CSPI CENTER FOR SCIENCE IN THE PUBLIC INTEREST
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Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

Re: Docket Number 98N-0359, CFSAN Program Priorities for FY2004, 68 Fed. Reg. 33727 (June 5, 2003)

INTRODUCTION

The Center for Science in the Public Interest (CSPI) appreciates the opportunity to comment on the Food and Drug Administration (FDA) FY 2004 program priorities for the Center for Food Safety and Applied Nutrition (CFSAN).[1]

- **Bioterrorism**

With the enactment of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Bioterrorism Act of 2002), FDA has been given new tools to address the threat of intentional contamination of the food supply. FDA has identified as "A" list priorities the issuance of proposed rules relating to facility registration, prior notification of imported foods, record keeping, and administrative detentions, and has published proposed rules in all four areas. Although issuance of final rules for food facility registration and prior notification of imported

[1] CSPI is a non-profit consumer advocacy and education organization that focuses primarily on food safety and nutrition issues and is supported principally by subscribers to its *Nutrition Action Healthletter*.

food shipments are listed as "A" priorities, the development of final rules establishing record keeping requirements (sub-strategy 1.1.8) and administrative detention requirements (sub-strategy 1.1.9) are only listed as "B" priorities.

Promulgation of final rules relating to record keeping and administrative detention should be elevated to "A" priorities. In section 306(d) of the Bioterrorism Act, Congress mandated an expedited rulemaking for record keeping requirements, requiring that proposed and final regulations must be promulgated no later than 18 months after the date of enactment. Although FDA has indicated a "target date" for publication of a final record keeping rule, it is particularly important that FDA promulgate a final rule by the statutory deadline. Such records will provide the means to conduct a trace back in the case of an intentional contamination event and, therefore, a final rule should be adopted and implemented as soon as possible.

Although Congress did not set a deadline for promulgation of a final administrative detention rule, it is equally important that this activity also be moved to the "A" list. Section 303 of the Bioterrorism Act provides FDA with expanded authority to detain foods where they present a credible threat of serious adverse health consequences or death to humans or animals. A final rule implementing this authority should be promulgated as soon as possible to assure that FDA has the ability to prevent intentionally contaminated foods from entering the stream of commerce.

- **Seafood safety**

1) *Vibrio vulnificus.*

The FDA has established as one of its "A" level priorities for FY 2003 continuing to work with the Interstate Shellfish Sanitation Commission (ISSC) to implement a control strategy for *Vibrio vulnificus* in raw oysters. (Sub-strategy 1.5.3). While we agree that a control strategy for

Vibrio vulnificus must be a priority, we disagree that FDA should be looking to the industry-dominated ISSC to resolve this problem. In October 2002, FDA denied CSPI's citizen petition requesting that the Agency establish a performance standard requiring the reduction of *Vibrio vulnificus* to nondetectable levels in raw molluscan shellfish. According to FDA, its best course of action is to continue to work with the ISSC, which adopted a strategy for *Vibrio vulnificus*.[2] The ISSC's plan, however, continues to rely on consumer education as its primary strategy and would not impose any post-harvest controls, if any, until 2007.[3]

Consumers continue to become ill and die from *Vibrio vulnificus* related to consumption of raw Gulf oysters. Between 1998 and 2000, 92 illnesses and 52 deaths linked to *vibrio vulnificus*-contaminated raw shellfish were reported by public health officials.[4] Since January 2002, there have been at least 27 reported cases of *vibrio vulnificus* due to consumption of raw shellfish, resulting in 14 deaths.[5]

Because of FDA's failure to exercise leadership in this area, the California Department of Health Service has recently adopted an emergency regulation to restrict the sale of raw oysters harvested from the states bordering the Gulf of Mexico from April through October, unless the oysters are treated with a scientifically validated process to reduce *vibrio vulnificus* to non-detectable levels. Consumers can no longer afford to have the FDA defer to the ISSC, an

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[2] Letter to Michael F. Jacobson, Executive Director, CSPI, from John M. Taylor, III, Senior Associate Commissioner for Regulatory Affairs (Oct. 21, 2002).

[3] ISSC Final Report, *National Education Program to Influence Consumption Behavior of High-Risk Individuals Regarding Raw Molluscan Shellfish*, Phase III Final Report, at p. 1.

