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August 25, 2000

Food and Drug Administration  
Dockets Management Branch (HFA-305)  
Docket No. 98N-0359  
5630 Fishers Lane  
Room 1061  
Rockville, MD 20852

**Re: Program Priorities in the Center for Food Safety  
and Applied Nutrition; Request for Comments  
65 Fed. Reg. 39415 (June 26, 2000)**

On behalf of the Center for Science in the Public Interest (CSPI), we appreciate this opportunity to comment on the Food and Drug Administration's (FDA) program priorities for the Center for Food Safety and Applied Nutrition (CFSAN) for the Fiscal Year 2001 (FY 2001). CSPI is a non-profit consumer advocacy organization focusing largely on nutrition and food-safety policies. We accept no industry or government funding and are supported almost entirely by the over 800,000 subscribers to our *Nutrition Action Healthletter*.

• **Food Safety:**

Foodborne illness causes as many as 5,000 deaths and 76 million illnesses annually.<sup>1</sup> Therefore, CFSAN's priorities for the upcoming Fiscal Year are of particular import, in light of CSPI's recent findings about that FDA-regulated foods caused nearly four times as many outbreaks as foods regulated by the U.S. Department of Agriculture.<sup>2</sup> By far, the greatest number of outbreaks

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<sup>1</sup> Centers for Disease Control and Prevention, "Food-Related Illnesses and Death in the United States," *Emerging Infectious Diseases*, Vol. 5, No. 5 (1999).

<sup>2</sup> Caroline Smith DeWaal et al., *Outbreak Alert! Closing the Gaps in our Federal Food-Safety Net*, (Washington, DC: Center for Science in the Public Interest, rev'd. 2000), p. I. Due to funding deficiencies, the

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were caused by seafood and eggs.<sup>3</sup> CSPI believes that improving egg and seafood safety should be among CFSAN's highest priorities. Specifically, we offer the following recommendations on CFSAN's priorities for FY 2001.

*Implementation of the Seafood HACCP.* Implementation of the Seafood Hazard Analysis and Critical Control Point (HACCP) rule has been very disappointing. Although the rule went into effect in 1997, it has never been widely implemented or adequately enforced. According to data presented by the agency earlier this month at the International Association for Food Protection annual conference, only a 24 percent of all seafood processing plants have adequate HACCP plans and are implementing them to their full extent.<sup>4</sup> Approximately 30 percent of all seafood firms inspected had inadequate HACCP plans or unsatisfactory plan implementation.<sup>5</sup> The remaining 46 percent of the seafood plants have no HACCP plan, although FDA believes that only 16 percent of those plants actually need a plan.<sup>6</sup>

The 1999 inspection data showed a number of other deficiencies in the seafood HACCP program implementation:

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Centers for Disease Control (CDC), has not published a foodborne-illness outbreak listing since the mid-1980's. To help fill this critical information gap, the Center for Science in the Public Interest (CSPI) has been maintaining its own inventory of food-borne illness outbreaks that occurred since 1990. CSPI has documented 865 outbreaks representing over 50,000 individual illness cases. Our information on outbreaks includes CDC data made available through the Freedom of Information Act, together with other outbreaks reported in medical journals, government reports, and news reports that are confirmed by state health departments. Due to reporting gaps throughout the system, CSPI's outbreak list represents only a fraction of all foodborne-illness outbreaks that occur. Still, CSPI's inventory has the best available data on foodborne-illness outbreaks in the U.S.

<sup>3</sup> Finfish and shellfish together were responsible for 237 outbreaks. Eggs and egg dishes caused 170 outbreaks, mostly from *Salmonella enteritidis* (SE). When the figures for SE outbreaks in multi-ingredient foods are added in, SE-related outbreaks rise to nearly 200. *Id.* at i, 34-39.

<sup>4</sup> Mary Losikoff, Compliance with Food and Drug Administration's Seafood HACCP Regulations, Presentation Before the International Association for Food Protection (Aug. 2000). The data were drawn from forms filled out by FDA inspectors and sent to the FDA Office of Seafood.

<sup>5</sup> *Id.* For example, the Food and Drug Administration inspection data reveal that 61 percent of all scombroid processors have key hazard control deficiencies in their plans. *Id.*

<sup>6</sup> *Id.* The Food and Drug Administration estimates that approximately 30% of all seafood firms do not need HACCP plans at all. Conversation with Don Kraemer, Food and Drug Administration, Office of Seafood (August 17, 2000). By contrast, the U.S. Department of Agriculture's Food Safety and Inspection Service has stated that virtually all meat and poultry plants must have HACCP plans: "FSIS is currently unaware of any meat or poultry production process that can be deemed categorically to pose no likely hazards." U.S. Department of Agriculture, Food Safety and Inspection Service, "Pathogen Reduction; Hazard Analysis and Critical Control Point (HACCP) Systems; Final Rule," *Federal Register*, Vol. 61, No. 144 (1996), p. 38824. The Food and Drug Administration should take a similarly aggressive stance on requiring HACCP plans in seafood firms.

- 71 percent of the smoked fish processors lacked adequate pathogen controls in their HACCP plans;
- 69 percent of the vacuum-packed fish industry lacked adequate pathogen controls in their HACCP plans;
- 63 percent of the cooked, ready-to-eat seafood firms lacked adequate pathogen controls in their HACCP plans;
- 66 percent of all seafood firms lacked adequate sanitation controls; and
- 53 percent of all seafood firms had problems with cross-contamination.<sup>7</sup>

These figures are deplorable. Improving them should be a high priority of the program.

The failure of the seafood HACCP program is likely attributable to the lack of pathogen reduction standards, microbial testing requirements and sufficient FDA inspections. Unlike meat and poultry plants, which have continuous on-site U.S. Department of Agriculture inspectors and two levels of mandatory product testing, the FDA made testing optional and its inspections of seafood plants are infrequent--dropping from 3,146 inspections in 1998 to 2,796 inspections in 1999.<sup>8</sup> CSPI strongly urges the agency to amend its HACCP rule to require mandatory laboratory verification and to make increased inspection frequency under the seafood HACCP program a priority for FY 2001.

