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Summary

1. Debromination methyl linoleate has been polymerized at 290° and 300° for varying periods, and analysis has been made for monomer, dimer, trimer, normal, and conjugated linoleate.
2. The disappearance of normal linoleate follows a first order reaction rate with values of K = 0.10 hr.$^{-1}$ at 300° and 0.05 hr.$^{-1}$ at 290°.
3. Polymerization of mixtures of normal and conjugated linoleate indicate that dimer may be formed by their reaction with each other.
4. The value for K, the first order reaction velocity constant for disappearance of normal linoleate, decreases to a limiting value on dilution with methyl stearate. This limiting value is about one-fourth that obtained on undiluted linoleate.
5. The above facts are qualitatively explained by assuming that the mechanism of dimerization of normal linoleate is extensively:

$N \dashrightarrow C$ relatively slow
$N + C \dashrightarrow D$ relatively rapid.

Other possible reactions by which normal linoleate disappears may be:

$N \longrightarrow$ isolinoleate
$N + \longrightarrow$ oleate or isooleate
$N \longrightarrow$ cyclic monomer
$N + D \dashrightarrow$ trimer
$N + N \longrightarrow$ dimer.

6. A slight but definite polymerization functionality has been demonstrated for oleate. A dimer of methyl oleate was prepared which apparently has one double bond.

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Certain Aspects of Food Standardization After Ten Years Under the New Food and Drug Law[1]

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PROBABLY no statute is more important to the health and welfare of the people of this country than the Federal Food, Drug, and Cosmetic Act, regulating as it does the manufacture and labeling of all articles that pass our lips, be it food or drugs, as well as all cosmetics. It became a law 10 years ago (June 25, 1938) and much has been written and said in review of its first decade (1).

Chemists, and especially oil chemists, have played an important part in connection with the enactment of this law, its enforcement, and the promulgation of important regulations issued under it. While many aspects of and experiences under the statute are of possible interest to a group of this nature, this paper is limited to one provision of the Act and certain problems and questions connected with it.

I refer to Section 401 of the Act, under which the Federal Security Administrator has the power to promulgate a definition and standard of identity for any food, and, once promulgated, such definition and standard of identity has the force and effect of law. For a better understanding of the meaning and effect of this statutory provision, permit me to furnish you with what I believe to be some necessary historical and legal background.

The predecessor act of the Federal Food, Drug, and Cosmetic Act was the Food and Drugs Act of 1906 which, with amendments that were added thereto, was in effect from 1906 until the Federal Food, Drug, and Cosmetic Act became effective (2). Under the 1906 Act the Secretary of Agriculture (3) had no legal power to standardize a food although as time went on the need for such a power was recognized by many. However the Food and Drug Administration did issue what it called "advisory standards." These had no legal effect but were adopted as a guide for officials in enforcing the Food and Drugs Act. Accordingly, they were of considerable interest to industry as well as government.

These advisory standards were usually quite simple and very basic. For instance, the standard for flour read:

> The fine-ground product obtained in the commercial milling of wheat, consisting essentially of the starch and gluten of the endosperm. It contains not more than 15% of moisture, not less than 1% of nitrogen, not more than 1% of ash, and not more than 0.5% of fiber.

Another example is the advisory standard for farina, which read:

> The purified middlings of hard wheat other than durum.

By contrast, the legal standards for these two products which have been promulgated under the Federal Food, Drug, and Cosmetic Act cover in minute detail the numerous ingredients of the products and are

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very lengthy. These advisory standards represented a conscientious effort on the part of the Food and Drug Administration to improve the quality of foods and to prevent the label use of the name of a food for a product which did not meet the consumer understanding for a food bearing such name.

SINCE these advisory standards did not have the force and effect of law, the government could not refer to them in any court case in which a violation was charged. For instance, if a prosecution were started against a product labeled "Fruit Preserves," the government could not prove its case by submitting in evidence the advisory standard for fruit preserves and then proving that the product involved contained less than the minimum fruit content specified in such advisory standard. The government, after showing the actual fruit content of the product, would have to prove to the satisfaction of the court or jury that such product did not conform to the consumer understanding of "Fruit Preserves"; and such consumer understanding was shown by proving the customs of the trade and good manufacturing practices. Needless to say, these cases were very difficult to win, and not only did the government lose some of them, but this very difficulty was a potent deterrent to the institution of such a case unless the "violation" was a flagrant one.

