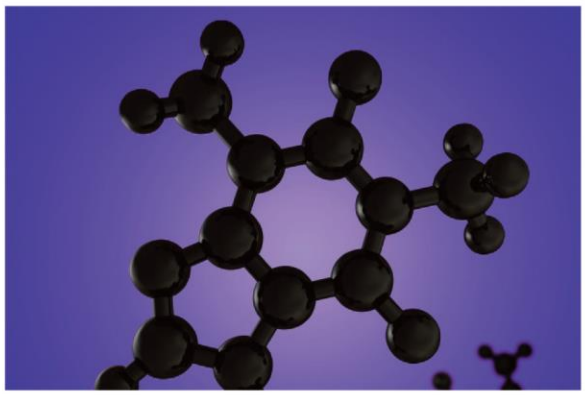
Canadian Food Inspection Agency
Agence canadienne d'inspection des aliments

Food Safety Action Plan

REPORT

2011-2012 Targeted Surveys

Chemistry



Antimony in Selected Foods

TS-CHEM-11/12

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 hazards.

The main objective of this targeted survey was to generate baseline surveillance data on the level of antimony in beverages, seed and nut butters, condiments, and frozen or shelf-stable heat-and-serve meals available on the Canadian retail market.

Antimony is a naturally occurring metal and its levels in the environment have risen due to increased industrial use. Since antimony is not known to fulfill a biological role in the human body, there is growing concern about its effects on humans. Antimony trioxide, used in the manufacturing of polyethylene terephthalate (PET) plastic, has been classified as a possible human carcinogen by the International Agency for Research on Cancer. Previous scientific studies have reported the leaching of antimony from packaging, particularly PET plastic, into food or beverage products.

The 2011-2012 Antimony survey targeted domestic and imported beverages, nut and seed butters, condiments, and frozen or shelf-stable heat-and-serve meals. A total of 621 samples were collected from grocery and specialty stores in seven Canadian cities between April 2011 and March 2012. The samples collected were packaged in various materials (i.e., plastic, glass, metal can, and Tetra Pak) and included 397 beverages, 75 seed and nut butters, 75 condiments, and 74 heat-and-serve frozen and shelf-stable meals.

Of the 621 samples analyzed, 609 (98%) did not contain a detectable level of antimony. The remaining 12 samples had a detectable level of antimony ranging from 0.0032 ppm to 0.0199 ppm. It is important to note that this survey cannot distinguish between antimony originating from natural sources, from environmental contamination, and/or leaching from packaging materials. Currently, no maximum level, tolerance, or standard has been established by Health Canada for antimony in food so compliance to a numerical standard could not be evaluated.

All data generated were shared with Health Canada for use in performing human health risk assessments. The antimony levels found in this survey were not considered to pose a concern to human health. Follow up actions could include additional sampling, additional inspections or ultimately the recall of the product from the Canadian market place. Based on the low levels of antimony detected in this survey, no follow up actions were required for any of the survey samples.

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 Canada's safety system for food, health and consumer products. The FCSAP initiative unites multiple partners in ensuring safe food for Canadians.

The Canadian Food Inspection Agency's (CFIA) Food Safety Action Plan (FSAP) is one element of the government's broader FCSAP 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.

Within FSAP there are 12 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 of 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.

Within the current regulatory framework, some commodities (such as meat products) traded internationally and interprovincially are regulated under specific Acts. These are referred to as federally registered commodities. Under the current regulatory framework, the non-federally registered commodities encompass approximately 70% of domestic and imported foods that are regulated solely under the *Food and Drugs Act* and *Regulations*. Targeted surveys are primarily directed towards non-federally registered commodities.

1.2 Targeted Surveys

Targeted surveys are used to gather information regarding the potential occurrence of chemical hazards 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, a group of federal, provincial and territorial subject matter experts in the area of food safety.

