

## **CITIZEN PETITION**

(Date) 2/16/2013

2013 FEB 21 P 2:42

Division of Dockets Management,  
Food and Drug Administration,  
Department of Health and Human Services,  
5630 Fishers Lane, rm. 1061,  
Rockville, MD 20852.

This petition is filed in memory of Dr Harvey W Wiley, who tried to protect the United States Health from Toxic Food Additives, but unfortunately wasn't successful in protecting the public from Bleached White Flour and the decline in health it may have caused.

## **ACTION REQUESTED**

The undersigned submits this petition under Federal Food, Drug, and Cosmetic Act, to request the Commissioner of Food and Drugs to remove Bleached White Flour from the GRAS (Generally Recognized As Safe) list, and prevent its sale into the United States food system. This includes all chemicals used in bleaching flour, and any other food, including but not limited to Chlorine Dioxide, Benzoyl Peroxide, potassium bromide, chlorine gas and any other reactive chemical used for bleaching.

## **STATEMENT OF GROUNDS**

History

UNITED STATES V. LEXINGTON MILL & ELEVATOR CO., 232 U. S. 399 (1914)

Dr Harvey W Wiley took Lexington Mill & Elevator to court over bleaching of flour, as he felt that the process used to treat the flour introduced poison to the flour. At that time Nitrogen Peroxide was used as the main bleaching agent. It was known that the process used (the Agene Process) added a certain amount of

FDA-2013-P-0228

2013-1314

CP

nitrogen by-products to the flour, of which Dr Wiley felt were toxic principles, of uncertain identity. The case worked its way all the way to the Supreme Court.

The crux of the Supreme Court decision is follows, as stated in the case by the Justices:

"Applying these well known principles in considering this statute, we find that the fifth subdivision of § 7 provides that food shall be deemed to be adulterated "if it contain any added poisonous or other added deleterious ingredient which may render such article injurious to health." The instruction of the trial court permitted his statute to be read without the final and qualifying words, concerning the effect of the article upon health. If Congress had so intended, the provision would have stopped with the condemnation of food which contained any added poisonous or other added deleterious ingredient. In other words, the first and familiar consideration is that, if Congress had intended to enact the statute in that form, it would have done so by choice of apt words to express that intent. It did not do so, but only condemned food containing an added poisonous or other added deleterious ingredient when such addition might render the article of food injurious."

Back in 1914, Dr Wiley did not have the evidence that the addition of "1.8 ppm Nitrogen" was injurious to health. Lexington Mill and others were using Nitrogen Peroxide to bleach the flour, and since nitrates were used in other foods, the Court Erred in favor of the defendant, thinking that exposing flour to this chemical agent was not deleterious to health. I stated Erred, because the FDA subsequently (46 years later) outlawed using this Nitrogen Peroxide process (the Agene Process) in around 1950. This was after scientific evidence became available from a study conducted in Britain, that dogs fed this adulterated flour would become mad, and died of seizures.

Further, the proposition has been put forth that a decline in health, and an increase in mental illness that occurred in the United States population, may in fact have been caused by the consumption of this adulterated food product. [Did consumption of flour bleached by the Agene process contribute to the incidence of

neurological disease? ] Medical Hypotheses, Volume 51, Issue 6, Pages 477-481  
C.Shaw, J.Bains

Unfortunately in 1950, FDA also permitted a replacement process to be employed, using Chlorine Dioxide. This new bleached flour was deemed safe, as it did not cause madness in dogs, as did the Agene process with Nitrogen Peroxide. Unfortunately, it again appears that FDA did not require sufficient testing of this new flour as time has now begun to show. The Chlorine Dioxide process appears to result in the addition to the flour of at least 1 toxic chemical, Alloxan. It should be noted that an exhaustive google search was conducted to find primary research into what other contaminants are produced upon bleaching of flour, and no references were found.

Reports have arisen that Alloxan is one potential contaminant resulting from a reaction between Xantophyll in flour and Chlorine Dioxide gas. Alloxan is a potent poison, and is known to kill of pancreatic cells, and cause diabetes.  
(Dr Joe A. Schwarcz Director, Office for Science and SocietyOffice: 110  
Phone: (514)398-6238Email: [Joe.Schwarcz@McGill.CA](mailto:Joe.Schwarcz@McGill.CA))

This agent is used to induce pancreatic failure to simulate diabetes into animals for study. Referring back to the supreme court case of 1914, in which it appears that the flour was let into commerce because there wasn't enough evidence that the flour "might actually cause" anyone any problem, I believe the science is now clearer on the subject of Alloxan. In all likelihood, bleached white flour is causing a decline in the health of USA citizens. This bleaching in fact destroys many nutrients in the flour, yielding a nutritionally devoid product. After destruction of the natural nutrients, synthetic nutrients are added back into the mix, to try to make-up for the loss.

Based on the addition of know and unknown toxic constituents through the bleaching process of flour, Bleached White Flour is Adulterated, as defined by the Act, and needs to be withdrawn from market. In all probability it contains hundreds to thousands of unknown and untested chemical products, as a result of the chemical treatments employed.

