Documents tabled at Tripartite workshops, 10 October 1983

Workshop on Food Contact Issues

Following documents have been distributed to the workshop attendants.

1. JPIF

- "Presentation at the Food Contact Workshop of the Tripartite Meeting".
- "Recent Aspects relating to Plastics in Contact with Food in Japan", October 1983, Japan Hygienic Olefin and Styrene Plastics Association (JHOSPA) and Japan Hygienic PVC Association (JHPA).

2. SPI

- "Recent Developments in United States Regulation of Food Packaging", Jerome H. Heckman, Keller & Heckman.

3. APME

- "Introductory statement for the tripartite workshop on Food Contact Issues" (ref. 13.12/6.0/83.10.05).

Corrected version of original statement

Introductory statement for the tripartite workshop on

Food contact issues to be held in

Düsseldorf on 10 October 1983

The APME Food Packaging Committee is concerned with regulatory developments in Europe relating to food contact safety of plastics applications including packaging, food contacting utensils, toys, pharmaceutical and medical articles. The Committee represents the industry towards EEC and other supranational authorities and monitors national developments. In the past two years it has dealt with legislation reported as follows.

1. European Communities

1.1 Adopted Directives

1.1.1. Directive laying down the basic rules for testing migration (O.J. no L 297/26 of 23.10.82).

This directive defines "plastics", lays down the field of application and gives the four food simulants and the time/temperature conditions which have to be used for migration determination. Furthermore procedures are laid down to adapt the directive to progress made in scientific and technical knowledge and to actual conditions which are basically different from specified test conditions.

1.1.2. Directive concerning materials and articles made of regenerated cellulose (O.J. no L 123/31 of 11.05.83). The directive includes a positive list of additives which may be used and which are limited in their content in the final object. There are no migration limits. The directive is not applicable to films which have a coating of more than 50 mg/dm2 and for sausage skins.
Concerning phthalates, which are listed amongst the additives in the directive, member states may refuse authorisation.

1.2. Proposed directives.

1.2.1. Directives for toys (O.J. no C 203/1 of 29.07.83).
These directives lay down the requirements for finished toys in respect of mechanical and physical properties and to flammability.
Further directives are planned which will deal with chemical and electrical properties.

1.2.2. Directive laying down a conventional classification of foodstuffs (not yet published, but expected end 83/beginning 84).
This directive will contain a comprehensive list of foods and beverages and specify which food simulants represent each different foodstuff. Adaptation factors will also be given in

certain cases, e.g. it is expected that migration into butter will be calculated by halving experimental values obtained by olive oil.

1.3. Draft directives under deliberation.

1.3.1. Monomer list.
A working group of the Commission of the European Communities has listed all monomers which are approved or accepted by national authorities for the manufacture of plastics. This working group consists of representatives of national authorities and of industrial organisations, including APME and Eutraplast. The EC Commission is proposing to classify these monomers into two groups. The monomers in the first group would have no specific limitation apart from a general overall migration limit of 60mg/kg. The monomers in the second group would have specific limitations regarding migration or content in the final object. Each group would be subdivided into monomers for general use and monomers approved only for certain plastics.
The representatives of the national authorities have not yet discussed these principles in the working group, a long and hot debate can be expected.
The EC scientific committee for food, an advisory committee of toxicologists from Member States, has reviewed all monomers and in many cases has asked for additional toxicological data which makes the situation more difficult.

1.3.2. Additive list.
The Commission of the European Communities has compiled a list of additives, which has not yet been checked for completeness nor discussed by the Commission working group. The Commission intends to adopt a similar approach as for monomers.

2. Council of Europe.
Whereas the European Communities (EC) are agreeing directives which have to be transposed into national laws by the 10 member states, the Council of Europe can only give recommendations or propositions to its 21 members states.

2.1. Booklet "Substances used in plastics materials coming into contact with food".
A second version of this booklet has been issued.
The Council of Europe itself has stated that this booklet is not a compilation or harmonisation of current legislation but contains conclusions of scientific experts and is not legally binding on member states.