Practically from the inception of the efforts of those interested in having Congress pass a more complete statute in this field (4), the sponsors recognized that a new law must provide for food standards which would have the force and effect of law. The law as passed did contain a very important and comprehensive provision in this regard.

One cannot understand fully the food standard provision of the Act without reading, in connection therewith, certain labeling provisions of the Act. First, there is Section 403(g) which provides that a food is misbranded:

> If it purports to be or is represented as a food for which a definition and standard of identity has been prescribed by regulations as provided by section 401, unless (1) it conforms to such definition and standard, and (2) its label bears the name of the food specified in the definition and standard, and insofar as may be required by such regulations, the common names of optional ingredients (other than spices, flavoring, and coloring) present in such food.

Then Section 403(i) provides that a food is misbranded:

> If it is not subject to the provisions of paragraph (g) of this section unless its label bears (1) the common or usual name of the food, if any there be, and (2) in case it is fabricated from two or more ingredients, the common or usual name of each such ingredient; except that spices, flavorings, and colorings, other than those sold as such, may be designated as spices, flavorings, and colorings without naming each . . . .

Accordingly you will note that in the case of an unstandardized food the label must state its common or usual name, if there be one, and in case it is made from two or more ingredients, the common or usual name of each such ingredient must be declared. If the food has been standardized, then the label must bear the name of the food specified in the standard and to the extent required by the standard, there must be a label declaration of the common names of the optional ingredients present in the food. You will note in this connection that in the case of a standardized food, the names of the required or mandatory ingredients are not to be declared, but the label must show only the optional ingredients present and then only to the extent required by the standard.

With this in mind permit me to quote the applicable provisions of Section 401:

> Whenever in the judgment of the Administrator such action will promote honesty and fair dealing in the interest of consumers, he shall promulgate regulations fixing and establishing for any food, under its common or usual name so far as practicable, a reasonable definition and standard of identity . . . . In prescribing a definition and standard of identity for any food or class of food in which optional ingredients are permitted, the Administrator shall, for the purpose of promoting honesty and fair dealing in the interest of consumers, designate the optional ingredients which shall be named on the label . . . .

WHEN these statutory provisions are considered together, you can see the pattern that has been established by the law. In the case of an unstandardized food consumers are to rely on the label declaration of ingredients for an understanding of the food they buy. In the case of a standardized food, however, the basic reliance of the consumer is on the name of the product because the product has been standardized to promote honesty and fair dealing in the interest of consumers. Optional ingredients in standardized foods must be labeled for the information of consumers only when it is necessary in promoting honesty and fair dealing in the interest of consumers. Since the food is standardized, the consumer does not have to be told by the label what the mandatory ingredients are. However, since she may not expect certain of the optional ingredients that are used, the Administrator is given the power to require the labeling of some or all of the optional ingredients.

Even though standard-making procedure was halted during the recent war, standards for a large number of foods have already been promulgated. Time limitations prevent my attempting to describe the steps followed in standard-making procedure (5). I could mention that such procedure is governed by certain provisions of the Act as well as by regulations adopted by the Administrator, and both the provisions of the statute and of the regulations are aimed at attempting to have standards that are as fair and reasonable as possible. However I think that you will be interested in some of the experiences and results under food standardization.

Many people, including some in the field, did not realize the full import and effect of a food standard, once promulgated, until the standards for flour and related wheat products were issued and the subsequent United States Supreme Court decision was rendered in the well known Farina case (6). The Administrator had issued a standard for Farina and a separate standard for Enriched Farina. The hearings on which these standards were based had been held at a time when vitamins and minerals were becoming items of widespread popular appeal. Certain brands of farina then on the market had one or more vitamins and/or minerals added. At that time, the name "Enriched Farina" was really unknown. Manufacturers who fortified their farina products showed the fortification on the labels in a variety of ways. There was no uniformity in the fortification nor in the manner used to declare, on the labels, the existence of the fortification.

Farina was standardized in keeping with the gen-

eral understanding of the product. The standard, however, did not provide for the addition of any vitamins or minerals, either as required or optional ingredients. A standard was also issued for "Enriched Farina," a name coined by the Administrator for the fortified product. Pursuant to the standard, Enriched Farina was Farina to which were added vitamin B_1, riboflavin,* niacin, and iron, as required ingredients, and to which could be added, as optional ingredients, vitamin D, calcium, and wheat germ; and a floor was set for each such added vitamin or mineral.

