

FDA's Persistent Ban on the Artificial Sweetener Cyclamate

Distaste for Aspartame May Help Drive the Re-approval of Cyclamates in the US

Tag Words: Cyclamate; Saccharin; Artificial Sweeteners

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Summary: The artificial sweetener, sodium cyclamate, is banned in the United States but it is used in many other Western countries without safety concerns. The FDA banned cyclamates in 1970 based on one (now seen as flawed) study in rats, and despite lack of evidence for any safety concerns, the FDA has not reapproved it. With the escalating distaste for aspartame, approving additional artificial sweeteners to be on the market would benefit both manufacturers and consumers. Reapproving cyclamates would provide for a greater variety of low-calorie and sugar-free foods and beverages to help meet consumer demand.

Video Link: <http://youtu.be/-smAlRou3bg>

History of the Artificial Sweeteners Cyclamate & Saccharin

Michael Svaeda discovered cyclamate in 1937 at the University of Illinois while he was working on synthesizing anti-fever medication (1). Svaeda was smoking a cigarette while performing a routine procedure and put the cigarette down to free his hand. Upon picking up the cigarette again and smoking it he discovered the remarkably sweet taste of cyclamate. Svaeda, at the time, was an employee for DuPont, which eventually patented the chemical for use as an artificial sweetener. It was not until 1951 that the FDA approved cyclamate for use as a commercial sweetener and its use skyrocketed as a result. Before the discovery of cyclamate, saccharin was the only artificial sweetener on the market. Saccharin is 300 times sweeter than sugar but it had one flaw- a bitter metallic aftertaste (2). Cyclamate is about 30 times as sweet as sugar and has no bitter aftertaste. Scientists found that when the two products were combined together, the saccharin gave the powerful sweetness while cyclamate masked the bitter after taste. The formula consisted of 10 parts saccharin and 1 part cyclamate and was the major component of many foods and beverages through the 1960s (3).

Saccharin, like cyclamate, was also discovered by accident in 1878 by Constantin Fahlberg, a chemist at Johns Hopkins University (4). When Fahlberg came home from work, he had dinner with his family and when he touched his lips with his hands he noticed a very sweet taste. Fahlberg immediately knew that this sweetness came from a chemical byproduct of the reactions he was doing at the lab. Fahlberg eventually figured out the process for making the substance that was 300 times sweeter than sugar and he named it saccharin. Saccharin became a source of salvation for diabetics as it was as sweeter than regular sugar but it did not affect blood glucose levels. The widespread use of saccharin, however, was not established until World War II, as table sugar became a limited resource (5). Saccharin became the main sweetener in almost all foods and drinks because it was cheaper and sweeter than table sugar. After the war, both

consumers and manufactures continued using saccharin because the public became more conscious about their daily caloric intake.

Sodium cyclamate

Sodium cyclamate began to attract negative attention when a controversial study in 1969 released data that rats exposed to cyclamates after a long period of time began to develop liver and bladder cancers. In response to the study's results, the FDA posed a ban on cyclamates due to their protocol of removing hazardous food items from US markets. Many critics of the scientific community expressed unfavorable opinions directed towards the FDA's decision based on the study's findings. For instance, the rats were being exposed to huge amounts of cyclamate, roughly 350 cans of soda's worth of the substance daily for several years. In addition, only 8 out of the 200 rats showed signs of cancer development in their bodies (12, 13). The director of the study himself expressed his belief that the study may have not provided enough substantial evidence that cyclamates are harmful when consumed. In 1984, the cancer assessment division of the FDA confirmed their belief that cyclamates on their own are not carcinogenic when consumed in safe and moderate amounts and this belief has been supported by several studies in the years to follow. Many agencies across the globe including the Food and Agriculture Organization/World Health Organization's Joint Expert Committee on Food Additives (JECFA) and the Scientific Committee on Food (SCF) of the European Commission declare their belief that cyclamates are safe for human consumption when ingested in moderate quantities. As a result, cyclamates are legal and a primary source of artificial sweetener in many countries across the world including Canada, Australia, and many parts of Europe. Although difficult to determine what amount is considered safe and moderate, JECFA decided that the acceptable daily intake (ADI) for cyclamates should be set at 11 mg/kg of body weight whereas the SCF set their standards at 7 mg/kg (13, 14).

Are Cyclamates Carcinogenic?