2.2. Monographs of the European Pharmacopoeia related to plastics.
Up to now only monographs for plastics containers made of HDPE, LDPE and PP have been accepted. A monograph for PVC has been accepted and is now published. More are under discussion.

In case industry wants to take part in this work, this must be done via the national authorities as contacts with APME have been shunned by the Council of Europe working group.

2.3. Coloured plastics for food contact.
A working group of the Council of Europe has elaborated working papers regarding the colouration of plastics for food contact. The industries concerned which consist of the plastics manufacturers and both the producers of organic and inorganic colourants are trying to develop harmonised views on these working papers, which are not officially available. Some elements of these working papers, however, have caused great concern.

3. WHO-Codex Alimentarius commission.
The EC have asked APME for certain information concerning AN, VC, Styrene and DEHP, following a similar request to EC from the Codex Alimentarius.
APME intends to point to the existing regulations in the national laws concerning these substances. In our opinion it is superflous that the Codex Alimentarius commission should start discussing substances which have already been discussed exhaustively in national and international bodies.

4. National developments.

4.1. Cadmium.
Sweden, having issued a cadmium-ban (with certain exemptions) in 1982, will be followed by Denmark which has published a draft of comparable regulation, intended to come into force in 1984. The influence of such a regulation spreads far beyond the national borders as many processors in other countries will not keep two types of stocks and therefore demand "cadmium free" for all their products.

4.2. Acrylonitrile
There are still different limitations for AN migration in different European countries, but the EC do not intend to issue a special directive for AN, like they have done for VC. The EC intend to regulate AN with the monomer list mentioned under 1.3.1.
In 1982, the Federal Republic of Germany has published a method for testing AN migration into food, with which migration must be undetectable. The detection limit (reproducibility) of this method is 20 ppb.

4.3. DEHP + DEHA
Italy has published a decree (Gazzetta Ufficiale of 11.12.82) limiting the use of DEHP and DEHA to some articles in contact with only certain foodstuffs.

5. APME Product Registration File.
The next edition of the APME Product Registration File will be issued by the end of 1983 and will include the contributions from Japan and USA.

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APME ASSOCIATION OF PLASTICS MANUFACTURERS IN EUROPE

TRIPARTITE MEETINGS APME/SPI/JPIF

Düsseldorf, 10 October 1983

Workshop on Food Contact

List of participants / page 1

Name	Organsation/Company	Signature
G. BALLET	[illegible]	[illegible]
[illegible]	[illegible]	[illegible]
[illegible]	[illegible]	[illegible]
[illegible]	[illegible]	[illegible]
A. Zandvoort	Unyelin Polymers	[illegible]
T. MORI	J.P.I.F. / Nippon Steel Chem	[illegible]
T. OKABE	J.P.I.F. / (J.P.C.A)	[illegible]
[illegible]	[illegible]	[illegible]
M. TAKINE	JPMA JHPA	[illegible]
[illegible]	[illegible]	[illegible]
[illegible]	[illegible]	[illegible]
Y. SHIMAHARA	JPIF JPIA	[illegible]
[illegible]	[illegible]	[illegible]
[illegible]	[illegible]	[illegible]
[illegible]	[illegible]	[illegible]
[illegible]	[illegible]	[illegible]
S.J. RUPERT	HOOVER UNIVERSAL INC	[illegible]
J. H. HELKMAN	[illegible]	[illegible]
[illegible]	[illegible]	[illegible]
[illegible]	[illegible]	[illegible]
[illegible]	[illegible]	[illegible]
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[illegible]	[illegible]	[illegible]
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[illegible]	[illegible]	[illegible]

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ATTACHMENT 2

Letter from G. R. Munger
to Senator Orrin Hatch
re Pre market Notification
Procedure for Food Additives

The Society of the
Plastics Industry, Inc.

