



May 13, 2010

U.S. Trade Representative  
Chief FOIA Officer, Carmen Suro-Bredie  
Division of Freedom of Information  
1724 F Street, N.W., Room 514  
Washington, D.C. 20508

Email: [csuro-bredie@ustr.eop.gov](mailto:csuro-bredie@ustr.eop.gov)

Dear Ms. Suro-Bredie:

Pursuant to the Freedom of Information Act (FOIA), 5 U.S.C. § 552, the Center for Science in the Public Interest (CSPI) requests copies of all correspondence in the past year between the USTR and outside parties (including the food industry and the European Union) and between USTR and other U.S. government agencies (including the Food and Drug Administration) concerning the European law that will require labeling of most foods that contain artificial dyes beginning on July 20, 2010.

CSPI expects, as provided in the FOIA, the USTR to respond to this request within 20 working days. CSPI further requests that, to the extent that it reduces delay in receiving documents, the USTR provide responsive documents as they become available, rather than producing them at a later date all at one time.

If any part or all of this request is denied, please state the specific exemption that is being claimed corresponding to each segregable portion of the request, and please provide every non-exempt segregable portion. If any document requested is not in your possession or subject to your control, please state the reason and the present location or the present custodian of any copy or summary of the document.

CSPI requests that all fees in connection with this FOIA request be waived in accordance with 5 U.S.C. § 552(a)(4)(iii), because CSPI does not seek the records for a commercial purpose and disclosure "is in the public interest because it is likely to contribute significantly to public understanding of the operations and activities of the government." CSPI is a nonprofit research, education, and advocacy organization that focuses on informing consumers about health, food safety, and nutrition, protecting consumers' rights in the marketplace, and promoting healthier, safer diets. The material will not be used by CSPI for commercial purposes.

CSPI regularly publishes reports based, in part, upon information acquired through the FOIA. Those reports are presented in the form of articles and editorials in our Nutrition Action

Healthletter (U.S. circulation: 750,000), reports, papers in the medical literature, press releases, speeches, and other media. Many can be accessed on our web site at [www.cspinet.org](http://www.cspinet.org) (which receives about 400,000 hits a month). Those reports are distributed to consumers, journalists, public interest groups, academics, and other interested parties free of charge (or, in the case of our newsletter and reports, at low cost). We intend to use information we receive in response to this FOIA request to educate the public and make policy recommendations in similar ways.

Thank you for your prompt attention to this request. Please telephone me with any questions at (202) 777-8328.

Sincerely,

A handwritten signature in black ink that reads "Michael F. Jacobson". The signature is written in a cursive style with a long, sweeping underline.

Michael F. Jacobson, Ph.D.  
Executive Director

EXECUTIVE OFFICE OF THE PRESIDENT  
OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE  
WASHINGTON, D.C. 20508

August 20, 2010

Michael F. Jacobson, Ph.D  
Executive Director  
Center for Science in the Public Interest  
1875 Connecticut Avenue, N.W.  
Suite 300  
Washington, D.C. 20009

Dear Dr. Jacobson:

This letter is USTR's partial response to your Freedom of Information Act request for **“copies of all correspondence in the past year between the USTR and outside parties (including the food industry and the European Union) and between USTR and other U.S. government agencies (including the Food and Drug Administration) concerning the European law that will require labeling of most foods that contain artificial dyes beginning on July 20, 2010”**.

Please be advised that we are releasing three (3) documents in full.

We will provide additional documents as they become available. Should you have any questions please call the FOIA office at (202) 395-3419.

Sincerely yours,



Carmen Suro-Bredie  
Chief FOIA Officer

Case File #10051323

**What are the applicable international standard the report makes reference to?  
Where is the specific language that does not suggest warning label requirements?**

- A. These colors have been the subject of safety reviews by the United Nations FAO/WHO Joint Expert Committee on Food Additives (JECFA). All have been assigned a numerical Acceptable Daily Intake (ADI) by JECFA which establishes the number of milligrams of the color an individual can consume per kilogram of body weight every day without adverse effect. The JECFA safety review and establishment of an ADI is necessary before the colors can be incorporated into the Codex Alimentarius Commission's (Codex) General Standard for Food Additives (GSFA). The GSFA includes provisions for Sunset Yellow, Allura Red, and Ponceau 4R. The GSFA also contains draft provisions for Quinoline Yellow, Carmoisine, and Tartrazine, but Codex has not yet adopted provisions relating to these three colors.