THE effect of these standards and of food standards as a general matter is well pictured when we look at a product of the Quaker Oats Company that was on the market at the time the hearings were held. Starting at a time prior to the beginning of these hearings, this firm had marketed a farina which was fortified with vitamin D and only with vitamin D. The label of the product very clearly and conspicuously stated that the product was farina plus vitamin D. The addition of the vitamin D to the farina served a good purpose when you remember that a large amount of the farina purchased is consumed by children. Yet, even though this product was pure and wholesome, and honestly and clearly labeled, the Government charged and the U. S. Supreme Court said that to ship it in interstate commerce violated the Federal Food, Drug, and Cosmetic Act.

Obviously, the Quaker Oats product was not Enriched Farina because it was fortified only with vitamin D; it was not Farina because the standard for Farina did not permit the addition of vitamin D. However, since consumers could think from taste and appearance that the Quaker Oats product was either Farina or Enriched Farina, the product violated Section 403(g) of the Act since "it purports to be or is represented as a food for which a definition and standard of identity has been prescribed by regulations as provided in Section 401" and it does not conform to such definition and standard.

This is a result of the so-called "exclusive appropriation" theory of a standard. A standard can and does result in illegalizing a perfectly good and honestly labeled product. A product which is the subject of a standard, or "purports to be or is represented as a food" for which a standard has been promulgated, can contain only such ingredients as are specifically included in the standard. No matter how beneficial an ingredient may be or how clearly its presence is stated on the label, if it is not included in the standard, its use in a standardized product results in a violation of the Act and a shipment of such product in interstate commerce is a federal crime (7).

Let me emphasize that a label declaration of the presence in a standardized food of an ingredient not included in a standard, does not result in preventing a violation of the law. For example, catsup was standardized, and sodium benzoate, an ingredient used at times before the standard, was not included in the standard as an ingredient. A product was put out on the market containing sodium benzoate and the product was labeled "Tomato Catsup With Sodium Benzoate." All of these words were given equal prominence. In other words, the product was so labeled that "Tomato Catsup With Sodium Benzoate" was the name of the product. Yet, both the trial court and the Circuit Court of Appeals held that this product violated the law. It purported to be catsup and actually it was not catsup because it contained sodium benzoate (8). As a result of the standard, catsup or any product which purports to be or is represented as catsup cannot contain any sodium benzoate regardless of how the presence of the sodium benzoate is declared on the label.

YOU can appreciate therefore the sweeping effect of a standard. Once a standard has been promulgated for a food, you cannot use in such food any ingredient which is not specifically included in the standard, no matter how beneficial it may be to the consumer nor how improved the product may be as a result thereof.

Furthermore, a result of standardization is not only to "freeze" the standardized product but may very well tend to prevent the creation of a new product since such new product may be held as purporting to be or represented as the standardized food and accordingly this new product could then not be shipped because it does not comply with the standard.

It is clear how the actual time that a standard is promulgated can have an effect upon technological improvements and scientific creations. Once a product is standardized, the freedom of action formerly possessed by the manufacturer in that field has been radically changed. Before standardization, if a manufacturer wanted to improve his product by adding a new ingredient, he could do so as long as the ingredient was non-deleterious and it was declared on the label. Now, with the existence of a standard, the manufacturer may not do this, regardless of the benefit to the consumer unless and until the standard is changed, if ever, to permit the use of such ingredient.

Furthermore, if one of you, as a result of considerable research, experimentation, and testing, creates a new food product, you cannot assume that it is legal to ship it merely because the product is wholesome, delicious, and a distinct improvement over anything that is on the market. You must be sure, and at your own risk, that it will not be held as purporting to be or as representing a food for which a standard has been promulgated. If it is so held, your new product, as fine and important as it is, would violate the law.

