will also increase the effectiveness of the unit. Notice that a separate unit is used aboard the carrier vessel for charging the positive electrode on the pump head. The negative side of the pump head unit is grounded to the sea bottom on the other side of the boat.

This new unit has not yet been tried out on fish but is currently being built at the Smith Research Company. Plans are to make fishing trials again in the 1961 Maine sardine season, when once again *It's Roundup Time in Maine.*

Fishery Products and Food Additives

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MANY OF US ARE CONVINCED that our food doesn't taste like that which Mother used to cook. That view could be just the effect of comparing memories recorded in the technicolor of youth against the black and white of daily adult reality. But it is true that many of the foods that we now buy already prepared, processed, and conveniently packaged, contain ingredients that were never found in Mother's pantry. Often these ingredients, acting as antioxidants, emulsifiers, preservatives or in some other role, make possible, or are an inevitable accompaniment of, the modern form of the marketed food.

Such substances, now referred to as "food additives," have come into use in increasing numbers and in growing volume during the past two decades, until at last it was realized that a new law was needed to deal with them. Many of those already in use had not been studied sufficiently to make sure they were safe, because the old law did not require an additive to be proven safe before it was used in food. True, legal action could be taken if a food was found to contain any added ingredient that was poisonous or deleterious, unless such added ingredient was required or could not be avoided by good manufacturing practice and was covered by a tolerance, but the difficulty was that if a product was put on the market without adequate testing, the Food and Drug Administration had first to find out about it, then get samples, conduct long-term toxicity studies, and ultimately take legal action if the product was in fact found to contain a poisonous or deleterious component. Meanwhile, the public would be eating this particular food.

To improve this situation, in September, 1958, Congress enacted the Food Additives Amendment to the Federal Food, Drug, and Cosmetic Act. The amendment provides a system for regulating food additives and it is designed to give the consumer better protection. With certain exemptions, it defines a food additive as any substance which may reasonably be expected to become a component of food or otherwise affect its characteristics, whether added directly or indirectly. No substance coming within the definition may be used unless a regulation has issued permitting and specifying the conditions of its use.

The definition exempts those substances which are generally recognized as safe by experts qualified to evaluate them. There are, of course, a great many

such substances, ranging from sugar and salt to much less familiar ones. While the law does not require us to do so, we thought that it would be helpful if we could identify at least some of the substances which we regard as generally recognized as safe—or GRAS, as they have come to be called—and thus exempt from the application of the Food Additives Amendment. With this in view, we published a substantial list of items in December, 1958, which we felt would be in that category; but because the Act refers to recognition by scientists qualified to evaluate the safety of food additives, we sent this list to over 800 scientists throughout the nation. We obtained several hundred replies and on the basis of these, we published on November 20, 1959, much of the original list in final form. Our experience with this special way of handling the first list of substances thought to be generally recognized as safe convinced us that it was not a very efficient way of dealing with the matter. We observed with satisfaction that this and other proposed GRAS lists that we subsequently published received quite wide publicity in trade and technical journals. In the future we will probably publish proposed GRAS lists, if any more are needed, wait a reasonable time for adverse comments, then make the list final if no significant exceptions are taken.

Incidentally, there has been some misunderstanding as to what is meant by "generally recognized as safe." A substance may in fact be a very safe one, but not be recognized as such simply because little or nothing is known about it in the scientific community. Information developed about it may have been guarded as a trade secret or may not have been published for some other reason. Even though a manufacturer has data which we acknowledge will show the substance to be safe, if scientists generally do not know anything about the substance, and are not acquainted with the data, it cannot be "generally recognized as safe." Such a substance is a food additive and requires a regulation to authorize its use.

