(Appendix C Addendum)

U.S. DEPARTMENT OF COMMERCE

Business and Defense Services Administration

Washington, D. C. 20230

February 10, 1965

Mr. William T. Cruse
Executive Vice President
The Society of the Plastics Industry, Inc.
250 Park Avenue
New York 17, New York

Dear Mr. Cruse:

Reference is made to your letter to me of June 19, 1964 in which you listed "Government Regulations of Food and Drug Packaging Materials" as a major problem of the plastics industry.

Shortly afterwards, I explored briefly the seriousness of this regulation, calling someone in your organization who stated that I should contact the SPI's general counsel in Washington for this information. I was rather unsuccessful in obtaining any actual or specific objections, but only an objection that the act was too broad.

We propose again to take another look at the Food Additive Amendment Act of 1958, and ascertain what changes, if any, are desirable.

However, we will need the help and cooperation of your organization and industry to give us the supporting facts as to the specific objections, burdensome costs of compliance, particular cases wherein it is believed that the Food Additive Amendment of 1958 should not be applied to resins and plastic materials, suggested specific changes in the act that could be supported as desirable, and other pertinent information dealing with this act.

Your response in this endeavor will be greatly appreciated.

Sincerely yours,

T. Allan Davis
Chemicals and Allied
Products Division

APPENDIX E

Edited Transcript of Mr. Heckman's Report
on European Food Additives Regulation and
Discussion at Meeting of June 22, 1965

Jerome H. Heckman: There is one important point that must be made clear at the very beginning of this so that you won't, in any way, be misled. Often you give the impression that you're an expert because you are from out of town, or you've been there, and nobody else has. If ever there was an area where I would not claim for one-half of one minute to be any kind of an expert, it is with regard to this matter of European regulation of food packaging, or food additives generally. This is one area where you can use every effort you know how to use to get all of the pertinent information, believe you have the final word, and find out that somebody passed a decree three years ago that you didn't catch in your research but which deals directly with your problem.

All I really hope to do then is to give you a bit of a survey and simply tell you what I did in Europe, who I met, and what my own personal feelings are about the situation there. Then, I would like to supply you with a pretty substantial amount of material by the way of a Bibliography that I will append to this report. I will do my best to see to it that the Appendix gives you some references you can use as a way to get some of the documents. I cannot promise to be able to do that in every case because, in some instances, I, frankly, do not know where I would get additional copies of material I picked up as I went along.

With so much in the way of caveats and advance apologies, let me now get down to cases and, as indicated by the agenda, proceed with the interesting task of giving you this report on my reaction to the packaging regulatory systems in Europe. This task is not only filled with danger, it is downright difficult. For this reason, I followed an old American custom of "passing at least part of the buck." I imposed on some of the very capable European counsel with whom we have associated on matters for our individual clients and asked them to give me special reports on the regulatory situations in their countries, to the degree that they were willing to do so. These gentlemen were most cooperative in supplying general statements in most of the instances. Thus, I am pleased to be able to supply their statements for the Minutes. I will discuss the reports as time allows, tell you about the Italian situation, since this is the one I know the best, and advise you very briefly about the situation in Spain. We have counsel in Spain, but he was unable to supply a statement in time for this meeting.

* * *

Question from floor: How about Germany?

Mr. Heckman: Well, let me explain why I don't have a particular report on Germany. Actually, we have associate counsel on tap there, but he has not been used. The reason is that the German laws are relatively easy to obtain, and are quite clear--clear enought to hurt in many cases.

I did not go to Germany on this trip, but I expect to be there within the next year so perhaps I can fill in that gap for you thereafter.

* * *

Returning to the report, perhaps an overall comment or two might be the best way to start. It is difficult enough to make a rationale or sense out of what one single Food and Drug Administration, that of the United States, does; to make a rationale out of what a number of very, very independent nationalistic countries on the continent do, is naturally going to be a lot more difficult. Variances in approach are quite extreme. As an overall opinion, and I pass this out to you for what it is worth, my feeling at the moment is that perhaps the best approach an American company can use in wanting to assure itself of clearances throughout Europe is, (1) to get clearance in this country, to the degree possible, either by FDA letter or by regulation, and (2) then attempt, through any means available to you, to have the European Economic Community (EEC) act in some way, which will, in effect, give you a clearance with your product.

Probably, almost all of you know that the EEC operates in this area of regulation primarily through an organization called in English the EEC Commission. The Commission has permanent staff, with headquarters in Brussels. Among the people I talked to there was a Dr. Sust, a German, charged to a large extent with dealing with pesticide matters, but also interested in plastics and food packaging matters. He works under a Dr. Steiger, who is the head of the Agriculture Commission, a Division of the EEC Commission. Incidentally, please do not hold me to precision on the agency nomenclature since I am using English designations which are in no way official.

With regard to the way the Commission operates, firstly, you should understand that the Treaty of Rome is the basic document which governs EEC activity in all of its various aspects. Articles 100 and 101 are the articles that call for maximum harmonization or "approximation"--that is the term used--of the regulations of the European Economic Community,

the aim being to remove non-tariff and other trade barriers between the members of the community to the greatest degree possible. It is under the aegis of these sections of the Treaty of Rome, that the EEC Commission has been charged with the responsibility of instituting the promulgation of uniform regulations for the community.

As a procedural matter, the way this works (and this is another area where I may sound quite clear cut, but don't you believe it; I talked to about ten different people, and received ten different versions of how things work) the EEC Commission is the organization that will theoretically institute a proposed new type of regulation, normally in the form of a proposed Directive. The Commission, as a practical matter, seems glad to receive advice from industry as to what type of regulation might best be promulgated; my understandin is that the people on the Commission Staff welcome industries getting together and supplying them with detailed proposals that they can then promulgate or propose as EEC regulations.

In the plastics field in which you are most interested, there is a relatively new European industry organization called the Bureaux Internationaux Techniques Des Motieres Plastiques (BITMP). The BITMP is still a somewhat informal operation. Acting as a sort of Executive Secretary for it is a Mr. Armand Guilmot, whose main job is as the Director General of the Federation of Chemical Industries of Belgium which, among other things, publishes a regular magazine called the "Revue Belge des Matieres Plastiques."