Let me give you a single example along these lines, with reference to a product that you are familiar with. We know that today both mayonnaise and "salad dressing" are sold in large quantities; and that mayonnaise was the first on the market. Let us assume that mayonnaise had been standardized under this Act prior to the invention of "salad dressing." Because of appearance, flavor, packaging, odor, and use, it could well be held that "salad dressing" purports to be or is represented as mayonnaise. As already stated, mere labeling would not be enough to save the situation. Therefore under this set of hypothetical facts, since salad dressing purports to be mayonnaise and mayonnaise is a standardized product you could not ship salad dressing since it purports to be mayonnaise and does not comply with the standard for mayonnaise (9).

*The requirement to use riboflavin in Enriched Farina was postponed.

MANY people in the field feel that the freezing effect of a standard has definitely slowed down or prevented progress and improvements, which, in turn, has not been to the consumer's advantage. This has frequently been pointed out to officials of the Food and Drug Administration and their answer usually is that the statute contains a procedure for amending a standard. However, this remedy is not as practical as it may appear to be at first blush.

The statute provides (10) that "The Administrator, on his own initiative or upon an application of any interested industry or substantial portion thereof stating reasonable grounds therefor, shall hold a public hearing upon a proposal to . . . amend . . . any regulation contemplated by" Section 401 of the Act. Once a hearing is called to amend a standard, the procedure is pretty much the same as in the case of a standard-making hearing. This means, among other things, that appropriate notice of the hearing must be given, the hearing must take place not less than 30 days after the notice, that at some time following the hearing the Administrator issues his proposed order, and that sometime thereafter the final order is issued which cannot take effect prior to 90 days after it is issued except if the Administrator finds emergency conditions exist necessitating an earlier effective date.

Therefore, in order to have a standard amended, without the Administrator doing it on his own initiative, a petition has to be prepared and filed by the industry or a substantial portion thereof. You can appreciate the difficulties that may result in connection with this formal requirement. Certainly one manufacturer does not constitute an industry, and it would only be in an exceptional case that a single manufacturer would constitute a "substantial portion" of an industry. Therefore, as the statute reads, a manufacturer who would like to have a standard amended is not always certain that he can start the amendment procedure going. It is obvious that in many cases it would be impractical, impossible, or inadvisable to have the required petition filed by the industry or a substantial portion thereof. The manufacturer could attempt to interest the Administrator in the latter's doing this on his own initiative; but in view of the realities of the situation, it is too much to expect that the Administrator would always act on his own initiative in the large number of cases that could well arise of manufacturers each desiring to amend a standard in some fashion or other.

Then, even if the above problems are hurdled and a hearing is called, considerable time will have to elapse before any amendment will become effective. Based upon past experiences, it could well take from one to two years from the time a petition is filed until an amendment becomes effective. The expense factor should probably also be mentioned.

Delay in time, serious as it is, is obviously not the only drawback. Actually, problems mount by the score. Perhaps some of you have read of the "Dr. Peters Case of the Dusty Farina (11). The standard for Enriched Farina permits calcium carbonate as an optional ingredient. A manufacturer found that calcium carbonate made his product dusty but eventually discovered that the condition could be eliminated by using a very small amount of vegetable oil which would not be of any disadvantage whatsoever as far as the product is concerned and actually could not be detected by the consumer. However, the standard for Enriched Farina does not permit the use of vegetable oil in any amount for any purpose. Accordingly, this manufacturer had the alternative of either going through the standard amending procedure or continuing with a dusty product. He preferred the latter.

TO demonstrate further the difficulties involved let me take a hypothetical case. Oleomargarine is standardized, and the standard does not permit an antioxidant either as a required or as an optional ingredient. Let us suppose that the chief chemist for a margarine manufacturer announces one day, with much pride and even happiness, that after several years of investigation and experimentation, he now has a fine antioxidant for oleomargarine and he is going to start improving his product immediately by using this ingredient forthwith. His company is about to proceed with this ingredient, feeling that it now has improved its product and the consumer will gain a distinct advantage. However, the company's attorney states that this cannot be done; that at best the company may start using the antioxidant in from six months to one year and that, actually, he cannot promise that the company will ever be able to start using it.

The chief chemist is flabbergasted. He explains the constant effort, time, and expense that went into the project. He tells about the testing that went on in outside laboratories to make sure that the substance is absolutely non-deleterious. He goes into great detail about the need for an antioxidant in fat foods to help prevent the loss of perfectly good and very much needed food. He does not feel any better when his attorney tells him that notwithstanding what has been explained, the ingredient cannot be used in oleomargarine because it is a standardized food, but that it can be used in a non-standardized food by merely declaring the presence of the ingredient on the label.

