for specific chemical and microbiological hazards.

The main objective of the propylene oxide (PPO) in selected foods targeted survey was to generate baseline surveillance data on the levels of PPO in non-starchy foods potentially treated with fumigant, specifically cocoa, nutmeats, dried herbs, dried fruit, and spices.

Propylene oxide is a highly volatile chemical which does not occur naturally in the environment. It is manufactured for use as a fumigant for food and for industrial applications[1]. PPO has been used as an insecticide and antimicrobial fumigant in dried fruits, nuts, and spices in the Unites States for over fifty years. While it is not registered for use as a fumigant/pesticide in Canada, Canadians may be exposed to this chemical via consumption of imported finished foods and food ingredients[2].

Although the primary route of human exposure to propylene oxide is by inhalation, foods treated with PPO may contain residues of this fumigant unless adequate ventilation/aeration of the treated commodity is provided[3]. According to the toxicological studies submitted to Health Canada's Pest Management Regulatory Agency (PMRA), evidence of the potential for propylene oxide to cause cancer in animals was identified after lifetime exposure. As such, a cancer risk assessment was conducted, which demonstrated that consumption of PPO-treated food commodities originating from the US will not pose a human health concern to any segment of the Canadian population, including infants, children and seniors.

Although not approved for domestic use, PMRA, under the authority of the *Pest Control Products Act* in 2009, established a maximum residue limit (MRL) of 300 parts per million (ppm) for PPO in almonds to permit the import and sale of almonds that may contain this residue. PMRA is currently in the process of establishing new MRLs for PPO in/on the entire tree nut crop group and herbs and spices crop group. These values are expected to be consistent with established residue tolerance levels in the U.S. for nutmeats, cocoa, dried fruits, and dried herbs/spices[4]. Other PPO-treated food products imported into Canada are currently subject to the General Maximum Residue Limit (GMRL) of 0.1 ppm under Division 15 (B.15.002(1)) of Health Canada's *Food and Drug Regulations.*

One hundred samples of dried spices and herbs, dried fruit products, cocoa powder, and nuts (of both domestic and imported origin) were analyzed for PPO in 2009-2010. Additionally, nine hundred and sixty-four samples of dried spices and herbs, dried fruit products, cocoa and chocolate products/powders, and nuts (of both domestic and imported origin) were analyzed for PPO in 2010-2011. Propylene oxide was not detected in any sample tested. The overall compliance with the MRL for almonds or the GMRL (as applicable) was 100%.

1 Introduction

1.1 Food Safety Action Plan

In 2007, the Canadian Government launched a five-year initiative in response to a growing number of product recalls and concerns about food safety. This initiative, called the Food and Consumer Safety Action Plan (FCSAP), aims to modernize and strengthen the food safety regulatory system. The FCSAP initiative unites multiple partners in ensuring safe food for Canadians.

The CFIA's Food Safety Action Plan (FSAP) is one element of the Government's broader FSCAP initiative. The goal of FSAP is to identify risks in the food supply, limit the possibility that these risks occur, improve import and domestic food controls, and identify food importers and manufacturers. FSAP also looks to verify that the food industry is actively applying preventive measures and that there is a rapid response when/if these measures fail.

Within FSAP, there are twelve main areas of activity, one of which is risk mapping and baseline surveillance. The main objective of this area is to better identify, assess, and prioritize potential food safety hazards through risk mapping, information gathering, and testing foods from the Canadian marketplace. Targeted surveys are one tool used to test for the presence and level of a particular hazard in specific foods. Targeted surveys are largely directed towards the 70% of domestic and imported foods that are regulated solely under the *Food and Drugs Act and Regulations,* and the *Consumer Packaging and Labelling Act* and *Regulations*, and are generally referred to as non-federally registered commodities.

1.2 Targeted Surveys

Targeted surveys are pilot surveys used to gather information regarding the potential occurrence of chemical residues in defined commodities. The surveys are designed to answer specific questions; therefore, unlike monitoring activities, testing of a particular chemical hazard is targeted to commodity types and/or geographical areas.

Due to the vast number of chemical hazards and food commodity combinations, it is not possible, nor should it be necessary, to use targeted surveys to identify and quantify all chemical hazards in foods. To identify food-hazard combinations of greatest potential health risk, the CFIA uses a combination of scientific literature, media reports, and/or a risk-based model developed by the Food Safety Science Committee (FSSC), a group of federal, provincial and territorial subject matter experts in the area of food safety.

