FOOD CHEMICAL NEWS

A weekly Washington publication for executives providing in-depth information regarding regulation of food additives, colors, pesticides, and allied products.

$200 a year Additional subscriptions $125

Volume 17, Number 11 • June 2, 1975

HIGHLIGHTS of the news

FDA/APHIS merger receives new impetus from Kennedy bill. Page 26
PBB GUIDELINES provide margin for safety, FDA's Kolbye says. Page 47
PCB RESIDUES lead to Michigan coho salmon seizures by FDA. Page 36
TOXICOLOGICAL effort by food, allied groups is urged. Page 13
MUTAGEN-screen for carcinogens status reported at symposium. Page 27
SLUDGE-treated soy beans show high cadmium content. Page 38

NUTRIENT COMBINATION applications invited by FDA for 45 days. Page 5
DIETARY SUPPLEMENT link to food additives explained by FDA. Page 3
DIETARY HEARING cross-examination is opened up by FDA. Page 11
CITIZEN PETITIONS require balanced presentation of issues. Page 22
INFORMAL public meetings to get wider use by FDA. Page 24
HEARING CLERK data submission rules are clarified by FDA. Page 16
ADMINISTRATIVE procedure methods of initiation explained. Page 21

CANDY GMP'S, finalized by FDA, become effective in 60 days. Page 53
NET WEIGHT candy exemption proposal hit by FTC, NCWM, CMA. Page 34
SIRUP SWEETENER report offers little data on allergy potential. Page 40
IODINE dietary intake levels are matching nutrient needs. Page 40
MILK PRODUCTS microbiological limits weighed by Codex group. Page 46
"PACKED IN FLORIDA" label requirement gets FDA approval. Page 43

FOOD AD TRR is reissued by FTC with new statement of need. Page 51
FOOD ADDITIVE specification compliance results reported. Page 43
RESIDUES in meat and poultry rise 1.3% in first quarter 1975. Page 32
ENVIRONMENTAL impact analysis report for Shell NADA reassessed. Page 52
METHOPRENE is cleared by FDA for use in cattle. Page 44

RECALL double-check for botulism asked of States by NCA. Page 35
CANNED CHICKEN is recalled because of alleged underprocessing. Page 52
QUAIL, smoked pheasant with nitrite and nitrate are seized. Page 45
PISTACHIO NUT certification program is being reviewed by FDA. Page 37
BRAZILIAN COFFEE detentions for insect contamination discussed. Page 31
CONSUMER complaint uniform handling is recommended in study. Page 49

MONS 028832

LOUIS ROTHSCHILD, Jr., Editor and Publisher, 420 Colorado Bldg., 1341 G St., N.W., Washington, D.C. 20005

For subscribers only—copyrighted © FOOD CHEMICAL NEWS, Inc. 1975

STerling 3-7472

Second-Class Postage Paid at Washington, D.C. 20013

ASPARTAME review by expert pathologists at MIT has been forwarded to FDA by G. D. Searle. The agency has decided not to reveal the conclusions until other groups, including FDA's own scientists (See FOOD CHEMICAL NEWS, May 12, Page 43), have had an opportunity to review slides of the uterine polyps developed in test animals fed diketopiperazine, a breakdown product of aspartame.

AGENCY FOR CONSUMER ADVOCACY poll run by Opinion Research Corp., which indicated 75% opposition to a consumer protection agency was biased, according to a Library of Congress study of the poll (See FOOD CHEMICAL NEWS, March 31, Page 41). The analysis of the $25,000 poll, which was financed by business groups, was requested by Sen. Percy (R-Ill.), a backer of the ACA bill. The critique of the poll said the questions were framed to show that most of those questioned are "opposed to more bureaucracy, not necessarily that they are opposed to the consumer protection agency."

GENERAL MILLS was asked by a coalition of citizen's groups to stop test-marketing its new cereal called Magic Puffs, which the consumerists estimate to be 40-50% sugar. The marketing of such cereals "thwarts the progress of sound nutrition education," charged the coalition made up of Agribusiness Accountability Project, Action for Children's Television, the American Society for Preventive Dentistry, the Center for Science in the Public Interest, Consumer Action, Inc., Consumer Federation of America and the National Consumers League.