**What does it mean that the "certified equivalents of three of the six colors" were FDA approved for food use? What is a certified equivalent?**

- A. A certified equivalent is a substance that can be treated in the same manner with respect to safety (i.e., the food or food additive can be concluded to be as safe as the conventional food or food component).

**Are the other three not safe for food use or just have not gone through the FDA approval process?**

- A. All of these colors have been approved for use in the European Union and by other governments around the world. Three of the colors are not approved by the U.S. Food and Drug Administration for use in food because industry has not applied for approval.

**Is the disagreement focused on the label itself or the content of the warning statement?**

- A. The disagreement is focused on the insufficient scientific evidence cited by the EU to support the labeling requirement. As noted in the SPS Report, the EU's list of colors and the subject of hyperactivity was addressed in a much criticized research piece known as the Southampton Study. This study concluded that these six color additives presented a risk of hyperactivity. In November 2009, EFSA released scientific opinions on the color additives evaluated in the Southampton Study. EFSA's opinions contradicted the results of the Southampton Study, concluding that the currently available data did not substantiate a link between the individual color additives and possible behavioral effects.

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As also noted in the SPS Report, the United States disagrees that these color additives, if FDA-certified, have negative health impacts for children when these colors are included in food products in amounts prescribed under U.S. law, and therefore does not believe a warning label is necessary.

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**What quantitative impact will this have on trade? What dollar amount of goods from the U.S. to EU would fall under this requirement?**

- A. We don't have those figures. He should contact industry representatives such as Mars and the Grocery Manufacturers Association for that data.

**Is discussion about the US stance on the food labeling requirement happening outside of the confines of the SPS Committee meetings? Is it being brought up in bilateral discussions?**

- A. The United States and the EU continue to discuss this issue in bilateral fora as well as within the WTO SPS Committee in an attempt to resolve the serious trade concern.

**The report notes that technical discussions are underway? Can you provide more information on those? Are these discussions delaying implementation of the labeling requirement?**

- A. Those technical discussions are confidential. However, as a general matter, the United States continues to urge the EU to delay implementation of this measure to minimize negative effects on trade while these technical discussions are underway.

**Is there any possibility this could move towards WTO action?**

- A. The United States recently raised this issue on the floor during the March 2010 WTO SPS Committee meeting.

## The European Union Requirement for Warning Labels on Food Products Containing Certain Synthetic Colors

### Background:

In December 2008 the European Parliament and the Council of Ministers approved the Regulation on Food Additives (EC No. 1333/2008) which included as Article 24 the requirement that food containing any of 6 designated colors must be labeled with the statement “[name or E number of the color] may have an adverse effect on activity and attention in children.” The inclusion of Article 24 was the result of a compromise reached between Parliament and the European Commission to secure Parliament’s support for approval of the Regulation.

The implementation date for Article 24 is 20 July 2010. The EU notified the pending Regulation on Food Additives to the WTO in 2006 but Article 24 in its present form was not included.

The colors designated as requiring warning labels are shown in the table below along with their approval status in the European Union, United States, FAO/WHO Joint Expert Committee on Food Additives (JECFA), and Codex Alimentarius.

Color name/E #	EU Approval Status	U.S. Approval Status (1)	JECFA ADI Mg/kg body weight & Date Set	Codex Status (2)
Allura Red/E129	Yes	Yes. FDC Red #40. GMP	7 (1981)	Approved
Carmoisine/E122	Yes	Not listed	4 (1983)	Step 6
Ponceau 4R/E124	Yes	Not listed	4 (1983)	Approved
Quinoline yellow/E104	Yes	Not listed	10 (1984)	Step 6
Sunset Yellow/E110	Yes	Yes. FDC Yellow #6. GMP	2.5 (1982)	Approved
Tartrazine/E102	Yes	Yes. FDC Yellow #5. GMP	7.5 (1964)	Step 6

(1) GMP means use limited only by Good Manufacturing Practice

(2) Step 6 in Codex refers to the procedural phase where a draft standard is sent to all Members and interested international organizations for comment on all aspects.