Once negative press is released about a food substance, it is very hard to reverse public opinion. Many critics of the scientific community felt that the FDA's ban on cyclamates was irresponsible and premature and should be free of political pressure (15). Multiple case studies determined that the cyclamate molecule when isolated and combined with saccharin in a 10:1 ratio came to the conclusion that cyclamates were safe for consumption in recommended concentrations (16). The concern that cyclamates were carcinogenic stemmed from that cyclamates can be metabolized and broken down into cyclohexyl amines in the gut, potential carcinogens. Rats that were fed cyclamates showed trace amounts of cyclohexylamine in their urine and feces. The concentration, however, varied greatly, suggesting that the amount of cyclamate converted depended greatly on the specific metabolic makeup of the rats' gastrointestinal tract and the amount of enzyme that converts cyclamate to cyclohexylamine. The rats that converted larger amounts of cyclamate to cyclohexylamine were labeled as high converters, and vice-versa. Since human and rat metabolic composition vary, it is important to focus on the effects of cyclamate digestion in primates and humans versus rats.

In 1999, a study exposed 21 non-human primates to large doses of cyclamates (100mg/kg-500mg/kg) starting from a few days after birth until the age of 24 for 24 years. Little evidence of

cancer was noted. At the end of the study, only three of the monkeys fed cyclamates developed tumors; one in the colon, one in the liver, and one in the prostate. Their controlled counterparts contained no signs of cancer in the body. Cyclohexylamine concentrations were also analyzed in the cyclamate-exposed group and it was found that three of the 21 monkeys were considered “high converters”. Of the three high converters, only one of them showed signs of slightly irregular spermatogenesis, but no tumors whatsoever. The study concluded that after 24 years of heavy exposure to cyclamates, only three cases of sporadic malignant tumors is not enough evidence to suggest that cyclamates cause carcinogenic effects in primates when consumed in safe amounts (17).

Ban on Cyclamate

The controversy of cyclamate usage arose in 1969 after the findings of Dr. Jacqueline Verrett (6). Verrett injected chicken eggs with concentrated solutions of cyclamate and found that upon hatching, every chick was born with malformations and defects. She presented her findings on a segment of NBC’s Huntley-Brinkley report and it was then that the public became weary of the low calorie sweetener that they came to love. However, the amount of cyclamate that Verrett injected into the chicken eggs was more than a human can ever ingest without getting sick. If a human subject would consume the same amount of cyclamate in the same dose to body weight ratio, the human would vomit before the sugar was ever metabolized. A few weeks later, a study was released showing that laboratory rats were developing cancer as a result of saccharin/cyclamate consumption. The report stated “Papillary transitional cell tumors were found in the urinary bladders in 8 rats out of 80 that received 2600 milligrams per kilogram of body weight per day of a mixture of sodium cyclamate and sodium saccharin (10:1) for up to 105 weeks” (7). Once again, these researchers gave the lab rats extreme doses that are almost impossible to consume by humans. These scientists failed to tell the public this simple fact, and so everyone believed that cyclamate was carcinogenic.

In the following months, the FDA removed cyclamate from the GRAS list and established a ban on the use of cyclamate for both public and private use as a sugar substitute. Interestingly, saccharin was not banned and its use continued unrestricted. The FDA attempted to ban saccharin later on as well but was unsuccessful due to popular demand. It seems that the only reason cyclamate, and not saccharin, was because in her experiment, Dr. Verrett used exclusively cyclamate when injecting the solution into the chicken eggs. After that it was assumed that cyclamate was the carcinogen and not saccharin. Since the ban, saccharin remained the most widely used artificial sweetener (although now overtaken by aspartame).

FDA's persistent ban on cyclamates - is it unjustified?

As leaders of the free world, it is our duty as Americans to lead by example in the realm of allowing our citizens to choose the contents of their diets, as long as they are deemed safe by scientific trials. One of the primary objectives of the FDA is to ensure that all nutritional products distributed in the United States are safe. However, some have the opinion that the FDA should not have the authority to infringe on our freedoms to choose, especially if some of these banned products are declared safe for consumption in scientific studies. Since its ban in 1969, there have been multiple studies declaring cyclamates safe for consumption, thus to maintain the

integrity of their responsibilities, it behooves the FDA to reverse the ban of cyclamates. It is unjustified for the FDA to continue to ban a food additive based on the grounds that has since been found not to be toxic to humans.

Cyclamates were banned after the results of just two studies were released yet after multiple studies declaring them safe, the FDA stands behind their original decision. This suggests that the process to reverse a ban at this time is either more challenging than expected, or just not considered necessary. At the present time, a food additive petition was filed with the FDA to remove the ban on cyclamates, but this petition is currently being held in abeyance (not actively being considered). This would suggest that the FDA's concerns about cyclamate are not cancer related (18). In 1985, the National Academy of Sciences (NAS) reaffirmed the claim that cyclamates are safe for human consumption. At the present time, the FDA claims it will review the NAS report and other statistical data related to the daily intake of cyclamates (18). Since the current status of cyclamate review by the FDA appears to be moving at a minimal pace, if at all, it appears that the FDA does not see any urgency in the situation. Since there are already an abundance of alternatives to sugar available and many of the largest manufacturers are content with the alternative sweeteners they're using in their products now, there may not be a dire need to approve cyclamates at this time (18).