I talked with Mr. Guilmot for a good while, in company with Dr. Rodeyns of Solvay, who was exceptionally helpful to me in Brussels. In this way, I learned that the BITMP was formed when it was recognized that, first of all, plastic packaging materials are a little different in the eyes of Europeans, than other packaging materials. I am told that Europeans still view plastics with a degree of suspicion. This is not entirely untrue in this country, but the impression that I got from European companies and European personnel who are active in these areas, including for example, Dr. Rodeyns, is that the European distrust of "synthetics" is more of a problem there.

Dr. Rodeyns, I believe, was one of the moving parties in bringing together in an association the biggest chemical complexes in Europe. I gather that this was no minor feat and that nothing like it had really been accomplished before. The first series of projects of BITMP looks towards the adoption of regulatory proposals to give to the EEC Commission on polyvinyl chloride, polyethylene, and polystyrene. In recent months, the BITMP has been pushed to move more rapidly because the Commission is anxious to make more progress on the "harmonization of food laws" which must be completed by 1970, the end of the so-called third stage provided for by the Treaty of Rome.

The BITMP, which is broken down into working committees on the various polymers, has had many meetings at which some of your companies have been represented. As a result, it has come up with a series of proposals on PVC, polyethylene, and polystyrene. The general approach is what I, for lack of a better name, would call an ingredients listing approach, whereby it is proposed to list the things that you may use in polyethylene, PVC or polystyrene. As the proposals are now written, I believe it is fair to say that a manufacturer would not, at least in theory, be allowed to make any of the aforementioned resins using things other than those on such lists.

This constitutes a potentially significant departure from the situation in this country. For example, I believe consideration is being given to requiring lists of such things as catalysts, whether or not they would be extractable as we generally use this term. Problems have already arisen for some of our companies because the first lists were prepared before they were entirely alerted to the BITMP activity, and its potential significance. Thus, whereas those companies that were on the BITMP Committees from the beginning, made certain that most of the components in which they are interested (some of which have not been approved here, by the way) are on the lists, it's a little more difficult now to get the BITMP Committees to agree to add some things.

The best example I know of at the moment is the Wingstay problem, as it relates to polystyrene. Had the Wingstays been put on the proposed polystyrene lists, I doubt that there would have been any problem. Now, the BITMP Polystyrene Committee wants supporting data for the inclusion.

The next step for the BITMP is to give its material and proposals to the EEC Commission. It is not entirely clear to me yet as to whether some of the proposals have been delivered or are still being held up for further study. I got the impression in Europe, somehow or another, that much of the material has been given to EEC but, since my return, I have talked with American company representatives directly involved in the BITMP effort, so I now have some doubts about the status.

Presumably, once the proposals are officially given to the Commission, the EEC Commission Staff people will prepare a draft "Directive" to be submitted to the Parliament of Europe (Paliamenta de Europa), sometimes referred to in English as the "Assembly". The European Parliament is made up of delegates from all of the members of the Community. Under the Treaty, Germany, France and Italy, have 36 delegates each, Belgium and the Netherlands, 14 each, and Luxembourg 6.

Once the Parliament of Europe has approved a Directive referred to it for consideration, usually it is then further reviewed by an entity called the Economic and Social Committee. This Committee, according to Article 193 of the Treaty, is "composed of representatives of the various categories of economic and social life, in particular, representatives of producers, agriculturists, transport operators, workers, merchants, artisans, the liberal professions and of the general interest." Actually, this is a sort of government-industry committee of 101 members which has consultative powers only. As a practical matter, however, I believe these powers are almost veto-like in some instances.

Once a proposed "Directive" clears these hurdles, it goes to the Council of Ministers. Nothing is an official regulation of the Economic Community unless and until it is passed by this Council, which is the real "decider". The Council is composed of one delegate from each member country, and passes resolutions in the area of our interest by unanimous vote only. Unlike Commission employees, its members are not independent but act in a truly representative capacity, i.e., they represent their own country.

Once the Council of Ministers adopts a resolution, it then becomes incumbent on every member of the Community to put that regulation into effect in its area. This means that, with regard to all regulations like those already adopted by the Council, a member country like Germany, for example, has no choice but to put an EEC approved substance on its approved list.

Generally speaking, any country which has not already approved an EEC regulated substance, must allow its use within one year but, in some of the resolutions, longer delays are possible under special Ad Hoc provisions. Each country is free to allow use of additional substances which are not on the list in their own country if they want to, but they must include and allow the use of anything that is on the EEC list. This, of course, is why I feel that, in the future, and depending on whether the EEC survives its present crises, perhaps one of the most direct approaches to the overseas problem will be to seek to have an EEC regulation adopted on anything in which you are really interested.

Following this course will not be quick or easy, especially since, first of all, you will have to find a European company to push your project; only those who are in the Community have status to propose EEC action. Nevertheless, such an effort would seem most worthwhile since it seems clear to us that if you have U.S. and EEC approval, obtaining approval in any other country in the world should be almost automatic. I say this partly because I have found that the characteristic European approach on most clearance problems involves an initial colloquy somewhat along these lines:

"Where else is it approved? Is it approved in the United States? Is it approved in any other European country? We would like to have copies of any other approvals that you have on this product."

When I say that I feel if you have U.S. and EEC approval, you would probably be 75% of the way home in any other country, I include the so-called Outer Seven, or European Free Trade Area countries. I think the Outer Seven are thinking in terms of maybe making EFTA a more potent organization, instead of just a defensive in-name-only-alliance designed to counteract the EEC. They have discussed, I think at a meeting they held not too long ago, adopting or starting to work on some regulations of their own. Nevertheless, at least as matters now stand, the EEC approach looks best to cut down on country-by-country effort.