These colors are widely used by the global food industry and have been the subject of safety reviews by the United Nations FAO/WHO Joint Expert Committee on Food Additives (JECFA). All have been assigned an Acceptable Daily Intake (ADI) by JECFA which establishes the number of milligrams of the color an individual can consume per kilogram of body weight every day without adverse effect.

These colors have also been incorporated into the Codex Standards for many foods which requires a thorough safety evaluation by JECFA as a prerequisite. At present Codex has approved these colors for use in most categories of food.

All the colors are approved for use in the European Union and by many Governments around the world. Three of the colors are not approved by the U.S. Food and Drug Administration for use in food because industry has not pursued approval.

The debate on food colors in the EU is driven in large part by strong Scandinavian opposition to their use. The immediate catalyst for the European Parliament's warning label scheme was a study conducted at Southampton University in the United Kingdom in 2007. Results were published in September 2007.<sup>1</sup> The study concluded that the mixtures of a preservative and the colors studied caused hyperactivity in some children. As a consequence of the study, European food companies and retailers were attacked in the media if their products included these colors. The media gave little attention to the science underpinning the approval of these colors in the EU and elsewhere, or to the limitations of the study, its interpretations, or to the high concentrations of the additives used compared to normal dietary consumption.

In March 2008 The European Food Safety Authority (EFSA) convened a panel of experts in behaviour, child psychiatry, allergy and statistics to consider the study. EFSA concluded that the study provided limited evidence that the mixtures of colours and sodium benzoate had an effect on the activity and attention of children in the general population and that there was not enough evidence to change the current limits or use of these additives. The Panel concluded:

*"... the McCann et al. study provides limited evidence that the two different mixtures of synthetic colours and sodium benzoate tested had a small and statistically significant effect on activity and attention in children selected from the general population excluding children medicated for ADHD, although the effects were not statistically significant for the two mixtures in both age groups.*

*Since mixtures and not individual additives were tested in the study by McCann et al., it is not possible to ascribe the observed effects to any of the individual compounds. The clinical significance of the observed effects also remains unclear.*

*In the context of the overall weight of evidence and in view of the considerable uncertainties, such as the lack of consistency and relative weakness of the effect and the absence of information on the clinical significance of the behavioural changes observed, the Panel concludes that the findings of the study cannot be used as a basis for altering the ADI of the respective food colours or sodium benzoate.*<sup>2</sup>

Other food safety authorities concurred with the EFSA evaluation. These included the U.S. Food and Drug Administration and the Australia-New Zealand Food Safety Authority.

Nevertheless, the European Parliament set aside the findings of its own food safety authority and approved the requirement for food products that include these colors to carry warning labels. It was and is another example of the subordination of science to media exploitation and politicization of food safety that is not limited to the European Union.

### **Consequences for the Global Food Industry and Global Trade:**

The consequences for the food industry and food trade are very significant. Despite the exact wording, the EU warning label scheme sends the ominous message that the designated colors could harm children's physical and mental well-being. No parent is likely to purchase food products for their household when they are presented as posing a threat to their children.

Regardless of individual company use of colors or presence in the European market, the EU warning label scheme is recognized as a profound departure from science based regulation. Manufacturers are being told to warn consumers of the negative effects of their products on children when in fact the alleged

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<sup>1</sup> McCann et al. *Food additives and hyperactive behaviour in 3-year-old and 8/9-year-old children in the community: a randomised, double-blinded, placebo-controlled trial.* Lancet. Published Online September 6, 2007 DOI:10.1016/S0140-6736(07)61306-3

<sup>2</sup> European Food Safety Authority. EFSA-Q-2007-171

negative effects are not proven. In fact, the preponderance of evidence shows no relationship between food colors and hyperactivity in children.

