Canadian Food Inspection Agency | Agence canadienne d'inspection des aliments

FOOD SAFETY ACTION PLAN

REPORT

2008-2009
TARGETED SURVEYS - CHEMISTRY
TS-CHEM-08/09-02

PATULIN IN APPLE JUICE PRODUCTS

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Special Surveys | Enquêtes spéciales
Chemical Evaluation | Évaluation chimique
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Executive Summary

Patulin is a toxic secondary metabolite produced by fungi from the *Penicillium*, *Aspergillus,* and *Paecilomyces* species. The main source of patulin in the human diet is apple juice. The 2008-2009 Patulin in Apple Juice Products study was undertaken in order to determine whether patulin concentrations in apple juice were being sufficiently monitored by the Canadian Food Inspection Agency's (CFIA's) regular programs. Specifically, the study was designed to:

- Assess compliance of apple juice manufacturers with international guidelines
- Provide patulin concentration data for risk assessment

The 104 samples of apple juice and apple juice concentrate (94 imported, 10 domestic) were collected from distributors and importers across Canada. These samples were analysed for patulin by a CFIA laboratory.

Overall, the results of this study indicate that 88.5% of the samples had patulin levels below the reporting limit of 10 parts per billion (ppb). Of the 44 apple juice samples collected, 37 samples (84%) had patulin concentrations below 10 ppb. Fifty five of the 60 samples (92%) of apple juice concentrates had patulin concentrations below 10 ppb. The highest measured level of patulin was 26.7 ppb in apple juice and 24.0 ppb in apple juice concentrates. All of the samples were below the Codex draft maximum level of 50 ppb for patulin.

There was no difference in compliance rate between imported and domestic products nor was there any relationship between country of origin and the measured patulin level. No difference in patulin concentration was observed between apple juice and apple juice concentrate.

The results of this study indicate that patulin levels in apple juice in Canada do not currently present a risk to the health of children or to the general population of Canada. Therefore, further targeted studies of patulin in apple juice products will not likely be undertaken unless additional information becomes available pointing to a need for a targeted survey. However, as the protection of the health of Canadian children is a priority for the CFIA, the CFIA will continue to monitor patulin levels in apple juice products through its regular monitoring activities.

1 Introduction

1.1 Food Safety Action Plan

The Food Safety Action Plan (FSAP) aims to modernize and enhance Canada's food safety system. The FSAP includes multiple partners and processes that work collectively towards providing safe foods for Canadians.

The Canadian Food Inspection Agency (CFIA) has been given the lead in the area of enhanced surveillance, an important initiative of the FSAP. The CFIA works on this initiative with input from 1) Federal partners, including Agriculture and Agri-Food Canada and Health Canada, 2) Provincial and Territorial (P/T) representatives and 3) industry and other non-government organizations (NGOs).

As part of the FSAP enhanced surveillance initiative, targeted surveys are used to test various foods for specific hazards. Targeted surveys are a complementary approach to the CFIA's regular monitoring activities and will allow the CFIA to ask specific questions regarding the level and presence of various chemical and microbiological hazards in targeted foods.

1.2 Targeted Surveys

Targeted surveys can be considered special or pilot surveys that are used to gather preliminary information about the occurrence of chemical hazards in food. They are designed to answer a specific question. Therefore the testing activity is targeted to a sample population (such as commodity types and/or geographical areas). Due to the large number of chemicals and food types that exist in the world today, it is not possible to use targeted surveys to identify and quantify all chemical hazards in foods. The CFIA uses a prioritization approach to identify food-hazard combinations of greatest potential health risk. Risk prioritization is performed by 1) consulting the results of a risk-based model, 2) consulting the scientific opinion of Federal, Provincial and Territorial (F/P/T) partners and non-government organizations (NGOs), and 3) using existing survey/monitoring data.

The risk-based model was developed by a multi-disciplinary Food Safety Science Committee (FSSC). Publicly available hazard and food exposure information is entered into a model that generates a relative risk score. The hazards are further evaluated by FSSC members and a consensus is reached on their overall priorities.

The current targeted survey reports on the level of patulin in apple juice and apple juice concentrate.

1.3 Apple Juice and Apple Juice Concentrate

1.3.1 Definition of Apple Juice

In this targeted survey, apple juice refers to the drink created by crushing or squeezing apples, whether at its natural strength or in concentrated form. For the purposes of testing and reporting, concentrated apple juice is diluted with water according to manufacturer's instructions for consumption prior to analysis, in order that un-concentrated and concentrated forms may be directly compared, in the form in which they are to be consumed.

