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**Re: Proposed Rule; Food Additives: Food Contact Notification System [Docket No. 99N-5556]**

On behalf of the Food, Drug, and Cosmetic Packaging Materials Committee of The Society of the Plastics Industry, Inc. (SPI)<sup>1/</sup>, we hereby respectfully submit these comments on the above-referenced Proposed Rule, which was published in the *Federal Register* on July 13, 2000 (65 *Fed. Reg.* 43269). The Proposed Rule is intended to implement the Food Contact Notification (FCN) process for food-contact substances (FCSs), consistent with the relevant premarket notification provision in the Food and Drug Administration Modernization Act of 1997 (FDAMA) (Public Law 105-115).<sup>2/</sup> Our comments also address the companion guidance

<sup>1/</sup> Founded in 1937, The Society of the Plastics Industry, Inc. (SPI) is the trade association representing one of the largest manufacturing industries in the United States. SPI's 1,700 members represent the entire plastics industry supply chain, including processors, machinery and equipment manufacturers and raw material suppliers. The U.S. plastics industry employs 1.5 million workers and provides \$304 billion in annual shipments.

<sup>2/</sup> We suggest that it would be preferable, for Food Contact Notifications, to use a designation other than premarket notification, or "PMN," to avoid confusion with the "PMN" (premanufacture notice) that is filed with the Environmental Protection Agency (EPA) under the (continued...)

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document entitled "Preparation of Premarket Notifications for Food-Contact Substances: Administrative" (Administrative Guidance), the availability of which was announced in the proposed rule.

We first would like to thank the Food and Drug Administration (FDA) for drafting the Proposed Rules and revising the draft Administrative Guidance in a way that will allow the FCN program to be implemented as envisioned under FDAMA. In all substantive respects, we find the Proposed Rule and Administrative Guidance to provide a suitable, straightforward path to appropriate operation of the FCN process. Our review indicates only a few instances in which we believe some clarification is in order. Overall, the Agency is to be commended for developing satisfactory rules and guidance for this important regulatory reform. Having worked closely with FDA to bring this program into being, we appreciate the opportunity to comment on the Proposed Rule and draft Administrative Guidance, and we hope our input will be useful in finalizing the FCN procedures.

In these comments, we are proposing some pro forma clarifications to the Proposed Rule and/or Administrative Guidance document to take care of the following four points of concern to SPI: (1) it is our belief that, under the statute, the 120-day review period runs from the date of receipt by FDA of the FCN, not from the date of acceptance or acknowledgment of the FCN by FDA; (2) it has been our view that Form 3480 is intended to provide lists and brief summaries of information contained in the the FCN, not to duplicate the full FCN discussion; (3) we submit that, consistent with long-standing FDA policy, Good Laboratory Practices (GLPs), as this term is normally used by the Agency, are required only for toxicology studies, not for migration testing; and (4) we remain of the view that FCNs are required only for food-contact substances that meet the statutory definition of "food additive," and companies are fully entitled to determine for themselves that a substance is not a food additive, and we understand that this is FDA's position as well. We urge clarification on these issues, and believe that the Proposed Rule and the Administrative Guidance document will be completely satisfactory guides for the successful implementation of the FCN program if the minor changes we are recommending are made.

#### A. Beginning of 120-Day Review Period

Section 170.104(b) of the Proposed Rule states that, "[i]n order for the 120-day review period to begin, FDA must *accept* that notification" (emphasis added). Upon first reading, we

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<sup>2</sup>(...continued)

Toxic Substances Control Act (TSCA). It seems to us that a designation such as Food-Contact Notification (FCN) might be suitable for these filings and eliminate the potential for confusion with the TSCA PMN process, which already has occurred among some in industry. We will use the FCN terminology in these comments.

interpreted this provision as starting the 120-day review period from FDA's acceptance of an FCN, rather than from receipt of the FCN by the Agency. This would be inconsistent with Section 409(h) of the Federal Food, Drug, and Cosmetic Act, which states that "[a] notification submitted under paragraph (1) shall become effective 120 days after the date of *receipt* by [FDA]" (emphasis added), unless the Agency objects within that timeframe.

Based on informal guidance from FDA, however, we understand that Section 170.104 is not intended to create a starting point for the review period different from the one (date of receipt) provided in the statute. The procedure, as described to us by FDA, will have the 120-day period run from receipt of the FCN unless FDA determines that the FCN is not acceptable on its face for one or more of the reasons set forth in the Proposed Rule or unless the notifier submits significant missing information before being advised that the FCN is not acceptable (in which case the 120-day period will run from the date of the additional submission).