Of course, one of the main reasons that I think the EEC effort might be the most worthwhile approach, at least eventually, is because it should eliminate some of the splintering activity that does cost a lot of money. Also, there is still the chance that Great Britain and the other European countries may ultimately be a part of the EEC. All of these things do tie together to a degree.

As far as the EEC attitude generally is concerned, and this really applies to all of Europe, my own feeling is that there is a considerable and understandable misunderstanding on what the law in the United States stands for, what it means, and how it is administered. Just reviewing the complications we have discussed at this meeting today should make it easy for you to understand why the Europeans might not quite grasp what our law is all about. It would be almost unnatural if they did not feel that our laws are so complicated, partly as a device for keeping out European products; and I think that that feeling exists to some extent.

Forgive me for taking some license here, but I cannot help but observe that, in my opinion, the Food Additives Amendment of 1958 has served to mislead most of the rest of the world about the danger of packaging materials, and about the proper way to regulate them. The only ones that, again in my personal opinion, have not been so misled up to now, are our neighbors to the north in Canada, who have expressly excluded packaging materials from their food additives law. Other than there, I think the whole world has been given the idea that packaging materials are a real threat to the health and safety of the people, and, on this assumption which I think we have created, most countries propose to adopt laws regulating packaging materials; almost every major country has such a law in effect or on the way.

What is worse, is that in some cases they have taken what I consider to be one of our errors, and are moving one step further to a logical, but very impractical, conclusion. I am now referring to the confusion that has been created by FDA's policies in so-called "no-migration" situations. As you know, this policy has led to the filing of petitions and the issuance of regulations for substances in circumstances where they are clearly "not expected to become components of food"; indeed, in some cases, FDA's willingness to promulgate a regulation is based on its being satisfied that there will be no detectable migration. This is the basis for the adhesives and "rubber articles for repeated use" regulations.

Unfortunately, a European looks at a regulation like our adhesives regulation, or the rubber regulation, and he begins to think in terms of what George Ingle calls the "laundry list" concept. He receives the impression that, in the United States, which has the most advanced food additives regulatory scheme in the world, FDA prescribes lists of materials that you may use in making a product, i.e., FDA regulates the ingredients that may be used to produce a package or packaging component, not just what might get into foods from the finished product.

It is undoubtedly true that some of the more sophisticated technical people in Europe have a better understanding of our system than this, but I truly feel that the administrative and legal people I talked with think our regulations constitute allowable ingredients input lists for packaging materials. For this reason, the approach they use in their own countries in many instances is to say: "In order to make such and such, you may use this list of things. Then you apply these tests to make sure that some of these things are not extractable because if they are, even though they are on the permitted list, you may not use them."

For obvious reasons this is a matter of considerable concern because, if you do understand the U.S. laws correctly and even though the Food and Drug Administration has incorporated some "non-migrants" in food additive regulations, the basic concept here is that substances which "may not be expected to become a component of food" need not be listed anywhere to be used legally in packages. My experience is that this concept is either not understood, or not accepted in most of Europe. Thus, if you advise officials there that you are using certain things, I believe you will find that they will always ask you to clear them and to have them added to the positive list of the particular country. It will not usually be enough for you to prove no detectable migration, although this might make it somewhat easier to have the substance added to a positive list.

As you can see, this matter of FDA refusing to give "no-migration" letters, keeps coming back to haunt us, not only here, but overseas. This is one of the things that stood out in my mind everywhere I went.

By way of closing out on the EEC report, let me note here that, to the best of my knowledge, the EEC has not, as yet, adopted any packaging regulations, per se. It has adopted some regulations on direct food additives, colorants, and there is a new regulation on antioxidants which has been adopted by the Parliament of Europe, and is expected to be adopted by the Council of Ministers by the end of this year.

I have already tested your perseverance, I am afraid, but I do want to comment briefly on the situations in the individual countries I visited and, at the same time, provide you with my overseas colleagues' reports.

The United Kingdom

As far as England is concerned, all of you probably know a good deal more about the British approach than about other places because we have good contact with the British Plastics Federation. The report from our British associate is an especially good one. It was prepared by Messrs. L. P. Tylor and N. Fox Bassett of the firm of Coward, Chance and Co., and reads as follows:

"Note on the Law relating to the use of plastics packaging materials for food in England

1. There are no regulations in force in England which expressly permit or prohibit the use of any particular food packaging materials, either for food generally or in the case of any particular food. Nor is it possible to obtain any official ruling on whether the proposed use of any particular packaging material would be permited.

2. The use of packaging materials is indirectly controlled by the operation of the general law relating to the sale of food and drugs, contained principally in the Food and Drugs Act, 1955 (the Act) and also the numerous Orders and Regulations which have been made under the authority of the Act and other acts dealing with subjects connected with food and drugs, some of which have been replaced by the Act.

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3. Section 1 of the Act provides:-

> '(1) No person shall add any substance to food, use any substance as an ingredient in the preparation of food, abstract any constituent from food, or subject food to any other process or treatment, so as (in any such case) to render the food injurious to health, with intent that the food shall be sold for human consumption in that state.'

If, therefore, by using a packaging material, food is rendered injurious to health, then a person offering such food for sale is guilty of an offence under the Act. For example, should ink from paper or possibly plastic wrapping material render the food injurious to health, then indirectly the use of such material for that particular food is prevented. There are possibly certain well known instances where plastics materials affect food by this 'leaching' process, and reference is made below to antioxidants.

4. Section 4 of the Act gives the Minister of Agriculture, Fisheries and Food and the Minister of Health, power to make regulations:-

> '(a) For requiring, prohibiting, or regulating the addition of any specified substance, or any substance of any specified class, to food intended for sale (for human consumption) or any class of such food for the use of any such substance as an ingredient in the preparation of such food, and generally for regulating the composition of such food.'

By the leaching process it is, therefore, possible that substances may be introduced into food which are subject to regulations made under this section although they may not be injurious to health such as preservative, colouring or other additives.

No attempt is made to set out these regulations as they are too numerous and might well be irrelevant to the components of plastics materials. Should a particular substance be suspected of being a controlled additive, it would be easy to check this.