To gather evidence that bleached white flour is harming health, there would need to be a study comparing 2 populations, which in most regards are quite similar, yet the main difference would be exposure of the population to bleached white flour. We are very fortunate in this regard, indeed. Much of Europe does not allow the bleaching of flour by any method. Their Food Safety Board found that Bleached

White Flour was probably deleterious to health, and upon finding that the Agene Process with Nitrogen Peroxide was toxic, outlawed all bleaching of flour. So we need to check on the health of Europeans to see if their health is any different then ours. Again we are very fortunate to have a study,

Health Affairs, 26, no. 6 (2007): w678-w686 Differences In Disease Prevalence As A Source Of The U.S.-European Health Care Spending Gap  
Kenneth E. Thorpe, David H. Howard and Katya Galactionova

Arthritis

U.S.: 53.8%

Europe: 21.3%

--

High blood pressure

U.S.: 50%

Europe: 32.9%

--

Heart disease

U.S.: 21.8%

Europe: 11.4%

--

High cholesterol

U.S.: 21.7%

Europe: 19.6%

--

Diabetes

U.S.: 16.4%

Europe: 10.9%

--

Cancer

U.S.: 12.2%

Europe: 5.4%

--

Chronic lung disease

U.S.: 9.7%

Europe: 5.4%

Indeed US Citizens are less healthy then our European, bleached flour free counter parts. The agency should take special note of the fact that US has an unexplained rising diabetes rate, and that for those over 50 years old, the rate is approximately

50% higher for those older US residents, then our European counter parts. Since it is logical that the damage done by consuming Bleached Wheat Flour is cumulative, the damage would be most pronounced in the older population, as it appears.

The problem with bleaching of any food is based on organic chemistry. It is known that when a strong chemical reactant ie chlorine dioxide reacts with a complicated organic molecule, many different offspring chemicals are produced. Organic substrates have multiple locations for highly reactive molecules to attach and rearrange. In the case of wheat flour, when chlorine dioxide reacts with the 100's of natural entities in the flour, potentially thousands of offspring chemicals are produced. A review of the literature reveals that proper analysis of these chemicals has not been done. Of these thousands of chemicals, many are potentially toxic, and some potentially carcinogenic.

Unlike the addition of a single agent to food, which can be comprehensively tested, and then permitted, and restricted, when strong reactants are permitted to be added to food, where potentially thousands of reactions occur, the safety of consuming this food cannot be determined with any confidence.

Further there is evidence that when chlorine gas is used to disinfect water, disinfection by-products are produced. Several classes of disinfection by-products have been identified, Trihalomethanes , Haloacetic acids, Chlorite. These families of chemicals each contain a multitude of chemicals, all of which are suspect in cancer. In the case of water disinfection, minute amounts of organic material dissolved in the water react with the chlorine gas, and produce many different halogenated organic compounds. Some of these compounds are known to the EPA as carcinogens, mutagens, and have other toxic effects. Since this reaction occurs with minute amounts of dissolved carbon compounds in water, the amount of these same and similar compounds in flour might be exponentially higher, since the quantity of organic material available for reaction is exponentially higher. Yet EPA has put limits on the amount and species of these contaminants in the water supply. Is FDA's position that these or other contaminants are not produced? What science is this based on?

It is necessary to point out that according to the in the study previously cited, the United States appears to have a cancer rate over twice as high as Europeans over 50 years old. Could this increase in cancer be due to the consumption of Bleach White Flour in the USA, and not in Europe?

Residues- One unconvincing argument used by the industry to support its use of chlorine dioxide in bleaching is that there is "no chlorine dioxide left in the flour after processing". This argument is scientifically invalid. While it may be true that negligible chlorine dioxide can be found upon analysis, this would be the expected result since nearly all the chlorine dioxide would react with constituents in the flour to produce a multitude of chemical offspring. It is these offspring that are the problem, not the chlorine dioxide per say.

A search of the link on FDA's website for Toxicological Research for data regarding the compounds produced in bleached white flour comes up empty handed. With Bleached White Flour being one the top agents added to food in the USA, according to quantity consumed, could it be that no science exists to the chemicals produced when flour is exposed to chlorine gas? It appears so.

The petitioner requests the FDA, to produce a listing of all known chemicals produced when chemically reactive Chlorine Dioxide, or other bleaching agents are introduced into Flour. Further FDA should produce all toxicological data on all the chemicals in this list. Since it appears this has not been completed, or even started, petitioner requests the removal from the market, of all Bleached White Flour, as soon as possible, in an orderly fashion.

## **ENVIRONMENTAL IMPACT STATEMENT**

The action requested by this petition qualifies for a categorical exclusion under 21 CFR 25.31(a) Therefore, it is submitted, an environmental assessment is not required.

## **ECONOMIC IMPACT STATEMENT**

Pursuant to 21 C.F.R 10.30(b), information on the economic impact of this action requested by this Petition will be submitted if requested by the Commissioner.

It should be noted that the cost to the consumer of this action is expected to be small, and maybe negligible. Since Europe does not allow any bleaching of flour, we could look to the price of flour in Europe to find what cost might be associated. It is not believed that flour is priced much different in Europe then in USA.

## CERTIFICATION

The undersigned certifies that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner, which are unfavorable to the petition.

  
(Signature)

Douglas Barasatian, Pharmacist, Petitioner

[REDACTED]

[REDACTED]

[REDACTED]

Douglas Barasatin

[REDACTED]  
[REDACTED]

U.S. POSTAGE PERMIT NO. 100

ROCKVILLE, MD 20852



**CITIZEN PETITION**

(Date) 2/16/2013

Division of Dockets Management,  
Food and Drug Administration,  
Department of Health and Human Services,  
5630 Fishers Lane, rm. 1061,  
Rockville, MD 20852.

.....|||