The chief chemist then wants to know what he must do to use the antioxidant in oleomargarine. He is told that first a hearing must be called by the Administration to amend the standard so as to permit this particular ingredient; that since the company is neither the industry, nor a substantial portion thereof, it would appear that the statute does not provide for such a hearing if only this particular company files a petition. Accordingly, the company must try to get all or a large number of other margarine manufacturers to join in the petition. If this is not possible, then attempts must be made to get the Administrator to call a hearing on his own initiative.

The attorney then goes on to explain that even if he could assume that a hearing will be held, then the company must be prepared, at the hearing, to show, among other things, exactly what the substance is, how it is used, that under customary conditions of manufacture, transportation, distribution, and use the substance is efficacious and will produce no undesirable results, that it is non-deleterious, that it cannot result in any abuses, and that its use will promote honesty and fair dealing in the interest of consumers.

Then, in considering further what must be shown at such a hearing, our friends come up against what appears to be an insurmountable obstacle. How is the chief chemist going to test the ingredient in actual use without violating the law? Obviously, if the anti-

oxidant were used in the oleomargarine made by this company and it were shipped in interstate commerce, a crime would be committed because the standard does not permit the use of such an ingredient. The chief chemist decides that as unsatisfactory as it is, he would limit the shipment of oleomargarine containing the antioxidant to points within the state in which his factory is located. However, it turns out that this too cannot be done because, like many other states, the state in which this factory is located, by state law, has adopted the federal standards.

And so the discussion goes on with difficulty after difficulty arising. During the course of this very unhappy meeting the attorney announces, as gently as possible, that at a hearing the full details of the ingredient must be disclosed and, since the patent protection is unavailable or is worthless, the entire benefits of the work of the chief chemist and his assistants will be given to his competitors.

Is it too much to believe that in this particular case the chief chemist and his company would follow Dr. Peters' course? Would we be surprised if they felt that there was no point in attempting ever to improve a product once it became standardized?

AT this point let me make one thing clear. Nothing I have said should be construed by any of you as a criticism of the Food and Drug Administration. I have often praised the ability, honesty, and sincerity of this government agency and its personnel. The Food and Drug Administration has a statute to administer, and it consistently does its best to enforce it in what it believes to be the proper fashion. Very good reasons and explanations can be furnished for the consequences narrated above. The regulated industries under the Act have often gone on record in praising the Food and Drug Administration, and this praise was really meant and richly deserved. However, it is to be expected that there are some aspects of food standardization on which the Food and Drug Administration may disagree with some in industry.

Contrary to some others in industry, I have always felt that in view of the provisions of the Act and its declared purposes, a standard must have a freezing effect. While this may be deemed by many to be unfortunate, it is just another case of giving up some rights for the greater good of the greater number. At the same time, I submit that the Food and Drug Administration, cognizant of the severe and at times drastic effects of standardizing a food, should exercise its standardization power with discretion and caution and, to the fullest extent possible, attempt to prevent or avoid some of the unfortunate effects of standardization, which really do no one any good.

At the recent standard hearings for mayonnaise, French dressing, and related salad dressings, I proposed a concept which, after much consideration, I felt would alleviate the situation somewhat. It is based upon the fact that in practically every product there are the so-called mandatory ingredients and optional ingredients. As their names imply, mandatory ingredients are those which must be used in a standardized product and, at times, the standard requires minimum and/or maximum limits; on the other hand, optional ingredients may or may not be used, depending upon the choice or desire of the manufacturer.

I submitted that the mandatory ingredients are those which give the product its basic character or nature. In the case of mayonnaise, for example, these are vegetable oil, vinegar, and egg; without these, you simply cannot have mayonnaise. When a consumer buys a product labeled mayonnaise, she has a certain expectation which cannot be realized unless vegetable oil, vinegar, and egg are used. Therefore, I submitted that the freezing effect of a standard should be limited solely to these basic or mandatory ingredients.