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One example which does have relevance to plastics materials containing BHT, is the Antioxidants in Food Regulations, 1958, (SI1958 No. 1454) which prohibits the addition of antioxidants except for certain maximum proportions in the case of anhydrous edible oils and fats, butter for manufacturing purposes and essential oils. These regulations were the subject of a review in 1963, Part VII of which is relevant to this note.

'18. The question of the possible leaching of small quantities of antioxidants from plastics and other containers, has been brought to our notice. Ministers have already asked us to undertake in due course a general review of the question of additives adventitiously introduced into food in the course of preparation and processing, including the leaching of substances from wrappers. We have this under consideration, but until such a review is made, we make no recommendation on this matter in this report on food additives.'

5. There is at the moment a Food Additives Committee set up by the Minister of Agriculture, Fisheries and Food, which is considering a wide range of topics, with special emphasis on preservatives. Packaging materials come within its very wide terms of reference and it is understood that plastics materials are being specially considered. No report has yet been published and it is not expected before the end of this year. It is possible that the report will contain recommendations controlling the use of plastics packaging materials, but it would take several years to implement these, if accepted by the Minister, due to the necessary period that would have to be allowed for consultations and representations.

COWARD, CHANCE & CO."

We are fortunate enough to have Mr. Wechsberg here from Great Britain, if he would like to add any comments to this report. My only summary comment is that the situation in his country, as we view it with the experiences we've had, is not only different, but refreshing.

Mr. Wechsberg: Well, there is no way, really, to get approval, as such in Britain. They don't have that kind of a preapproval law. (Note: Mr. Wechsberg made some additional general comments about the work of BIBRA and Dr. Goldberg which were not recorded.)

Mr. Heckman: I gather that Dr. Goldberg sort of informally passes on the acceptability of plastic pipe for potable water and that some of the manufacturers want his approval, although it is very informal. We have some information about that and I'm glad you mentioned Dr. Goldberg's work.

* * *

Responsive to a question raised by someone at this point, Mr. Heckman stated: *

Well, let me say this. I think that Dr. Van der Heide and, more directly, Professor Reith, are playing a substantial part in the work of the BITMP. I don't know whether Professor Reith necessarily has as much influence as the German representatives who continually remind the groups that they have the most complete law, that they had it first, that their activities have been very successful in this area, and that they are not willing to give very much on their proposals. I do not believe the Germans have been as complete in their regulation of packaging as they have been about direct additives.

There is apparently a considerable amount of "push-pull" in the BITMP work, and I am sure that Professor Reith is playing a part. The Professor came over here and met with a lot of our FDA people who advised him as to the meaning of some of our regulations. For example, he was told that it would not be too smart for any European country to base an extensive approval of American products, or components of American products, on the fact that a component is listed in the repeated use rubber or adhesive regulations.

Responsive to another question:

Mr. Heckman: No, it is the Council of Ministers that has the final and really only effectuating power in the Economic Community. As far as food additives are concerned, most of the people I talked to in Europe feel that the Council of Ministers is likely to approve any Directive which has been proposed by the Commission and has cleared the Parliament and Economic and Social Committee. For example, no one expects the Council to change the new antioxidants regulation.

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*In many instances, the recorder did not pick up the questions very well, if at all. This is the reason that some of the questions are not reported verbatim.

The place to catch a problem if you possibly can, is at the EEC Commission promulgation level with the staff people who are working with industry to draft a regulation.

* * *

Returning to my country-by-country summary, as to Spain, I do not really have a report, as I told you at first. Our Spanish associate, Mr. Segura de Luna, has sent me some information which may not be generally available.

There is a Spanish food labelling law which was passed a long, long time ago, and there is an industry-government group--called the "Assistant Commission of Experts for the Writing of the Food Code in Spain"--that has been meeting for at least five years in an attempt to develop a new Codigo in Spain. The Codigo really will amount to the regulations that will be adopted under the Spanish law.

I have copies of some of the drafts or "Projectos" that they have come up with so far. Among other things, they have set forth some of the basic concepts on packaging. I have picked out the parts that I think you might be interested in and will reference them in our Bibliography. As far as I know, the last work done on the packaging drafts was in March of 1960.

The approach concept used appears to be a very broad one whereby, for example, you could use any plastic material on a proposed permitted list of "natural or synthetic resins of high polymer, which are not susceptible to degrading under conditions of fabrication and use." There are more specific regulations dealing with prohibited raw materials such as chrome-plated iron, tin and sheets of tin foil, and plastics materials "which release some of their compound" into food and drinks.

The entire situation in Spain is best described as "in a state of flux" but the draft work done thus far certainly points the way towards Spain's ultimate adoption of a law that will exclude anything not made from "authorized materials". As now drafted, the authorized materials list is broadly written so as to allow (1) natural or synthetic resins, not susceptible to degradation under conditions of manufacture or use; (2) solvents or volatiles which leave no residual in the finished product; (3) non-toxic plasticizers; and (4) authorized secants, pigments, colorants and antioxidants. The proposed "prohibited materials" list is also written in broad terms leaving much to be filled in, or imagined. Whether the gaps will be clarified or left to "administrative discretion" remains to be seen, but I would be inclined to bet on the latter possibility.

France has a law governing packaging materials made from plastics. It embodies the authorized and unauthorized substances approach. In other words, you are supposed to apply and get a substance put on the authorized list before you can use it in packaging materials. In reviewing the French law, it is easy to see where the Spanish may have obtained most of their ideas. Our colleague in Paris, France, Mr. Boris Naslednikov, has supplied us with an excellent report which, among other things, references every official circular issued by the French government, and related in some way to our interests, since the basic law was adopted in 1912.

There is one "practical" observation that I will make before simply setting forth Mr. Naslednikov's report in the Minutes. My own understanding about the ways of dealing in France, at least at the moment, is that most companies sell first, and ask questions only if something makes this essential. On occasion, prospective customers want to be assured that something is on the authorized or approved list. I have seen situations where companies, in response to that kind of a request, have written a letter to the Ministry of Agriculture and have just said, "we make this and we use these compounds." Often, nobody acknowledges such letters, but they are shown to customers so that they know something has been submitted to the Ministry.