[4] FDA, *Shellfish-Related Vibrio vulnificus Cases/Deaths, 1989-2000.*

[5] FDA, *Shellfish-Related Vibrio vulnificus Case/Deaths, 2000-2002*, obtained through Freedom of Information Act request.

industry-dominated organization. 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 this deadly pathogen. Although FDA has rejected CSPI's petition to establish a performance standard for *vibrio vulnificus*, FDA should reconsider that decision and make one of its top priorities establishing a performance standard for *vibrio vulnificus*.

2) *Methylmercury*

FDA has identified as an "A" priority action to revise its consumer advisory on methylmercury in commercial seafood. Although this represents a small step in addressing the threat of methylmercury in seafood, FDA needs to take more protective actions in the form of a regulatory response. These actions should include:

- adding as an "A" priority responding to CSPI's citizen petition, first filed over twelve years ago, requesting the Agency to set a regulatory limit for methylmercury in fish. In July 2000, CSPI again petitioned FDA to act on this important public health issue.[6] However, despite the 2000 National Academy of Sciences' report[7] and 2001 CDC data adding to the body of science showing the adverse effects of low-level methylmercury exposure on developing fetuses, FDA has yet to act. FDA should demonstrate the Agency's commitment to ensuring the health and safety of pregnant women and their children by making a regulatory response to the methylmercury problem an "A" priority; and

- moving from a "B" to "A" priority review of CSPI's petition requesting that

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[6] CSPI, *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*, filed July 17, 2000.

[7] National Academy of Sciences, Toxicological Effects of Methylmercury (2000).

FDA establish a microbial testing program for hazards in seafood products (sub-strategy 1.5.10).[8] This petition requests FDA to design a mandatory government program to test not only for the levels of methylmercury in large predatory finfish, but also for *Listeria monocytogenes* in ready-to-eat fish and shellfish, the levels of ciguatera in tropical and sub-tropical reef fish, and the presence of *Vibrio* species in raw shellfish. Review of CSPI's petition should be elevated to an "A" priority because contaminated seafood continues to be a critical public health problem.[9] Indeed, FDA's own Evaluation of the Seafood HACCP Program for Fiscal Years 2000/2001 has identified continued problem areas, including control of pathogens by processors of cooked, ready-to-eat (RTE) seafood and smoked seafood and control of scombrotoxin by processors of scombroid species.[10]

- **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. Outbreak data compiled by CSPI for its publication, *Outbreak Alert!,* show that eggs have been implicated in over 200 SE outbreaks between 1990 and 2001.[11]

Although the Egg Safety Action Plan identified FY 2002 as the deadline for a final rule

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[8] CSPI, *Petition for Regulatory Action to Establish a Microbial Testing Program for Hazards in Seafood Products* (Oct. 9, 2002).

[9] CSPI has documented 539 seafood outbreaks with a known etiology that occurred between 1990 and 2002. *See* CSPI, *Outbreak Alert! Closing the Gaps in Our Federal Food-Safety Net* (rev. 2002), at pp. 8, 18-24.

[10] FDA, Center of Food Safety and Applied Nutrition, *FDA's Evaluation of the Seafood HACCP Program for Fiscal Years 2000/2001* (Sept. 30, 2002), at p. 5, available at <*http://www.cfsan.fda.gov/~comm/seaeval2.html*>.

[11] CSPI, *Outbreak Alert! Closing the Gaps in Our Federal Food-Safety Net* (Washington, D.C., 2002), at p. 9.

adopting a nationwide SE reduction program for egg production, FDA has taken no action to date to adopt on-farm controls for shell eggs. In a letter to CSPI dated June 14, 2002, Dr. Crawford affirmed that FDA's goal to publish a proposed rule addressing on-farm risk-reduction measures for shell eggs remains a "high priority." Therefore, we are pleased that FDA has identified as an "A" list priority the publication of a proposed egg safety rule (sub-strategy 1.7.1). We encourage FDA to propose such a rule during this fiscal year, particularly a rule that will implement and enforce proven SE control programs, such as measures that include environmental testing and diversion after a SE-positive result.

- ***Listeria***

Listeria monocytogenes (*L. monocytogenes*) remains one of the most serious foodborne pathogens. Listeriosis is associated with higher hospitalization rates than any other pathogen and had the highest case-fatality rate in 2000 of the FoodNet pathogens.[12] For this reason, we are pleased that FDA has identified as an "A" priority the issuance of a revised risk assessment on *L. monocytogenes* contamination in ready-to-eat foods (sub-strategy 1.8.1). However, the item listed as a "B"priority – developing draft guidance advising processors on steps to reduce *Listeria monocytogenes* contamination in ready-to-eat foods -- should be elevated to an "A" priority level. Moreover, FDA needs to go beyond mere guidance and adopt a regulatory response. Over the past 10 years, outbreaks of listeriosis have been documented in FDA-regulated foods, including chocolate milk and queso fresco cheese. The chocolate-milk outbreak sickened 69 individuals living in three states.[13] In the queso-fresco cheese outbreak, there were 12 reported cases. Ten of

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[12] Centers for Disease Control and Prevention, *FoodNet Surveillance Report for 2000 (Final Report)*, Sept. 2001, at pp. 11-12 (finding that 90.5% of reported cases were hospitalized).

