



CPMA

**COLOR PIGMENTS
MANUFACTURERS
ASSOCIATION, INC.**

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April 3, 2003

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

Attn: Docket Numbers 02N-0276 and 02N-0278

Re: Comments of the Color Pigments Manufacturers Association, Inc. on the Food and Drug Administration Proposed Rules for Registration of Food Facilities, 68 Fed. Reg. 5378, Docket Number 02N-0276 and Prior Notice of Imported Food, 68 Fed. Reg. 5428, Docket Number 02N-0278, Under the Public Health Security and Bioterrorism Preparedness and Response Act

Dear Sir or Madam:

I am writing on behalf of the Color Pigments Manufacturers Association, Inc. ("CPMA") in response to the Food and Drug Administration Proposed Rules for Registration of Food Facilities, 68 Fed. Reg. 5378, Docket Number 02N-0276 (the "Proposed Registration Rule") and Prior Notice of Imported Food, 68 Fed. Reg. 5428, Docket Number 02N-0278, (the "Proposed Import Rule"), proposed under the Public Health Security and Bioterrorism Preparedness and Response Act (collectively, the "Proposed Rules").

The CPMA is an industry trade association representing color pigment companies in Canada, Mexico and the United States. CPMA also represents small, medium and large color pigment manufacturers throughout Canada, Mexico and the United States, accounting for 95% of the production of color pigments in these countries. Color pigment manufacturers located in other countries with sales in Canada, Mexico and the United States, and suppliers of intermediates, other chemicals and other products used by North American manufacturers of color pigments are also members of the Association. Color pigments are widely used in product compositions of all kinds, including paints, inks, plastics, glass, synthetic fibers, ceramics, color cement products, textiles, cosmetics and artists' colors.

INTRODUCTION

Our members are aware of the need to protect our nation's security, and we support the initiative FDA is taking under the Public Health Security and Bioterrorism Act of 2002 (Public Law 107-188) to increase security and prevent the possible intentional or unintentional contamination of foods. However, as discussed in more detail below, based on our members' review of the Proposed Rules, we find little, if any, benefit to the application of these Proposed Rules to the manufacture and import of regulated indirect food contact color pigments which may be used in the manufacture of packaging for food.

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These comments are not aimed at the manufacture and use of direct food colorants. Direct food colorants are regulated for the coloring of foods and food additives. To the contrary, these comments are aimed at indirect food colors, which are used in the manufacture of plastics, polymers and coatings used in food packaging, which may, in turn, come in contact with foods.

These comments will first discuss background descriptions for the products represented by the CPMA. Following that, the general requirements of the Proposed Rules and the basis of our concern, namely that the Proposed Rules will unnecessarily burden suppliers of color pigments to the packaging industry without any discernable security benefit, will be discussed in detail.

REQUIREMENTS OF THE PROPOSED RULES

Under these Proposed Rules, "food" will be defined to include food and feed and additives, including substances that migrate into food from food packaging and other articles. This would include all substances which can migrate into food from any food packaging in contact with food. Indirect food contact color pigments could therefore be regulated under the Proposed Rules.

The Proposed Registration Rule would require that each facility, including foreign facilities, provide a detailed certification including a description of the facility and the products produced.

The Proposed Prior Notice Rule would require the purchaser or importer of food to submit a notice to the FDA by noon of the calendar day before the day of arrival of food into the U.S. This notice must contain the name of the individual and the firm submitting the notice, the entry type and U.S. Customs entry number associated with the import, the FDA product code, the identity of the article of food being imported, the brand name for each article of food being imported, the quantity, lot numbers, the manufacturer, all growers, the country of origin, the shipper, the country from which the food was shipped, the anticipated arrival, the importer, owner, the consignee and the carrier. Additionally, the notice must be updated if the port of entry or arrival time changes one hour, if earlier, and three hours, if later, than the original predicted arrival time. This notice must be submitted to the FDA electronically.

These Proposed Rules would establish a considerable reporting burden on many companies which produce or market indirect food contact pigments. As discussed in more detail below, importers with no actual knowledge that imported pigments will be used in contact with food, will be required to provide these extensive reports with no discernable security benefit for the FDA. Since food is defined to include all food contact substances, the impact of the Proposed Rules will go well beyond only those facilities which produce food colors used as direct food additives.

BACKGROUND, CPMA INDIRECT FOOD CONTACT COLOR PIGMENT PRODUCTS

The CPMA represents the following classes of organic and inorganic color pigments. Individual members of these pigment classes are used, or regulated for use, in indirect food contact applications. All of the pigments used in indirect food contact applications have been shown to the FDA to be safe in food contact

Phthalocyanine Pigments

The phthalocyanine pigment class is characterized by a unique ring system which all of its members share. These pigments vary in color from blue to green depending on their chemical substituents and crystal structure.