The undermining of science based regulation is a threat to the entire global trading system and puts virtually all products at risk of accusations being rapidly translated into restrictive measures without prior objective evaluation. Other nations have already begun to mimic the EU which presages a trend toward deterioration of the science-based regulatory fabric that holds the global trading system together.

The European food industry association, CIAA, the largest manufacturing sector, major employer and exporter in the EU, expressed its concern to the European Government over the labeling requirement stating that it set a *"worrying precedent for future risk assessment decisions by disregarding important principles. Those are:*

- *The need to underpin legislation with sound evidence;*
- *The need for policy decisions to take into account recognised scientific evidence, in this case the opinion of EFSA;*
- *The need to undertake an appropriate regulatory impact assessment, which is actually stipulated within the better regulation principles advocated by the EU institutions."*

The World Trade Organization's Application of Sanitary and Phytosanitary Measures (SPS Agreement) recognizes the right of member countries to determine their own level of sanitary or phytosanitary protection and to apply that standard to domestic and imported products. At the same time, member countries agree to base their SPS measures on scientific principles and a risk assessment. Both the SPS and the Agreement on Technical Barriers to Trade encourage countries to base their regulatory measures on international standards such as Codex and JECFA, and requires them to provide adequate justification should they choose to impose a stricter standard. In this case, the European Union has ignored its own food safety authority as well as internationally recognized standards and scientific evidence and has chosen instead to implement this labeling scheme.

### **The Implications for Food Safety:**

Of potentially greater concern is the limited availability of safe alternatives when manufacturers are denied the use of safe synthetic color additives. Natural colors derived from vegetables, fruits, plants, and insects are an alternative in some cases but many lack the safety evaluations that have historically been required of synthetic additives. Reputable food companies are not willing to use a food additive whether natural or synthetic in advance of fully developed safety dossiers.

Both natural and synthetic color additives also present technological challenges including stability, solubility, durability, and effect on nutrients in foods. All colors do not work in all foods where color is desirable. With respect to natural colors which are typically derived from fruits, vegetables, and plants attention must also be given to sustainable supply, that is, the impact on food crops if large quantities of source material are diverted from the food chain for use in food coloring.

There is a genuine interest among some consumers in "natural" food. Food manufacturers are responding to this preference with new or modified products. As the industry works through the technical and food safety challenges involved, consumers' right to make a choice can best be preserved by requiring that food labels declare the presence of all additives both synthetic and natural. The EU requirement for warning labels for certain colors goes far beyond what is necessary to enable consumers to make that choice and does so at the expense of science based risk assessment and the ability of manufacturers to use safe and trusted color additives.

**EU Artificial Colour Warning Labels – Concerns of the United States**

WTO SPS Committee March 2010

Version: March 11, 2010

***Issue:*** The European Union is about to impose warning labels for food products which contain certain synthetic colors despite questionable scientific support for these measures..

***Talking Points:***

- Madame Chairman, the United States wishes to raise concerns on the European Union's Regulation (EC) No 1333/2008 on food additives, Article 24 which requires warning statements on food products that contain one or more of these six color additives: Sunset Yellow (E110), Quinoline Yellow (E104), Carmoisine (E122), Allura Red (E129), Tartrazine (E102), and/or Ponceau 4R (E124). The United States is concerned with this provision's scientific basis, its potential negative impact on trade, and the transparency of its adoption.
- Many of the six color additives are widely used by the global food industry in such products as confectionary and beverages.
- When the European Community notified its draft regulation as SPS/N/EEC/291 on August 10, 2006, the proposal did not contain these warning statement provisions. The United States reviewed the EC's notification of adoption, made on July 2, 2009, and discovered Article 24 on warning labels had been inserted. We are not aware of the warning label addendum being made known to trading partners or industry prior to the final adoption of the European Community's (EC's) food additive regulations on July 2, 2009.
- In 2007, the University of Southampton conducted a study regarding the potential link between the use of these color additives in children's food and hyperactivity. In November 2009, the European Food Safety Authority (EFSA) released scientific opinions on its re-evaluation of the color additives used in the Southampton Study. EFSA's scientific panel on food additives concluded that currently available data—including the Southampton Study—did not substantiate a link between the individual colours and possible behavioural effects.
- We are concerned that the EU plans to implement this measure in July 2010.
- While the United States supports a Member's right to impose measures to protect public health, we do not support the use of warning labels without sufficient scientific evidence to support the measure.