*Methylmercury in Seafood.* This past July, the National Academy of Sciences (NAS) released a report concluding that more than 60,000 children born each year are at risk for neurological problems due to low-level methylmercury contamination from seafood eaten by pregnant women.<sup>9</sup> The new NAS report echoed concerns raised nearly a decade ago in a 1991 NAS report that was highly critical of the FDA's weak standard on methylmercury in seafood.<sup>10</sup> Unfortunately, the FDA has never revised its methylmercury action level even though, as far back as 1996, FDA officials told Congress that it was "imperative" that the agency's methylmercury

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<sup>7</sup> Losikoff, *supra* note 4.

<sup>8</sup>The number of FDA seafood HACCP inspections dropped from 3,146 inspections in 1998, to 2,796 inspections in 1999. *Id.*

<sup>9</sup> National Academy of Sciences, *Toxicological Effects of Methylmercury*, 276 (not yet published), available at <http://www.nap.edu/openbook/0309071402/html/276.html>. The FDA's biomarker and exposure levels for methylmercury are four times higher than the NAS specifically endorsed in its report.

<sup>10</sup> Center for Science in the Public Interest, *Letter and Petition to Set a Regulatory Limit for Methylmercury In Seafood That Reflects the Risk to Pregnant Women and Children From the Intake of Seafood Containing Methylmercury* (FDA Docket. No. 00P-1411/CP 1), (July 17, 2000).

action level be reevaluated and promised that the work would begin.<sup>11</sup> Therefore, it was highly troubling to see CFSAN drop the methylmercury risk assessment from an "A" list to a "B" list priority three days after the most recent NAS report was released.<sup>12</sup> The FDA must immediately begin to establish a regulatory limit for methylmercury that protects pregnant women and their unborn children. (See Attachment A). Further delay would be unconscionable.

*Shellfish Safety.* The agency's record on shellfish safety, particularly on measures to control the pathogenic strains of *Vibrio*, has been wholly inadequate. Since 1989, nearly 240 individuals have become sick or died from *Vibrio vulnificus* in raw molluscan shellfish. Further deaths and illnesses are unnecessary because various technologies exist to eliminate the pathogen in raw oysters.<sup>13</sup> The FDA has repeatedly looked to the industry-dominated Interstate Shellfish Sanitation Conference (ISSC) to resolve this problem, but this July, the ISSC voted to delay post-harvest treatment standards and other *Vibrio vulnificus* risk reduction measures for another year. Consumers can no longer afford to have the FDA defer to the ISSC. The agency has the authority--and the obligation--under the Public Health Service Act and the Federal Food, Drug and Cosmetic Act to protect consumers from these deadly pathogens.<sup>14</sup>

*Egg Safety.* CSPI has long been an advocate of mandatory national farm-to-table egg safety standards to address the public health threat of *Salmonella enteritidis* (SE) in raw or undercooked eggs. Therefore, we urge the FDA to implement and enforce mandatory on-farm SE controls that include environmental testing and diversion after an SE-positive result.<sup>15</sup> We also encourage the agency to finalize its proposal on the labeling and refrigeration of shell eggs sold at retail, consistent

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<sup>11</sup> *Inspection of Seafood Products, 1996: Hearings Before the Subcomm. on Livestock, Dairy, and Poultry of the House Com. on Agriculture*, 104th Cong. (1996) (testimony of Dr. Michael Friedman, Deputy Commissioner for Operations, Food and Drug Administration), available at <http://www.fda.gov/ola/1996/cfood.html>.

<sup>12</sup> Food and Drug Administration, Center for Food Safety and Applied Nutrition, "CFSAN 2000 Program Priorities: Accomplishments Through July 14, 2000," Encl. 3, available at <http://vm.cfsan.fda.gov/~dms/cfsan700.html>.

<sup>13</sup> Center for Science in the Public Interest, *Petition for Regulatory Action to Establish a Standard for Vibrio vulnificus in Raw Molluscan Shellfish of Undetectable Levels* (FDA Docket No. 99P-0504), (June 29, 1998).

<sup>14</sup> We understand that the FDA's risk assessment for *Vibrio parahaemolyticus* will be published soon. We look forward to the opportunity to review this risk assessment because, even though this strain of *Vibrio* is not as deadly as the *vulnificus* strain, it has caused a significant number of illnesses.

<sup>15</sup> See, Center for Science in the Public Interest, "Comments on Egg Thinking Papers" (FDA Docket No. 00N-0504), (Aug. 14, 2000).

with the requirements of the *1999 Food Code*<sup>16</sup> and sufficiently protective of public health.<sup>17</sup> These measures, taken together, will help to eliminate further illnesses and deaths from SE-contaminated eggs.

*HACCP Programs.* The FDA must strengthen all of its HACCP programs by requiring appropriate laboratory verification of product samples and by increasing the frequency of on-site visits conducted by its inspection staff. Both testing and inspections are essential to give the agency the appropriate oversight over the implementation of HACCP programs. Otherwise, the FDA's HACCP programs are little more than industry honor systems.

In addition to changes in the agency's seafood HACCP program mentioned above, we recommend the following changes to other FDA HACCP programs:

- Juice HACCP rule. The agency should finalize the HACCP rule for juices it first proposed in 1998. We believe the juice rule must include a mandatory heat pasteurization as a critical control point in all processing operations, regardless of the size and/or volume produced, until alternative pathogen reduction processes are proven to be as safe and reliable.<sup>18</sup>
- Dairy HACCP program. We urge the agency to propose a Dairy HACCP rule this year or, at the very least, to expand its Dairy HACCP program to more plants.
- Retail HACCP program. While the Retail HACCP program is now included in the 1999 FDA Model Food Code, this means little unless the FDA successfully encourages all of the states to adopt it.<sup>19</sup>

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<sup>16</sup> The 1999 Food and Drug Administration *Food Code* mandates a storage temperature of 41 °F or less for "potentially hazardous" foods. U.S. Department of Health and Human Services, Public Health Service, Food and Drug Administration, *Food Code*, (Springfield, VA: U.S. Department of Commerce, 1999), § 3-501.14.