However, when it comes to optional ingredients, there does not appear to be any real benefit served by freezing them to specifically named substances. Take seasonings for example. Why should these be limited only to certain named seasonings? If, due to scientific improvements or trade availabilities, a new seasoning is available in the future, why should its use be prohibited? It would not change the basic nature of the product because the product would still be mayonnaise. It would in no way prejudice the consumers' interests. The consumer is interested in the taste of the product and really does not care what combination of seasonings is used to accomplish the end result. In fact, I think it is safe to say that if a certain seasoning ingredient would improve the flavor of the mayonnaise, the consumer would want it to be used even though it may not be specifically mentioned in the standard for mayonnaise. The same could be said about other types of optional ingredients.

IN addition to types of ingredients used, I suggested the same treatment for ingredients not in current use that may be used in the foreseeable future. Using antioxidants again as an example, you know that considerable work has been done on this particular type of ingredient; and you also know that the use of a suitable antioxidant in a product like mayonnaise would be a distinct advantage to the purchasing public. At the time of the hearings no specific antioxidant was being used in mayonnaise although many of the research people in the industry had experimented with some antioxidants and testified that one or more suitable ones would probably be available in the near future.

If the standard for mayonnaise and these other dressings for salads are promulgated without any permission to use an antioxidant, you can appreciate from what I have already said what the effect may be on the future beneficial use of a substance of this nature in these products. It will obviously deter, if not prevent, the use of antioxidants for a long time after they are actually available. Yet, since no particular antioxidant was in current use at the time of the hearings, the industry could not ask for the inclusion in the standard of a specifically named antioxidant.

Accordingly I requested, and others joined in this request, that the standard permit the use, on an optional basis, of a "harmless, suitable antioxidant." The standards have not as yet been issued, and accordingly, I cannot tell you the government's official answer. If I were to venture a guess, based on the government's line of questioning at the hearings and statements made by officials of the Food and Drug Administration, I would say that this request will be denied and that my concept will be rejected. I hope

I am wrong since I am convinced that by the adoption of this approach there will be some sort of a middle ground which will give rigidity where rigidity is needed and yet remove much of the well understood criticism of food standards.

Some hope can be derived from a statement recently made by C. W. Crawford, Associate Commissioner of Food and Drugs, at the spring meeting of the Food Industries Advisory Committee of the Nutrition Foundation. He said:

> There may be validity to the criticism that some of the identity standards have been drawn with such rigidity that inconsequential variations which in no wise impinge upon consumer interest are not permitted. In future work it is our purpose to recommend the greatest latitude within standards that seems possible without undue risk. However, we must move with extreme caution when new and insufficiently tested chemicals may be prematurely used in foods through lax wording of the standards . . . (12).

While this does not go as far as some in industry would like, it is at least a step in the right direction. Of course, it remains to be seen exactly what will be done, and when, along these lines.

WE are quick to agree with the Associate Commissioner that extreme caution should be exercised so that new and insufficiently tested chemicals may not be prematurely used in foods. However, it seems to us that this is not the case when we are talking about the use of antioxidants which, in fact, must be "harmless." After all, and as has already been pointed out, a manufacturer is permitted to use a harmless antioxidant in a non-standardized food as long as he declares it on the label. Why, therefore, should he be prohibited from having the same opportunity in the case of a standardized food? What is there in the theory, concept, or effect of a standard that should prevent his being able to do this. This gets us back to the fundamental thought that when a consumer purchases a standardized product she is relying on the name of the product for its basic make-up. As already stated, the mandatory ingredients give the product the character expected by the consumer. The presence of an antioxidant in mayonnaise does not and cannot change its basic character or nature. Accordingly, we feel that the standardization of a product should not deprive the manufacturer of the right to use harmless, suitable substances for optional ingredients, and he should have at least as much freedom in this regard for a standardized food as he has for an unstandardized food.

Another incident at the hearings with respect to mayonnaise and other dressings may be of interest to you in connection with this general subject. As probably all of you know, mayonnaise traditionally has been made from a vegetable oil or vegetable oils, and the exact oil or oils used has usually not been declared on the label. The government proposed that the name of each specific oil used must be declared on the label. The industry unanimously was against this proposal because, while serving no beneficial purpose of any kind, it would impose an unreasonably great burden on the industry and, in effect, would be a requirement which would, in many cases, be impossible to comply with.

The government made this proposal on the basis that each vegetable oil used in mayonnaise is an optional ingredient. If you will go back to the applicable provisions of the law, you will understand why the government went so far as to try to maintain that while vegetable oil is a mandatory ingredient, the particular vegetable oil or oils used are optional ingredients. The Act states that in the case of a standardized food, the Administrator shall designate which optional ingredients must be declared on the label, and only such optional ingredients must be so declared. In other words, the Act does not permit the Administrator to require the labeling of mandatory ingredients in a standardized food.

