APPENDIX B

NEW ASPECTS OF FOODSTUFFS LEGISLATION IN THE GERMAN FEDERAL REPUBLIC */

Ladies & Gentlemen:

I would like to give you some items about new aspects of foodstuffs legislation in the German Federal Republic. It will not be superfluous to give a short summary of the current legal regulations before going into a discussion on the prospective new paths which the legislature of the German Federal Republic proposes to follow. Such a review will make it easier to understand the intentions which guide the legislature in formulating the new foodstuffs laws. Like all laws, the food laws are a reflection of all kinds of developments. Typical of this was that, in 1958, the term "Fremdstoffe", was introduced into the law. An accurate translation for "Fremdstoffe" can't be given. I shall use, "foreign substances" even if it is by no means correct. From the following, you will see what is to be understood by this term. As I said, the term "Fremdstoffe" was introduced into the law. The demands for purity in foodstuffs had grown with the rising standard of living. As we shall see, the decree requiring that foodstuffs should be free of foreign substances was not issued with the intention of preventing danger to health. Thus we are already confronted with foodstuffs regulations which we, as manufacturers and processors of plastics materials, have to observe where our products are likely to come into contact with foodstuffs. In the first place, we have the directions which forbid the access into foodstuffs of substances that are dangerous to health, and, secondly, we have the regulations which forbid the access into food of substances which, although they are actually non-injurious to health, are, nevertheless, to be considered as foreign to the foodstuff. Naturally, we are primarily interested in the regulations that govern the materials with which the foodstuffs can in any way come into contact and, of course, even more particularly, the use of plastic materials. We can establish that: all materials or articles that come into contact with foodstuffs, be they packaging materials, bottles, the interiors of refrigerators, pipelines for beverages, rubber gloves used in the household or in foodstuffs factories, covering materials for shop counters and so on, are articles of use which are subject to the following regulations:

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*/ Presented by Dr. Georg Triem, Technical Applications Department, BASF Corporation, at the June 10, 1970 meeting of the Food, Drug and Cosmetic Packaging Materials Committee of the Society of the Plastics Industry, Inc. This meeting was held in Washington, D.C. at the Mayflower Hotel.

Paragraph 3.2a of the foodstuffs law imposes a general veto on all articles of use which, because of their components are likely to be injurious to human health.

Paragraph 4a forbids the addition of "foreign substances" to foodstuffs.

First of all, we must ask what are "foreign substances," and then, what is understood by "addition." The definition of foreign substances which do not contain any digestible carbohydrates, digestible fats or digestible protein (the scope of the legal definition is somewhat wider). Foreign substances are therefore substances which are not actually foodstuffs because they are eaten. The word, "addition," is not understood to include only intentional additions to a foodstuff. Paragraph 4a, states expressly that "addition" means also when a substance gains access into the foodstuff during storage; that means, for instance, from the packaging material.

The summing up of the prohibitions mentioned, and a very important limitation to these prohibitions, is given by Para. 4b, 5, which is the most important for us:

"It is forbidden to use articles of use in such a manner that foreign substances can gain access into foodstuffs or onto their surface, with the exception of ingredients that are not unacceptable on the grounds of health, odor and taste, and which are technically unavoidable."

The definitions contained in this Para. 4b, 5, have led to the issuing of "Recommendations" by the Federal Bureau of Health. The law, namely, does not say either what foreign substances are technically unavoidable, conversely avoidable, or what are the permissible amounts of those substances which are regarded as being technically unavoidable. As you see, the information given by the legislators is limited and the manufacturer or requisites and materials for use is given a degree of freedom which imposes upon him a considerable, though by no means intolerable, responsibility.