The CFIA regularly monitors metal analytes, including antimony, in a variety of foods under the National Chemical Residue Monitoring Program (NCRMP) and Children's Food Project. Targeted surveys focus mainly on products not routinely monitored under

these two programs. The purpose of this targeted survey was to establish baseline data on antimony levels in beverages, nut and seed butters, condiments, and frozen or shelf-stable heat and serve meals available on the Canadian retail market. The scope of this survey is complementary to the NCRMP and Children's Food Project monitoring of metals in processed products in that it includes additional commodities (i.e., juices and bottled water) not routinely monitored for antimony. Where applicable, the antimony levels observed in this survey were compared with previous CFIA NCRMP[1,2] and Children's Food Project[3,4] data, and two previous CFIA FSAP targeted surveys (2008-2009 FSAP Pesticides Residues and Metals in Fruit Juice Concentrates[5] and the 2010-2011 FSAP Antimony in Juice and Bottle Water)[6].

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* and *Regulations*.

Health Canada establishes the health-based maximum levels for chemical residues and contaminants in food sold in Canada. Currently, no Canadian maximum level, tolerance, or standard exists for antimony in food, although there is a Canadian drinking water quality guideline for antimony of 6 parts per billion (ppb)[7]. Given that no regulations have been established by Health Canada for antimony in food, compliance to a numerical standard could not be evaluated for the samples tested in this survey.

Internationally, a number of maximum levels have been established for antimony in water. The European Commission has set a maximum limit of 5 ppb antimony in natural mineral waters[8] and the United States has a maximum contaminant level for antimony in drinking water of 6 ppb[9]. The World Health Organization has set a 20 ppb guideline value for antimony in drinking water[10].

Food and beverages may be exposed to antimony as a result of its use in the production of some food packaging materials. Antimony trioxide, used in the manufacturing of polyethylene terephthalate (PET) plastic, is classified by the International Agency for Research on Cancer as possibly carcinogenic to humans[11].

Elevated levels of antimony in specific foods may be assessed by Health Canada on a case-by-case basis using the most current scientific data available. Follow-up actions are initiated in a manner that reflects the magnitude of the health concern. Actions may include further analysis, notification to the producer or importer, follow-up inspections, additional directed sampling, and recall of products.

2. Survey Details

2.1 Antimony

Antimony is a naturally occurring metal and its levels in the environment have risen due to its use in a variety of man made products (e.g., flame retardants, batteries, paint pigments, plastics, glass and pottery)[2]. Since antimony is not known to fulfill a biological role in the human body, there is growing concern about its effects on humans[12,13]. Antimony exposure at high levels can cause acute health effects such as nausea, vomiting and diarrhoea. Chronic exposure to antimony is associated with respiratory effects (e.g., inflammation of lungs, chronic bronchitis/emphysema) and cardiovascular effects (e.g., increased blood pressure, heart muscle damage)[14], as well as possible carcinogenic effects[7,11,14].

Dietary exposure to antimony may be from the consumption of food products packaged with PET plastic materials. As previously mentioned, antimony is widely used in the production of PET. Trace amounts of antimony are known to remain in the material and previous studies have reported that antimony may leach into bottled water and juice products from PET-based packaging[13,15,16]. A study comparing antimony levels in PET-based bottled water both before and after packaging found that average antimony levels were over ten times higher in bottled water than those in the source water[18].

Results of a survey conducted in Europe found that 19% of the juices analyzed contained antimony levels that exceeded the European drinking water guideline[15]. The observed levels were attributed to leaching from the packaging material, antimony being present in the juice prior to packaging, or a combination of the two[15]. Studies have reported elevated leaching of antimony from packaging in juices and carbonated waters, and some have attributed the elevated antimony level to the acidic nature of the beverage[16]. Other factors reported to affect the extent of leaching of antimony from the PET bottle into food were storage temperature and duration, sunlight exposure, as well as bottle quality (level of reuse) and the bottle size[16,17,18].

2.2 Rationale

Although antimony compounds are not believed to be used in the manufacture of non-PET based packaging materials, it is present from natural sources and the environment so background levels are anticipated. Beverages (i.e., juices, sports drinks, and bottled waters) were targeted in this survey, as these products are highly consumed by Canadians of all ages and are often packaged in plastic or glass (a known source of antimony). Nut and seed butters, condiments, and frozen or shelf-stable heat-and-serve meals were also targeted in this survey, as these are commonly consumed foods often packaged in plastic or glass.