The *Canadian Environmental Protection Act, 1999* (CEPA 1999) (Canada 1999) requires the Minister of the Environment and the Minister of Health (the Ministers) to categorize substances on the *Domestic Substances List* (DSL). Further to this activity, the Act requires the Ministers to conduct screening assessments of substances that meet the

categorization criteria to determine whether they meet the criteria of section 64 of the Act and are considered to be harmful to human health and/or the environment. The final screening assessment for propylene oxide concluded that PPO is a substance that may be entering the environment in a quantity or concentration or under conditions that constitute or may constitute a danger in Canada and therefore meets the criteria in paragraph 64c of CEPA 1999[5]. In that assessment, the maximum residue limit of 0.1 ppm PPO in imported fumigated nutmeat was used to calculate the intake estimate from the nuts and seeds category, as no other quantitative data for PPO in other foods were identified. Since the publication of that report, PMRA received an application to establish an MRL of 300 ppm to allow for the importation of PPO-treated almonds from the US. While the toxicological studies (submitted as part of this application) included evidence of the potential for propylene oxide to cause cancer in animals after lifetime exposure, the cancer dietary risk assessment demonstrated that consumption of PPO-treated food commodities originating from the US will not pose a human health concern to any segment of the Canadian population.

The purpose of the PPO targeted survey was to generate data on the levels of PPO in non-starchy foods potentially treated with fumigant.

1.3 Acts and Regulations

The *Canadian Food Inspection Agency Act* stipulates that the CFIA is responsible for enforcing restrictions on the production, sale, composition, and content of foods and food products as outlined in the *Food and Drugs Act & Regulations* (FDAR).

The FDAR allows the use of PPO as a food additive in starch up to a maximum level of 25%[6], however, the commodities targeted in this survey are considered non-starchy foods. Propylene oxide is also subject to the *Pest Control Products Act.* Although PPO is not registered for use as a pesticide/fumigant in Canada, it is approved for use on specific commodities in the United States. A 300 ppm maximum residue limit (MRL) for propylene oxide in almonds was established by Health Canada's Pest Management Regulatory Agency (PMRA) in 2009[7]. The MRL was established to permit the import and sale of almonds that may contain PPO residues. This MRL is consistent with established residue tolerance levels in the U.S. for nutmeats, cocoa, dried fruits, and dried herbs/spices[4] (see Table 1 in the Appendix). To our knowledge, no PPO limits in foodstuffs are established in other countries. Other PPO-treated food products imported into Canada are currently subject to the General Maximum Residue Limit (GMRL) of 0.1 ppm under Division 15 (B.15.002(1)) of Health Canada's *Food and Drug Regulations.*

All results from this targeted survey were compared to the Canadian regulatory limits outlined above at the time of assessment. Levels at or below this limit are in compliance with Canadian regulations and do not require further action. Levels above the regulatory limit are identified as violations and may be assessed by Health Canada for potential health risk to consumers. Follow-up actions are initiated by CFIA in a manner which reflects the magnitude of the health risk. Actions may include notification of the producer or importer, follow-up inspections, additional directed sampling, and product recall.

2 Survey Details

2.1 Propylene Oxide in Foods

Propylene oxide is a highly volatile chemical which does not occur naturally in the environment. It is used as a fumigant and in industrial applications[1]. PPO has been used as a fumigant to control insects and microbes in dried fruits, nuts, and spices in the United States for over fifty years. While it is not registered as a fumigant in Canada, Canadians may be exposed to this chemical via consumption of imported foods. Foods treated with PPO may contain residues of this fumigant unless adequate ventilation/aeration of the treated commodity is provided. When PPO breaks down during the fumigation process, its by-products may react with naturally-occurring bromine and chlorine molecules present in some foods. Thus, use of PPO as a fumigant may result in formation of propylene chlorohydrin (PCH) and propylene bromohydrin (PBH). These breakdown products may be less of a concern for dietary exposure than PPO, but may be more prevalent[2].

According to the toxicological studies submitted to Health Canada's Pest Management Regulatory Agency (PMRA), evidence of the potential for propylene oxide to cause cancer in animals was identified after lifetime exposure. As such, a cancer risk assessment was conducted, which demonstrated that consumption of PPO-treated food commodities originating from the US will not pose a human health concern to any segment of the Canadian population, including infants, children and seniors. Although the primary route of human exposure to propylene oxide is by inhalation, foods treated with PPO may contain residues of this fumigant[2].