<sup>17</sup> Department of Health and Human Services, Food and Drug Administration, "Food Labeling: Safe Handling Statements: Labeling of Shell Eggs; Shell Eggs: Refrigeration of Shell Eggs Held for Retail Distribution; Proposed Rule," Vol. 64, No. 28 (1999), p. 35494, [hereinafter cited as *Labeling and Refrigeration of Shell Eggs, Proposed Rule*]. See also, Center for Science in the Public Interest, "Comments on *Labeling and Refrigeration of Shell Eggs, Proposed Rule*" (FDA Docket Nos. 98N-1230, 96P-0418, 97P-0197), (Sept. 20, 1999).

<sup>18</sup> Furthermore, we call for pre-approval by FDA of any new technologies touted as equivalent to pasteurization before a company is allowed to use it as a replacement for heat pasteurization.

<sup>19</sup> In a separate matter (albeit not a "program priority"), CPSI is deeply concerned about the ongoing campaign by the restaurant industry to undermine important provisions of the Model Food Code--namely, the prohibition on bare-hand contact and the 41 °F refrigeration temperature requirement. We urge the agency to resist any efforts to weaken these standards.

CSPI believes that strengthening and expanding the agency's HACCP programs should be part of the agency's "A" list tasks this Fiscal Year.

*Listeria monocytogenes.* Despite repeated delays,<sup>20</sup> it is imperative that the FDA expeditiously complete its quantitative risk assessment for *L. monocytogenes* to identify the FDA-regulated foods most likely to harbor the pathogen, so that the agency can begin implementation of the *L. monocytogenes* action plan. We believe that the action plan must include a requirement for plants producing FDA-regulated foods at risk for *L. monocytogenes* (such as soft cheeses, pasteurized and unpasteurized milk products, seafood products and prepared salads) to test their environments and final products for the presence of the pathogen. Such testing is necessary to prevent further risks from foodborne listeriosis and to meet President Clinton's stated objective of cutting the number of illnesses caused by *L. monocytogenes* in half by 2005.

*Fruits and Vegetables.* The guidance published by FDA on voluntary good agricultural and management practices (GAP's and GMP's) to minimize microbial contamination of fresh fruits and vegetables is inadequate to protect consumers. For example, contaminated sprouts can cause serious and life-threatening illnesses, and the agency should move quickly to promulgate its recommendations as mandatory regulations for the safe production of sprouts. Unless the good agricultural practices, seed disinfection treatments, and testing requirements are made mandatory, some sprouters will likely continue to ignore FDA's recommended practices. The agency should include aggressive enforcement measures in the new regulations to promote compliance.

*Imports.* The need for tougher domestic produce standards is even more important because they serve as the measuring stick for exporting nations' food safety systems. If the U.S. standards are too lax, which we believe is true in the case of the voluntary produce GAP's and GMP's, then it becomes quite easy for exporting nations to claim that their standards are "equivalent". Since the consumption of both domestic and imported produce has grown in recent years, the agency should issue mandatory, stringent standards for domestic (and, by implication, foreign) fruit and vegetable producers. In addition, we urge the agency to conduct more on-farm inspections of foreign fruit and vegetable growers.

*Inspections.* Many of CSPI's concerns about FDA-regulated food products stem from the fact that CFSAN lacks direct control over a dedicated inspection force. FDA inspectors visit plants producing all types of FDA-regulated products, such as drugs, cosmetics, medical devices and foods.

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<sup>20</sup> It is unfortunate that agency decided to cancel the August 28, 2000, stakeholder meeting on the *Listeria monocytogenes* (*L. monocytogenes*) risk assessment, because the input of stakeholders would be valuable to the agency as it reexamines its methodology, data and/or conclusions. Moreover, the unwillingness of the agency to publicly reveal the status of, and concerns about, the risk assessment is inexplicable. In fact, it has been publicly stated that the draft *L. monocytogenes* risk assessment underwent internal review last December. U.S. Department of Agriculture, Food Safety and Inspection Service, Revised Action Plan for the Control of *Listeria Monocytogenes* for the Prevention of Foodborne Listeriosis, (May 2000), available at [http://www.fsis.usda.gov/OA/topics/lm\\_action.htm](http://www.fsis.usda.gov/OA/topics/lm_action.htm).

It is therefore difficult for FDA inspectors to develop an expertise in any one type of product or plant. It is equally difficult for FDA personnel to inspect food plants as often as they should. All too frequently, CFSAN's inspection priorities seem to be outranked by other priorities within the agency. CSPI strongly urges the agency to reorganize its inspection program so that CFSAN has its own inspection force and sufficient resources to allow them to fulfill their necessary duties.

- **Premarket Review of Additives & Ingredients**

*Genetically Modified Organisms.* CSPI supports the agency's decision to issue a proposed rule on genetically-modified foods; however, we believe that the proposal should be modified to create a fair, transparent, mandatory premarket approval or certification process, including an opportunity for meaningful public input.<sup>21</sup> CSPI, together with the Consumer Federation of America, sent a letter earlier this month to the FDA Commissioner outlining the measures we believe the agency should put in place. (Attachment B.)

*Improving the Premarket Review and Approval Process.* CSPI has had a longstanding interest in the agency's activities related to food and color additives. This past July, we submitted comments on measures the agency can take to improve its premarket review process for food and color additive petitions.<sup>22</sup> (Attachment C.) We propose the following as "A" list activities:

- Continued expedited review of food additives with antimicrobial properties against human pathogens;
- Expedited review of additives that make food more nutritious;
- New research on potential safety problems posed by new food and color additives;
- Re-evaluation of the safety of previously-approved food and color additives.

CSPI also recommends that the agency take immediate action on the specific food and color additives listed below:

*Olestra.* As per several CSPI requests since 1996, FDA should either ban olestra or require stronger, more prominent warning labels. The more than 18,000 adverse reaction reports must be given credence, especially in light of Proctor & Gamble's clinical studies demonstrating that Olestra

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<sup>21</sup> Letter from Michael F. Jacobson, Ph.D., Center for Science in the Public Interest, and Carol Tucker Foreman, Consumer Federation of America, to Dr. Jane Henney, Commissioner, Food and Drug Administration (Aug. 11, 2000).