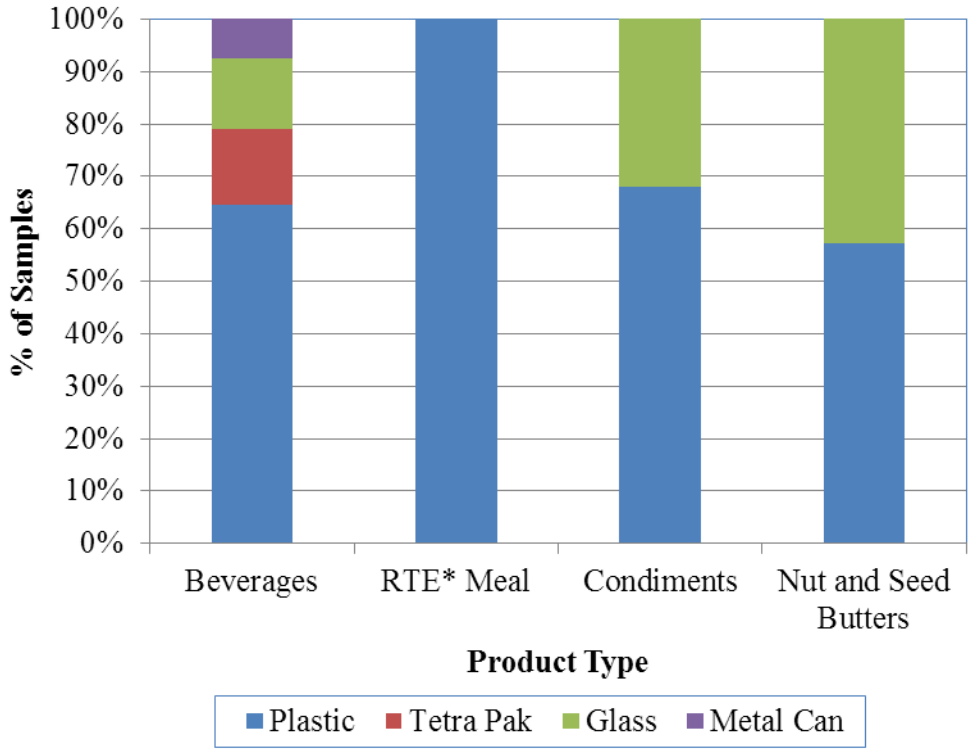
All data was shared with Health Canada for use in conducting human health risk assessments of antimony.

2.3 Sample Distribution

A total of 621 samples were collected from grocery and specialty stores in seven Canadian cities between April 2011 and March 2012. Survey samples collected included 397 beverages, 75 seed and nut butters, 74 condiments, and 74 frozen and shelf-stable meals.

The 621 samples collected included 356 domestic products and 265 imported products (from 28 countries). It is important to note that the products sampled often contained the statement "processed in Country X", "imported for Company A in Country Y" or "manufactured for Company B in Country Z", and though the labelling meets the intent of the regulatory standard, it does not specify the true origin of the product ingredients. Only those products labelled with a clear statement of "Product of", "Prepared in", "Made in", "Processed in", and "Manufactured by" were considered as being from a specific country of origin.

The samples collected were packaged in various packaging materials, including plastic, glass, metal can, and Tetra Pak. The percentage of samples by packaging type is presented in Figure 1. As the specific type of plastic packaging (e.g., PET) was not recorded for each sample, all plastic containers were categorized together.



*RTE (Ready-to-Eat) = frozen and shelf-stable meals (prepared meals/entrees)

Figure 1. Percentage of survey samples by packaging type

The 397 ready-to-drink beverage samples included 153 juices, 139 sport and soft drinks, and 105 bottled waters. Juice samples included pure fruit juices, tomato juices, tropical fruit and vegetable blends, nectars, coconut waters, iced teas, and cranberry cocktails. The 139 sports and soft drink samples included 67 sport drinks and 72 carbonated soft drinks. The 105 bottled water samples collected included sparkling, still, flavoured and unflavoured (spring, mineral, purified, and artesian).