STATE INSPECTION of meat and poultry products in New Jersey and Colorado will be taken over by the federal government effective July 1, as expected (See FOOD CHEMICAL NEWS, May 26, Page 48), according to a May 30 Federal Register notice.

FRIDAY CANNING Company's New Richmond, Wis., plant has been added to FDA's Cooperative Quality Assurance program (See FOOD CHEMICAL NEWS, Dec. 16, Page 2). The plant produces canned green beans, peas, corn, potatoes, mixed and dietetic vegetables. Two other Friday plants are expected to be added to the program.

SHELLFISH SANITATION regulations (See FOOD CHEMICAL NEWS, May 5, Page 31) "will strengthen the vital role of the States" FDA Commissioner Schmidt assured Chairman Magnuson (D-Wash.) of the Senate Commerce Committee recently. Schmidt indicated that FDA, as a result of comparative analysis of the present NSSP and the proposed regulation, is "confident that administratively sound and equitable procedural regulations can be developed without undue hardship on the shellfish industry."

CPA legislation is being readied for introduction in the House this week by Reps. Rosenthal (D-N.Y.), Brooks (D-Tex.) and Horton (R-N.Y.), with early hearings planned (See FOOD CHEMICAL NEWS, May 19, Page 45).

COLOR ADDITIVE labeling alternative approaches for cosmetics will be open for submission of supporting data for 60 days, FDA said May 30 (See FOOD CHEMICAL NEWS, March 3, Page 18). If grounds for an exemption are presented, the agency said it would issue a proposal.

COMMON OR USUAL NAME regulations for frozen heat and serve dinners and for seafood cocktails are expected to be stayed, as requested by the American Frozen Food Institute, pending the outcome of litigation (See FOOD CHEMICAL NEWS, May 12, Page 34).

FOOD CHEMICAL NEWS

Editor: Louis Rothschild, Jr. *Circulation Director: Shirley Galant*
Managing Editor: Raymond Galant *Production Manager: Dorothy Hill*
Assistant to the Editor: Natalie Pargas *Associate Editors: Cathy Cooper,*
Assistant Editor: Eileen Kugler *Gail Tapscott*



FDA SPELLS OUT LINK BETWEEN DIETARY SUPPLEMENTS AND FOOD ADDITIVES

The Food and Drug Administration on May 28 spelled out its new philosophy of regulating nutrients used in dietary supplements and special dietary foods under the safety provisions of the Food Additive Law (See FOOD CHEMICAL NEWS, May 26, Page 35).

The philosophy was spelled out in the preamble to tentative amendments to the §80.1 food standard for dietary supplements and to the §125 special dietary food regulations. Exceptions to the "tentative amendments" may be filed within 45 days.

As ordered by a court, FDA made flexible the limitations on the nutrients to be used in combinations in dietary supplements and the imposition of maximum levels by providing for the filing of petitions for additional combinations and higher levels. The agency junked the "drug" designation for nutrients used over the §80.1 maximum levels, and provided for applications for use of nutrients for which Recommended Dietary Allowances have not been established.

Substituting safety considerations for the strict limits which had been set in the controversial regulations, FDA said:

> "Any added vitamin or mineral which is not generally recognized among experts qualified by scientific training and experience, to evaluate its safety, as having been adequately shown to be safe under the conditions of its intended use in food is a food additive . . . and . . . such use is illegal in the absence of a food additive regulation approving such use."

For example, FDA said that molybdenum is not GRAS, and that a "molybdenum supplement" would be "subject to regulatory action . . ." If a claimant in a seizure action should "contend that molybdenum is generally recognized as safe and thus not a food additive . . .," the preamble said, "this would be a factual issue for determination in the civil seizure action in the absence of a regulation governing the status of the nutrient."

Noting that some nutrients are included as GRAS in FDA's published GRAS list (§121.101), FDA said it is "not practicable to list by regulation all substances that are generally recognized as safe for their intended use." The agency said that the Division of Regulatory Guidance in its Bureau of Foods will on request "advise whether, in its judgment, a particular use of a vitamin or mineral (not specifically governed by regulation) is generally recognized as safe . . . and thus lawful for use without a food additive regulation."

FDA noted that data developed in the GRAS review program or in the over-the-counter drug review might lead to additional restrictions or elimination of existing restrictions.