<sup>22</sup> Center for Science in the Public Interest, "Comments on Improving Premarket Review and Approval of Food and Color Additives in the Center for Food Safety and Applied Nutrition" (FDA Docket No. 00N-1262), (July 19, 2000).

can cause gastrointestinal problems. The FDA should reject the industry's request to remove the label notice.

*Petitions.* The FDA also should act on other food additive petitions that have languished to date. Specifically, the agency should respond to petitions to restrict the use of, or require better labeling of, the following additives:

- Potassium bromate--causes cancer in animals;<sup>23</sup>
  - Carmine/Cochineal Extract--may cause severe allergic reactions in humans;<sup>24</sup>
  - Sorbitol--causes severe diarrhea in humans;<sup>25</sup>
  - Salatrim--causes gastrointestinal symptoms, sometimes severe, in humans.<sup>26</sup>
- **Food Labeling**

*Updating the Nutrition Label.* The Food and Drug Administration should promptly propose or finalize regulations to update the nutrition label:

- **Trans Fatty Acids.** A top priority for FY 2001 must be the issuance of a final rule on the nutrition labeling of *trans* fatty acids. The agency should require that *trans* fatty acids be counted as saturated fat on nutrition labels.

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<sup>23</sup> The FDA has known since 1982 that potassium bromate can cause tumors of the kidney, thyroid, and other organs in animals. Subsequent studies on rats and mice confirmed that it causes tumors of the kidney, thyroid, and other organs. On July 19, 1999, CSPI petitioned the FDA to ban bromate.

<sup>24</sup> Another year has passed without the agency issuing a proposed rule on the declaration of carmine/cochineal extract on ingredient listings. Since this food ingredient may cause severe allergic reactions, it is important for the agency to initiate a rulemaking to address this health hazard.

<sup>25</sup> In September 1999, CSPI petitioned the FDA to require foods containing one or more grams per serving of sorbitol or other sugar alcohol, such as mannitol, to carry a better warning label that the foods may cause severe diarrhea and are not suitable for consumption by children. Center for Science in the Public Interest, *Petition to Improve the Existing Warning Label on Processed Foods That Contain the Sugar Substitute Sorbitol*, (Sept. 27, 1999).

<sup>26</sup> Center for Science in the Public Interest, *Petition to the Food and Drug Administration on the Generally Recognized As Safe (GRAS) status of salatrim*, (June 19, 1998).

- Added Sugars. The FDA should require the listing of amounts of both total and added sugars content, along with the percentage of a newly designated Daily Value for added sugars.<sup>27</sup>
- Caffeine. In 1997, CSPI and academic experts petitioned the FDA to require quantitative labeling of caffeine, as well as to perform a scientific review of the health effects of caffeine to determine if stronger measures should be taken to protect the public from the adverse effects of caffeine.<sup>28</sup> The agency should take those steps without further delay.
- Other Food Additives. The agency should also require better labeling of food additives, such as MSG, that can cause health problems.
- Percentage-Ingredient Labeling. In 1995, CSPI urged the Food and Drug Administration to re-propose percentage-ingredient labeling requirements for baby food products, to include disclosure of the percentage of the characterizing ingredient(s) on the front label of baby foods as well as percentage labeling of all significant ingredients on the back label.<sup>29</sup> Subsequently CSPI petitioned the FDA to extend percentage-ingredient labeling to all foods.

*Labeling Claims.* Enforcement of the FDA's food-labeling requirements has waned in recent years. As a result, misleading claims on food labels are increasing. We urge the following steps to remedy this problem:

- Promptly propose regulations pursuant to the U.S. Court of Appeals decision in *Pearson v. Shalala* that require all health claims not supported by significant scientific agreement to state immediately before such claim, and in lettering as large and conspicuous as the claim, the following statement: "The Food and Drug Administration does not consider the following statement to be scientifically valid."

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<sup>27</sup> See, Center for Science in the Public Interest, *Petition for Proposed Rulemaking to Establish a Daily Value for "Added Sugars," to Require Nutrition Labeling of "Added Sugars," and to Make Corresponding Changes to Nutrient Content and Health Claim Regulations*, (Aug. 3, 1999).

<sup>28</sup> Center for Science in the Public Interest, *Petition*, (July 31, 1997).

<sup>29</sup> In 1975, CSPI petitioned the Food and Drug Administration to require the percent-ingredient labeling of baby foods, and the following year, the Food and Drug Administration proposed such requirements in a Notice of Proposed Rulemaking (NPRM). However, the agency never issued a final rule and in 1991, after two decades of inaction, the Food and Drug Administration withdrew the NPRM as part of a larger effort to clear its dockets.

- Immediately propose implementing regulations for the health and nutrition claims sections of the Food and Drug Administration Modernization Act of 1997. Those regulations should require public docketing of all health claim notifications and confirm that all health claims must be supported by significant scientific agreement. In addition, such regulations should specify that health and nutrition claims based on authoritative statements of other government agencies are limited to statements that were intended to constitute dietary recommendations.
- Cease approval of product-specific health claims for breakfast cereals and other specific foods. Such claims provide consumers with potentially misleading dietary advice that is not supported by the public health community.
- Resume strict enforcement of the law with particular attention to violations of section 403(a) of the Act, including misleading claims pertaining to ingredients such as whole wheat, fruits, and vegetables. Violations of the Act that cannot be handled by the FDA due to resource constraints should be systematically delegated to state enforcement officials.
- Close the food standards review initiative. The initiative is opposed by consumer organizations and some segments of the food industry. In an era of increasingly limited resources, such effort should be terminated.
- **Functional Foods**

*Enforcement.* The FDA should step up its enforcement of the food additive provisions of the law and prevent companies from adding dietary supplements and other ingredients to foods that are not Generally Recognized As Safe (or approved additives). Foods must not be allowed to masquerade as dietary supplements in order to avoid sections of the law pertaining to food additives.