[13] CDC, *U.S. Foodborne Disease Outbreaks*, available at <*http://www.cdc.gov/ncidod/dbmd/outbreak/us_outb.htm*>.

these cases were pregnant women, five of whom lost their babies due to still births.[14]

Recently, the USDA's Food Safety and Inspection Service strengthened its regulations to reduce *L. monocytogenes* in RTE meat and poultry by issuing an interim final rule requiring establishments producing RTE products to take additional steps to reduce the incidence of that pathogen. FDA should not await completion of the risk assessment and should make it a priority to require plants producing FDA-regulated foods at risk for *L. monocytogenes* (such as soft cheese, pasteurized and unpasteurized milk products, seafood products, and prepared salads) to test their environments and final products for the presence of the pathogen.

- ***Transmissible Spongiform Encephalopathies*** **(TSEs)**

Although FDA lists two goals under the TSE program area, the Agency has failed to identify either of these as an "A" priority. Scientists have documented that if a cow has BSE, consuming small portions of its brain, spinal cord and other central nervous system (CNS) tissue could cause human cases of variant Creutzfeldt-Jakob Disease (vCJD).[15] The risk of infection from BSE increases with a cow's age. Although BSE has not been detected in U.S. cattle, its absence cannot be confirmed with certainty. Therefore, there is an overwhelming need to institute all reasonable public health precautions to prevent vCJD in the event that U.S. cattle are infected with BSE.

FDA should make it a top priority to cooperate with USDA to develop a regulatory approach to minimize human exposure to BSE from the use of bovine brain, spinal cord, and eyes

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[14] CDC, "Outbreak of Listeriosis Associated with Homemade Mexican-Style Cheese - North Carolina, October 2000-January 2001," 50 *Morbidity and Mortality Weekly Report*, pp. 560-62.

[15] Paul Brown, et al., *Bovine Spongiform Encephalopathy and Variant Creutzfeldt-Jakob Disease: Background, Evolution, and Current Concerns*, 7 Emerging Infections Diseases (Jan.-Feb. 2001), pp. 6, 10.

from animals 24 months or older in CFSAN-regulated products. The recent discovery of a cow in Alberta, Canada that tested positive for BSE demonstrates the need for increased protections.

Recent reports concerning the spread of chronic wasting disease (CWD) in eight states among wild deer and elk, as well as farmed elk, make it imperative that FDA work with USDA to quickly develop a regulation prohibiting the use of any part of an elk or deer exposed to CWD from CFSAN-regulated products. Because there are currently no regulations governing how deer carcasses are handled, regulations should be adopted as soon as possible to assure that no parts of animals exposed to CWD find their way into CFSAN-regulated products.

Banning the use of bovine materials from BSE or BSE high-risk countries in CFSAN-regulated products also is crucial and should be elevated from a "B" to an "A" priority. In December 2000, the USDA's Animal and Plant Health Inspection Service (APHIS) banned all imports of rendered animal proteins, regardless of species, from countries listed as BSE-positive or presenting a high risk of introducing BSE into the USA. While the FDA has issued import alerts, it has instituted no outright ban against the use of bovine material from BSE or BSE-high-risk countries in CFSAN-regulated products. We urge FDA to alter its priorities in this area and reclassify the goals relating to TSEs to category A.

- **Acrylamide**

Acrylamide contamination may be causing both thousands of cases of cancer per year in the United States and some less-quantifiable risk of neurologic illnesses. On June 4, 2003, CSPI filed a petition with FDA asking that it immediately establish interim acceptable levels for acrylamide in major food sources. On June 27, 2003, CSPI filed a comment in a proceeding on infant formula (Docket Number 95N-0309) asking that FDA immediately test every brand of infant formula to determine whether it contains detectable levels of acrylamide and then convene a

workshop to make recommendations to the FDA on how to reduce, if not eliminate, acrylamide in all infant formulas. These two matters should be an "A" priority.