Sweet Choices

Real Sugar vs Artificial Sugar

Generally speaking, artificial sweeteners serve a positive purpose in the average American diet. There are several nutritive sugar alternatives, like high fructose corn syrup and sorbitol, and non-nutritive sweeteners that have no or few calories per serving (Table 1). One clear cut and obvious function of artificial sweeteners is that it allows consumers to consume less sugar.

A diet high in sugar or nutritive sweeteners is a large contributor of obesity in America and around the world. When sugar is digested, it is broken down and stored as energy in our body. The fact that artificial sweeteners offers sweetness outside of plain sugar, this allows individuals to limit our sugar intake. In terms of caloric content, non-nutritive artificial sweeteners tend to have little or no calories per serving. This can be an attractive option for consumers who are conscience of their caloric consumption and sugar intake.

An important advantage that artificial sweeteners have over traditional sugar is that they are an option for diabetics. When sugar is ingested, the body secretes insulin, a peptide used to breakdown sugar and promotes glucose absorption in the blood. However, when someone has Type 2 diabetes (most common type in the U.S.) their cells do not respond properly to the insulin or there is just not enough insulin being produced. As a result, glucose is not absorbed properly and if blood glucose is not regulated, severe complications can result. Therefore, artificial sweeteners allow diabetics to enjoy most of the foods non-diabetics enjoy because they are made without any sugar, thus improving the quality of life for many Americans suffering from this disease.

Another significant health benefit to using certain sugar substitutes is that they do not contribute to tooth decay. Many dentists recommend sugar-free gum and sweets over snacks containing sugar for their advantages in terms of oral health. Acesulfame potassium and sorbitol are two examples of sweeteners used to give gum their sweet flavor without the use of actual sugar. Since these sweeteners contain no sugar, they do not cause tooth decay. In fact, chewing sugar-free gum is thought to decrease the bacteria responsible for tooth decay. Xylitol, a sugar alcohol, is a relatively newly marketed ingredient in dentist-approved chewing gums.

High-fructose corn syrup

The most common form of sugar used in processed foods in the U.S. today is high-fructose corn syrup. High-fructose corn syrup is used in many popular soft drinks and highly processed snack foods. Many scientists and nutritionists agree that high-fructose corn syrup can be potentially harmful, even more so than sucrose when consumed in high doses. In addition, many nutritionists believe that there is not enough data conducted on the long term effects of high-fructose corn syrup consumption. HFCS is an attractive sugar substitute for food companies because it is cheaper to process and has a longer shelf life than sucrose. However, it is believed that HFCS is a significant contributor to obesity and its moderation in the diet is recommended.

Other nutritive sweeteners.

Some other nutritive sweeteners available besides sucrose are agave nectar and honey. Agave nectar is extracted from the agave cactus and has a similar consistency to honey. Unlike honey however, it does not contain as many antioxidants. Agave nectar has been shown to reduce insulin sensitivity from beta-cells in the pancreas. Honey, unlike most sweeteners, contains vitamins and minerals. Studies also suggest it does not raise blood sugar levels quickly which can help maintain a basal metabolic rate. Both honey and agave nectar have a high caloric content and should be used in moderation by those concerned with their weight.

Table 1. Artificial Sweeteners Today (2014)

	Calories/t easpoon	Sweetness (compared with sugar)	Market Distribution	Comments
Non-nutritive				
Alitame	0	2,000x	Soft drinks, typically mixed with other sweeteners	Structurally similar to aspartame, derived from alanine
Aspartame	0	200x	Soft drinks, yogurt, gum	controversial opinions on health effects
Saccharin	0	200-700x	Soft drinks, canned goods, candy	Linked with bladder cancer, food labels usually contain warning
Rebiana (truvia, stevia)	0	150x	Diet drinks, individual packets (truvia)	Derived from staevia plant
Acesulfame potassium	0	200x	Soda, gum, gelatin	Distributed for 22 years, no current health concerns