*Structure/Function Claims.* The FDA should also respond to the report of the General Accounting Office on functional foods and issue regulations governing structure/function claims for such products. The agency should require that such claims be based on universally accepted statements of fact regarding the effect of a nutrient on the structure or function of the body. In addition, the FDA should apply to structure/function claims the nutrient qualification and disqualification levels that apply to health claims for foods. Lastly, the FDA should require companies to notify the agency of such claims at least 90 days prior to marketing.

- **Dietary Supplement Regulation**

The FDA is burdened with a weak law that limits the agency's authority to protect the public from unsafe and misleadingly labeled supplements. The agency should build a record detailing the need for greater authority and issue a report on the problems caused by the current law. In addition,

the agency should adopt a containment strategy that would help ensure that problems with the regulation of dietary supplements do not spread to the regulation of health claims for food or to the safety and efficacy requirements for drugs. The FDA also should revise its final rule on structure/function claims to prohibit claims identical to those used on over the counter drug labels.

- **International Affairs**

*Harmonization and Equivalency.* The FDA should encourage the Administration's trade policies to be not only consistent with the Federal Food Drug and Cosmetic Act, but also that they further the objectives of the Act. The FDA should ensure that public health takes precedence over trade concerns and should urge that international standards be harmonized upward. These factors should be taken into account as the agency finalizes guidance for equivalency determinations and when the agency takes positions on behalf of the U.S. government delegation to Codex meetings. The agency should also promptly respond to the recommendations of the Trans-Atlantic Consumer Dialogue.

*Seafood Standards.* International compliance with seafood HACCP regulation should be a top priority. With 50% of the seafood consumed in the U.S. coming from foreign sources, consumers face a higher risk of seafood-borne illnesses if imported seafood doesn't meet our minimum standards. In addition, FDA's lax approach to domestic HACCP implementation raises concerns that FDA is not adequately enforcing HACCP with our international trading partners. The FDA should ensure that any equivalency agreement with Canada raises seafood standards in both countries.

*On-Site Audits of Foreign Firms.* FDA should also put a high priority on conducting audits of food processing facilities in foreign countries that export food to the U.S. Such on-site audits are conducted by the USDA's Food Safety and Inspection Service for all countries that export meat or poultry products to the U.S. to ensure that the countries' programs are equivalent to the U.S. program. Where countries are not found to be equivalent, imports should be disallowed until the country is in compliance with our standards.

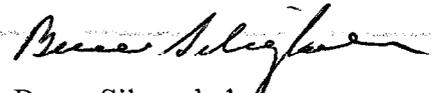
**CONCLUSION**

CSPI appreciates the opportunity to comment on CFSAN's priorities for FY 2001. The issues CFSAN addresses, and the actions it takes, are vital to the health and well-being of all U.S. consumers. Therefore, we strongly support the FDA's continued focus on ensuring the safety of our nation's food supply.

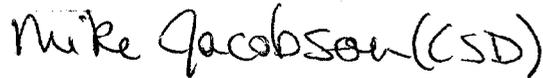
Sincerely,



Caroline Smith DeWaal  
Director of Food Safety



Bruce Silverglade  
Director of Legal Affairs



Michael Jacobson, Ph. D.  
Executive Director

July 17, 2000

Dr. Jane Henney  
Commissioner  
Food and Drug Administration  
5600 Fischer Lane  
Rockville, MD 20857

**Re: Petition to Set A Regulatory Limit for Methylmercury In Seafood That Reflects the Risk to Pregnant Women and Children From the Intake of Seafood Containing Methylmercury**

Dear Commissioner Henney:

More than 60,000 children are born each year at risk for neurological problems due to low-level methylmercury contamination from seafood eaten by pregnant women, according to a National Academy of Sciences (NAS) report released last week.<sup>1</sup> This warning is not new. Concerns about the effects of this toxic metal on pregnant women and their fetuses were raised nearly a decade ago, in a 1991 NAS report and in a citizen petition I submitted to the Food and Drug Administration (FDA) in 1992. Both the report and the petition were highly critical of the FDA's weak standard on methylmercury in seafood<sup>2</sup> and offered the agency specific guidance on performing a more rigorous risk assessment on the substance. Unfortunately, the FDA has never revised its methylmercury action level or responded to the petition. It is imperative that the agency act without further delay. On behalf of the Center for Science in the Public Interest (CSPI), I am resubmitting the attached petition urging the agency to set a regulatory limit for methylmercury in fish and shellfish that protects pregnant women and children from mercury contamination.

As in the earlier NAS report, several of the panel's recommendations, when applied to the FDA's guidelines on methylmercury, reveal fatal flaws in the agency's standard-setting process. Most importantly, the 2000 NAS panel validated the EPA's stringent regulatory limit for

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<sup>1</sup> National Academy of Sciences, Toxicological Effects of Methylmercury, 276 (not yet published), found at <http://www.nap.edu/openbook/0309071402/html/276.html> [hereinafter cited as 2000 NAS report].

<sup>2</sup> The FDA's action level for methylmercury is 1 part per million (ppm).

methylmercury,<sup>3</sup> but when the data used in FDA's risk assessment are plugged into the model, **the FDA's biomarker and exposure levels for methylmercury are four times higher than the NAS endorses.**<sup>4</sup> Specifically, the 2000 NAS panel found the following:

1. There is a "strong data base" of human and animal studies showing neurotoxic effects from in utero exposure to methylmercury and particularly the 1997 Faroe Islands study<sup>5</sup> on the effects of low-level chronic exposure.<sup>6</sup> *The FDA action level is based upon a 1971 study of two high-exposure poisoning episodes occurring in the 1960's. Although the FDA conceded in 1994 that long-term exposure to methylmercury in fetuses and infants might have adverse harm,<sup>7</sup> the agency did not reevaluate its action level when the Faroe Islands, Seychelles (1998) or New Zealand (1986, 1989) studies on developmental neurotoxicity were released.*<sup>8</sup>
2. Developmental neurotoxicity should be the end point used in calculating the appropriate regulatory level of methylmercury.<sup>9</sup> *The FDA used overt neurological symptoms in adults as the end point; therefore its action level is set to protect adult men weighing 154 pounds and over.*

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<sup>3</sup> Id. at 277, found at <http://www.nap.edu/openbook/0309071402/html/277.html>. The 2000 NAS report was issued following an 18-month review of the toxicological effects of methylmercury and the validity of the EPA's risk assessment on the substance. As part of its work, the panel of scientists analyzed the data and assumptions used by FDA, EPA and other agencies. Id. at 257, found at <http://www.nap.edu/openbook/0309071402/html/277.html>.