Also exempted from the definition of food additives are those products for uses which had been given approval—or as the law terms it, "prior sanction"—by either FDA, or the Meat Inspection Division or the Poultry Inspection Division of the Department of Agriculture before the enactment of the Food Additives Amendment. Even though the law did not require it at that time, many manufacturers discussed with our pharmacologists their plans to incorporate new ingredients into their products and made such toxicity studies as were needed, waiting to market the food containing the new ingredient until they and FDA pharmacologists had agreed on the safety of the additive. Incidentally, a prior sanction granted to one firm for a specific usage of a product now applies equally to all others using the same product in the same way. We have not published lists of prior sanctions, with the exception of a few items in the packaging field, but if anyone believes that a prior sanction for a specific item has been granted and will advise us of the name of the firm thought to have received it, we will be glad to check our records to determine just what the situation is.

The third and last group of substances exempt from the provisions of the Food Additives Amendment are pesticide chemicals used on raw agricultural commodities. Such substances are dealt with by the Pesticide Chemicals Amendment of 1954.

In this connection many of you probably know that certain fishery products

have been classified as raw agricultural products under the latter amendment and under its authority tolerances of 5 ppm were established for chlortetracycline for whole, headed, or gutted fish, shucked scallops, and unpeeled shrimp, in fresh, uncooked, and unfrozen form.

Let me repeat, additives not covered by the above exemptions may be legally used in food only when authorized by specific regulation. In order to ease the period of transition, the Amendment provided that extensions up to March 6, 1961 could be granted to additives used before January 1, 1958, if no undue risk to public health is involved. At the present time a great many such substances are in legal use under extensions granted in conformity with this provision. The law grants no authority for administrative action to prolong these extensions beyond March 6, 1961, and it is the responsibility of all concerned to see that appropriate petitions for regulations are submitted in sufficient time for the necessary regulations to be issued before that deadline. This should be done not only for substances that are added directly to your food products, but also for those that may get in indirectly from contact by the food with the surfaces of equipment, belting, and the like, or by migration from wrapping and packaging materials, or in other ways.

The law and the regulations promulgated thereunder set forth in detail the procedure for submitting requests or petitions for approval of the use of food additives and empower the Secretary of Health, Education and Welfare to issue regulations authorizing such use and establishing tolerance limitations where these are necessary. This authority has been delegated to the Commissioner of Food and Drugs. The petition shall give full information about the identity, chemical properties, toxicity, and proposed uses of the food additive. In evaluating a food additive, we must have clearcut evidence of safety; we just cannot take chances in this field. On the other hand we do not want to require any unnecessary pharmacological work. We have urged those who have problems which appear to need pharmacological studies for their solution to discuss their planned work with our Division of Pharmacology before starting it. While our people sometimes advise that the program is not sufficiently comprehensive, there are other times when they have been able to conclude that not all of the work planned is necessary, or to advise other approaches that give promise of more effective results.

Our original intention was that a food additive regulation would specify the substance, indicate the reason for its use, limit the amount that could be present in the food, and would describe in every case a good method of determining whether the limitation had been met, through examination of the finished food product in the laboratory. In the case of many direct additives we still regard this as a sound minimum objective. We have found, however, that in some cases, even involving direct additives, limitations on the maximum amount that could be present were not necessary and in such cases we have concluded that the method of analysis of the finished foods need not have the precision that would be necessary where a tolerance limitation had been set. With indirect additives, such as those encountered in the packaging field, we have come to realize that it is impossible to expect the early development of analytical methods which would enable us to examine food products and determine how much of what components of the packaging material had migrated. We have considered other approaches such as that illustrated by the polypropylene

regulation issued several months ago. There we have based our regulatory control on the requirement that the polypropylene itself meet certain specifications. Elaborate tests have shown that if it does there will be no problem of migration. We hope that this approach and modifications of it will work satisfactorily in the development of regulations covering other packaging materials.

So much for the broad background of the requirements of the Food Additives Amendment, now let us consider some of the specific cases where it applies to fishery products. The fishery industry has not been behind other segments of the food industry in exploring and experimenting with the use of additives which offer promise of some desired technical effect. For example, EDTA, ethylene diamine tetraacetic acid, has been suggested for use in canned shrimp and canned crab meat to prevent struvite formation and darkening. A regulation establishing a tolerance for EDTA for this use is under active consideration at this time.