1.3.2 Canadian Consumption of Apple Juice

Apple juice, in all forms, is widely consumed in Canada; its consumption rate is second only to orange juice, and is of special concern because it is highly consumed by children. The level of consumption of apple juice by Canadians has remained relatively constant between 2001 and 2008 at approximately 6.0 L/person/year[1]. The Canadian Pediatric Society recommends that juice intake (apple or other fruit) be limited to 140-180 mL per day for young children for proper nutrition[2].

1.3.3 Apple Juice Processing

Apples used for juicing must be free from major damage or contamination that can promote the growth of bacteria and mould. However, mechanical harvesting often causes bruising and abrasions which may result in mycotoxin contamination. All apples for juicing are thoroughly washed, and most of these apples are processed by milling[3]. In North America, the hammermill is the most common milling process and consists of free-swinging hammers that force the fruit particles through a screen. Different hammers are used depending on their function (sharp hammers for chopping and blunt hammers for pulverizing)[3].

As apples are not easily juiced, pectinolytic enzymes are used to break down the cell structure and degrade pectin in the juice to improve extraction efficiency. Other processes are also utilized, such as press aids (fibrous materials like coarse wood flour, rice hulls, wood pulp) and fruit presses (Stoll Press, Belt Press, Screw Presses). Apple juice also undergoes a clarification process and is commonly sold as a translucent product. Ascorbic acid is often added and pasteurization is performed to prevent polyphenol oxidation, which causes browning and contributes to pulp flocculation. As mentioned previously, pectinolytic enzymes may be added to facilitate filtration and prevent subsequent precipitation of pectin (which contributes to opalescence). Gelatin is often added to apple juices to overcome tannin precipitation[3].

1.4 Mycotoxins in Apple Juice

When dealing with fresh fruit and vegetables as food products, it is important to recognize that they are living tissues susceptible to fungal and bacterial invasion. In the case of fruit, tissues are generally acidic so spoilage is mainly caused by fungi. Fungi produce mycotoxins, which remain in the food product and can result in negative health effects, if spoiled fruit is consumed. In general, however, spoilage of fresh fruit due to moulds is of little risk to human health, as mouldy fresh fruit is normally rejected.

The most important mycotoxin present in apples and apple products, with respect to human health, is patulin. Patulin is a toxic secondary metabolite produced by species of *Penicillium*, *Aspergillus*, and *Paecilomyces*. These moulds are most often associated with brown rot on apples.[4] In some production processes, such as in the making of apple juice, it is difficult to detect and remove apples that have been contaminated with mould both due to the nature of the production process, and to the fact that mould growth is not always detectable on the exterior. This has been largely addressed by the code of practice set out by CFIA for manufacturers[4], such as not using fallen apples (i.e. "grounders") in apple juice production.

The main source of patulin in the human diet is apple juice. Studies have reported patulin concentrations in apple juice ranging between 0.005 and 1.130 mg/kg[5]. While concentrations generally are unlikely to be high enough to negatively affect adults, patulin presence in apple juice is a concern in children due to the higher rate of consumption, as well as an increased sensitivity to patulin. Therefore, monitoring is important to ensure that levels of patulin are not sufficiently high to pose a health risk to Canadian children.

The United Nations' Joint FAO/WHO Expert Committee on Food Additives (JECFA) set a provisional maximum tolerable daily intake for patulin of 0.4 μg/kg body weight.[6] The United Nations' *Codex Alimentarius* Commission set the draft maximum level for patulin in apple juice at 50 ppb[7]. This draft maximum level for patulin is enforced in Canada for domestic and imported apple juice products.

1.5 Targeted Survey Objectives

The 2008-2009 Patulin in Apple Juice Products study was undertaken in order to determine whether patulin concentrations in apple juice were being sufficiently monitored by CFIA's regular programs. In order to achieve this, a study targeting apple juice and apple juice concentrate was undertaken. Other apple products were excluded, as it was suggested that patulin concentrations would be highest in apple juice and especially in apple juice concentrate. The decision was also made to exclude alcoholic ciders as the fermentation process in cider production is known to destroy patulin[8].

Specifically, the study was designed to:

- Assess compliance of apple juice manufacturers with international guidelines
- Provide patulin concentration data for risk assessment

2 Survey Samples and Analytical Methods

2.1 Targeted Survey Sampling Overview

There were a total of 104 samples (94 imported, 10 domestic) collected for the Apple Juice Product survey from nine countries. Most of the samples were picked up by CFIA inspectors at importer warehouses and distributors, or apple juice manufacturers. Generally, the sample consisted of a small amount of liquid from larger holding tanks of concentrated apple juice or a sample of finished product.