Cyclamates	0	30-50x	None in US	Banned by FDA
Neotame	0	7,000-13,000x sweeter than sugar	Soft drinks, yogurt, frozen goods	Produced by same makers as aspartame
Advantame	0	20,000x	Gum, candy, soft drinks	Newest artificial sweetener on market
Monkfruit (nectresse)	0	150-200x	Herbal tea, soup	Extract from monk fruit, indigenous to China
Sucralose	1	600x	Canned fruit, fruit drinks	Not approved in US
Neohesperidine	0	1,500-1,800x	Alcoholic drinks, toothpaste	
Nutritive				
Sucrose	16	Sugar	Added to sweets, such as candy, baked goods.	Naturally found in fruit/real sugar cane
Agave nectar	20	200-300x	tea, cereal	similar to honey, extracted from agave cactus
High fructose corn syrup	17	Similar to sugar	cereal, soft drinks	cheaper than sucrose, long shelf life
Honey	21	1.5x	Cereal, baked goods, tea	Trace amounts of mineral and vitamins
Sugar alcohols				
Sorbitol	10	About the same as sucrose	Sugar-free candy, gum	Sugar free alternative to candy, does not cause tooth decay
Erythriol	0.2	70% as sweet as sugar	Fermented with glucose, yeast	Typically mixed with stronger sweeteners
Isomalt	2	About the same as sucrose	yeast, baked goods	derived from sugar beets
Maltitol	2	75-90% as sweet as sucrose	Nutrition bars, chocolate	Daily intake should not exceed 100g
Lactitol	24	About the same as sucrose	Probiotics	Derived from Lactose
Mannitol	1.6	50% as sweet as sugar	Baked goods	Not absorbed well by the body
Xylitol	2	150-200	Dairy products, gum	Derived from corn

Non-nutritive sweeteners

Sucralose is commonly used in products such as Splenda. Sucralose is about 600 times sweeter than sugar but may also contribute to negative biological responses in the gastrointestinal tract. Various studies have linked sucralose ingestion with reduction of “good-bacteria” that live in the gut and assist in digestion. Rebiana, extracted from the leaves of the stevia plant, is commonly referred to as its brand name Truvia and is sold in both packets and diet drinks. However, studies have linked Rebiana with DNA damage. Acesulfame potassium is marketed under the names Sweet one and Sunett. Ace K is typically mixed with other sweeteners on account of its bitter after taste. Ace K has been shown to decrease insulin sensitivity from the pancreas in rats but is considered safe for consumption by the FDA and European Union. Neotame, along with aspartame is in the compound sold as Nutrasweet, the no calorie artificial sweetener. Neotame is considered safe by the FDA and EU due to lack of substantial evidence to cause bodily harm. Neohesperidin (NHDC) was discovered in 1960 and is 1500-1800 times sweeter than sugar.

With a long shelf life, NHDC can be stored for up to five years and still be used making it an attractive option as an artificial sweetener. To date, NHDC has not appeared on the FDA's list of foods Generally Recognized as Safe.

Saccharin

Saccharin was one of the first widely distributed non-nutritive sugar substitutes used in America. Products such as Sweet n Low and Coca-Cola use either granulated saccharin or a combination of saccharin and aspartame as the main source of sweetness in their products. Saccharin is unique in both the scientific and industrial community in terms of its history. Despite a polar legal status today, there are some similarities between saccharin and cyclamates. For example, like cyclamates, saccharin was attracting negative attention from the FDA and the scientific community when experiments began to suggest that long term exposure to saccharin was leading to bladder cancer in rats. As a response, the FDA attempted to ban the substance in the early 1970's however the effort proved unsuccessful on the grounds of public and scientific support. Today saccharin is the third largest selling sugar substitute worldwide. Some of the more recent studies suggest that saccharine may affect the bacteria in the gastrointestinal tract. Rats given saccharin in their drinking water began to develop an intolerance for glucose whereas rats provided drinking water with just glucose experienced no such side effects. The glucose-intolerant rats were then given antibiotics and as a result, their tolerance for glucose returned (11). These results suggested that continuous saccharin consumption disrupted the microbiome somehow, possibly by altering the catalyzing abilities of bacteria in the gut. Studies such as this have suggested that perhaps these effects can hint towards more serious conditions such as metabolic syndrome, however there is not enough conclusive evidence at the moment to support such claims.

Cyclamate

Although the cyclamate remains banned in the United States, there are over 100 countries in the world - including many European countries – that use cyclamate extensively as a sweetener for many foods and drinks (8).

In the United States, the commonly used artificial sweetener Sweet n' Low contained the previously mentioned 10:1 ratio of saccharin to cyclamate until the FDA ban forced the company to remove cyclamate from their product. Today, there are many worldwide name brands that use cyclamate such as Sugar Twin (Canada), Assugrin Hermesetas, Suitli, Sucaryl, Chuker, SARL, Cologran, Novasweet, Rio, Sweet N' Low (Canada). Although these brands seem unknown, in their respective countries they are the very popular and widely recognized.

Advantame

The newest addition to the list of artificial sweeteners is Advantame. Advantame was approved by the FDA in May 2014. Advantame is a chemical derivative of aspartame, which is synthesized by the amino acid phenylalanine. One advantage advantame has over aspartame is that unlike aspartame, advantame is stable enough to cook with and will not degrade prematurely like aspartame. This can open up a new realm of use in terms of food distribution. The FDA's

approval grants the use of advantame in sugarless gum, drinks, dairy products, and other flavor enhanced products. According to various studies, advantame appears to be much less toxic than what some believe aspartame to be. Advantame also does not resemble the amino acid phenylalanine. People suffering from phenylketonuria, the inability to break down phenylalanine, must avoid substances containing the amino acid including aspartame. Since advantame does not resemble the amino acid's molecular compound, this opens up a new demographic of consumers who can now enjoy a wider range of sugar-free foods.