This responsibility for the safety of requisites from the health point of view, and also the responsibility for the maintenance of purity of foodstuffs has, indeed, been made less burdensome for the manufacturers of plastics and of requisites by the issue of the recommendations by the Federal Bureau of Health. Nevertheless, these responsibilities have by no means been removed. These recommendations comprise scientific appraisals prepared by experts, and issued by the Federal Bureau of Health. In view of the fact that they have been prepared by experts, they do, in fact,

reflect the present state of scientific knowledge and technology, so that anybody who follows the recommendations can claim that he has satisfied the requirements as to care.

However, this can be said only under one, but very important, condition, namely, requisites that have been manufactured in accordance with the recommendations must be suitable for the purpose intended. Every preamble to the recommendations refers to this aspect.

Having discussed what recommendations are, we must now state what they are not, namely that they are neither orders nor laws.

The starting and auxiliary materials named in the recommendations cannot be regarded as being permitted by law. They are merely recommended by the Federal Bureau of Health. The recommendations are to be regarded as giving help and advice approved by the Federal Bureau of Health. They do not constitute more than this.

It also follows, of course, that substances that have not been named in the recommendations are not excluded from use. Thus, it would be incorrect to say, "product X is not included in the recommendation, and therefore it may not be used." The plastics manufacturer and processor have the freedom to use materials that are not included in the Recommendations. In practice, however, all plastics materials that are used for the manufacture of requisites also comply with the Recommendations, and for the following reasons:

If a plastics manufacturer has found a new starting or auxiliary material whose use would be advantageous to him, and he knows it to be non-toxic, he will take steps to see that this material appears in a recommendation. To be quite frank about the matter, he does this because being able to call on the support of a recommendation is far from being ineffective in business.

As has already been said, a numerical definition of the technically unavoidable amounts of non-toxic foreign substances has not been laid down. This problem is at present unsolved and insoluble, but it has by no means been forgotten. It can be said that anybody who wishes for a method of determining total migration as a means of testing suitability, is actually asking for a simple answer to a complicated question.

The Federal Ministry of Youth, Family and Health has now, that is, in June 1969, put forward the "Draft of a Law for the Rearrangement and clarification of the Law Covering the handling of Foodstuffs, Tobacco Products, Cosmetics and Articles of Use." It has been rumored that the

law should be passed within this present session, and the well-known activity of the Minister of Health, Frau Kaethe Strobel leads us to think that this is by no means improbable.

Although this law is still in draft form, and the hopes and worries associated with it are, at the moment, specifically a German affair, I nevertheless believe that you will find a short discussion on it not without interest.

From the Minutes of your meeting of February 1970, I see that Mr. Thomas J. Hughes has made a report on the international developments in foodstuffs laws, in which he has made a brief reference to this draft law.

In my short discussion, I will limit myself to those regulations to be expected in it, that affect the manufacture of articles of use, and I will tell you quite frankly about the criticism which the draft will have to encounter. Nowadays, considerations of legal regulations are also made from the International aspects, too, and in Europe, therefore, also with regard to the regulations to be expected in the European Economic Community.

You will have the opportunity of obtaining further information during the subsequent discussion.

Dr. Trollope will be glad to supply you with such information, though I can tell you now that, particularly with the field of food additives touched upon by Mr. Hughes, even we are able to say little that is definite. In the opinion of experts, this particular paragraph is far from clear and consistent. Certainly, it is difficult to recognize any distinction between "direct" and "indirect" food additives in the draft. The only thing that is certain is that the former definition of foreign substances has been dropped.

According to the Federal Government, this law has the following objective in view:

A further reinforcement of consumer protection without unnecessary obstacles to economic development; and an appropriate regard to rapid progress in food technology and packaging.

To anticipate the situation, a consideration of the proposed legislation as far as it affects articles of use or requisites such as those in which we are principally interested, leads us to think that neither of the last-mentioned objectives will be achieved; indeed, it is more likely that their attainment will be hindered.

A new departure is the inclusion of dyes, varnishes and plastics-containing paints for interior use, media and articles for the improvement of odor in rooms, as well as the very generally formulated section: requisites and media of personal or domestic requirements or use, so far as their intended application or foreseeable use could constitute a danger to the human body because of their ingredients.