TO some of us this position of the government is untenable, not only on the facts, but also on the law. Since vegetable oil is definitely required in mayonnaise, how can you say that each and every vegetable oil is an optional ingredient? Since a standardized product may be made without the use of any optional ingredients, it follows that under the government's theory, you should be able to make mayonnaise without any vegetable oil.

In Mr. Crawford's above mentioned address, he sheds further light upon the thinking of the government behind this rather novel proposal. Permit me to quote a paragraph as follows:

> The statute provides for the recognition of optional ingredients which, in effect, create subidentities within identity standards and thus give desirable flexibility. If the opportunity to differentiate between such subidentities serves consumer interest, label declaration of the optional ingredients can be required. There has been some argument that the term "optional ingredient" should not be construed as including those of a group of ingredients from which any one or more may be selected, but where the use of at least one is mandatory. We know of nothing in the statute or its legislative history that supports this narrow construction. Unless and until the courts rule otherwise, we are disposed to follow the interpretation that lends the greater flexibility. For example, one might regard each of the vegetable oils, of which at least one must be used in making salad dressing, as an optional ingredient just as are sugar and other ingredients the use of which in salad dressing is permissive. Let me say that in using this illustration I am not forecasting the nature of any standard for salad dressing that may be recommended to the Administrator or what his action will be.

In other words, the government's theory is that by the use of optional ingredients subidentities are created within an identity. If we follow this through, the government is really saying that within the identity of mayonnaise, you have as a subidentity "cottonseed oil mayonnaise," and as another subidentity "corn oil mayonnaise," and as another subidentity "cottonseed and corn oil mayonnaise," and as another subidentity "corn oil and soybean oil mayonnaise," ad infinitum. Bearing in mind that a standard is based upon consumer understanding and realizing that to the consumer mayonnaise contains vegetable oil, with mayonnaise being mayonnaise regardless of what particular vegetable oil or oils are used, this theory and its effects appear to be untenable to many of us.

What perhaps is one of the most important aspects of this particular development is that, if anything, it could be construed to indicate that the government is tending in the direction of more rather than less rigidity. Bear in mind in this connection that it was only in 1941 that the Government standardized oleomargarine, a product made not only from vegetable oils of various kinds but also from animal fats and from combinations of vegetable oils and animal fats. In connection with oleomargarine, the

government did not in any way attempt this sub-identity theory. The oleomargarine standard merely requires a statement that the product is either made with vegetable fat, or from animal fat, or from a mixture of the two. If the same thinking were followed in connection with mayonnaise and related dressings, and bearing in mind that such dressings contain only vegetable fats, then it becomes apparent that the proposal of the government in connection with dressings represents a marked departure over the past few years in the direction of further rigidity and restrictions.

Food standardization is a very important subject to all of us, and it warrants the constant and careful thought of those interested in or affected by it, including government and industry. It is understandable how, with a new statute, the government proceeded most cautiously and, as some feel, even leaned over backwards. Now that the Act is 10 years old, we have had an opportunity to observe how the standards have worked, in peace and in war. We submit that these experiences have proven, or should have proven, that at least some changes in thinking and approach should be made so as to prevent unnecessary strangulation of initiative and improvement and to permit the consumer to receive the benefits she might receive if some needed changes would be made.

REFERENCES

1. O. Salthe, "Legislative History of the Federal Food, Drug, and Cosmetic Act," 3 Food Drug Cosmetic Law Quarterly (1948) 148; C. W. Dunn, "The Federal Food, Drug, and Cosmetic Act and the Food Industry," 3 Food Drug Cosmetic Law Quarterly (1948) 166; J. F. Hoge, "The Federal Food, Drug, and Cosmetic Act and the Drug Industry," 3 Food Drug Cosmetic Law Quarterly (1948) 178; C. W. Crawford, "Ten Years of Food Standardization," 3 Food Drug Cosmetic Law Quarterly (1948) 243; P. B. Dunbar, "Administrative Progress of the Federal Food, Drug, and Cosmetic Act," 3 Food Drug Cosmetic Law Quarterly (1948) 5.