2.2 Rationale

The present survey was designed to gain insight into the residual presence of propylene oxide in non-starchy foods. Its specific aim was to generate baseline surveillance data on the levels of PPO in non-starchy foods potentially treated with fumigant (often imported foods). Propylene oxide use is becoming more common as a replacement fumigant for methyl bromide outside of Canada[8]. Fumigants are used as soil sterilants and for pest control, and dried fruits and nuts are regularly subject to fumigation (the fumigant penetrates these bulk, densely-packed materials and then diffuses rapidly).

Foods which may have been subject to fumigation, such as dried foods (nuts, dried fruits, coffee, spices), are consumed in substantial quantities by most age groups in Canada[9]. As there is very little data available on the presence and/or levels of PPO residues (and its halohydrins) in or on non-starchy foods[10], and given the toxicity of PPO, a more comprehensive evaluation of these residues was warranted.

2.3 Sample Distribution

In 2009-2010 (FSAP Fiscal Year 2), a total of 100 samples were collected at grocery stores in Dartmouth, Nova Scotia. The samples consisted of 2 cocoa powders, 29 dried fruit products, 68 dried herbs and spices, and 1 sample of hazelnuts.

In 2010-2011 (FSAP Fiscal Year 3), 964 samples were collected at grocery and specialty stores in 10 Canadian cities (Halifax, Saint John, Ottawa, Toronto, Montréal, Québec City, Calgary, Saskatoon, Vancouver, and Winnipeg). The samples included 98 cocoa and chocolate powders/products, 291 dried fruit products, 285 dried herbs and spices, and 290 nut products (including 180 almond samples).

2.4 Method Details

In 2009-2010, the CFIA laboratory used a headspace GC/MS method to develop and validate the analysis of propylene oxide (PPO) and propylene chlorohydrin (PCH) in specific matrices. Quantitation was based on the method of standard addition, with matrix matching. PPO and PCH (spike concentration range of 50-300 µg/g) were spiked into spice, cocoa and dried fruit matrices to generate calibration curves. The detection limits of the methods were 0.02 µg/g for PPO and 0.33 µg/g for PCH. Spiked positive controls were also analyzed.

Samples taken for the 2010-2011 targeted survey were analysed by a laboratory under contract with the Government of Canada. The method, entitled "Determination of Propylene Oxide in Dried Foods", is also a headspace GC/MS method. The PPO limit of detection is 30 ppm and the analytical range is 30 – 300 ppm. Only PPO is analyzed in this particular method.

2.5 Limitations

The propylene oxide targeted survey was designed to provide a snapshot of possible residues of PPO from its use as a fumigant in non-starchy foods available for sale in Canada. Considering the variety of food products for sale that could potentially have been fumigated with PPO, and the number of importing countries from which these products could originate, 1064 samples can be considered a relatively small sample size.

Care must be taken when interpreting results. The data cannot be considered representative of residual levels of propylene oxide in all foodstuffs from specific countries of origin. In addition, country of origin could not be verified for many of the products tested. The products tested were consistent with CFIA labelling guidelines (i.e. use of "Imported by", "Packaged by", or "Imported for", etc.)[11], but many did not contain additional label information specifying the true country of origin (production) of the foodstuff. As a result, no inferences or conclusions were made regarding the data with respect to country of origin. Regional differences, impact of product shelf-life or cost of the commodity on the open market (i.e. correlations between product price and presence/absence of fumigants) are not examined in this survey.

3 Results

This survey was carried out over two fiscal years. The first year (2009-2010) consisted of data collected in the development and validation phase of the survey. In that year, all analyses were conducted in-house, and both PPO and PCH were analyzed and reported. The second year (2010-2011) survey data was generated by a laboratory under contract with the Government of Canada. Due to the absence of PCH residues in the 2009-2010 survey year samples, the contracted laboratory did not analyze the samples for PCH. Only PPO residues were reported during this year**.**

3.1 2009-2010 Survey Results

A total of 100 samples were analyzed for PPO and PCH in 2009-2010. The samples consisted of cocoa powder, dried fruit products, dried herbs and spices, and hazelnuts. The samples were of both domestic and imported origin. None of the samples contained detectable levels of PPO or PCH. See Figure 1 below for distribution of sample types and the number of tests for propylene oxide.