355 Lexington Ave
New York, New York 10017
(212) 573-9400

December 1, 1983

Honorable Orrin G. Hatch
Chairman
Committee on Labor and Human
Resources
135 Russell Senate Office Building
Washington, D.C. 20510

Re: Food Safety Modernization Act -
Indirect Additives

Dear Senator Hatch:

The introduction of the Food Safety Modernization Act of 1983 (FSMA) marked a laudatory step toward food safety reform. You and others involved in this effort are to be commended on a job well done.

As you are aware, The Society of The Plastics Industry, Inc. (SPI) has been heavily involved in this legislative effort with our primary interest being the indirect additive provisions of the legislation.*/ Our goals for reform of food-packaging regulations have had two main objectives. One goal is to require the Food and Drug Administration (FDA) to issue regulations

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*/ SPI represents some 1,200 member companies and is the major national trade association of the plastics industry. Its membership represents over 95% of the production and about 75% of the sales of plastics materials in the United States.

SPI has been the spokesman for the plastics industry in seeking reasonable supervision of food packaging and cautioning against over-regulation in this area. The Society's involvement can be traced to testimony in the 1958 congressional hearings which led to the passage of the Food Additives Amendment of 1958. Since 1979, SPI has actively participated in the process that lead to the introduction of legislation last session and testified at the June 1983, Senate hearings.

The scope of FDA's administrative problem was best summarized by a key FDA staff member in a published interview. He indicated that among the 200 or so people in the Bureau of Foods that work with food additives, approximately 85 percent of their time is spent reviewing packaging. Reform would free much of this staff time to concentrate on real public health issues.

As SPI's written statement demonstrated, the delay facing industry is staggering. Over 73 percent of the pending food additive petitions have been pending in excess of the six-month statutory time limit. Fifty-five percent of the petitions are pending after one year, and 37 percent are pending after two years. Approximately 24 percent are still pending three years after filing. This is so even though the number of petitions filed annually is hardly overwhelming, ranging from a low of 13 in 1978 to a high of 47 in 1982. These figures represent unacceptable delay and a waste of FDA resources.

C. Typical Problems PMNs Can Solve

To appreciate the rapid improvements that a PMN system would bring, six brief examples follow. Each example typlifies an existing regulatory trouble-spot which is not adressed by the FSMA in its present form.

1. **Expanding clearance within a class of materials**

In almost all cases, food additive regulations are promulgated in response to a food additive petition by a private company seeking to introduce a new or modified product or obtain approval for a new use for an existing product. Due to the nature of this system, companies submitting food additive petitions limit their petitions to the specific product or application they wish to promote. As such, a number of unwarranted restrictions or limitations appear in regulations simply because the petitioner limited the petition to its particular case.

A PMN system would provide a reasonable procedure for correcting these limitations while keeping FDA fully informed. For example, during his testimony before the Senate in June, former Commissioner Jere E. Goyan testified concerning the unacceptable delay the current regulatory system created in promul-

mechanism. Indeed, the absence of any public health problems from packaging is the best proof that the regulatory roadblock has no justification.

3. Removing non-critical technical barriers

Another limitation, similar in nature to the aseptic packaging situation, arises when a cleared material is characterized by some non-critical parameter that results from a proprietary technology. This may impose a regulatory restriction that should be removed. For example, assume that a particular cleared material is described as being prepared with the use of a solvent. If there are no health or safety concerns regarding the product per se, the same product made without the use of the solvent could be promptly cleared through a PMN system.

4. Clarifying prior-sanctioned or GRAS status

A food additive regulation is not required when a packaging material is prior-sanctioned or generally recognized as safe (GRAS). Often, there is some question concerning the existence or scope of the prior sanction or whether a particular material would be considered GRAS for a specific use. The PMN system would provide a ready procedure for filing information with FDA when clarification is needed. Given the cost and time of the food additive petition process, decisions concerning prior sanction and GRAS status are frequently made without FDA involvement. A PMN system would encourage a filing with the Agency in such instances and would keep FDA better informed.

