

Regulatory Concerns and Issues on the Rise in 2009



- No matter what your position in the grain-based foods industry—baker, scientist, or product developer—it is imperative that you stay current with emerging issues. This article offers a baker's perspective on the inclusion of several controversial ingredients which have garnered much attention in 2009.
- As new research evolves and as the demographic of our customer base continues to change, so does the evolution of emerging issues that may keep you awake at night, including new regulations on existing ingredients and health concerns raised regarding compounds that have been around for decades.
- Does the marketing mayhem that erupts from the use of undefined terms in the industry and the marketplace, such as “natural,” drive you into a frenzy? If so, read on ...

T. COGSWELL
BakerCogs, Inc.
Olathe, KS, U.S.A.

When writing about emerging issues, there is always one concern: by the time the article is published, will the list of emerging issues be out of date? As new research evolves and as the demographic of our customer base continues to change, so does the evolution of emerging issues that may keep you up at night. Does the Maillard reaction that gives your product that wonderful, foxy reddish-brown color on your potato bread cause concern for the formation of acrylamide? Are you trying to compete in the undefined world of “natural”? As scientists, we must stay up to date on the scientific and regulatory happenings on issues and events that affect our products. While I do not profess to have all of the answers pertaining to the issues of concern for today's cereal-based foods industry, I will attempt to provide some insight from a baker's perspective.

Acrylamide

In April 2002, the Swedish National Food Administration and Stockholm University announced the discovery of acrylamide in various processed foods (1). The results mainly focused on potato and cereal products that have been fried, baked, or deep fat fried. Since that time, researchers around the world have focused on the measurement of acrylamide in individual foods, as well as in the total diet, assess-

ments of health risks, and methods to mitigate acrylamide formation in food preparation.

The top ten list of foods of concern, as it pertains to acrylamide, includes breakfast cereals, potato chips, and soft bread. The cereal-based foods world needs to be aware of the issues, so that they can be prepared in case any of their products contain unsuitable levels. The addition or substitution of certain ingredients in the product formula can affect the levels of acrylamide in the final product. Some of the ingredients studied include the addition of asparaginase enzymes, the replacement of ammonium-based leaveners with sodium- and potassium-based systems, and the reduction of sugars (e.g., glucose, invert sugar, fructose, or honey) with sucrose.

The U.S. Food and Drug Administration (FDA) and the U.S. Department of Health and Human Services (HHS), in the August 23, 2009, Federal Register (Docket No. FDA-2009-N-0309) (5), published the notice entitled “Acrylamide in Food: Request for Comments and for Scientific Data and Information.” While FDA requested that comments and scientific data and information be submitted by November 24, 2009, industry has requested an extension to that date. The HHS National Toxicology Program (NTP) announced the release of acrylamide testing results in various food products. The results, intended for release in mid-October, had not been released by the end of October (and the writing of this article). Industry is asking for the comment extension so that the results of the NTP can be factored into the comments. Updates on this subject can be found at www.fda.gov by searching for the key term “acrylamide”; to find results of the NTP testing go to <http://ntp.niehs.nih.gov>.

Potassium Bromate

Many of you will see potassium bromate on the list of emerging issues and say, "Not again!" or "Still?" In either case, you would be correct. The issue with potassium bromate is that the FDA did not want potassium bromate to be the first of prior sanctioned ingredients to be banned. Working in conjunction with scientists from the Yamazaki Baking Company in Japan and the American Bakers Association, the FDA approved the industry guidance document that was released in late 2008. The document provides the guidelines for proper use, testing, and monitoring for those end-users who choose to continue to use this amazing oxidation agent. Monitoring should begin in the product development stage and continue to ensure that the finished product falls within the guidelines of <20 ppb. Yes, that is billion with a "b." The testing will include the high performance liquid chromatography (HPLC) method, which is highly accurate to 3 ppb. The "quick test" is based on chemiluminescence and is accurate to >20 ppb. The HPLC method should be utilized during development and start up to ensure that the laboratory parameters are being met in the production process. Once that is confirmed, then the quick test can be used to verify compliance during regular good manufacturing practice (GMP) checkpoints. The FDA has made it clear that it will continue to test finished products for compliance.

If you use potassium bromate and are unable to keep the residual level below 20 ppb in the finished product, there is assistance. The American Institute of Baking (AIB) is available to assist your company if you have compliance issues with the industry guidance document. AIB is a resource for inspections, training, and testing for any producer having residue issues with their finished product.

Potassium bromate is still alive and well for those manufacturers who are willing to follow the GMPs and work to keep their ppb of residue under 20. A full article on the industry guidance document was published in CEREAL FOOD WORLD in the September/October 2009 issue.

Azodicarbonamide

Azodicarbonamide (ADA) has long been used as a maturing agent in flour and also as a dough conditioner. Semicarbazide is found as the result of the thermal decomposition of ADA. The FDA linked ADA usage to the presence of semicarbazide in bread. Semicarbazide was detected with and without ADA on the label. This concerned the agency in light of the fact they believed ADA served as more than a pro-

cessing aid to the milling and baking industries.