Quinacridone Pigments

Quinacridones are pigments characterized by their linear, pentacyclic molecules manufactured either by oxidation of dihydroquinacridones, or by cyclization of 2,5-diarylaminoterephthalic acids. They are either opaque or transparent, high-tint strength pigments with high degrees of lightfastness, chemical resistance, heat stability and bleed resistance.^{1,2}

Monoazo Pigments

Monoazo pigments are characterized by a single azo group. Many members of this class are small in volume and used for special applications. The major volume monoazo pigments are reds made by coupling diazotized sulfonated aromatic amines to beta-naphthol or beta-oxynaphthoic acid followed by conversion to insoluble metal salts with, for example, calcium chloride.

Complex Inorganic Color Pigments

Nickel titanium yellow, chrome titanium, copper chromite and chrome oxide greens are in this group.

Nickel titanium yellow and chrome titanium yellow are mixed phase pigments based in titanium dioxide. The rutile lattice of titanium dioxide absorbs nickel oxide or chromium oxide as coloring components and antimony oxide for equalization of valency. The incorporated oxides completely lose their original chemical, physical and physiological properties since they no longer exist as chemical individuals in the mixed phase. Many of these pigments are used in indirect food contact polymers and packaging.

All these pigments are produced by a calcining process in which metal oxides are fused at temperatures at or above 1000° C.

THE UTILITY OF THE PROPOSED RULES FOR INDIRECT FOOD COLOR PIGMENTS

There would appear to be no discernable security benefit to requiring that indirect food contact pigments be registered or notified upon manufacture or import under the Proposed Rules. This is particularly true for colorants in food contact polymers where migration of the colorant to food is often immeasurable by the best of analytical equipment.

¹ Lewis, P.A., Editor, Pigment Handbook, Second Edition, John Wiley & Sons, 1987, pp. 601-607.

² Ehrich, F.F., "Pigments (Organic)," Encyclopedia of Chemical Technology, 2nd Edition, Volume 15, Wiley, New York, 1968, pp. 535-589.

In order to be regulated as an indirect food contact color pigment, the pigment must be proven safe and cannot migrate into the food in more than de minimis quantities (generally measured in part per billion concentrations). Color pigments must be proven safe and stable, both in the medium of use (such as a polymer) and the food the packaging may contain at the migration level anticipated. This proof must be established for listing in the Code of Federal Regulations as a regulated food contact substance. Alternatively, manufacturers must provide FDA with proof of non-migration pursuant to the Food Contact Notification Process in order to establish that indirect food contact pigments are not regulated, since these pigments do not become part of the enclosed food.

For example, in order for FDA to approve a notification under the food contact notification process, the applicant must prove that the substance does not migrate above de minimis amounts under conditions of use. The process allows the FDA to agree with the proof of non-regulation, meaning that the substance does not migrate and is not a food or a food additive. Food contact notification pigments which are not regulated should not be defined as indirect additives and, therefore, food under the Proposed Rules.

The point of the long-standing FDA regulatory process in this area is that the essential proof required by FDA for a product to be marketed as an indirect food contact color is that the product does not become a significant part of the enclosed food. If indirect food colors are not part of the food because they do not migrate to food, it does not appear reasonable for FDA to now regulate these color pigments as food for purposes of security, because it is highly unlikely that such a route could be utilized to impact the food stream.

Furthermore, the chemistry and function of color pigments is such that, if these products were, or could be, sufficiently adulterated to pose a threat by migration into foods from packaging, the pigment would not function correctly in the packaging, polymer or coating systems. Since color pigments must be almost completely insoluble in the medium in which they are used, particularly for food packaging, the amount of contaminants which would be required to pose a threat to food by migration from polymers and coatings is such that the basic stable coloration of the pigment would almost certainly be compromised.

It must be kept in mind that color pigments are almost always used in polymer and coating systems at very low loading concentrations, often no more than one or two percent. The color pigment must have sufficient color strength to provide stable uniform color at these low loading concentrations. A color pigment which is sufficiently adulterated to pose a threat by migration to food through the barrier of the polymer or coating would almost certainly not be able to provide the stable and completely insoluble specific color intended for the application.

Additionally, food contact colors are several steps removed from the preparation and packaging of actual foods moving through commerce. The chain of commerce for color pigments which might be used in indirect food contact applications is a complex one. Ordinarily, a manufactured color pigment which can be used under the regulations for indirect food contact applications can also be used for many other purposes unrelated to food and food packaging. Color pigments are often used first by dispersion or concentrate producers which prepare colored plastics, coatings or inks in a concentrated form for use by others. The concentrated product is then sold to other manufacturers that produce plastic articles, or coatings and inks. These products, in turn, are sold to finished product manufacturers or packaging

manufacturers and then users that would actually place food in the package. As a result, there are always several steps in commerce before these products are even used in food packaging. Therefore, the decision to use a color pigment in food packaging may not be made until well after the product is sold in commerce to manufacturers of dispersions and concentrates.