The distribution of samples with respect to country of origin is depicted in Figure 2-1. The country of origin is the country of manufacture as stated on the label of the finished product or on the shipping container. The determination of the country of origin can be hampered by a number of issues. One is that the country of manufacture is not stated. Another issue is that the raw materials (apples or juices) are sourced from different countries and are mixed or blended prior to transformation into the final product. This uncertainty exists for all samples collected in the survey.

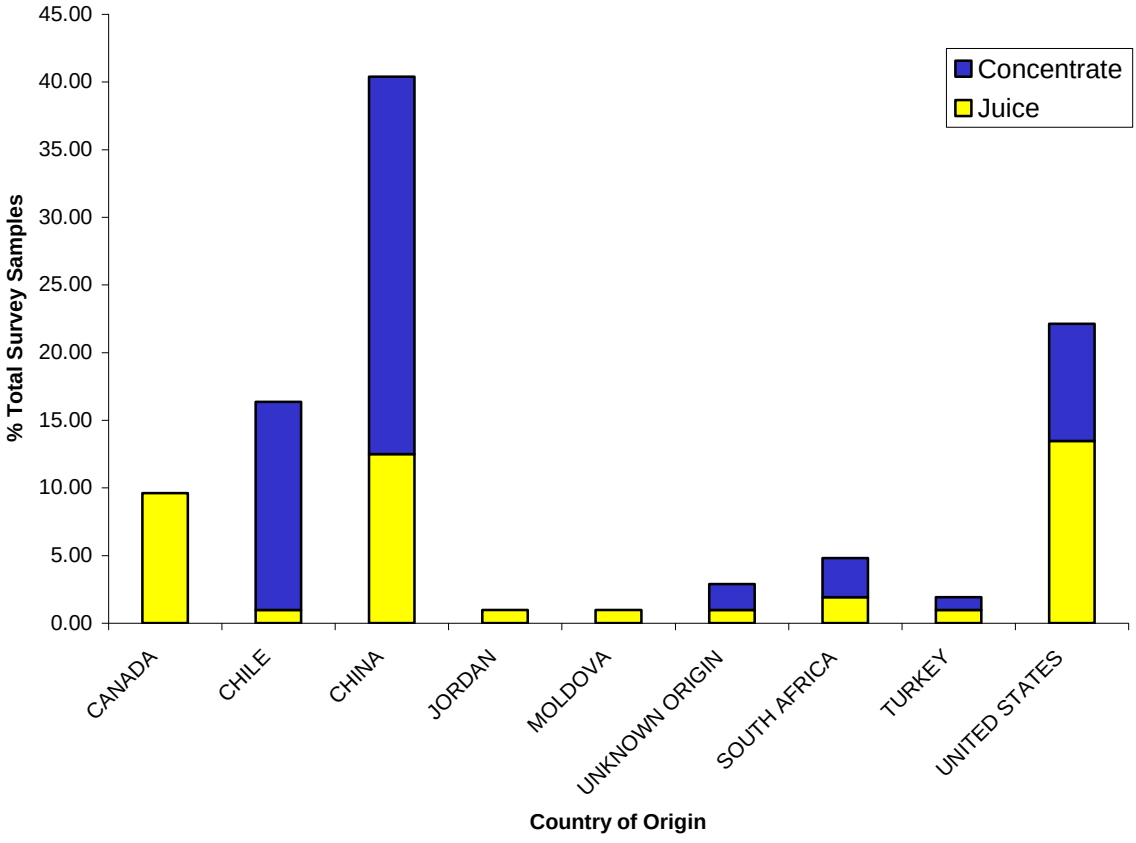

Figure 2-1. Distribution of Samples by Country of Origin

2.2 Survey Limitations

The patulin in apple juice survey is designed to give a snapshot of the apple juice and apple juice concentrate industry. There are a limited number of samples (104 in total) that are used to collect information on apple juice/apple juice concentrate as a whole. Conclusions regarding sample country of origin cannot be made due to very limited sample sizes per country and as it is impossible to confirm where the apples used to manufacture the products were grown. The term 'country of origin' refers to the country of manufacture, as indicated on the product label. The survey does not examine seasonality, year-to-year trends or impact of product shelf-life. The survey also does not consider the cost of the commodity on the open market.