The situation is a little strange, but I believe that most companies--and I think any lawyer in France would confirm this--do sell first and ask questions later. There may come a day when, for some reason, unannounced to anybody, and perhaps not understood by anybody, the prefect of police will pick up a product and charge a violation for using perhaps one of about 10 "unauthorized" components that might be in a package.

There is no sense in asking why one component is denounced and not the other nine, because there probably is no answer.

Responsive to a question or comments made by Mr. Mack of M & T indicating his disagreement with Mr. Heckman's general observations:

Mr. Heckman: Well, frankly, I'm glad that you are saying that because, as I told you at the beginning of this report, the best I can give you is what I got in the short time I was there, and I'm sure there is room for differences of opinion, even on the fundamentals.

Mr. Mack: I have two or three cases pending in France now.

Mr. Heckman: Are these indirect food additives situations?

Mr. Mack: Yes.

Mr. Heckman: Well, is it possible that these are especially sensitive situations? Are you talking about a metals situation, for example?

Mr. Mack: (Unrecorded explanation)

Mr. Heckman: Well, I think you are talking about a special case. I think we are saying substantially the same thing in different ways. You realize that if something is on our lists, that doesn't mean that it is on the French list. If I understand you correctly though, you are saying that in those cases the best thing to do is to go ahead with your program and don't necessarily worry too much about getting specific French approval for that product. You realize that from a purely lawyer's point of view, it is inconsistent to say that you've got to clear some things because they are new (which makes sense, technically, I would agree), but you don't have to clear others, even though they are not on the authorized list.

I think that is part of the problem. I think that some of the specific things you are talking about should be cleared somewhere before they are used. In a way, you are saying that if you went to the trouble of clearing them here, you probably would not be in too much difficulty over there. What you are saying is, if I am not mistaken, that you have a kind of material that has not been cleared anywhere and might involve a special risk, then you ought to go ahead and pre-clear it in France. Otherwise, go ahead and sell it.

Mr. Mack: (Unrecorded comments on trend to stricter regulation.)

Mr. Heckman: I think you are right. I think the trend is definitely in the direction of more strict enforcement of the French law, but the advice that I am still getting from our counsel in Paris is don't hold up your whole sales program until you get clearance of an additive when you are reasonably certain that there isn't any special problem.

At this point, I commend to your attention the following fairly exhaustive report sent to us by our colleague in Paris, Mr. Boris T. Naslednikov, Avocat A La Cour de Paris:

Boris T. Naslednikov
Avocat A La Cour de Paris
44, Rue du Colisee
Paris (VIII^{e}), France

"PLASTIC PACKAGING OF FOOD SUBSTANCES IN FRANCE

The French system concerning plastic packaging of food substances is based on the idea

- -that certain plastics and the substances therein contained are authorized, by virtue of the already existing texts and positive lists
- -concerning the others, that is the plastics and substances which ARE NOT yet authorized, an application for authorization should be filed.

Therefore, the plastic packagings of food substances which are not authorized are forbidden.

There exists, however, the possibility to ask for clearance of a substance which is not yet authorized by the existing legislation.

TEXTS-

The basic text concerning the coloring, the preserving and the packaging of food substances and beverages, is:

The Decree of June 28, 1912
(J.O. June 29, 1912).

The development of the plastics industry made necessary the establishment of a new text, complementary to the Decree of June 28, 1912, and which may be considered as the basic text concerning plastics which come into contact with food and that is:

The Circular No. 159 of June 23, 1950
(J.O. July 20, 1950).

These two basic texts: The Decree of 1912 - general - and the Circular of 1950 - plastics - have been completed and amended by the following eight texts or circulars:

BASIC -

General: Decree of June 28, 1912
(J.O. June 29, 1912)

Plastics: Circular No. 159 of June 23, 1950
(J.O. July 20, 1950)

COMPLEMENTARY OR AMENDING -

Circular No. 162 of April 25, 1952
(J.O. May 13, 1952)

Circular No. 165 of January 12, 1954
(J.O. January 20, 1954)

Circular No. 170 of April 2, 1955
(J.O. April 16, 1955)

Circular No. 172 of June 26, 1956
(J.O. July 7, 1956)

Circular No. 175 of March 25, 1959
(J.O. April 16, 1959)

Circular No. 176 of December 2, 1959
(J.O. December 30, 1959)

Circular of November 6, 1959

Circular of September 12, 1963
(J.O. September 26, 1963
Rectified J.O. October 3, 1963)

It should be pointed out that ever since 1950, the legislator has had the intention to publish a new general law governing this field - the road to hell is paved with good intentions-.

In the meantime, the legislator, rather bashfully, uses the expression: "tolerance is granted" instead of is authorized.

A - Authorized plastics

B - Unauthorized plastics
(application for authorization)

A - AUTHORIZED PLASTICS -

TOLERANCE is granted to plastics which come into contact with food when they meet simultaneously the three following conditions:

(Circular No. 159 of June 23, 1950)

1. That they do not transfer to the food substances they are in contact with any trace of those of their components that are not normally part of the food,

nor any proportion of a normal element susceptible of entailing an excess of the content normally found in products available to the consumer.

2. That they satisfy the following tests:

   - tests of corrosion from acids, alkalines, fat, hydrogen sulfide

   - aging tests of tinned food such as fish in oil, tomato juice, vegetables and salted meat.