- We thank the EU for their continued willingness to discuss the matter with the United States and we will continue to urge them to delay the July 2010 implementation date until we are able to resolve this important trade concern.

***Background:*** On July 2, 2009, the EC notified the WTO of adoption of its final regulations on food additives. The adopted regulations contained a provision, Article 24 and related Article 35 and Annex V, not present in the draft regulations, which mandated the inclusion of warning statements on food products containing certain synthetic colors. Specifically, by July 20, 2010, manufacturers will have to include the statement, “name or E number of the colour(s): may have an adverse effect on activity and attention in children” on products containing one or more of the six artificial colors used in the Southampton Study. This provision is the subject of several different concerns of the United States.

First, the United States was not aware of the EC’s intent to adopt such a provision until its final publishing of the regulation on July 2, 2009. The EC notified an addendum that stated that “the proposal notified in EEC/291 has been adopted as [Official Journal Citation]”. It is this measure that included the warning label provisions. It is unclear whether other trading partners or industry had an opportunity to review the measure before adoption. This raises transparency concerns and the question of how the EC will take WTO members’ concerns into account.

Second, many of the six color additives listed in Annex V are widely used by the global food industry. The six color additives have been evaluated by the Joint FAO/WHO Expert Committee on Food Additives (JECFA), and have proposed draft or adopted provisions in the General Standard for Food Additives (GSFA). Therefore, relevant international standards exist, most explicitly for Sunset Yellow, Allura Red, and Ponceau 4R, which have adopted provisions listed in the GSFA. The GSFA also contains proposed draft and draft provisions for Quinoline Yellow, Carmoisine, and Tartrazine, but these provisions have not yet been adopted by the Codex Alimentarius Commission. The US FDA permits the use of only certified equivalents of Sunset Yellow, Allura Red, and Tartazine in food, and Quinoline Yellow’s certified equivalent is permitted for use in drugs, cosmetics, and medical devices. Ponceau 4R and Carmoisine are not regulated for use in any FDA-regulated product.

Third and finally, the EC’s list of color additives and the subject of hyperactivity was addressed in a much-criticized research piece known as the Southampton Study. Questionable daily intake levels and synthetic color mixtures, rather than individual color administration, have cast doubt on the usefulness of the study’s conclusions. Moreover, EFSA, the EU’s authority for food safety risk assessment, cited the “lack of consistency and relative weakness of the effect and the absence of information on the clinical significance of the behavioral changes observed” in the Southampton Study to recommend against altering ADIs based on the study. It would be important to determine the scientific studies on which the EC based their labeling provision.

The EC proposal is not a restriction on the use of these color additives, per se. The EC proposes requiring warning statements to be listed on products that contain one or more of these six colors. The US, for its part, simply requires that manufacturers list artificial colors subject to certification as part of the required ingredient list. Because there are no FDA regulations for the

use of Ponceau 4R, Carmoisine, and Quinoline Yellow in food, we do not foresee US industry concerns with the EC proposal to label these colors specifically, unless industry makes specific products for the European market. Because the certified equivalents of Sunset Yellow, Allura Red, and Tartrazine have been approved by FDA for use in food, products containing these color additives potentially could be exported to the EU and therefore would be subject to different requirements between the two regulatory jurisdictions. Rather than singling out only FDA-approved color additives for complaint, it seems more consistent and effective to express the US' concerns with the implementation of special warning statements for color additives generally, because such warnings regarding hyperactivity do not appear to be science-based.