Lists of GRAS, Non-GRAS Nutrients To Be Proposed

The agency disclosed plans "to initiate new rulemaking to particularize more comprehensively than existing §121.101(d)(5) the vitamins, minerals, and/or mineral properties which are GRAS (specifying potency limitations where recognition of safety depends upon such limited use) and to list as well those substances which are not GRAS at any level of use." Proposals will appear in the Federal Register.

Presenting "in the meantime" some "tentative views regarding safety" of some nutrients, FDA said it does not believe "that current scientific knowledge warrants any potency restrictions in the interest of safety" on any of the mandatory or optional vitamins listed in the §80.1 standard or on choline.

However, FDA expressed the opinion that "synthesized vitamin K (menadione) could only be intended for therapeutic use, and, because of the potential for harm involved in its use, that it should be dispensed only on prescription." Naturally occurring vitamin K (phylloquinone), however, "appears to be generally recognized as safe for use as a dietary supplement at levels providing 100 mcg. per recommended daily quantity," the agency said.

All of the minerals listed in §80.1 are GRAS up to 150% of the U. S. RDA, FDA said, but "toxicity concerns arise if higher potencies are chronically consumed, and, if practicable, it would be useful to particularize by regulation, in the forthcoming rulemaking, the potency levels at which these nutrients cease to be GRAS."

Manganese appears to be GRAS for adults and children four or more years of age at levels up to 7.0 mg. per recommended daily quantity, FDA said, and chlorine and sodium may cease to be GRAS for dietary supplement use "at certain levels." The preamble added:

> "Finally, in the absence of any reliable data existing at this time to indicate a safe level for addition to food, and in view of recognized toxic potentialities, the Commissioner has tentatively concluded that chromium, molybdenum, nickel, selenium, silicon, tin, and vanadium are not GRAS for addition to food for dietary supplementation and that any such use would require a food additive application."

FDA said these "observations" were "offered simply as a matter of information concerning the Commissioner's present, tentative views on the GRAS status of particular nutrients; the forthcoming proposed rulemaking will include a detailed discussion of safety concerns, if any, which arise with regard to each nutrient, together with citations to published literature."

Noting that the tentative amendments of §80.1 and §125 do not place restrictions upon the potency of vitamins or minerals sold individually, FDA said that "restrictions

on maximum potency or other restrictions on availability or use may be imposed for reasons of safety by other regulations . . ."

There are currently limitations on some nutrients, as follows:

Vitamin A is limited to an Rx drug at a dosage exceeding 10,000 IU per dosage unit or recommended daily intake, and the "sale of a product exceeding this potency as a dietary supplement would be illegal."

Vitamin D in excess of 400 IU per dosage unit or recommended daily intake is an Rx drug, and a product "exceeding this potency as a dietary supplement would be illegal."

Folic acid is limited under a Food Additive Order (§121.1134) to a maximum daily adult intake not exceeding 0.4 mg., except for a limit of 0.8 mg. for pregnant or lactating women.

Iodine is permitted under a Food Additive Order (§121.1073) to be added to food for its mineral property, if it is contributed as potassium iodide with the maximum daily intakes for adults generally not to exceed 225 mcg. and for pregnant and lactating women not to exceed 300 mcg. Another Order (§121.1149) permits addition to food of kelp as a source of iodine, with the same potency limits.

Copper is GRAS for addition to food up to 0.005% by weight of the finished food product, with "use of copper gluconate in a dietary supplement in excess of this level . . . illegal in the absence of a food additive regulation approving such use."

Fluorine is GRAS only at low levels in water as approved by the Public Health Service, so that "the inclusion of fluorine in a dietary supplement product would be illegal."

Potassium salt preparations providing 100 mg. or more of potassium per tablet (or 20 mg. or more per ml.) are Rx drugs.

●

45 DAYS ALLOWED FOR APPLYING FOR ADDITIONAL NUTRIENT COMBINATIONS

The Food and Drug Administration, in the tentative amendments to its dietary supplement regulations published May 28, provided 45 days for the filing of applications for additional combinations of nutrients under the §80.1 standard for supplements or for higher doses than are now provided in the regulations.

"Applications received after that date will be held in abeyance pending review after all other issues relating to this matter are disposed of," FDA said in its preamble.

The agency requested "that the affected industries consolidate their interests and file joint applications, documented in the manner set forth . . ., for a small number of additional formulations."