2.3 Analytical Method

Both apple juice and apple juice concentrate were analysed by a CFIA laboratory according to the CFIA's patulin reference method. The method used in this study for analysing patulin in apple juice and apple juice concentrate is based on HPLC-PDA (photodiode array), with a reporting limit of 10 ppb. The apple juice concentrate was diluted according to manufacturer's instructions for consumption prior to analysis.

3 Results and Discussion

3.1 Overall Results

The results from this targeted survey are presented graphically below. The supporting information is presented in tabular form in the appendices. In this study, a "positive" refers to a sample whose patulin concentration exceeds the 10 ppb reporting limit. A "negative" refers to a sample whose patulin concentration is below the 10 ppb reporting limit.

All samples tested were compliant, i.e. the patulin concentrations were below the Codex draft maximum level of 50 ppb[2]. There is no difference in compliance rate between apple juice and apple juice concentrates. However, there were differences in the positive rates between apple juice and apple juice concentrate. Seven of the 44 (15.9%) apple juice samples tested were positive for patulin. Five of the 60 (8.3%) apple juice concentrate samples tested were positive for patulin (see Figure 3-1). The highest level of patulin reported was 27.6 ppb in apple juice and 24.0 ppb in apple juice concentrate. The average concentration of patulin in apple juice was 15.9 ppb and 15.4 ppb in apple juice concentrate.