I referred earlier to the permitted use of CTC, chlortetracycline, in unprocessed fish, scallops, and shrimp under the provisions of the Pesticide regulations. There is also pending a petition for the use of this compound on fish fillets under the Food Additives regulation. Final action has not been taken on this petition pending the outcome of investigations designed to show whether or not such use of CTC actually inhibits decomposition or merely tends to mask its more obvious manifestations. In this connection I should point out that the law prohibits approval of a food additive if the proposed use of the additive would promote deception of the consumer or would result in adulteration or in misbranding of the food.

Of possible interest to your industry would be the permitted use of ammonium chloride in ice to keep the ice from shattering. This use in amounts up to 117 ppm is regarded as generally recognized as safe.

With many of your products you have problems of discoloration of the food during transportation and storage. A number of chemical substances have been and are used to overcome this. In addition to the EDTA mentioned above, there are citric acid, phosphoric acid, aluminum sulfate, and in some instances sulfur dioxide and sodium metabisulfite. These latter items have been recognized as safe as used in good commercial practice.

Various buffering and neutralizing agents are used, such as aluminum sulfate, aluminum sodium sulfate and aluminum ammonium sulfate. These too, are generally recognized as safe when used for this purpose in good commercial practice.

No doubt sodium benzoate and perhaps sorbic acid are sometimes used in some of your specialty products as preservatives. These too, are generally recognized as safe, although I should point out that their effectiveness as preservatives is often limited.

Many plants cook directly with steam or let the steam come in direct contact with the food in some other operation. Use of boiler compounds as rust inhibitors, antifoam agents, or for other purposes opens an avenue for indirect addition of food additives that must be taken into consideration. Nonvolatile materials such as trisodium phosphate, sodium hexametaphosphate, sodium hydroxide, sodium sulfite, sodium silicate and sodium aluminate cause no problem, but volatile chemicals such as morpholine, cyclohexylamine and octadecylamine require clearance. There are prior sanctions for 10 ppm of

morpholine or cyclohexylamine in steam coming in direct contact with foods, except milk. Octadecylamine is still under consideration.

Many fishery products are used for animal feed and it may surprise some of you to learn that the Food Additives Amendment applies equally to substances added to animal feed. This happens because the basic 1938 act defines food to include any article used for food or drink for man or animals and components of any such article. Thus, when a product within the definition of a food additive is incorporated into animal feeds the provisions of the Food Additives Amendment must be met. And here we have a double concern, for not only must the food additive be safe for feeding to the animal, but if it results in residues in the edible meat or milk of the animal this too must be taken into account.

It is possible that in your research laboratories you are experimenting with the use of additives other than those I have mentioned, which you feel will improve the character of your products. Let me urge that, unless these are generally recognized as safe by qualified experts, you also proceed now to acquire the necessary information regarding composition, toxicity, minimum amounts required, and analytical methods, to support petitions for food additive regulations authorizing their use.

Where there is any question of possible migration of additives into food products from wrappers, coatings, boxes, labels, or from any other source, we urge you to get the facts before continuing to use the particular articles. In many cases, you will undoubtedly find that the matter has been investigated by the supplier or original manufacturer and certainly if there are any specific questions about the law, do not hesitate to get in touch with us. We realize that in making this offer we probably are only adding to the heavy burden of correspondence which we have had ever since the enactment of this amendment. We will, however, do our very best to comply with each and every request for comment when we are supplied with sufficient facts upon which to base an opinion.

The Economic Potential of the Calico Scallop Fishery of the Gulf and South Atlantic With Special Reference to the East Coast of Florida

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THE LARGEST KNOWN SCALLOP BED in the entire world was recently discovered off the east coast of Florida by exploratory fishing personnel of the U.S. Bureau of Commercial Fisheries. First indications of the new seafood find were noted in January, 1960, during inshore explorations off Daytona Beach by the motor vessel, *Silver Bay*. Further explorations in April revealed that this bed extends from Daytona Beach south to Ft. Pierce—a distance of 135 miles. Commercial concentrations have been found over a 1,200 square-mile area. These same