Due to its versatility and clean track record to date, it is a likely possibility that advantame will replace aspartame as the primary artificial sweetener of choice. It would not be surprising that aspartame will be viewed as not as desirable to that of advantame. However, since it is new, the transition to advantame will take some time to be incorporated into products and this product ingredient switch will prove costly to manufacturers. .

The approval of advantame can be a positive indirect force on the approval for cyclamates. While the long term health effects of advantame can be studied further, the reappraisal of cyclamates can serve as a buffer period to allow large distributors to maintain sales and product distribution. It is unclear what the future will hold for the use of products like advantame, but it appears that the decline in popularity of aspartame is a slippery slope and at this point may be non-redeemable.

Aspartame

Aspartame is one of the most common artificial sweeteners used today in the United States. Brand name products such as Equal and NutraSweet both use aspartame as their primary sweetening compound. Aspartame was approved as a sugar substitute in the early 1980's by the FDA as a drink sweetener and dry food additive. Since its introduction to the US market, some believe that aspartame can be linked to several negative health effects including depression, weight gain, insomnia, fatigue, and cancer.

Shortcomings of Aspartame

Despite its widespread distribution and approval, there is evidence that supports the long term negative effects of prolonged ingestion of aspartame. Aspartame can cause damage in the brain by over stimulating sensitive neurons. Shortly after ingesting aspartame, high levels of activity in neurotransmitters occurs. This over stimulation can cause an influx of calcium and other ions into the cell which can cause high levels of instability and free radicals which damage the cell. These harmful molecules then travel all throughout the body causing multifocal cellular and tissue damage. Thus, there is reason to believe that over exposure to aspartame for long periods of time can be linked to neuronal degeneration. This risk is especially prevalent in children whose brain is still developing. The blood brain barrier in the brain effectively blocks substances from entering the brain, however, with a child's blood brain barrier not fully developed, this can leave them especially susceptible (9).

To support this theory, there are several imposing toxicology studies conducted in recent years that have reignited the concerns of the possible link between aspartame and cancer. One such

study conducted in 2005 involved treating rats with aspartame, starting from the 12th day of fetal life, showed a higher than expected rate of leukemia, lymphoma, and breast cancer (10). These and similarly reported findings should be thought provoking especially among the younger population with developing gastrointestinal organs. Although studies involving humans are limited, there is still an important element of awareness and precaution that should be taken when ingesting foods containing aspartame. Despite these findings, the current situation in the United States is that the FDA stands firm in the position that aspartame does not have toxic effects on humans when ingested.

Movement to Steer Away from Using Aspartame

Since its approval in 1981, there has been a growing concern among the population that aspartame is carcinogenic and people do not want it added in their food. Aspartame, however, is one of the largest sugar alternatives in the United States today. The use of aspartame has grown beyond just sugarless gum and products and is now used in a variety of medicines, food, and beverages. In 1981, the U.S. commissioner of Food and Drugs approved the use of aspartame despite suggestions by the FDA not to do so. Overruling the Public Board of Inquiry, Section 409(c)(3) of the Food Drug and Cosmetic Act (21 U.S.C. 348), which says that a food additive should not be approved if tests are inconclusive.

Overtime, and despite a forceful approval, the public opinion of aspartame and products containing aspartame has been on the steady decline.

<https://www.facebook.com/aspartamedanger> is a facebook page used to express the public's feelings towards aspartame and has the support of over 8,000 likes. The page is a collection of documents, suggestions, and a place where committed activists can show their support and help raise awareness towards their concern towards aspartame. Several petitions also exist which demand that products containing aspartame have some sort of warning or label so the consumer is aware of the contents of their products and can have a conscious mind when purchasing food at the store. <https://www.change.org/p/fda-say-no-to-hidden-aspartame-chemicals-in-milk-other-dairy-products> is an example of a petition that insisted that dairy products that contain aspartame should be forced to mention this on their label. The petition is now closed, but it gained the support of over 23,000 signatures. These large numbers suggest that many people have a negative attitude towards aspartame. It is important for a consumer to be fully aware of the products that they choose to purchase for themselves and their families. Just the simple fact that distributors do not want to label the contents of their products suggest that people may think twice about purchasing a food product if they knew it contained aspartame. This of course is alarming to some food distributors as their foods contain contents that may be considered harmful to consumers.