2. The Federal Food, Drug, and Cosmetic Act did not become fully effective until one year after it became a law.

3. The Food and Drug Administration was part of the U. S. Department of Agriculture and, accordingly, the Secretary of Agriculture was the chief enforcement official. This was true also for the Federal Food, Drug, and Cosmetic Act until the Food and Drug Administration and the enforcement of this Act were transferred to the Federal Security Agency and the Federal Security Administrator by a Presidential Reorganization Plan.

4. The original bill, S.1944, was introduced on June 12, 1933, in the 73rd Congress. After this and three succeeding bills all failed of passage in the 73rd and 74th Congresses, S.5 was finally passed on the 75th Congress on June 13, 1938, and signed by the President twelve days later.

5. For a very interesting article on this subject, see H. Thomas Austern, "The Formulation of Mandatory Food Standards," 2 Food Drug Cosmetic Law Quarterly (1947) 532.

6. Federal Security Administrator vs. Quaker Oats Company, 318 U. S. 218.

7. Many states, by state law, have adopted the federal standards. Accordingly, intra-state shipments, in such states, of foods which do not comply with the federal standards violate state law.

8. Libby, McNeill & Libby vs. U. S. 55 Fed. Sup. 725 (CCA-2, 1945) 148 Fed. (2d) 71.

9. Of course, this is purely hypothetical as to facts. Actually, both mayonnaise and salad dressing today are in the course of being standardized under the Act. Some government officials have for years felt that "salad dressing," for certain reasons, should not be standardized. However, many of these very same officials realize that if you standardize mayonnaise, you practically have to standardize "salad dressing" in order to legalize it and prevent there arising the hypothetical situation described above.

10. Section 701(e) of the Federal Food, Drug, and Cosmetic Act.

11. F. N. Peters, "Are Standards of Identity Assets or Liabilities in the Food Industry?" 1 Food Technology (1947) 583.

12. 3 Food Drug Cosmetic Law Quarterly (1948) 243,248. The writer urges all those interested in this subject to read Mr. Crawford's address, since it very well states the thinking of the government on the subject of food standards and explains, in most capable fashion, the reasons underlying the policies and approach of the government.

Testing of Colloidal Solutions by Dye Solubilization*

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THE theoretical and practical aspects of solubilization phenomena have been discussed extensively in recent literature. By the most general definition solubilization is the ability of solutions containing surface-active agents to bring into stable colloidal solution substances insoluble in the solvent alone. It has been established that the solubilized material is not present in suspended particles or emulsified droplets but is adsorbed onto or incorporated in the colloidal micelles formed by the surface-active agent in the solvent. A comprehensive article on the structure and the general physical properties of colloidal solutions was recently published by Ralston (19).

Solubilization in non-aqueous solutions of surface-active agents was described by McBain *et al.* (14), and its application in textile processing was discussed by Creely (1). The solvent action of aqueous detergent solutions for organic materials was reviewed some years ago by Hartley (3) and Lawrence (8), who included a number of references to earlier work. Recently, McBain and Richards (15) and Stearns *et al.* (21), have published solubilization data for a large number of organic liquids and hydrocarbons in aqueous solutions of various soaps and detergents.

The solubilization of water-insoluble dyes in soap, detergent, and other colloidal solutions has been studied extensively by McBain and collaborators (2, 9-13, 16) and also by Kolthoff and Stricks (5). These studies helped to elucidate solubilization phenomena which, in turn, gave valuable data pertaining to the formation and structure of colloidal micelles. Solubilization values were given also for various commercial surface-active agents with the implication that dye solubilization can be used in evaluating the relative efficiency of such compounds.

It might be well to point out that the performance of surface-active agents in a specific application can hardly be predicted on the basis of dye solubilization alone. In the case of detergency, for instance, it was stated by Hartley (3) and Preston (18) that solubilization plays only a secondary role in the usual washing process. Hartley and also Tomlinson (22) suggested, however, that in some instances—washing hands for example—soap is freely applied and the relatively high concentration will lead to the removal of certain soils by actual solubilization.

In any event, it appears that a quantitative solubilization test can be used as a measure of colloid formation in solutions containing surface-active agents. This property varies widely and is characteristic of each class of surface-active agent(e.g., wetting agents, detergents, emulsifiers, etc.). Hence,

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