At the 2008 AACC Intl. Annual Meeting in Honolulu, G. O. Noonan (4), FSAN, presented a paper as to the effect of ADA on loaf volume. The results lead to the conclusion that ADA has a positive impact on enhancing loaf volume and therefore serves as more than a processing aid in the bread-making process. The FDA issued a letter to the American Bakers Association in May 2008 indicating that ADA must be declared on the ingredient legend (*unpublished*). This mandate from the FDA prompted many bakers and millers alike to work to remove ADA from their formulas and processes. If not removed, manufacturers are now labeling this ingredient.

Diacetyl

Based on the use of butter flavorings containing diacetyl and their possible link to adverse health concerns, most notably lung disease and their use in food manufacturing, the Occupational Safety and Health Administration (OSHA) began an investigation earlier in 2009. The panel OSHA put together was a result of the Small Business Regulatory Enforcement Fairness Act (SBREFA) of 1996. This 1996 act requires the formation of a small business panel to understand the ramifications of potential legislation on small business. As a consultant that represents small bakeries and ingredient suppliers, I was asked to sit on this panel. The panel consisted of many types of small businesses, from popcorn to dairy to potato chips to flavors, and even a winery.

The two possible approaches and exposure ranges to managing the exposure to diacetyl and food flavorings containing diacetyl are: permissible exposure limit (PEL)—0.02 ppm for short term exposure (15 minutes) and 0.03 ppm for 8-hour time weighted average; and nonPEL—while there is no proposed regulation to date, one is expected in early 2010 (6). On the state level, California held a hearing on occupational exposure to food flavorings containing diacetyl in November. For more information, visit the California Department of Industrial Relations' website at www.dir.ca.gov/oshsb/Diacetyl.html.

Sodium

The FDA continues its discussions about legislation to enforce the reduction of sodium levels in food. Many companies have added sodium reduction to new product development processes in order to get and stay ahead of the curve. It was announced in October 2009 that ConAgra Foods, Inc. will reduce sodium in its food products by 20% by 2015. A spokesperson for ConAgra

says that work has already begun on removing 10 million pounds of salt out of American diets (2).

The concern is that for bakeries (and other protein-based foods), salt provides a functional effect on the protein and in the dough-making process. Salt aids in strengthening the protein in the dough matrix. While there may be an opportunity to reduce sodium in baked goods, to some extent, it needs to be understood that the functional effect creates a significantly different paradigm than reducing the sodium in soups or salty snacks. One thing that is for sure is that we haven't heard the last on sodium reduction.

Natural

From a regulatory perspective, the term "natural" remains undefined. However, according to consumer research, natural resonates with consumers more than the term organic (3). Many new product development introductions are utilizing the term "natural" to attract consumers to their category and product.

The quickest way to regulation is to push the envelope when marketing this type of product. One debate that recently played out in the media was whether high fructose corn syrup was natural in a soft drink. Is your company willing to have media exposure if it pushes the limits and gets called to task by one of the consumer watchdog groups? This is a question only your corporate marketing and legal departments can answer. But as scientists and regulators, it is our job to make the decisions makers in our companies aware of the risk.

Another approach many companies use to define "natural" is to use the Whole Foods Market's (1) list of unacceptable food ingredients. Included here is a partial list from their website: acesulfame-K (acesulfame potassium); acetylated esters of mono- and diglycerides; ammonium chloride; artificial colors; artificial flavors; aspartame; azodicarbonamide; benzoates in food; benzoyl peroxide; butylated hydroxyanisole (BHA); butylated hydroxytoluene (BHT); bleached flour; bromated flour; and brominated vegetable oil (BVO). It is ironic that ingredients covered in this article appear on this list.

The only thing certain on a given day is *change*. Given the wide range of topics discussed in this article, it is recommended that you keep your eyes and ears open for updates and possible new FDA guidelines or regulations on these topics.

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Theresa Cogswell, a graduate from the Department of Grain Science and Industry at Kansas State University, Manhattan, KS, U.S.A., began her professional career in baking as a research baker with the Continental Baking Company, now part of Caravan Ingredients. In 1992, Cogswell joined Interstate Bakeries. In 1994, she advanced to director of R&D, and in 1995, Cogswell was named vice president of R&D, serving for 15 years. In 2007, Cogswell began a consulting business to the baking industry, Baker-Cogs, Inc. She serves as executive director for a half-time position with The Baker's National Education Foundation. She also is on retainer with the American Bakers Association (ABA) and is on the editorial staff for *Baking and Snack* magazine. In 2006, she was elected the first woman chairman of the American Society of Baking. She also serves as president of the Society of Bakery Women and is a member of the AIB International Scientific Advisory Committee, ABA's Food Technical Regulatory Affairs Committee, AACC International, including the AACC Intl. Scientific Advisory Committee, IFT, and the Allied Trade in the Baking Industry. Cogswell can be reached at bakercogs@sbcglobal.net.

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