FDA already mandates a comprehensive system of Current Good Manufacturing Practice ("CGMP"). The CGMP regulations cover all manufacture, processing, packing or holding of food, food ingredients and regulated food additives. These regulations assure that all foods related manufacturers meet the requirements for safety in food preparation. 21 CFR §110. All manufacturers and importers of foods and food packaging are required, therefore, to ensure that no adulterated ingredients enter the food supply. Since food and food packaging manufacturers are tasked with compliance under this comprehensive system of regulation and since regulated indirect food contact color pigments are supplied to these manufacturers in intermediate products for use in regulated packaging, a system whereby purity in ingredients is required already exists. FDA's resources should be directed toward those manufacturers with some direct connection to the food supply.

ECONOMIC ANALYSIS

Benefits of the Proposed Rules

FDA indicates that an overall goal of the Proposed Import Rule is to allow FDA personnel to be ready to respond to shipments that appear to be adulterated, whether through intentional or accidental means, as well as when FDA receives credible evidence that an entry represents a serious threat to human or animal health. The regulation of color pigments that in a small percentage of cases could be used for indirect food contact will only drain away FDA and industry resources that could be used to achieve that goal. Since only a small portion of those color pigments regulated for food contact by FDA are actually used in food contact applications, this regulation will have an unintended impact on many other non-food products and processes.

FDA indicates that "historical evidence suggests that a terrorist or other intentional strike on the food supply is a low probability, but potentially high-cost event." 68 Fed. Reg. 5454. Since intentional or unintentional contamination of the food supply using indirect food contact color pigments is nearly impossible, there would appear to be no likely benefit from FDA's expansion of the definition of "food" to include indirect food contact pigments.

FDA supports its analysis of the benefits of the Proposed Rules with examples of harm and costs incurred in reacting to food born illnesses. There has never been a food born illness, that we are aware of, attributed to a contaminant migrating from a color pigment used in food packaging. It would appear highly unlikely that there will be such an event in the future. We are aware of no biological contaminants which are likely to, or could, occur in food and also survive in the harsh environment of bulk commercial color pigments or the severe environment which occurs in the manufacturing formulation of plastics, inks and coatings.

Small Business

The FDA indicates in describing the costs of the Proposed Import Rule that 77,427 businesses will be impacted. Of this number, FDA indicates that most of these businesses are small, having less than 500 employees. FDA goes on to indicate that the cost of compliance with the Proposed Import Rule will be \$770.00 per importer. 68 Fed. Reg. 5457. This very brief and apparently inadequate analysis makes a number of assumptions. It assumes that compliance will fit within some average which admittedly does not include the cost of computer equipment for those importers that do not have this equipment.

Additionally, the analysis makes no effort to differentiate those businesses, such as importers of indirect food contact color pigments, that import color pigment products for purposes other than food contact packaging. Many, if not the vast majority, of these products are used in other commercial colored products which have no relationship to food or food packaging. As an example, the same colored plastic which is used for specific food packaging applications may also be used for plastic furniture or automotive applications. The burden on small businesses to differentiate these possible uses for the FDA and provide notice when and where appropriate is not considered in the Proposed Rules.

FDA also appears to assume that sufficient employees trained in the necessary research and reporting techniques required by the Proposed Rules will be available to small businesses to comply with the regulation. Many, if not most, of the importers that will be impacted are very small businesses which may have fewer than five employees in a brokerage or import businesses and no actual manufacturing plant or storage in North America. There is no reason to assume that these businesses will have the resources required to make timely notifications to FDA for every color pigment imported which might, if downstream customers request, use specific portions of the imported products for indirect food contact purposes.

CONCLUSION

FDA indicates that the hypothetical case in which someone would impact the food supply by adulterating food has a very low probability. 68 Fed. Reg. 5409. The possibility of adulterating food using food contact color pigments is a far more remote possibility. The Proposed Rules will require that the regulated community provide a massive amount of information to the FDA on a continual basis. Since the FDA and other concerned Federal agencies have limited resources with which to monitor all of the possible scenarios which could conceivably pose a threat to security, regulation of indirect food contact colors would appear to be an added burden which does not achieve the goals of the proposed regulatory structure. The limited resources of the FDA would be better used to monitor those processes and products which may pose a more realistic threat.

Therefore, the Proposed Rules appear to be over broad in their scope and application. Indirect food contact color pigments should not be regulated with the same information requirements intended for actual food and direct food additives. The inclusion of indirect food contact color pigments in this rule when finalized would be a mistake and an unnecessary burden on an already overtaxed FDA. We therefore

urge strongly that FDA remove indirect food contact colors from this proposed regulation and consider these products in a separate measure, if needed, which would more accurately address the remote risk posed by these products.

Please call if there is any further information that we can provide.

Sincerely,



J. Lawrence Robinson
President

cc: Office of Information and Regulatory Affairs
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JLR:jldd