On the other end, International Food and Dairy Admin. (IFDA) and the National Milk Producers Federation (NMPF) have issued petitions to the FDA with the intention of not mentioning any artificial sweeteners in their milk products. Low fat and fat-free milk are growing in popularity especially in the younger population as obesity is on the rise. In an effort to lower the calorie content of school lunches, low and fat free milks are becoming a popular choice among children. Sugar does not usually come to mind when one thinks of milk, however in order to make low fat milk more enjoyable, artificial sweeteners and flavors are added in addition to sugar. The

purpose of one particular petition was to persuade the FDA to allow the use of artificial sweeteners in dairy products without the need to label them in the product. This can be considered very deceitful as it purposely promotes ignorance among the consumer when they purchase their dairy products because it allows the use of artificial sweeteners such as aspartame to be used in milk without the consumer knowing.

<https://www.federalregister.gov/articles/2013/02/20/2013-03835/flavored-milk-petition-to-amend-the-standard-of-identity-for-milk-and-17-additional-dairy-products> is a link that allows the public to state their opinion on the petition conjured up by the IFDA and NMPF on their desire to not mention the use of sweeteners in their dairy products. As a result of the IFDA and NMPF's petition and the petition's counter-part, the FDA responded in April 2013 allowing the public to comment their concerns and beliefs on what the potential change in food labeling would mean for them. They stated that they wanted the public to be informed on both sides of the argument and that their feedback would be considered when responding to the petition. To find out more on the matter, visit the FDA's update page and search for Docket No. FDA-2009-P-0147

In May 21, 2013 the FDA responded to the public's comments and the petition proposed by the IFDA and NMPF stating, "NACCHO does not support amending the standard for identity for milk to allow use of non-nutritive sweeteners in dairy products without a nutrient content claim on the label". The National Association of County and City Health Officials (NACCHO) argue that in order to promote well informed health and consumer choices, it is paramount that all of the contents within a product are labeled and easy to read and identify (19).

Many other formats for public awareness such as <http://www.nationofchange.org/aspartame-new-name-same-health-risks-1403190778> are gaining support in their message. Here, the author explains that it is important for consumers to understand that although aspartame has had its name changed to "Aminosweet" it is still important to understand that it is the same chemical compound as aspartame. The audience this article is trying to reach is fairly general but is most likely geared to younger consumers who are now just becoming lucrative contributors to commercial and food markets are not necessarily familiar with the history or current negative press associated with aspartame. Thus, it is important to inform all consumers, especially young adults who are surfacing as the new generation of consumers, the importance of food content and labeling associated with potentially toxic artificial sweeteners such as aspartame.

With the growing support of more informative food labels and the negative opinion of the most widely used sugar alternative today, the idea of a safe sugar substitute would be ideal. This is a huge advantage to allowing cyclamates to be used again as it will allow people to still enjoy some of their favorite foods without the toxic effects associated with products such as aspartame.

Community Action: Gaining Support for the FDA's Approval of Cyclamates

It is our objective to encourage the FDA to lift their ban on cyclamates. To do this, we feel that if we have big companies such as Pepsi and Coca Cola to lobby the FDA, it may be enough public and commercial pressure to encourage the FDA to reconsider the petition proposed by Abbott labs to lift the ban on cyclamates. In 1973, Abbott labs, the creator of cyclamates proposed a petition to lift the ban on cyclamates. After 7 years, the petition was rejected. In

1982, Abbott labs submitted another petition backed with scientific evidence requesting the ban on cyclamates to be lifted. The FDA responded to the petition stating that although scientific evidence concludes cyclamates are not carcinogenic in lab rats, the ban would not be lifted. To date, there has been no further response from the FDA with regards to the Abbott petition (18).

As of November 18, 2014 the petition by Abbot Laboratories titled as FAP 2A3672 to lift the ban on cyclamate is currently held in abeyance. This means that after review, the Office of Food Additive Safety (OFAS) has found the petition to be deficient. According to the OFSA, once all the information required to address the deficiency or deficiencies is provided, a petition will be refiled and assigned a new filing date. Abbott Laboratories stated that there is no new information on the status of the petition and that it is still in abeyance.

At the present time, we are preparing to contact several of the most popular food and beverage distributors in the country and bring to their attention the current negative opinions via signed petitions and Facebook links on the use of potentially toxic and disliked additives such as aspartame. By informing these companies of the strong following against the use of aspartame, this will hopefully open the floodgates and invigorate a new found interest in cyclamates, which will hopefully be a step towards lifting their ban. We hope that these large manufacturers rally for the re-approval of cyclamate and write to the FDA in support of providing another artificial sweetener to be available for American consumers.