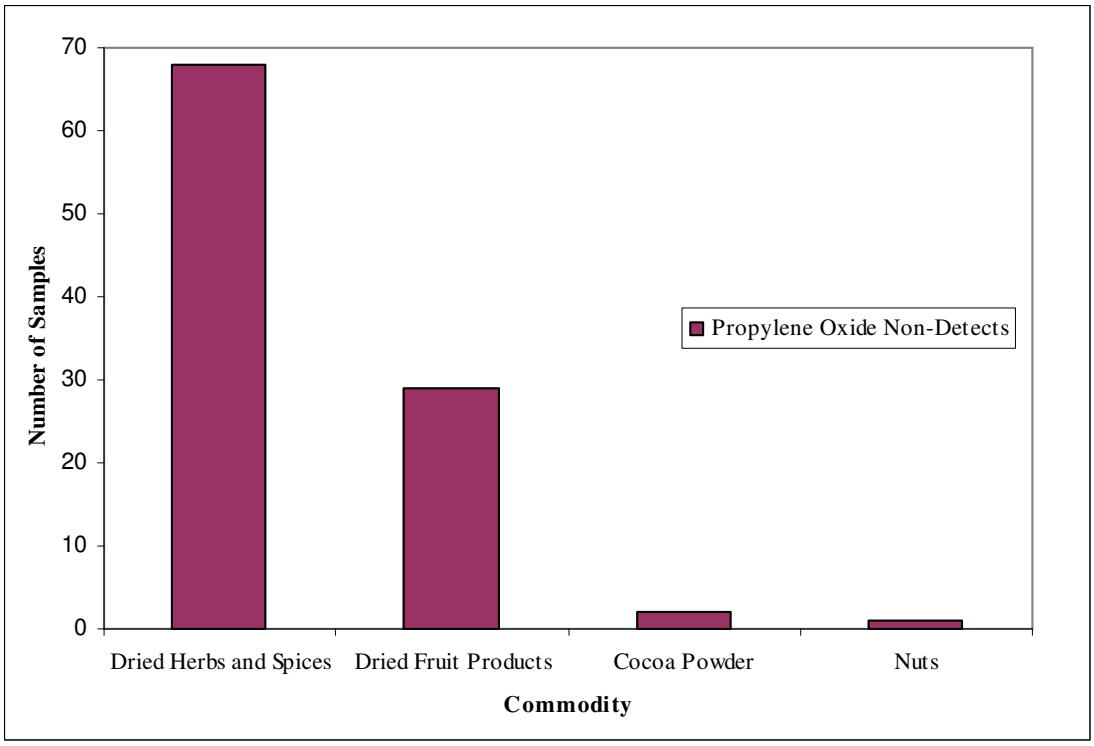

Figure 1. Distribution of Targeted Foodstuffs by Product Type and Number of Samples with PPO Residues (2009–2010)

The dried fruit products included apple, apricot, banana, cantaloupe, dates, goji berries, gooseberries, kiwi, mango, mulberries, peach, pear, pineapple, plum, prunes, raisins, strawberry, and mixed fruits/berries. The dried herbs and spices included allspice, anise,

basil, bergamot, caraway, cardamom, celery seed, chervil, chives, cinnamon, cloves, coriander, cumin, dill, garlic, ginger, lime leaves, lavender, marjoram, mint, mustard, nutmeg, oregano, paprika, pepper (various varieties), sage, savory, sumac, thyme, turmeric, vanilla, and assorted spice mixes.

3.2 2010-2011 Survey Results

The 2010-2011 propylene oxide targeted survey consisted of 964 samples analysed for PPO only. The samples included cocoa and chocolate powders/products, dried fruit products, dried herbs and spices, and nut products (including almond samples). The samples were of both domestic and imported origin. None of the samples contained detectable levels of PPO. See Figure 2 below for distribution of sample types and the number of tests for propylene oxide.