3. That they be made up of authorized components.

List of authorized components*

Liste des substances autorisées comme composants des vernis destinés au revêtement intérieur des boîtes de conserves alimentaires et comme composants des matières plastiques servant à l'emballage des aliments,:

Circulaire N° 159 - Résines naturelles ou synthétiques et hauts polymères insolubles inactifs à l'égard des matières alimentaires

Circulaire N° 159 - Solvants de point d'ébullition inférieur à 150° C, ainsi que White Spirit et essence de térébenthine, sous réserve que ces solvants soient totalement éliminés dans le produit fini

Circulaire N° 159 - Plastifiants: Huile de paraffine, huile de ricin, glycérine, triéthylèneglycol, propylèneglycol, stéarates et ricinoléates d'éthyle, de butyle, d'amyle et de métaux non toxiques (comme le calcium), benzo-mono-butyl-amide, phtalate de di-
Circulaire N° 165) 2-étyl-hexyle, triheptanoate de glycérol, sébacate d'octyle (2-éthyl-hexyle), adipate d'octyle (2-éthyl-hexyle), cire de montana purifiée et estérifiée (au maximum 3 p.100), acétylcitrate de tributyle,
Circulaire N° 175 (phtalate dioctylique, phtalate double d'heptyle et de nonyle, phtalate diheptylique

- more -

* The list is supplied in French so as to avoid translation errors in this important technical area.

Circulaire N° 159, modifiée par circulaire N° 165 / Circulaire N° 175	- Stabilisants: Hexaméthylènetétramine et sels métalliques non toxiques (notamment stéarate, ricinoléate, lactate, silicate et carbonate de calcium, phosphate et lactate de sodium), Diphénylthiourée (au maximum 0,5 p. 100), urée, carbonate de sodium, acétate de sodium, alkylsulfonate de sodium (au maximum 3 p. 100), noir de carbone, sous réserve qu'il soit exempt de benzo 3-4, pyrène et que l'extrait benzénique soit inférieur à 0,1 p. 100, thio-bis (matylbutyl-(tertiaire)-phénol)
Circulaire N° 159, modifiée par circ. N° 162	- Siccatifs: Résinates de métaux non toxiques (notamment résinates de cobalt et de manganèse)
Circulaire N° 159	- Pigments: Colorants autorisés par l'arrêté du 28 Juin 1912 6 Liste publiée au Recueil de Textes concernant la Répression des Fraudes - Matériaux en contact des aliments - 1964, p. 9 à 13
Circulaire N° 176	- Pigments et colorants admis dans les emballages placés au contact de denrées alimentaires - Liste publiée au Recueil de Textes concernant la Répression des Fraudes - 1964, p. 45à 51
Circulaire N° 159	- Améliorants ou charges: Talc, mica, oxyde de titane, farine de bois, kieselguhr et autres corps inertes. L'oxyde de zinc sera autorisé uniquement pour la préparation des vernis antisoufre
Circulaire N° 162	- Cires: Cires de paraffine, cires minérales raffinées, ozokérite, cérésine, sous réserve que ces cires ne renferment aucune trace de substances cancérigènes Cire d'abeilles, Cire de Carnauba, Colophane, Triacétine, tributyrine, tripropionine, stéarochlorure de chrome

Circulaire N° 170 du 2 Avril 1955 - p.37, concernant les papiers d'emballages des aliments.

Sont autorisés:

- Des pellicules cellulosiques, régénérées de la viscose, assouplies le cas échéant par la glycérine ou les plastifiants autorisés par les circulaires N° 159, 162 et 165 en date des 20 Juillet 1950, 13 Mai 1952 et 20 Janvier 1954

- more -

- Des feuilles d'acétate de cellulose

- Du papier sulfurisé, papier qui a été traité par immersion dans l'acide sulfurique en vue de lui donner une faible porosité, une grande imperméabilité à l'eau et aux corps gras et une grande résistance à l'état humide

- Des papiers enduits de vernis, résines synthétiques ou matières autorisées par les circulaires visées au 1er paragraphe ci-dessus

- Des papiers dont l'enduit contient du dibutyl-tertiaire-paracrésol, substance antioxygène dont l'usage a été admis sous cette forme par le conseil supérieur d'hygiène publique de France dans sa séance du 13 Décembre 1954, dans la proportion maximum de 2 pour mille de la matière d'enduction.

Liste des substances dont l'utilisation a été admise depuis le 2 Décembre 1959 pour l'élaboration des matières plastiques destinées à entrer au contact des alimentes

(Complément aux circulaires N° 159, 162, 165, 170, 172, 175 et 176.)

- Thio-dipropionate de lauryle

- Amides des acides gras ci-après:
  Plamitique, stéarique, oléique, linoléique, étant entendu que ces amides devront être exemptes de toutes impuretés autres que celles provenant de la présence, lors de la fabrication, d'autres acides gras alimentaires

- Huile de soja époxidée, à condition que son taux d'oxirane soit au maximum de 6 p. 100

- Dioctylsulfosuccinate de sodium dans la proportion maximum de 1 p. 100

- 2 phényl-indole dans la proportion maximum de 1 p. 100

- Thio-bis - méthyl-butyl (tertiaire), phénol -

- Sebacate de di-n-butyle

- Phtalate de di-n-butyle

- Azo di-carbonamide

- Ester de l'acide B-aminocrotonique avec le butylèneglycol 1-4

- Esters de l'acide B-aminocrotonique avec des alcools gras de 16 à 18 atomes de carbone

- Alcools gras aliphatiques de 16 à 18 atomes de carbone.

* * *

B - UNAUTHORIZED PLASTICS APPLICATION FOR AUTHORIZATION

If a product is not authorized by the existing legislation, then a special procedure is foreseen to ask for permission to use it.

The authorization is given by an

Interministerial Decree after consulting:

The Superior Board of Public Health

and

The National Academy of Medicine

The procedure itself is regulated by the Circular of September 12, 1963 (J.O. October 3, 1963).

APPLICATION FOR AUTHORIZATION
FOR THE USE OF A SUBSTANCE OR
MATERIAL ENTERING INTO CONTACT
WITH FOODS

- - - - - - - - - - - - - - -

1. The files of the application should be addressed in three fold to the Minister of Agriculture, Bureau of Standards, - 42 bis, rue de Bourgogne, Paris 7e.