<sup>4</sup> Id. at 17, 277, found at <http://www.nap.edu/openbook/0309071402/html/17.html>, <http://www.nap.edu/openbook/0309071402/html/277.html>. The FDA's action level for methylmercury is based upon a biomarker in adult blood of 0.2 ppm (or a concentration of 0.02  $\mu\text{g/g}$  of blood, including a safety factor of ten, which equates to 20  $\mu\text{g/L}$  of blood). Removing the safety factor leaves a blood concentration of 200  $\mu\text{g/L}$  of blood, and applying the 250:1 blood:hair ratio results in 50 ppm in hair.

<sup>5</sup> See, 2000 NAS report at Chapter 6: Comparison of Studies for Use in Risk Assessment at 209-226, found at <http://www.nap.edu/openbook/0309071402/html/209.html> - <http://www.nap.edu/openbook/0309071402/html/226.html> for a discussion of the Faroe Islands study as well as the Seychelles and New Zealand studies on exposure to methylmercury and developmental neurotoxicity.

<sup>6</sup> 2000 NAS report at 275, found at <http://www.nap.edu/openbook/0309071402/html/275.html>.

<sup>7</sup> FDA, Mercury in Fish: Cause for Concern?, FDA Consumer (Sept. 1994, rev'd. May 1995).

<sup>8</sup> See, *supra*, note 5.

<sup>9</sup> 2000 NAS report at 275, found at <http://www.nap.edu/openbook/0309071402/html/275.html>.

3. The risk assessment should be based upon a benchmark dose limit (BMDL)<sup>10</sup> corresponding to 12 ppm in hair.<sup>11</sup> *The FDA action level corresponds to a biomarker of 50 ppm in hair, which is more than 4 times the NAS recommendation.*
4. A regulatory limit for methylmercury of 0.1 µg/kg/day—the EPA standard—is “scientifically justifiable for the protection of public health.”<sup>12</sup> *The FDA’s action level is equivalent to 0.4 µg/kg/day.*

The NAS report adds to the large body of science showing the adverse effects of low-level methylmercury exposure on developing fetuses and documents that 60,000 children are born each year at risk of developing neurological problems from mercury exposure linked to seafood. It is imperative that FDA act now to protect women of child-bearing age and their children from this hazard. First, FDA should immediately adopt EPA's standard for methylmercury as an "action level." Second, FDA should monitor methylmercury levels in shark, swordfish and tuna and remove seafood from the market that violates FDA's standard. Third, FDA should act on the attached 1992 petition by initiating rulemaking to adopt a tolerance for methylmercury that fully protects the children of women who are or may become pregnant. Further delay by the agency would be unconscionable.

Sincerely,

Caroline Smith DeWaal  
Food Safety Director

Encl.

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<sup>10</sup> “Benchmark dose” (BMD) refers to the estimated dose that corresponds to a specified risk above the background risk. BMDL denotes the corresponding lower limit. *Id.* at 228, found at <http://www.nap.edu/openbook/0309071402/html/228.html>. For example, the benchmark dose of 11 ppm of mercury in hair was calculated as the 95% lower confidence limit on the maternal-hair concentration corresponding to a 10% extra risk level. The lower confidence limit is the BMDL. *Id.* at 258, found at <http://www.nap.edu/openbook/0309071402/html/258.html>.

<sup>11</sup> *Id.* at 277, found at <http://www.nap.edu/openbook/0309071402/html/277.html>. The NAS determined that the BMDL used by EPA (11 ppm) is “nearly identical” to the panel’s recommendation of 12 ppm in hair. *Id.*

<sup>12</sup> *Id.* at 277, found at <http://www.nap.edu/openbook/0309071402/html/277.html>. The 2000 NAS report was issued following an 18-month review of the toxicological effects of methylmercury and the validity of the EPA’s risk assessment on the substance. As part of its work, the panel of scientists analyzed the data and assumptions used by FDA, EPA and other agencies. *Id.* at 257, found at <http://www.nap.edu/openbook/0309071402/html/277.html>. The panel’s findings reveal serious defects in the methods and data that FDA used in determining its action level for methylmercury.

Center for Science in the Public Interest • Consumer Federation of America

August 11, 2000

Dr. Jane Henney, Commissioner  
U.S. Food and Drug Administration  
5600 Fisher Lane  
Rockville, MD 20857

Dear Commissioner Henney:

We write regarding the Food and Drug Administration's (FDA) recently announced plan to strengthen its regulation of genetically modified (GM) foods. Although the FDA's proposal to make its voluntary consultation process mandatory would be a modest improvement over the current system, we urge the agency to make more sweeping changes in its regulations.

The FDA's review process for GM foods has been criticized by many for being too weak and opaque, attributes that could result in health risks to consumers. We note that new and potentially more challenging GM foods based on additional GM crop and animal innovations are poised to enter the regulatory arena. To bolster public confidence in the agency's oversight, the FDA has indicated that it plans to improve its system. Unfortunately, many critics' concerns will not be satisfied by the FDA's announcement on May 3 that it will require companies to notify the agency of their intent to market GM foods and to submit specific information for agency review. That is because the FDA's proposal would not create the type of system that the public deserves: a fair, transparent, mandatory premarket *approval or certification* process, including an opportunity for meaningful public input.

The FDA's reluctance to establish such a process is inexplicable, especially considering that the two other federal agencies that share oversight of GM foods with the FDA conduct their reviews in a more open and formal manner (although we do not agree with every aspect of their processes.) Unlike the FDA, both the U.S. Department of Agriculture (USDA) and the Environmental Protection Agency (EPA) conduct mandatory premarket approvals of those GM food crops that they have determined to fall under their jurisdiction. That is, they prohibit companies from commercializing new products until they are formally approved. Both agencies solicit public comments during the review process, respond to those comments in formal decision documents, and make the details of their final decisions available to the public.