Paragraph 29 introduces a new aspect dealing with the transition from substances to foodstuffs, namely, "it is forbidden to employ articles commercially as requisites, or to introduce them on to the market for such purposes, in such a manner that ingredient substances can migrate into foodstuffs, or on to their surface, other than ingredients that are technically unavoidable and are not objectionable on the grounds of health, odor or taste."

A new feature, compared with the old Paragraph 4b, 5, is that the term "foreign substances" has disappeared. Indeed, their definition has vanished from the law entirely. At the corresponding point, only those substances are mentioned that are not foodstuffs. What has remained, however, is the admissibility of migration of technically unavoidable amounts. There has been no change whatever in the hitherto existing legal requirements.

However, an entirely new situation has been created by the powers which are to be given to the minister by Paragraph 30 of the new act. The important feature is the intention to grant the minister the legal power to:

Firstly: prohibit the use of certain substances or groups of substances in the manufacture of requisites; and

Secondly: prescribe that only certain substances may be employed in the manufacture of certain requisites.

This means that the minister will be empowered to set up negative and positive lists, that is, lists of non-admissible and admissible substances. In turn, this means that all substances which have not been included in a positive list, are excluded from use in the manufacture of articles of use or requisites, whether they coustitute a danger to health or not.

Of course, we do not wish to complain against the setting up of negative lists. There is nothing new in this. By dealing with the situation wisely, both the manufacturer and processor of plastics materials will hardly be obstructed by negative lists, since no one will want to use substances that truly constitute a danger.

The situation is, however, very much different in the case of setting up positive lists with an exclusive character.

The objections to these are both of a commercial and, even more so, of a scientific nature.

Hitherto, the use of recommendations has functioned excellently. There is not a single case known of damage or contamination having resulted where the various industries have carefully watched over the manufacture and composition of their products, that is, they have exercised a sense of responsibility in observing the content of the preamble of every recommendation, namely, that the plastics material must be suitable for the intended application. It is emphasized once more that it is just this passage in the preamble that calls upon the processor and consumer to act with responsibility. A changing or supplementing of a recommendation does not involve a change of law, and can be carried out with a relatively simple procedure.

If for instance, a manufacturer has developed something new and useful, and he is sure that it is non-injurious to health, he can enjoy the fruits of his research without any great loss of time. On the other hand, if it is first of all necessary for him to follow the tedious path of ministerial permission, in order to employ his new product, a product, which, as I have already emphasized, he is quite sure from his investigations is suitable and non-injurious, so much time can be lost that its manufacture has ceased to be of interest.

Much more important, are the scientific objections. It is simply not possible for even the wisest legislator to make allowance for all possible combinations of foodstuffs and packaging materials. A framework of legal regulations cannot be created that completely covers every circumstance in practice, however full it may be. If positive lists have been made, it is no longer necessary to make tests of suitability on ones own responsibility. In such an event, the responsibility would rest on the legislator.

It can be seen, therefore, that the greater protection sought for the consumer by preparing positive lists with a legal character cannot be achieved, unless, of course, the legislator is so sparing with his permits that no accidents can happen. This last situation would mean, however, that new developments would be seriously restricted. The adequate consideration of technical progress in the service of the consumer, an objective of the new food law, is therefore hardly achieved.

These doubts with regard to the planned positive lists are shared by the plastics-producing industry, the Foodstuffs Law and Foodstuffs Science Association, and the Minister of Economics.

You may perhaps have the unpleasant feeling that misleading construction is being put on the situation with the ulterior motive of representing that freedom of action for manufacturers and processors is to the public benefit.

All the same, it must be said that an undisturbed, although by no means unrestricted, further development is to the advantage of the consumer. It is then possible to make available better and more useful requisites by the exploitation of new methods of application in the manufacture and distribution of foodstuffs.