We have sent the letter below to:

Muhtar Kent
Coca-Cola CEO
THE COCA-COLA COMPANY
P.O. BOX 1734
ATLANTA, GA 30301, USA
800.438.2653

Marvin Eisenstadt Chairman Cumberland Packing Corp
Corporate Headquarters
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Indra Nooyi
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Ken Powell
General Mills, Inc.
P.O. Box 9452
Minneapolis, MN 55440

763-764-8330

Lisa Borgen
American Crystal Sugar Company
Corporate Office
101 North 3rd Street
Moorhead, MN 56560
Tel: 218-236-4400

Jeffery Bender
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
1-888-INFO-FDA (1-888-463-6332)
Contact FDA

John Mackey
Whole Foods Co CEO
550 Bowie Street Austin, TX 78703-4644

Feb 18, 2015

To whom it may concern,

Advantame is the newest sweetener on the market that the FDA approved in May 2014 for use in the food and beverage industry. The Ajinomoto Company of Japan is the only company that produces Advantame as it holds the patent for its production. This new sugar is made from a combination of aspartame and vanillin (the main component of vanilla). Advantame is 20,000 times sweeter than sucrose (table sugar) but with no caloric content. Currently, the production of Advantame is still in the beginning stages as the FDA only recently approved it, and major companies such as yours are still weary of its usage. With the public opinion of aspartame declining, it is hard to tell how the public will react to Advantame – a substance made from aspartame.

A sales representative at Ajinomoto recently (Jan 2015) told us that there are a few major companies looking into using Advantame in their products but no official contracts have yet been signed. He explained that the names of these companies are confidential, but he did say that there are a few major gum and beverage companies that are very interested in the product. Also, there is a small beverage company based in California that is in the process of using Advantame in their chocolate milk, but the name of this company is also confidential until the company formally announces it. Should these contracts be signed, the predicted full-scale roll out of Advantame into the consumer market is expected to be somewhere around the second half of 2015.

Currently, the cost of Advantame is \$8250/gram on Alibaba.com, but this is sold via a third party that is not affiliated with the Ajinomoto Company, so this is not likely the wholesale price. Since

the production of this new sugar is not optimal, it is relatively expensive as supply is low. While the production and worldwide opinion of Advantame is still in the beginning stages, it may be a smart strategy to use cyclamate in the meantime, as it is currently much cheaper at just \$1500/Metric Ton. We have been exploring FDA's ban on sodium cyclamates in the US. Currently, cyclamates are widely distributed in 55 countries – many of them being Western countries. The Philippine FDA most recently approved cyclamate in 2013 in the Philippines. The public opinion of cyclamate is already established and its users in Europe and even in Canada can vouch for its efficacy and safety.

As you are aware, cyclamates are a non-toxic artificial sweetener that is 30 times sweeter than sugar. Invented in 1937, cyclamates were used in the US until their ban by the FDA in 1969 based off of the results of two field experiments that were considered crude among the scientific community. Since its ban, Abbott labs (cyclamates creators) and the Calorie Council have made several petitions in 1973 and 1982 attempting to convince the FDA to lift their ban on cyclamates. Along with the petitions, scientific data was also submitted to ensure the safety of cyclamate consumption.

As of November 18, 2014 the FDA holds the petition for the lifting of the ban on cyclamate in abeyance. This means that the Office of Food Additive Safety (OFAS) will not actively work on this petition because it has found the petition to be deficient. After contacting the OFAS, everyone we spoke to declined to comment on the reason behind the abeyance of the petition or the exact reasons why it was deficient. Abbott Laboratories also said that there is no new information about the status of the petition and that it is still in abeyance. Abbott Laboratories does not have the lobbying capabilities nor the political power that companies such as yours do, and with your help we can help push the FDA to uplift the ban.

The re-approval of cyclamates is important to companies like yours because there is a growing concern for the use of products containing aspartame and other artificial sweeteners that have been shown in some scientific studies to be toxic. The growing disdain towards products containing aspartame can lead to a significant loss of sales among your informed and health concerned consumer demographic. The approval of cyclamates will allow companies like yours to have access to alternative artificial sweeteners as the negative attitude towards aspartame grows. Below are a few links to some petitions and Facebook pages that allow consumers to express their thoughts towards aspartame products.

[-http://www.nationofchange.org/aspartame-new-name-same-health-risks-1403190778](http://www.nationofchange.org/aspartame-new-name-same-health-risks-1403190778)

[-https://www.federalregister.gov/articles/2013/02/20/2013-03835/flavored-milk-petition-to-amend-the-standard-of-identity-for-milk-and-17-additional-dairy-products](https://www.federalregister.gov/articles/2013/02/20/2013-03835/flavored-milk-petition-to-amend-the-standard-of-identity-for-milk-and-17-additional-dairy-products)

[-https://www.facebook.com/aspartamedanger](https://www.facebook.com/aspartamedanger)

[-https://www.change.org/p/fda-say-no-to-hidden-aspartame-chemicals-in-milk-other-dairy-products](https://www.change.org/p/fda-say-no-to-hidden-aspartame-chemicals-in-milk-other-dairy-products)

By pressuring the FDA to reconsider the petitions proposed by Abbott labs and the Calorie Council, we can meet the health needs of the consumer population as well as ensure the loyalty of your consumers with the satisfaction of delivering their favorite products free of aspartame.