The 75 seed and nut butters collected included 17 seed butters (sesame/tahini, pumpkin, and sunflower) and 58 nut butters (almond, hazelnut, peanut, soy, walnut, cashew, macadamia, and nut blends).

The 74 condiments samples collected included steak and barbecue sauces, salad dressings, relishes, mayonnaises, mustards, ketchups, salsas, and vinegars.

The 74 frozen and shelf-stable heat-and-serve meals (which are referred to as ready-to-eat (RTE) meals) included pasta-based entrée meals (e.g., macaroni and cheese, spaghetti bolognese, etc.), meat/poultry-based entrée meals (e.g., meatloaf, chicken and vegetables, beef or pork pot roast), vegetarian entrée meals (e.g., mixed grilled vegetables and vegetables with rice/couscous), and meals targeted at infants and toddlers (e.g., meat/vegetable/cheese pasta, meat/vegetable purée, and meat/vegetables with rice/barley).

2.4 Method Details

Survey samples were analyzed for antimony by a laboratory under contract with the Government of Canada. Laboratories used by the government of Canada are accredited by the Standards Council of Canada (SCC) and/or by the Canadian Association for Laboratory Accreditation Inc. (CALA).

Samples were tested as sold, meaning that the product was not prepared as per the package instructions (if applicable). The laboratory used microwave digestion and inductively coupled plasma mass spectrometry to analyze and confirm metal analytes in the samples. The method has a limit of detection (LOD) for antimony of 0.003 ppm and a limit of quantitation (LOQ) of 0.01 ppm. The current survey, the previous FSAP surveys[5,6], NCRMP[1,2], and Children's Food Project[3,4] utilized similar analytical methods and had similar reporting limits.

2.5 Limitations

The current targeted survey was designed to provide a snapshot of the levels of antimony in beverages, nut and seed butters, condiments, and frozen or shelf-stable heat-and-serve meals in various packaging types available for sale in Canada, and to highlight commodities that warranted further investigation. This survey cannot distinguish between antimony originating from natural sources, from environmental contamination, and/or leaching from packaging materials. The limited sample sizes analyzed represent a small

fraction of the products available to Canadian consumers. Therefore, care must be taken when interpreting and extrapolating these results.

3. Results and Discussion

3.1. Overview of Antimony Results

The 2011-2012 Antimony in Selected Foods survey consisted of testing 621 samples obtained at the Canadian retail level. Of the 621 samples analyzed, 609 (98%) did not have a detectable level of antimony. The remaining 12 samples contained a detectable level of antimony ranging from 0.0032 ppm to 0.0199 ppm. Samples with a detectable level of antimony were packaged in glass or plastic containers. No positive results were associated with products packaged in Tetra Paks or metal cans. See Table 1 for the minimum, maximum, and average levels of antimony by product type and Table 2 for the summary of antimony levels detected in the survey samples by product and packaging type. It should be noted that average values were calculated using only results for samples with a detectable level of antimony.

Table 1. Minimum, maximum, and average levels of antimony in various product types (in order of increasing average level)

Product Type	Number of Samples	Number of Samples with Detectable Levels (Percentage)	Minimum (ppm)	Maximum (ppm)	Average (ppm)
Seed and Nut Butters	75	0 (0%)	< LOD	-	-
Beverages	397	3 (0.8%)	0.0032	0.0041	0.0036
Ready-to-Eat Meals	74	3 (4.1%)	0.0032	0.0064	0.0045
Condiments	75	6 (8.0%)	0.0034	0.0199	0.0106
Overall	**621**	**12 (1.9%)**	**< LOD**	**0.0199**	**0.0073**

Note: Average values were calculated using only results for samples with a detectable level of antimony
LOD = Limit of Detection (0.003 ppm)