If there is a law that apparently - and only apparently - provides for all precautions, the rigid exhaustion of all the legal possibilities could produce a situation where it might well be said, "to exploit all rights to the full is also a crime;" summa lex, summa injuria.

Paragraph 54 states, without any limitations whatever, that articles that do not satisfy the paragraphs already cited can be confiscated.

These paragraphs will thus bring about a considerable tightening up of the existing regulations.

It is certainly true that articles of use could be, and were, confiscated before, where their use might endanger the health of the user.

However, the situation has been otherwise, up to now, where a requisite might not conform to the relevant recommendation, but at the same time, it could not be held to constitute a danger to health or give rise to the contamination of foodstuffs.

If, for example, a given film were to be used for the packaging of meat, even though it contained more plasticizer than permitted by Recommendation I for such film and for this particular application, there was no immediately available legal device to prevent the use of this film, to confiscate the film or to punish the user. The fact is that the recommendations do not constitute legal standards, and their contravention did not necessarily imply a contravention of the law. It would have, indeed, been necessary for the impounding authority to prove that here had been an offense against Paragraph 4b, 5, of the Foodstuffs Law. You see, a departure from a Recommendation is no proof of an offense against the law.

If however the legislators now give positive lists a legal standing, proceedings may be taken without such proof, since articles of use or requisites, which do not conform to positive lists infringe against a law or order, whether they constitute a dnager to health or not.

The probability that legally enforceable positive lists will actually be set up is great. Paragraph 36 of the review draft states, namely, that orders can be issued in accordance with this law, for the purpose of alignment with the legal and administrative requirements of the member states of the European Economic Community.

The fact cannot be disregarded that a large proportion of these member states favors positive lists.

Summarizing, it can be said, and indeed it must be said, that the provisional draft of the new German Foodstuffs Law is the result of efforts made by lawyers who have allowed themselves to be guided by wishful thinking.

There has been no advice given by experts, so that the result is theoretical in concept and, in many places, it lacks the logic of practice.

There was a hearing at which experts, manufacturers, processors, foodstuffs manufacturers and foodstuffs legal experts were able to suggest corrections which were very courteously acknowledged by the ministry and zealously noted.

The leading lawyer of the ministry admitted on this occasion that the draft had given rise to serious legal doubts, and that it would certainly have turned out differently if practical men had been consulted before it had been drawn up. It is to be expected that a second draft will appear shortly.

The world of abstract theories and the world of hard facts are two different things, a fact which can hardly be better understood than by scientists.

APPENDIX C

REPORT OF TECHNICAL INFORMATION SUBCOMMITTEE
SPI FOOD PACKAGING MATERIALS COMMITTEE

June 10, 1970

Recently Issued Food Additive Regulations

The following final new food additive regulations and amended regulations deemed of interest to the SPI Food Packaging Materials Committee have been published in the Federal Register since our last meeting:

TYPE & SECTION	REFERENCE	PETITIONER	SUBJECT
Amended 121.2520	F.R. 35(50) Page 4502 3/13/70	Imperial Chemical Industries, Ltd.	Provide for the safe use of tris(2-methyl-4-hydroxy-5-tert-butyl-phenyl) butane as a component of food-packaging adhesives.
Amended 121.2566b	F.R. 35(50) Page 4502 3/13/70	Imperial Chemical Ind., Ltd.	Added on additional limitation for Tris (2-methyl-4-hydroxy-5-tert-butyl-phenyl) butane: Item 4 - as provided in 121.2520.