- **Potassium Bromate**

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 can cause such tumors. On July 19, 1999, CSPI petitioned the FDA to ban bromate. FDA lists bromate as a "B" priority in its 2003 Program Priorities (sub-strategy 2.1.3), but has taken no public action to respond to our petition to restrict the use of this additive. We urge that this matter be given higher priority.

- **Sorbitol and Mannitol**

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.[16] The FDA should accord this petition priority attention.

- **Salatrim**

As discussed in our 1998 petition to the FDA, salatrim may cause diarrhea in humans and products containing this ingredient may be misbranded.[17] The FDA has taken no action on this matter. We urge that it be given priority attention.

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[16] *Petition to Improve the Existing Warning Label on Processed Foods that Contain the Sugar Substitute Sorbitol (Sept. 27, 1999).*

[17] *Petition to FDA on the Generally Recognized as Safe (GRAS) Status of Salatrim* (June 19, 1998).

- **Carmine/Cochineal Extract**

CSPI is disappointed that the Agency downgraded from an "A" to a "B" priority the development of a proposed rule to require the declaration of carmine/cochineal extract, a color additive, on products containing it (sub-strategy 1.13.3). As we stated in our 1998 petition, carmine/cochineal extract may cause severe allergic reactions in humans. The issuance of this proposal should be upgraded to the FDA's "A" list.

- **Quorn Mycoprotein**

We urge the FDA to give priority attention to banning the sale of this product for the reasons set forth in our numerous letters to the Agency over the past 18 months. This product has caused serious health problems including anaphylaxis, severe vomiting, and diarrhea. It should be removed from the market.

- **Allergens**

On May 26, 2000, nine state attorneys general petitioned the FDA to combat food allergen problems with new labeling and stricter good manufacturing practices. The attorneys general urged the changes "to ensure the safety and welfare of the five million U.S. citizens possessing food-related allergies."[18] This was a highly unusual action for attorneys general. The petition states that ambiguous or insufficient labeling has caused serious consequences, including death. Although FDA held a hearing on July 25, 2001, and listed a proposed rule as B* on the 2003 priority list (sub-strategy 1.13.7), little concrete action has been taken.[19] This matter should be elevated to an "A" priority. We further urge that level "A" priority attention continue to be

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[18] Petition from Nine Attorneys General, 00P-1322, May 30, 2000.

[19] FDA, CFSAN 2003 Program Priorities <http://www.cfsan.fda.gov~dms/cfsan303.html>.

given to developing and implementing an allergen enforcement strategy to prevent cross-contamination (sub-strategy 1.11.2).

For FY 2003 CFSAN gave an "A" priority to validiating a commercially available immunochemical peanut protein test kit. CFSAN recently reported that it completed this validation on May 3, 2003, and so for FY 2004 CFSAN should upgrade from "B" to "A" the development of guidance on the use of test kits to detect the presence of peanut protein for regulatory purposes. In addition, for FY 2004 CFSAN should maintain its "A" priority for evaluating its FY 2002 food allergens inspections.

- **Caffeine**

In 1997, both the American Medical Association and CSPI asked the FDA to require that the amount of caffeine in foods be declared on the label. For FY 2003, CFSAN assigned a "B" priority to conducting "a survey to identify and characterize the sources of caffeine in the food supply." The July 2003 *Consumer Reports* published a story disclosing the hidden amounts of caffeine in various foods and discussing the possible health consequences of caffeine on children – nausea, vomiting, diarrhea, cramps, and muscle twitching. In addition, both the FDA and physicians advise pregnant women to avoid caffeine or consume only small amounts because of the correlation between the daily consumption of several cups of coffee with low birth weight, miscarriages, and other adverse effects on pregnancy. Accordingly, CFSAN should make it an "A" priority to initiate a rulemaking to require that the amount of caffeine in foods be disclosed.

- **Functional Foods**

The FDA should enforce the food additive provisions of the law and prevent companies from adding herbal medicines and other novel ingredients to foods that are not Generally Recognized as Safe (or approved as food additives). Dietary supplements must not be allowed to

masquerade as foods in order to avoid sections of the law pertaining to food additive approval. Thus we support sub-strategy 2.1.3 and urge that it remain an "A" priority.

The FDA should also respond to the CSPI petition seeking implementation of the recommendations contained in a report by the General Accounting Office.[20] Among its numerous recommendations, the GAO report concluded that regulations be adopted on the safety-related information required on labels; the nature and extent of evidence companies need to adequately support structure/function claims; a notification procedure prior to the use of novel ingredients; and the use of the same disclaimer as is currently required on dietary supplements. It also called for the establishment of an advisory committee to reevaluate the current labeling approaches for foods with novel ingredients to determine whether the distinctions between structure/function and health claims are understood by consumers and identify other changes needed to improve consumer understanding of health-related claims.