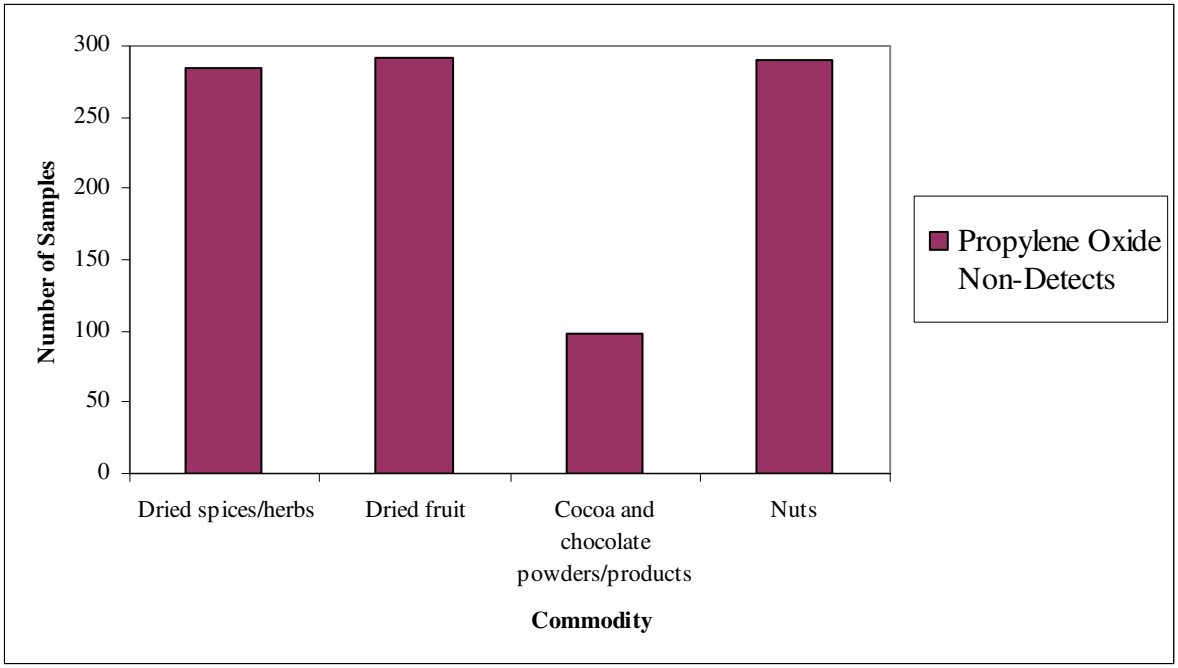

Figure 2. Distribution of Targeted Foodstuffs by Product Type and Number of Samples with PPO Residues (2010-2011)

The dried fruit products included currants, figs, grapes, plums, prunes, and raisins. The dried herbs and spices included allspice, basil, celery seed, cilantro, cinnamon, cumin, curry powder, dill, fennel, garlic, mustard, nutmeg, onion, oregano, paprika, parsley, pepper (various), rosemary, sage, tarragon, and thyme. The nut products included almonds, Brazil nuts, cashews, filberts/hazelnuts, macadamia nuts, peanuts, pecans, pistachios, and walnuts.

4 Discussion

Propylene oxide was not detected in any sample tested. The overall compliance with the MRL for almonds or the GMRL (as applicable) was 100%. This is not unexpected given the volatility of PPO, and the likelihood that the products tested were not hermetically sealed. It has been shown that PPO breaks down in the presence of water[10], which may also be a contributing factor to the lack of detectable residues in the products sampled. One hundred and eighty samples of almonds were analysed (including US almonds), and none were found to have detectable PPO residues. Other sample types tested that are frequently subject to fumigation (dried fruits, other nuts, etc.) also had no detectable PPO residues. The limited number of samples also analysed for propylene chlorohydrin in the 2009-2010 survey had no detectable PCH residues.

5 Conclusions

The 2009-2010 and 2010-2011 propylene oxide targeted surveys provided baseline surveillance data on the levels of PPO in non-starchy foods potentially treated with fumigant. A total of 1064 samples of commonly-treated foods (dried herbs, spices, and fruit, cocoa, and nut products) were purchased at retail. No detectable residues of propylene oxide were found in any sample tested, thus no sample result was in violation of Canadian regulations (i.e. the MRL for almonds or the GMRL). The overall compliance rate for this targeted survey was 100%. No detectable residues of propylene chlorohydrin were found in the limited sample set tested.

Appendix

Table 1: US tolerances established for residues of propylene oxide when used as a post-harvest fumigant (§ 180.491 (a) (1))

Commodity	Parts per million
Cacao bean, dried bean	200
Cacao bean, cocoa powder	200
Fig	3.0
Garlic, dried	300
Grape, raisin	1.0
Herbs and spices, group 19, dried	300
Nutmeat, processed, except peanuts	300
Onion, dried	300
Plum, prune, dried	2.0

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