TYPE & SECTION	REFERENCE	PETITIONER	SUBJECT
Amended 121.2519 121.2520	F.R. 35(61) Page 5220 3/28/70	FHC Corp.	Provide for safe use of tributoxyethyl phosphate as a component of defoaming agents used in the manufacture of paper and paperboard and as a component of food-packaging adhesives.
Amended 121.11	F.R. 35(69) Page 5810 & 5811 4/9/70	FDA	Statement of policy: All food additive status opinions are revoked.
Amended 121.2526	F.R. 35(70) Page 5946 4/10/70	Hercules, Inc.	Amended by changing "molar percent" in Acrylamide-B-methacrylyloxyethyltrimethylammonium methyl sulfate copolymer resins from "5" to "10" molar percent of B-methacrylyloxyethyltrimethylammonium methyl sulfate and containing less than 0.2% of residual acrylamide monomer.

TYPE & SECTION	REFERENCE	PETITIONER	SUBJECT
Amended 8.501	F.R. 35(72) Page 6046 4/14/70	FDA	Provisional lists of color additives is amended by changing the closing date of all color additives listed therein to Dec. 31, 1970.
Amended 8.503	F.R. 35(72) Page 6046 4/14/70	FDA	Temporary tolerances is amended by adding "D&C Red No. 36".
Amended 121.1160	F.R. 35(89) Page 7180 5/7/70	Hercules, Inc.	Providing for the safe use of hydroxypropyl cellulose in food. Amended by lowering the minimum viscosity specification to that set forth below to permit certain improvements in the additive's technical effects.
Amended 121.2521	F.R. 35(89) Page 7180 5/7/70	Air Reduction Co., Inc.	Provide for additional safe use of vinyl chloride-propylene copolymers in contact with food.

TYPE & SECTION	REFERENCE	PETITIONER	SUBJECT
Amended 121.2603	F.R. 35(89) Page 7180 & 7181 5/7/70	FDA	The amendment provides for use of poly(2, 6-dimethyl-1, 4-phenylene) oxide resins in food-contact articles to correct the subject calculation.
Petition (FAP OR2512)	F.R. 35(89) Page 7195 5/7/70	Morton International, Inc.	Provide for the safe use of phthalocyanine blue, phthalocyanine green, titanium di-oxide-barium sulfate, and carbon black (channel process) as colorants in polyethylene containers for dry food.
Amended 121.12	F.R. 35(93) Page 7414 5/13/70	FDA	Statement of policy: Food & Drug Administration no longer regards glycine and its salts as generally recognized as safe for use in human food and all outstanding letters expressing sanction for such use are recinded.
Amended 121.2574	F.R. 35(93) Page 7414 5/13/70	Mobay Chemical Company on behalf of Farben-fabriken Bayer A.G.	Provide for the safe use of a2, a6-bis(6-hydroxy-m-tolyl) mesitol in the production of branched polycarbonate resins intended for food-contact use.

TYPE & SECTION	REFERENCE	PETITIONER	SUBJECT
Amended 121.2520	F.R. 35(96) Page 7646 5/16/70	E.I. duPont de Nemours & Company	Provide for the safe use of (3-Allyloxy-1, 2-propanediol) and a-Hydro-omegahydroxypoly-(oxytetramethylene) in the formulation of polyurethane resins used in food-packaging adhesives.
Amended 121.2505	F.R. 35(103) Page 8276 5/27/70	Buckman Labs., Inc.	Provide for the safe use of 2-(thiocyanomethylthio) benzothiazole and 2-hydroxypropyl methanethiosulfonate as slimicides in the manufacturer of food-contact paper and paperboard.
Amended 121.2514 121.2520	F.R. 35(107) Page 8552 6/3/70	Tenneco Plastics Div. of Tenneco Chemicals	Provide for the safe use of tridecyl alcohol as a component of resinous and polymeric food-contact coatings and food-packaging adhesives.
Amended 121.2566	F.R. 35(107) Page 8552 6/3/70	American Hoechst Corp.	Provide for the safe use of Poly(1, 3 - dibutyldistannthianediylidene)-1, 3-dithio, as a stabilizer in certain semi-rigid and rigid polyvinyl chloride materials used in the manufacture of food-contact articles.

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