2. The applications should be accompanied by the following information:

(1) Chemical denomination of the substance and, eventually, the quantitative and qualitative composition of the material, with the indication, if possible, of the developed formula of the substance and of each of its components;

(2) The degree of purity of the substance and, eventually, of each of its components; nature and percentage of the impurities possibly therein contained;

(3) Methods of analysis used by the applicant;

(4) Directions for use of the material substance; indication of the foods or groups of foods the materials containing this substance are to come in contact with;

(5) Technical or other proof favorable to the use of the material or substance;

(6) Summary of the experimental datum relative to the physiological and pathologic effects of the substance concerned and to these same effects of each impurity that may accompany it.

These data must be obtained according to the attached protocol (not included in this report); they may be obtained through experiences made either in France or abroad, but, in any case, they must be accompanied either by a detailed report of the experiences, or by precise and complete bibliographic references;

(7) Eventually, any documentation concerning the known effects on man;

(8) References of authorization of use in the countries of the European Common Market, and eventually in other foreign countries;

(9) Translation into French of any foreign documentation."

* * *

Mr. Heckman: In Belgium, there are no specific regulations adopted yet regarding the use of packaging materials. Perhaps the Belgians will wait for EEC regulations and follow them very closely.

The Belgians have recently adopted a new list of permitted direct additives under a new law that was passed last year.

Fortunately, our Belgian associate, Mr. Richard Zondervan, Avocat a la Cour D'Appel in Brussels, has been good enough to give us his report on the regulatory situation in his country. The report is as follows:

"Richard Zondervan
Avocat a la Cour D'Appel
23 Rue Brederode
Bruxelles 1

June 9, 1965

Mr. Jerome H. Heckman
Keller and Heckman
1712 N Street, N. W.
Washington, D.C. 20036

Dear Mr. Heckman:

Further to your letter of May 24 and to mine of June 7, I take pleasure in giving you hereafter a summary of the law in Belgium which might have a bearing on the use of plastics packaging materials.

1.

The use of plastics in packaging for food materials is not, at the present, regulated in Belgium by specific laws or by specific decrees of the Department of Public Health.

2.

There is in force the basic enabling law of August 4, 1890, which allows the Government (i.e., the Department of Interior and/or the Department of Public Health and Family) to adopt and enforce regulations governing foods (for both human and animal consumption).

On the authority of this basic law, a Royal decree of December 10, 1890, has been enacted which has a bearing on the matter. It provides essentially that the use of any kind of containers in the processing, the preservation or the packaging of food materials intended to be sold or distributed, is prohibited when the parts of the containers coming in contact with the foods are made of poisonous components or of components injurious to the health, or include some of these components.

- more -

The Royal decree also provides that things that must be considered as poisonous or as harmful to the health, among others, are lead, zinc as well as the combinations, tinnings, weldings and enamels including these metals, arsenic, antimony, or their components, and also the toxic colourings listed in the regulation dealing with dyeing matters.

It can be seen that the decree -as is natural, due to the time of its promulgation- took cognizance essentially-though not only- of metal containers.

Other provisions of the decree rule on the extent of the prohibition as to the sale, the storage, the transportation, etc., of prohibited packaging and/or food materials contained in such prohibited packaging, on the labeling of metal packaging, etc.

3.

A Royal decree of September 15, 1891, grants exemptions for containers to be used only under circumstances when food materials will remain in them only for a limited duration (such as mugs, teapots, etc.).

4.

A Royal decree of March 20, 1936, rules that the provisions of the Royal decree of December 10, 1890, quoted above, are not applicable when the contact between the food materials and the container is limited to the unavoidable small fins resulting from application, outside the container, of a smoldering consisting in lead and tin.

This provision seems to apply mainly, if not only, to metal packaging.

5.

Under relevant provisions of the regulatory scheme, fines and/or imprisonment are provided for non-compliance, and the food and perhaps the packaging material are subject to seizure.

- more -

6.

To the above mentioned law and decrees, should be added as relevant to the matter the general section of the Penal Code dealing with bodily harm caused by negligence. Indeed, if some bodily harm should result from plastics food packaging put to use by industrialists, then obviously those responsible (manufacturer, commercial user, etc., of the plastic packaging) would be liable to penal prosecution. One needs only to make a passing reference to the adverse publicity inherent to the mere fact of such prosecution irrespective of its ending.

7.

To summarize, the possible legal consequences of the use of plastics packaging for food materials in the case such packaging would be proven as containing prohibited components under conditions specified, are as follows:

(a) penal prosecution: (1.) under the terms of the decree regulating the use of containers for food materials; and (2.) under the relevant provisions of the Penal Code dealing with misdemeanors in connection with the manufacture and sale of foods;

(b) penal prosecution under the general provisions of the Penal Code in case, inter alia, where bodily harm would have originated in plastics packaging;

(c) civil action for damages by anyone able to bring evidence of injury sustained as the result of plastics packaging.

8.

In short, at the present time, there are no regulations in force governing specifically the use of plastic materials which come into contact with foods.

The regulatory scheme of general application is one leaving liberty to the industrialist to use plastics packaging--it being understood that these packagings must not contain poisonous or injurious materials, some of the materials recognized as poisonous or injurious having

been listed as examples in the regulatory scheme, this listing being merely exemplary and not exhaustive.

The regulatory scheme is thus not one looking towards pre-clearance of products and/or packaging, it rests entirely with the industrialist to make, alone and without the assistance of any authority, the decision on safety. The responsibility lies with industry.

Thus, the legality of the use of plastics packaging need not be established formally or informally in order to sell or use it.

But, should the Authorities contend and prove that any plastics packaging is poisonous or injurious within the meaning and conditions of the above quoted regulations, then the sale and/or use of such packaging would fall within the scope of the regulations and the responsible persons (food packager, plastics manufacturer, and others) would be subject to prosecution.

9.

It should be noted that the competent subcommittee of the Direction Generale de l'Agriculture, of the Communaute Economique Europeenne (Common Market), in Brussels, has under consideration at this writing a proposed Resolution dealing with the labeling and the wrapping and/or packaging for food materials. The relevant working papers are still confidential and are not available for publication.