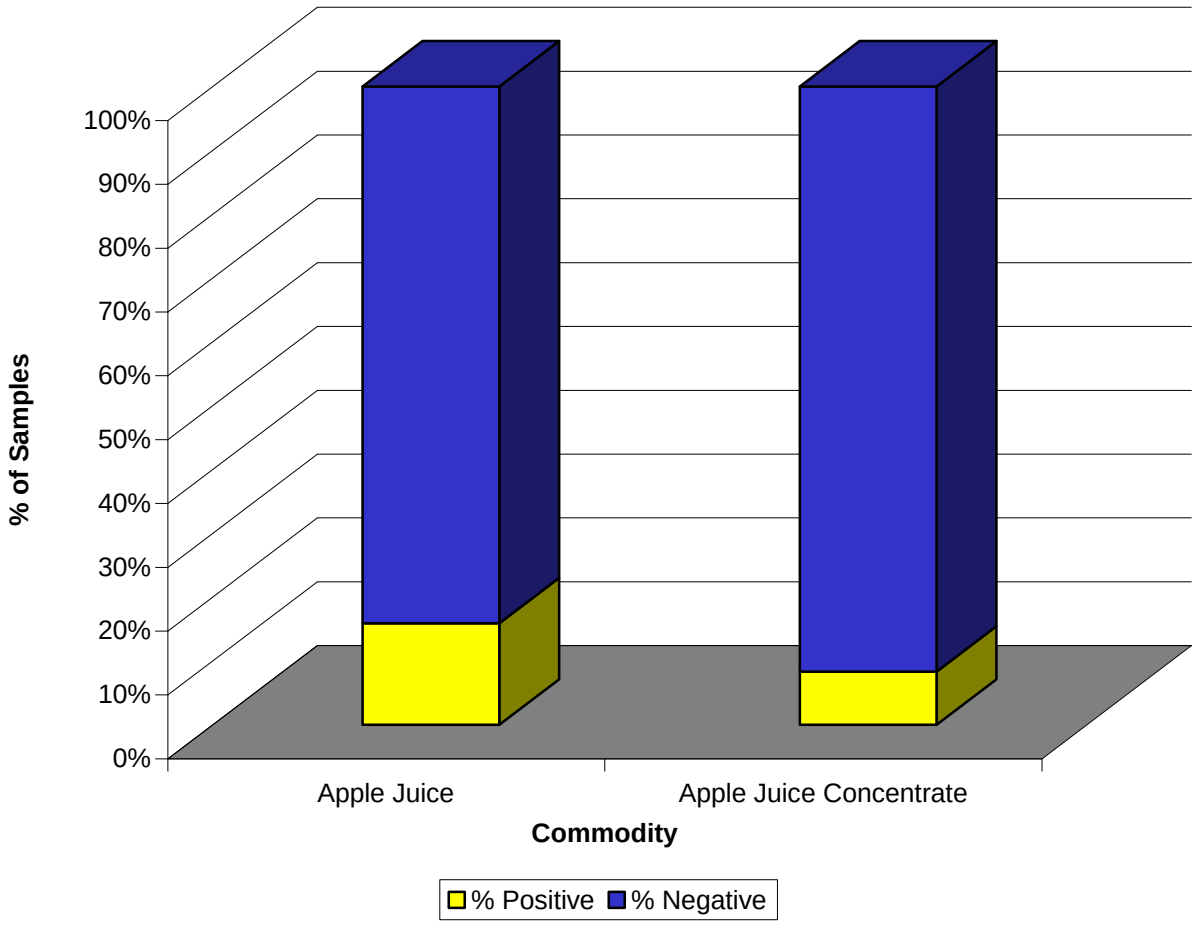

Figure 3-1. Distribution of Positive Samples by Commodity Type

3.2 Patulin in Apple Juice

Forty four apple juice samples from nine countries were analysed for patulin. Table 3-1 presents the number of samples, the number of positives, the percentage of positives and the patulin levels in apple juice as a function of country of origin. It is important to note that there were only seven positive samples. Jordan, Moldova and Turkey had no positives but only one sample per country was analysed. Four of the positives were associated with countries for which only one (Chile, unknown country) or two (South Africa) samples were analysed. Because of the low sample numbers for these six countries, these positive or negative findings should not be considered representative of the apple juice from these countries. The other three positives were associated with somewhat larger sample numbers; one of the positive samples originated in Canada (10 samples analysed), one in the United States (14 samples analysed) and one in China (13 samples analysed). The positive rates for these three countries were comparable (7 to 10%).

Table 3-1. Summary table of patulin in apple juice, by country of origin.

Country of Origin	Number of samples	Number of Positives	% Positives	Patulin level, ppb
CANADA	10	1	10.00%	10.3
CHILE	1	1	100.00%	17.4
CHINA	13	1	7.69%	10.1
JORDAN	1	0	0.00%	< 10
MOLDOVA	1	0	0.00%	< 10
UNKNOWN ORIGIN	1	1	100.00%	26.7
SOUTH AFRICA	2	2	100.00%	12.6 12.5
TURKEY	1	0	0.00%	< 10
UNITED STATES	14	1	7.14%	21.5
Total	44	7	15.91%	Mean = 15.9

The patulin levels ranged from 10.1 ppb (China) to 26.7 ppb (unknown origin). The overall mean patulin concentration in apple juice was 15.9 ppb (the calculation of the mean excludes any negative samples). All of these levels were below the Codex draft maximum level of 50 ppb and do not represent a human health risk.

There is no difference in compliance rate between domestic and imported apple juice.

3.3 Patulin in Apple Juice Concentrate

Sixty apple juice concentrate samples from six countries were analysed for patulin according to the method in section 2.3 Table 3-2 presents the number of samples, the number of positives, the percentage of positives and the patulin levels in apple juice concentrate as a function of country of origin. It is important to note that there were only five positive samples. There is no clear relationship between country of origin and patulin level.

Table 3-2. Summary table of patulin in apple juice concentrate, by country of origin.

Country of Origin	Number of samples	Number of Positives	% Positives	Patulin level, ppb
CHILE	16	2	12.50%	19.9 12.5
CHINA	29	2	6.90%	10.4 10.1
UNKNOWN ORIGIN	2	0	0.00%	10.1
SOUTH AFRICA	3	1	33.33%	24.0
TURKEY	1	0	0.00%	< 10
UNITED STATES	9	0	0.00%	< 10
TOTAL	60	5	8.33%	Mean = 15.4

The patulin levels ranged from 10.3 ppb (China) to 24.0 ppb (South Africa). The overall mean patulin concentration in apple juice was 15.4 ppb (the calculation of the mean excludes any negative samples). All of these levels were below the Codex draft maximum level of 50 ppb and do not represent a human health risk.

No domestic apple juice concentrates were analysed so it is not possible to compare compliance rates between domestic and imported apple juice concentrates.

4 Conclusions

The results of the 2008-2009 Patulin in Apple Juice Products targeted survey indicate that patulin concentrations in the majority of samples (88.5 %) were below the reporting limit of 10 ppb. The highest measured level of patulin was 26.7 ppb in apple juice and 24.0 ppb in apple juice concentrates. All samples complied with the Codex draft maximum level of 50 ppb. None of the observed levels of patulin in the 104 apple juice products tested (10 domestic, 94 imported) represented a risk to the health of Canadians.

There was no difference in compliance rate between imported and domestic products nor was a relationship observed between country of origin and patulin levels. No apparent difference in patulin levels was observed between apple juice and apple juice concentrate.

The results of this study are similar to results from regular CFIA monitoring programs, and indicate that patulin levels in apple juice do not present a risk to general Canadian population nor to the more vulnerable population of children. The CFIA will continue to monitor patulin levels in apple juice products under its routine monitoring program.

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