The USDA's Animal and Plant Health Inspection Service (APHIS) publishes a notice in the *Federal Register* and creates a public docket whenever it receives a petition for a determination of nonregulated status under the Federal Plant Pest Act, which is the final review step before commercialization of a GM food crop. General information about the petitions is also made available on the Internet. After completing its review of a petition, APHIS publishes a second *Federal Register* notice announcing its final decision. The agency also publishes a determination document, in which it explains the rationale for its decision and responds to any public comments.

Similarly, the EPA uses the *Federal Register* and the Internet to notify the public and provide a 30-day public-comment period when it receives petitions for genetically modified plant-pesticides. Upon completion of its review, the EPA announces its decision in a second *Federal Register* notice and establishes a new comment period in which written objections and formal hearing requests may be submitted. For both registration applications and pesticide petitions, the EPA makes documents that explain the scientific basis for its decision publicly available.

Unfortunately, the FDA's tentative proposal as described on May 3 falls short in two important respects. First, it would not create a premarket approval or certification process; rather, the agency would continue to review submissions without making a final, published decision regarding a product's safety for humans and the environment. Second, the proposed changes would do little to enhance the transparency of the FDA's review because the agency apparently does not intend to place in a public docket or on the FDA's web site any of the scientific information submitted until *after* completion of the consultation process. Nor, apparently, does the FDA intend to establish a formal public-comment period, respond to public comments in a published document at the end of the approval process, or include the possibility that a post-approval monitoring process may be necessary in some cases.

To maximize confidence in the FDA's review process and to assure both consumers and industry that the agency's oversight of GM foods under its jurisdiction is thorough, scientifically accurate, fair, and transparent, the undersigned urge a process with the following elements:

- The agency should require companies to: 1) apply to it; 2) wait for timely review of the application; 3) receive formal FDA approval, certification, or comparable written permission; and 4) comply with all other applicable laws, prior to marketing GM foods.
- FDA should publish a *Federal Register* notice announcing the receipt of an application and the availability in a public docket of all non-confidential information submitted regarding the food. All additional information received by the agency -- whether from the company or other party -- should be added to the docket upon receipt. All FDA documents pertaining to the food, including the agency's final decision and related materials, should also immediately be placed in the docket. Ideally, all of the information in the docket also would appear on the FDA's web site; if that is impractical, the web site should at least contain a list of all GM foods, their review status, and instructions regarding how the information in the public docket may be obtained.
- Upon completion of its review, the FDA should publish a notice in the *Federal Register* announcing the agency's final decision. The notice should summarize the agency's findings, rationale, and supporting information and should announce a final public-comment period. The notice should indicate that all relevant information may be obtained from the public docket and that, in some cases, companies would be required to undertake post approval monitoring of a product.

Increasing the transparency of the FDA's review process would yield obvious benefits. A sure way to engender suspicion from both consumers and the affected industry about a government regulatory program is to shield -- or even to create the impression of shielding -- agency actions from outside scrutiny. Though savvy groups may understand how to obtain information about the FDA's current evaluation process by submitting a request under the Freedom of Information Act, the lack of a public docket and Internet information relevant to ongoing reviews excludes others who may wish to monitor or participate in the process. And the absence of a final agency decision regarding safety to humans and the environment, including a description of the agency's rationale, prevents outside observers from judging the adequacy of the FDA's review.

By taking the steps outlined above, the FDA would both enhance the quality of its scientific review and help quell consumer concerns about the rigor and openness of the agency's activities. We hope that the FDA, as a part of its long overdue effort to strengthen its oversight of GM foods, will propose new regulations that include all of the suggested improvements.

Sincerely,



Michael F. Jacobson, Ph.D.

Executive Director

Center for Science in the Public Interest



Carol Tucker Foreman

Distinguished Fellow and Director

Food Policy Institute

Consumer Federation of America

# CSPI CENTER FOR SCIENCE IN THE PUBLIC INTEREST

Publisher of *Nutrition Action Healthletter*

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July 19, 2000

U.S. Food and Drug Administration  
Dockets Management Branch (HFA-305)  
5630 Fishers Lane, Rm. 1061  
Rockville, MD 20852

Re: **Improving Premarket Review and Approval of Food and Color Additives in the Center for Food Safety and Applied Nutrition; Request for Comments**  
Docket Number 00N-1262  
65 Fed.Reg. 26215 (May 5, 2000)

On behalf of its more than 700,000 American members, the Center for Science in the Public Interest ("CSPI") appreciates the opportunity to comment on how the Food and Drug Administration (FDA) can improve its premarket review process for food and color additive petitions. CSPI has had a longstanding interest in the agency's activities related to food and color additives. We have filed numerous citizen petitions and comments seeking FDA action on additives that we believed were unsafe or inadequately tested.

CSPI applauds the agency for seeking public input on how its new resources should be used to address the public-health issues related to food and color additives. The influx of new resources offers FDA an excellent opportunity to take several immediate steps to improve the Office of Premarket Approval.

## **FDA Should Change the Name of the Office of Premarket Approval to the "Office of Food Chemical Review"**

CSPI's first suggestion would cost FDA little or no money. The Office of Premarket Approval, which is responsible for *reviewing* -- without necessarily approving -- the safety of proposed food and color additives, should be renamed the "Office of Food Chemical Review." That would eliminate any perception that approval of additives is preordained. It would also make it plain that the food and color additives under review are "chemicals" and that the safety review includes an examination of data from toxicological and other tests appropriate to chemical additives. Though largely symbolic, the name change would help assure the public that the office understands its primary role to be safeguarding consumers from unsafe chemical additives.

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On the Internet at [www.cspinet.org](http://www.cspinet.org) • Executive Director: Michael F. Jacobson, Ph.D.

00N-1262

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## **FDA Should Continue to Give High Priority to Reviewing Antimicrobial Additives and Should Also Expedite Review of Additives That Make Food More Nutritious**

CSPI strongly supported FDA's decision in early 1999 to expedite review of food additives with antimicrobial properties against human pathogens, and we believe that that policy should remain in effect. Helping to eliminate foodborne illness caused by microbial contamination is a particularly important and laudable function for food additives.