- **Dietary Supplements**

We support maintaining at A level sub-strategy 2.3.4, which is to take enforcement action against supplement ingredients that raise safety problems. We also support efforts by the Agency to initiate targeted research programs on dietary supplements where there are significant safety concerns. Although this is currently listed as a "B" priority (sub-strategy 3.1.11), it should be elevated to an "A" priority. Further, the FDA, should expand the National Academy of Sciences' study of dietary supplement safety. More products should be covered, and the study should be expanded to efficacy as well.

The FDA is burdened with a weak law that limits its authority to protect the public from

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[20] CSPI, *Petition for Rulemaking on Functional Foods and Request to Establish an Advisory Committee*, Docket No. 02P-0122/CP1. Mar. 21, 2002.

unsafe and misleadingly labeled supplements. Recently, members of Congress have introduced or called for new legislation. The FDA should, upon request, provide information detailing the need for a new approach to dietary supplement regulation, including the need for explicit statutory authority to impose mandatory adverse event reporting requirements.

- **Impact of the Growth of International Trade on Food Safety**

The FDA should encourage that the Administration's trade policies 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 (sub-strategy 3.2.5) and when it takes positions on behalf of the U.S. government delegation to Codex meetings. The Agency should issue an analysis of the food safety implications of the proposed Free Trade Agreement for the Americas.

- **Trans Fatty Acids**

The FDA should make it a top priority to propose new rules for nutrient content and health claims involving foods that contain *trans* fatty acids, and/or significant quantities of saturated fat, and/or cholesterol. The regulation of such claims should also be made an "A" priority.

- **Added Sugars**

The FDA should give priority attention to proposing a rule that would require the listing of amounts of both total and added sugar content, along with the percentage of a newly designated Daily Value for added sugars as described in our previous petition to the Agency. The

grounds for this request is set out fully in our 1999 petition to the Agency.[21]

- **Food Choking Hazards to Children**

The FDA should give priority attention to protecting young children from choking on foods by requiring companies to label certain products as potential hazards. Every year in the U.S., more than 70 children die from choking on food and more than 10,000 children are treated for such problems in emergency rooms. Some companies voluntarily label products (such as hard candies and other foods) as inappropriate for consumption by young children or provide label instructions on how the product should be prepared by parents (chopped, sliced, etc.) in order for it to be consumed safely. The FDA should require all food companies that sell products that constitute choking hazards to provide standardized safety instruction labeling.

- **Percentage Ingredient Labeling**

CSPI has petitioned the Agency to extend percentage-ingredient labeling to all foods. QUID is necessary for consumers to compare the relative amount of specific ingredients between seemingly similar products. In the EU, Australia, and New Zealand, QUID requirements are already in place. The FDA should work with the Working Group of the Codex Committee on Food Labeling that has been formed to develop an international standard for QUID. We note that the U.S. Department of Agriculture has recently finalized a rule requiring percentage ingredient labeling of the meat component of frozen pizza. The FDA should expand its work in this area as well.

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[21] *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).

- **Misleading Ingredient 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 Agency to enforce the law with particular attention to misleading claims pertaining to healthful ingredients such as whole wheat, fruits and vegetables. Violations of the Act that cannot be handled by the FDA because of resource constraints should be systematically delegated to state enforcement agencies.

- **Health Claims**

The FDA should delay the issuance of qualified health claims until consumer perception studies provide data about the most effective way to present such claims to consumers. The FDA should also delay the issuance of qualified claims until the resolution of legal questions concerning the FDA's authority to modify notice and comment rulemaking requirements imposed by the Nutrition Labeling and Education Act.

The FDA should further 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 for foods 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.

The FDA should 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.

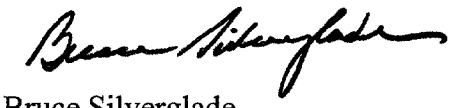
- **Food Standards**

The FDA lists the development of a proposed rule on guiding principles for standards of identity as an A priority (sub-strategy 3.5.2). This matter should be dropped. The initiative is not supported by consumer organizations and some segments of the food industry. In an era of limited resources, the effort should be terminated.

CONCLUSION

CSPI appreciates the opportunity to comment on CFSAN's priorities for FY 2004. The issues to which the FDA chooses to give priority attention will have a vital impact on the health and well-being of all Americans.

Sincerely,



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