5. Increasing FDA knowledge and awareness

Indeed, a PMN system would potentially improve public health protection. Based on our collective experience with the food packaging and processing industries, we have observed that firms which process or package food demand some form of FDA clearance or other assurance of regulatory acceptability. If a PMN system was created as an alternative to the current food additive petition process, marketplace realities would encourage packaging fabricators or resin suppliers to file PMNs even

the Medical Device Amendments of 1976, FDA labeled contact lenses and devices used for laboratory analysis as "drugs" for the simple reason that, unless it did so, the Agency would have had no power over these commodities other than the authority to find adulterated or misbranded articles and seize them or prosecute the sellers. In other words, to permit the Agency to obtain premarket information, the language of the drug provision of the statute was given an exceptionally expansive reading.

The same experience has been true for food packaging. In Monsanto Co. v. Kennedy, 613 F.2d 947 (D.C. Cir. 1979), FDA attempted to exercise jurisdiction over the acrylonitrile bottle by contending that theoretically projected but undetectable migration made the bottle a food additive. This contention can only be understood as the Agency's effort to find a basis for jurisdiction over a potentially widely-used packaging material.

As Section 414 is now written, the same unintended result may well occur. FDA might write the definitional regulations so broadly as to make it virtually impossible for any food-contact substance to be marketed without going through the food additive petition process. A distortion of legislative intent would be far less likely if a premarket notification system were in place. In that event, the consequences of a broad food additive definition could be ameliorated by permitting PMNs to be utilized.

E. Proposed Language

The concept we support is embodied in the following language which could be added to Section 414:

> Within two years after the date of enactment of the Food Safety Modernization Act of 1983, the Secretary shall, by regulation, establish one or more classes of substances which are reasonably expected to become a component of food under intended conditions of use for which, in lieu of the food additive petition, a premarket notification may be filed with the Secretary. A premarket notification shall become

ATTACHMENT 3

Roster of Members of
FDCPMC Steering Committee

The Society of the
Plastics Industry, Inc.

SPI

Membership Roster

355 Lexington Avenue
New York, New York 10017
(212) 573-9400

DECEMBER 27, 1983

FOOD, DRUG & COSMETIC PACKAGING MATERIALS COMMITTEE

STEERING COMMITTEE

Leo W. Ziemlak - CHAIRMAN
2804 Tiburon Drive
New Port Richey, FL 33553

L.J. DeCorte
ARCO CHEMICAL COMPANY
3801 West Chester Pike
Newtown Square, PA 19073
(215) 359-2000

David Gordon
CIBA-GEIGY CORPORATION
3 Skyline Drive
Hawthorne, NY 10532
(914) 347-4700

William Hoyle
CONTINENTAL GROUP, INC.
711 Jorie Blvd.
Oak Brook, IL 60521
(312) 986-0333

George Chandler
EASTMAN KODAK COMPANY
P.O. Box 431
Kingsport, TN 37662
(615) 229-2000

Peter Morison
EASTMAN KODAK COMPANY
Building 150 A
Kingsport, TN 37662
(615) 229-3279

Richard Haas
GOODYEAR TIRE & RUBBER COMPANY
1144 East Market Street
Akron, OH 44316
(216) 794-3840

Shirley Keahey
HERCULES, INC.
910 Market Street
Wilmington, DE 19899
(302) 575-5000

Donald W. Pugh
NATIONAL DISTILLERS & CHEMICALS CORPORATION
4900 Este Avenue
Cincinnati, OH 45232
(513) 482-2294

A. Merrill Schnitzer - VICE CHAIRMAN
PHILLIPS CHEMICAL COMPANY
Seneca Building
Bartlesville, OK 74004
(918) 661-5950

David W. Thornburg
PHILLIPS CHEMICAL COMPANY
Plastics Technical Center
Bartlesville, OK 74004
(918) 661-3519

Fran W. Lichtenberg
SOCIETY OF THE PLASTICS INDUSTRY, INC.
355 Lexington Avenue
New York NY 10017
(212) ~~573~~-9458

SCC
5-1806