Thank you for your time.

Kind regards,

Carlos Domingues, Alex Leybelman, and Julie M. Fagan, Ph.D.
Rutgers, The State University of New Jersey

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Letters to the Editor

Dear Editor of the Asbury Park Press,

Please consider my following statement for publication in an article in your newspaper. Imagine a sugar substitute that is nearly free of calories, tastes 30 times sweeter than sugar and is referred to around the world as the “magic sugar”. Sounds like an appealing product, thus surely you or I have experienced some sort of beverage or treat sweetened with this special sugar. Not entirely, at least not if you’re an American.

Sodium cyclamate is one of the most commonly used sugar substitutes in the entire world yet the United States is the only developed country which enforces a strict ban. Even our neighbors to the north enjoy their soft drinks sweetened with this artificial sweetener while were stuck with aspartame and equally unappealing options.

The natural question that comes to mind is, “Well why is this additive banned when clearly it is safe for consumption?” The reason is because studies in the late 60’s involving rats consuming cyclamate treatments resulted in a certain number of specimens ending up with cancer cells in the bladder. Shortly after this finding the FDA had banned the use of cyclamates in food and beverage products virtually removing them completely from our shelves. Members of the

scientific community however feel that the protocol in these experiments were flawed and that the FDA acted too swiftly on the matter. For one, the study showed that out of 240 specimens, only 8 developed cancer also, these results had never been replicated. In addition, the amount of cyclamate these rats were consuming were equivalent to 300-350 cans of soda a day for an extended period of time. Obviously consuming 300 cans of anything in a single day is not possible so these exposure levels cannot be replicated with humans.

Dr. Fagan of Rutgers University and myself plan on contacting Splenda and other companies of name brand sweeteners with the goal of informing them of the public disapproval of products containing aspartame as well as introducing them to the idea that cyclamates might be a more appealing option as an additive. With support from these companies and the public especially, it is possible to influence the FDA to consider lifting its ban on cyclamates so we can enjoy this “magic sugar” like the rest of the world.

If you would like to lend your support, views, or ideas, on this subject, please contact me.

Sincerely,

Carlos Domingues
Rutgers University
Senior

Dear Editor of the Daily Targum,

Please consider my following statement for publication in an article in your newspaper.

Sodium cyclamate is an artificial sweetener that is much sweeter than glucose, and much cheaper than saccharin (a commonly used sweetener), but is banned in the United States. The substance was banned from the US in 1969 after Dr. Jacqueline Verret reported that after injecting the artificial sweetener into chicken eggs, the chicks were born with defects. Later studies showed that after being given tremendous amounts of cyclamate daily for 105 weeks, some lab rats formed ulcers in their urinary bladder. However, Dr. Jacqueline Verret blamed the damaging effects on the chicks exclusively on cyclamate even though the solution she injected consisted of a 10:1 ratio of sodium cyclamate to saccharin. The results of the studies on lab rats are also skewed because the lab rats were given the equivalent of approximately 350 cans of soda per day!

Currently there are over 100 countries in the world (mostly Western) that use cyclamate in products such as soda, juice, cake, and various other foods. None of these countries have a population with an elevated level of cancer, nor is the percentage of children born with defects greater in any of these countries. In fact, most European countries have *lower* rates of cancer and birth defects as compared to the United States. Cyclamate was used in Sweet n’ Low in the United States in a 10:1 ratio as previously mentioned until it was banned. Currently, Sweet n’ Low in Canada still uses cyclamate and Canadians are relatively healthy.

The sweeteners that are most prevalent on the market today are high fructose corn syrup and aspartame. Saccharin is still relevant but its use is slowly decreasing. High fructose corn syrup is

degraded in the body much faster than sucrose (table sugar). The glycosidic bonds in HFCS are cleaved much easier by the enzymes in the body resulting in a huge spike in glucose concentrations in the blood. This excess glucose is then stored as fat in our bodies, eventually leading to obesity. Aspartame is fairly new to the market but extensive research is being done on it and results are showing that it can over-stimulate neurons in the brain, which can lead to brain degradation.

As you can see, the products that we currently use on the market are much more harmful than cyclamate - which has been banned unjustly and prematurely. By publishing this information, we can educate people about what manufacturers put in our food. Once people realize that sodium cyclamate is a much safer sweetener, companies will be forced to change the ingredients they use.

Sincerely,

Alex Leybelman