Table 2. Summary of antimony levels detected by product and packaging type (in order of increasing antimony level)

Product Type	Packaging Type	Commodity	Antimony Level (ppm)
Beverages	Plastic	Grape Juice	0.0032
		Fruit Punch Sports Drink	0.0036
		Mixed Berry Sports Drink	0.0041
Condiments	Glass	Barbecue Sauce	0.0034
		Barbecue Sauce	0.0035
		Barbecue Sauce	0.0076
		Barbecue Sauce	0.0138
		Yellow Mustard	0.0151
	Plastic	Marinade	0.0199
Ready-to-Eat Meals	Plastic	Beef Pot Roast	0.0032
		Beef Pot Roast	0.0039
		Pork Rib Roast	0.0064

Antimony was not detected in any of the seed and nut butters, bottled waters, or soft drinks tested.

The antimony levels observed in positive samples may be present for a variety of reasons. It may be present in a finished food product due to the presence of antimony in the ingredients or the water used in the preparation of the food, leaching from the packaging, or other factors such as the production process, storage conditions, acidity of the beverage, etc. [16,17,15,19]

It has been proposed that the citric acid in some juices enhances extraction of antimony from packaging[15], which may partly account for the antimony levels found in the juice/sport drink samples in this survey. Antimony trioxide is used in the manufacture of plastics as well as glass[7], and the leaching of antimony from glass has been documented[20]. It should be noted that other samples of beverage or food/packaging combinations identical to those in which antimony was found did not have a detectable level of antimony in this survey.

All the results from this survey were evaluated by Health Canada. The antimony levels observed were not considered to pose a concern to human health. No product action was necessary.

3.2. Antimony Results by Product Type

More detailed results by product type are presented in the following sections with comparison, where feasible, to results obtained from the NCRMP[1,2] , the Children's Food Project[3,4](CFP) monitoring programs, the 2008-2009 FSAP Pesticides Residues and Metals in Fruit Juice Concentrates[5] and the 2009-2010 FSAP Antimony in Juice and Bottle Water[6] surveys, all conducted by the CFIA.

3.2.1. Beverages

Of the 397 read-to-drink beverage samples analyzed, 394 (99.4%) did not have a detectable level of antimony (Table 1). Antimony was not detected in any of the soft drink or bottled water samples tested. The three samples that tested positive for antimony (one juice and two sports drink samples) had levels ranging from 0.0032 ppm to 0.0041 ppm, and were all packaged in plastic bottles.

Comparison of the level of antimony detected in beverages with the drinking water guideline is not directly relevant given the different consumption patterns of water and juice; however, it is included as a point of reference. The antimony levels in the three beverage samples with detectable residues were lower than the Canadian drinking water guideline of 6 ppb (0.006 ppm), as well as other levels reported in the scientific literature for similar bottled beverages[21].

The positive beverage samples in the current survey had lower levels of antimony compared with those of the 2008-2009 FSAP Pesticides Residues and Metals in Fruit Juice Concentrates[5] and the 2009-2010 FSAP Antimony in Juice and Bottled Water[6] surveys. See Table 3 for a comparison of the data generated from this survey and other CFIA survey results. Nine of the 186 juice concentrate samples analyzed in the 2008-2009 survey had detectable levels of antimony ranging from 0.034 ppm to 0.239 ppm. Eight of the 185 juice samples analyzed in the 2009-2010 survey had a detectable level of antimony ranging from 0.0038 ppm to 0.0572 ppm. The juice samples tested in the 2008-2009 and 2009-2010 surveys were packaged in glass, metal can, or Tetra Pak.

Only one of the 174 bottled water samples analyzed in the 2009-2010 Antimony in Juice and Bottled Water survey had a detectable level of antimony (0.0031 ppm). The level detected was well below the Canadian drinking water guideline. Similarly, in the current survey no samples of bottled water contained a detectable level of antimony.