Though review of food additives that enhance food safety should remain FDA's highest priority, new additives that make food more nutritious should also be reviewed ahead of additives that offer little or no health benefits. Therefore, FDA should review additives that increase the nutritional value of foods more expeditiously than additives offering no nutritional or food-safety benefits.

Of course, the agency would have to establish criteria for determining whether an additive actually improves the nutritional quality of food. That task should be relatively straightforward. We suggest that FDA consider such factors as whether the additive would facilitate the production of foods containing higher levels of fiber or micronutrients or less fat (especially saturated and *trans* fats), added sugars, or sodium, and whether the additive would encourage the consumption of healthy foods that many Americans do not include in their diets.

## **FDA Should Invest More Heavily in Ensuring the Safety of Approved Additives**

CSPI has been disappointed by the low priority FDA places on addressing lingering safety questions posed by additives (or GRAS substances) that have already been approved by the agency. FDA should use some of its new funding to re-evaluate the safety of approved additives that have raised safety concerns.

A simple, relatively inexpensive step that FDA could take immediately would be to devote additional staff time to conducting reviews of the scientific literature related to food-additive safety. That review should be comprehensive and ongoing, and there should be a system in place to get relevant information from the literature about unsafe additives to the appropriate agency personnel without delay.

FDA should also devote some its resources to improving its post-market surveillance for adverse reactions to food and color additives. Admittedly, conducting such surveillance effectively is a challenging task, because tracing an adverse reaction to a particular additive in a person's diet obviously can be quite difficult. However, FDA should explore new ways to increase health-care providers' awareness that additives can cause gastrointestinal symptoms, allergic reactions, and other health problems. It should also develop new mechanisms to encourage health-care providers to ask patients suffering from such symptoms questions about their use of food-additive-containing products and to report adverse reactions to the agency.

Because animal and *in vitro* toxicity and allergenicity tests offer only limited insight into how food and color additives may affect consumers, post-market surveillance could play a

critical role in the detection of unsafe additives. Accordingly, FDA should use some of its new resources to develop and test new ways to conduct post-market surveillance. We note that improving adverse event reporting (AER) is among the agency's stated goals under the FY 2001 Performance Plan, but that this effort is to be focused on dietary supplements and other special nutritional products.<sup>1</sup> We urge FDA also to increase its efforts to monitor and evaluate adverse events due to food and color additives (and GRAS substances) as part of its AER activities.

When post-market surveillance, literature reviews, or other information indicates that an approved additive may be unsafe, FDA should ensure that follow-up research is conducted to ascertain the extent of the problem and to determine an appropriate regulatory response. FDA should either undertake that research itself or require the company marketing the potentially unsafe additive to do so.

In addition, FDA should devote additional resources to responding more quickly to citizen petitions seeking agency action to address potentially unsafe additives. CSPT's petitions have tended to languish. For example, FDA has yet to respond to our 1997 petition requesting the agency to conduct a safety review of caffeine and require appropriate labeling, our 1998 petition seeking a complete ingredient listing or prohibition on the use of cochineal extract and carmine color additives, or our 1999 petition calling for a ban on potassium bromate in baked goods. While companies and industry trade associations have been vociferous critics of the length of time it takes FDA to approve new food additive petitions, the sluggish pace of citizen-petition review is the unaddressed flip side of the coin. In this regard, we note that FDA has included as a goal under its FY 2001 Performance Plan reducing the percentage of overdue food and color additive petitions, but the agency has no similar goal regarding citizen petitions related to food additives.<sup>2</sup> That should change. In terms of public health, responding to concerns about risks should take precedence over approving most food additives.

#### **FDA Should Fund or Conduct New Research on Potential Safety Problems Posed By Additives**

FDA should use some of its new resources to fund research to shed light on potential safety problems posed by new food and color additives. The agency has an important role to play in fostering the development of improved safety tests for chemical additives and for incorporating the latest science into its review process. Among other research activities, FDA should fund or conduct studies aimed at the following:

- ▶ Developing more sensitive animal and *in vitro* methodologies to test for carcinogenicity and toxicity;

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<sup>1</sup> Food and Drug Administration, *FDA FY 2001 Performance Plan*, p. 9, available at <http://www.fda.gov/ope/fy01plan/foods01.html>>Internet [hereinafter cited as *FY 2001 Performance Plan*].

<sup>2</sup> *FY 2001 Performance Plan*, pp. 6-7.

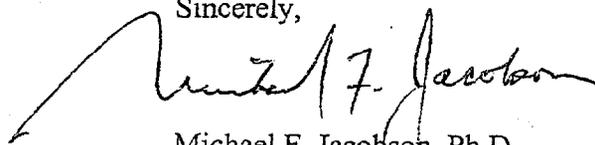
- ▶ Developing tests to assess food sensitivities and allergenicity;<sup>3</sup> and
- ▶ Investigating links between diet and Attention Deficit/Hyperactivity Disorder (ADHD).

#### **FDA Should Improve its Policies Regarding Advisory Committees**

The Office of Premarket Approval should ensure that any advisory committees convened to review the safety of proposed (or existing) additives are balanced, have access to all appropriate information, and that members have adequate opportunity to review the data. As we have noted in the past, the committee that reviewed olestra was heavily skewed toward industry consultants. Moreover, the FDA failed to appoint any members on carotenoids, despite having discussed that matter with CSPI staff prior to the meeting. Having a balanced committee with expertise in the key relevant areas would not only help the FDA come to the best decision, but it would also enhance the credibility of the process. In addition, the FDA should provide full information to the public about possible biases and conflicts of interest of committee members, along the lines that the National Research Council does for some of its committees.

Thank you for the opportunity to provide this input.

Sincerely,



Michael F. Jacobson, Ph.D.  
Executive Director

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<sup>3</sup> For instance, monosodium glutamate sensitivity has been a lingering controversy that could be easily settled by appropriate tests. FDA should ensure that those tests are done.