It might not be impossible eventually to secure some of these papers through some private channels.

10.

Finally, it might be of interest to note that the University of Brussels has just decided, a few days ago, to establish a Center for the study of Law on food materials.

I happen to have friendly relations, for many years, with the head of this Center, Professor E. J. Bigwood, former Head of the University of Brussels.

I hope the above proves to be of some assistance to you.

With best regards,

Sincerely yours,

Richard Zondervan"

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"Richard Zondervan
Avocat a la Cour D'Appel
23 Rue Brederode
Bruxelles 1

June 22, 1965

Mr. Jerome H. Heckman
Keller and Heckman
1712 N Street, N. W.
Washington, D. C. 20036
U.S.A.

Dear Mr. Heckman:

I assume that you have received my letter of June 9, submitting a brief summary of the Belgian regulations relating to the status of plastics food packaging materials.

I think I must add that the regulations mentioned in this summary are those in force at the present time but that they are bound to be modified in the near future.

Indeed, a recent law of June 24, 1964, has decided that the Regulations in force, at the present time, will remain in force until such time as they will be abrogated by the new Regulations which this law enables the Government to issue.

The new regulatory scheme is one providing:

a) That the only "technicological additives" permissible in packaging materials will be those listed as such by the Department of Health;

b) that the use of an additive not listed as required will be permitted only after pre-clearance in accordance to a specified procedure.

- more -

But, I repeat, no regulations have been issued as of today on the authority of the basic enabling law of June 24, 1964 - and the matter is thus still regulated by the standing rules and regulations summarized in my memorandum of June 9.

Awaiting to hear from you, I am, with best regards,

Sincerely yours,

Richard Zondervan"

In Austria, as in some of the other "Outer Seven" countries, the procedures generally followed are somewhat akin to those FDA used prior to 1958, and those still used in obtaining Meat Inspection Division clearances here.

The report of our Austrian associate, Dr. Vladimir Allmayer-Beck, should make this fairly clear. It reads as follows:

"Dr. Max Vladimir Allmayer-Beck
1, Parkring 2
Wien, Austria

REPORT ON THE LAW RELATING TO THE USE OF PLASTICS PACKAGING MATERIALS FOR FOOD IN AUSTRIA

1.) At the present moment there does not exist any legislation relating directly to the use of plastic packaging materials for food in Austria.

2.) The use of plastic packaging materials, however, is indirectly controlled by the operation of the general law relating to the sale of food as set forth in the Austrian Food Act 1951.

3.) Section 8 of the Act provides:

'Use of stuffs that have not been employed in the production of utensils until now:

(1) Stuffs that until now have not been employed for the production of vessles for eating and drinking and cooking, for food-containers, for utensils, for scales, for

balances and other measuring instruments all intended for the use with food are not to be employed for the production of said objects unless they have obtained clearance by the Federal Ministry for Social Administration.'

4.) Because of the above quoted Section 8 of the Austrian Food Act, all food containers made of plastic have to be approved if they are composed of ingredients and other stuffs that have not been cleared in Austria already.

5.) Nobody may sell or use such food-containers of which the different components have not received clearance. The persons interested in said food-containers have to ask for clearance before selling or using it in Austria. Clearance is obtained from the Austrian Federal Ministry for Social Administration. The clearance is dependent on a careful chemical analysis of the different components performed at the Austrian Institute of Food Examination.

6.) The Austrian Authorities in question do not distinguish between direct and indirect additives. Also, those components of any plastic packaging materials for food have to be submitted for clearance that are officially admitted in other countries.

7.) As far as I am informed, there is no intention to alter or to enlarge the present legal situation by issuing a specific Austrian law concerning packaging materials for food."

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The officials at the Federal Ministry for Social Administration are most interested in being advised about applicable regulations in other countries; our understanding is that if you can demonstrate that there has been some rather full-scale clearance in other countries, you are not likely to haveawhole lot of trouble.

What you really get there is a proprietary type clearance, usually by letter, I believe. Furthermore, the entire treatment is on a confidential basis with no published report on a composition. Austria does have a Codex or set of papers on various substances that is unofficial but is relied upon in decision making. A third edition of the Codex is now in preparation, and it may cover substances important in packaging materials.

Finally, as regards Italy, it has quite a complete law using the permitted list approach. The law was enacted on April 30, 1962. Two official decrees have been promulgated under it, one of which is brand new, i.e., it was adopted at the end of March, but it has just been published in the Italian Gazette. The dates of the decrees, by which they are known, are: January 19, 1963, and March 31, 1965.

Generally speaking, the Italians are following the same approach as we follow, except that they are more stringent about wanting things to be on the permitted list, whether they migrate or not. While there, I met with Dr. Muntoni, a scientist connected with the Ministry of Health (who has now, unfortunately, changed jobs) and had occasion to ask him if he did not agree that you have to consider conditions of use in approving or disapproving a packaging material, not just whether its components are on the permitted list or not. His first reaction was, "Well, we consider conditions of use to some extent, but it should be on the permitted list."

I then inquired: "Well, let me just ask you this question. How do you regulate ink used on packaging materials?"

After thinking this over, Dr. Muntoni said, "Well, now, that is something I've been thinking about very seriously and I have decided that I am going to try to convince the other people, my higher-ups, that we should take a different point of view on substances that may not be expected to become components of food. So, I'm trying to get matters around to where you don't have to get things like ink approved if they do not migrate." How long some of these developments will require is indeterminable, but, in the meantime, you have to deal with packaging problems on a case-by-case basis.

In the Italian ministry, I believe there are five people altogether assigned to deal with all phases of the food additives problem, direct and indirect, and I don't think any of the five people, now that Dr. Muntoni is no longer working in this area, are very experienced in the field. My information is that most of the other people are fairly new. They act very slowly on petitions for clearance. I've had occasion to file some and they are still handling them.

* * *

The European laws report by Mr. Heckman was thereafter concluded with a supplementary question-and-answer session which was not accurately transcribed and is, therefore, not reported on herein.

Idh