The beverage samples with detectable levels of antimony in the current survey had lower levels than the majority of beverages analyzed for metals under the NCRMP (2010 to 2012)[1,2] and the Children's Food Project (2010 to 2012)[3,4]. Two of 94 beverages analyzed under the Children's Food Project contained a detectable level of antimony ranging from 0.0095 ppm (flavoured water in plastic bottle) to 0.038 ppm (fruit juice in a Tetra Pak container). Three of 48 juice samples tested under the NCRMP had a detectable level of antimony ranging from 0.0043 to 0.0428 ppm. All three samples were pineapple juices in metal cans.

Table 3. Comparison of antimony levels detected in the current survey with previous CFIA survey results

Survey	Product types tested	Number of samples tested	Number of samples with no detectable residues (%)	Range(ppm)
Current FSAP Survey (2011/12)	beverages (juice, sports drinks, bottled water)	397	394(99.4)	0.0032 - 0.0041
FSAP Survey (2008/9)	juice concentrates	186	177(95.2)	0.034 - 0.239
FSAP Survey (2009/10)	juice	185	177(95.7)	0.0038 - 0.0572
FSAP Survey (2009/10)	water	174	173(99.4)	0.0031
NCRMP Survey (2010-2012)	juice	48	45(93.8)	0.0043 - 0.0428
CFP (2010-2012)	beverages (juice, bottled water)	94	92(97.9)	0.0095 - 0.038

3.2.2. Seed and Nut Butters

Antimony was not detected in any of the 75 seed and nut butters samples analyzed in this survey. Similarly, antimony was not detected in any of 20 nut butters (e.g., peanut, almond, macadamia, soy, and cashew) samples analyzed in the 2011-2012 Children's Food Project[4].

3.2.3 Condiments

Of the 75 condiments samples analyzed, 69 (92.0%) did not have a detectable level of antimony (Table 1). The remaining six (four barbecue sauces, one yellow mustard, and a marinade) had a detectable level of antimony level ranging from 0.0034 ppm to 0.0199 ppm (Table 2). The condiment samples with detectable antimony levels were packaged in plastic or glass.

Antimony was not found in any of the ten condiment (ketchup and salsa) samples analyzed under the Children's Food Project (2010 to 2012), nor in any of the seven (ketchup) samples tested under the NCRMP (2010 to 2012).

3.2.4. Ready-to-Eat Meals

Of the 74 ready-to-eat meal samples analyzed, 71 (94.7%) did not have a detectable level of antimony (Table 1). None of the frozen pasta, vegetarian meals, or meals targeted at infants and toddlers (frozen and shelf-stable) in this survey had a detectable level of antimony. The remaining three ready-to-eat meals had a level of antimony ranging from 0.0032 ppm to 0.0064 ppm, and were all packaged in plastic trays (Table 2).

Only one of 274 ready-to-eat meal samples tested under the Children's Food Project had a detectable level of antimony at 0.0039 ppm, similar to the concentrations seen in the present survey.

4. Conclusions

The 2011-2012 Antimony in Selected Foods survey generated baseline surveillance data on the levels of antimony in beverages, seed and nut butters, condiments, and frozen or shelf-stable heat-and-serve meals, in a variety of packaging types, available on the Canadian retail market.

Of the 621 samples analyzed, 609 (98%) did not contain a detectable level of antimony. The remaining 12 samples had detectable antimony levels in products packaged in glass and plastic, and ranged from 0.0032 ppm to 0.0199 ppm. Detectable levels of antimony were observed in a variety of products such as juices, sports drinks, condiments, as well as ready-to-eat meals. Comparison with previously published CFIA results indicates that the levels of antimony are low and infrequent. The products in which the antimony was found are very diverse and are not limited to a particular product/packaging type.

Although a Canadian drinking water quality guideline for antimony of 0.006 parts per million (ppm) exists currently, no maximum level, tolerance, or standard has been established by Health Canada for antimony levels in food so compliance to a numerical standard could not be assessed in this survey. All data generated were shared with Health Canada for use in performing human health risk assessments. The antimony levels found in this survey were not considered to pose a concern to human health. No product recalls were associated with this survey.

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