We are pleased to learn that the beginning of the review period for acceptable FCNs will remain fixed at the date of receipt by FDA, as intended and explicitly provided in the statute. It also seems reasonable for FDA not to accept and waste resources reviewing FCNs that are not acceptable for the reasons stated in the Proposed Rule. The current language of Section 170.104(b), however, seems very susceptible to our initial incorrect interpretation. We suggest revising this provision along the following lines:

(b) For the 120-day review period to continue to run from the date of receipt of the PMN [preferably FCN] by FDA, the PMN must be accepted by FDA.

We consider it preferable for clarification to be provided in the regulation itself, not solely in the preamble to the final rule or in some other fashion, so that the proper interpretation will be apparent to readers subsequently relying on the Code of Federal Regulations as their guide to the FCN procedures.

#### **B. Relationship Between Form 3480 and the FCN**

The Proposed Rule requires the submission of FDA Form 3480 (which is attached to the Administrative Guidance document) as an essential element of an acceptable FCN. The Administrative Guidance (at Section III G) indicates that the form is intended to contain "a summary of the chemical, toxicological, and environmental information submitted with the notification." The form itself, however, is extensive and, if taken literally, could constitute a reiteration of the entire contents of the FCN.

We think that it would be helpful for notifiers (and reduce the paperwork burden on them and FDA) if the Agency provides more specific guidance to the effect that Form 3480 is not intended to contain the same full discussion as the FCN on subjects such as the notifier's safety determination. In comments on behalf of SPI concerning the toxicology guidance document, we

already have discussed what we consider overly onerous and somewhat duplicative paperwork recommended by FDA for the toxicology section of the FCN itself. We would like to see confirmation by FDA that Form 3480 does not envision anything more than a brief summary of the essential elements of the safety determination and similar abbreviated treatment of other types of information in the FCN.

**C. Good Laboratory Practices**

In Section 170.101(c) of the Proposed Rule, FDA would require that all non-clinical laboratory studies submitted as part of an FCN be performed under Good Laboratory Practices (GLPs) as indicated in 21 C.F.R. Part 58 or validated by an independent third party. At first blush, this requirement seems broad enough to apply to analytical testing such as migration studies. However, 21 C.F.R. § 58.3(d) defines non-clinical studies that are subject to the GLP requirement as “in vivo or in vitro experiments in which test articles are studied prospectively in test systems under laboratory conditions to determine their safety . . . The term does not include basic exploratory studies carried out to determine whether a test article has any potential utility or to determine physical or chemical characteristics of a test article.” We assume that FDA did not intend Section 170.101(c) to extend GLPs to migration studies, but, to avoid misinterpretation, we suggest that the Agency explicitly refer to Section 58.3’s definition of “non-clinical studies” in the Proposed Rule, thereby clarifying that only toxicological or biological studies are subject to the GLP requirement.

**D. Clarification that a Notification Is Needed Only for Food-Contact Substances that Also Are Food Additives**

In the preamble to the Proposed Rule, FDA states that “[u]nder section 409(a) of the [Federal Food, Drug, and Cosmetic] Act, in the absence of an effective notification, an FCS cannot be lawfully marketed.”<sup>3/</sup> A literal reading of this statement would lead the reader to conclude that *all* FCSs, regardless of whether they are food additives, require FDA premarket clearance.

We recognize that, elsewhere in the preamble (at p. 43271), FDA states the correct principle - - “Notifications are required only for FCS’s that are food additives . . .” In our view, however, it is important for FDA to be consistent and clear in all written communications on this critical and much misunderstood point. Potential confusion could be avoided by simple changes, such as revising the statement at issue to read as follows:

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<sup>3/</sup> 65 *Fed. Reg.* 43269, 43274 (July 13, 2000).

“Under section 409(a) of the act, in the absence of an effective notification, an FCS *that is a food additive* cannot be lawfully marketed.” (Additional language in italics).

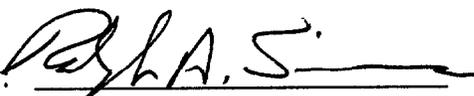
In addition, while FDA acknowledges at page 43271 that FCNs are not required for FCSs that are not food additives, the Agency cites only two of the three possible bases on which an FCS may not be a food additive. Specifically, FDA correctly identifies prior sanctioned and generally recognized as safe (GRAS) substances as not being food additives and not requiring an FCN. FDA has omitted from this discussion substances that are not food additives because they are not reasonably expected to become components of food and, therefore, are outside the statutory definition of a food additive. The explanation of the Proposed Rule also does not explicitly acknowledge that companies may determine for themselves, without consulting FDA, that a substance is not a food additive for its intended use. We respectfully submit that discussion of these principles by FDA would help provide the full context for the FCN process.

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SPI appreciates the opportunity to comment on FDA's Proposed Rule and Administrative Guidance. The Society would be pleased to respond to requests FDA for additional information pertaining to these comments.

Respectfully submitted,

THE SOCIETY OF THE PLASTICS  
INDUSTRY, INC.

By:   
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