Publishing the court-ordered amendments -- on which 45 days are allowed for the filing of exceptions -- FDA said it "is trusting industry to exercise restraint and

common sense in restricting itself to applications with some legitimate basis and hopes that it will not be necessary to respond to an 'avalanche' of applications with the sanction suggested by the Court . . ."

The Court said that if an avalanche of petitions should be filed, FDA "would be justified in denying all applications (except those as to increased dosages of vitamin C and vitamin B complex supplements), without prejudice to subsequent renewal, on this ground alone."

New Regulations Present NHF with Choice

Publication of the tentative FDA amendments presents the National Health Federation and other opponents of the regulations with a choice. The alternative to the regulations -- which do away with any automatic classification of nutrients at high levels as "drugs" -- is pending legislation which would restrict the §80.1 standard for dietary supplements to products for children and for pregnant and lactating women (See FOOD CHEMICAL NEWS, May 12, Page 32).

FDA said applications may be filed "for additional combinations of vitamins and/or minerals and/or for increased potency of any vitamins or minerals within a combination." The agency noted that any formulation incorporating a substance or potency that is not "generally recognized as safe" also would require the filing of a Food Additive Petition (See preceding story).

The applications, which must be filed in quadruplicate, would have to include:

"(a) A description of the formulation sought, containing a list of all vitamins and/or minerals to be included, the potency of each, and an explanation of how the formulation differs from those presently authorized . . ., together with the name proposed by the applicant for such formulation.

"(b) A statement of the nutritional or other physiological rationale, if any, which the applicant believes justifies the formulation. One or more affidavits by qualified experts, and/or copies of published scientific literature in support of any such rationale shall be included.

"(c) A statement of any other rationale which the applicant believes shows a need for the formulation. If an existing consumer demand or market for the formulation is asserted on behalf of the product, the applicant shall include copies of labeling for the existing product, including labels, cartons, leaflets, etc., and an affidavit(s) with accompanying documentation establishing the scope of the existing market, including data on the number of units sold and the wholesale and retail value involved."

FDA said it will not be necessary for anyone to file an application for a high-potency vitamin C product, which was mentioned in the court decision, or for any other high-potency product composed of a single vitamin or mineral. The agency amended the final orders so that the regulations "will impose no potency limitations on products consisting of a single vitamin or mineral."

The standard for combinations was amended "to make clear that future revisions regarding permissible formulations might involve greater product potencies as well as different combinations of ingredients, when such revisions would promote honesty and fair dealing in the interest of consumers."

FDA discussed multi-component supplements, as follows:

> "The Commissioner remains convinced that, in the case of multi-component supplements, consumed by individuals who wish to assure themselves that they consume the range of vitamins and/or minerals important for good nutrition, the vitamins and/or minerals included should be present in potency ranges generally recognized by qualified experts to be appropriate for such purposes, reflecting reasonable balances among the vitamins and/or minerals.
>
> "The concept of standardized multi-component supplements is that they provide essential vitamins and/or minerals which are useful for supplementation purposes (i.e., those which are not only essential to good health but for which there is a reasonable possibility of dietary deficiency) at levels that are nutritionally useful and that maintain reasonable balance among the vitamins and/or minerals.
>
> "In the Commissioner's judgment, such combination products should not provide excessive quantities of a vitamin or mineral which are wasteful, i.e., nutritionally useless and immediately excreted out of the system, and which serve only to create consumer confusion leading to false bases of comparison and competition between products, which may lead to higher prices but not to better products."

The differing approaches to single nutrient products and to multi-component products, FDA said, "preserves the integrity of the multi-component dietary supplements while assuring the public that dietary supplements consisting of a single vitamin or mineral will be available individually with no upper limits except those dictated by safety."

Applications Can Be Filed for Non-RDA Nutrients

Noting that the Court ordered consideration for nutrients for which RDAs have not been established, FDA said it "will give unbiased consideration to any application which concerns additional multi-component combinations involving vitamins and/or minerals for which no U. S. RDA has been established, and . . . (the Commissioner) recognizes his obligation under the decision of the Court to consider permitting a limited number of additional formulations under the conditions established by the Court."

However, FDA amended the regulations to require that a supplement containing a nutrient for which no RDA has been established "bear a statement to inform

the consumer of this fact." The label would be required to bear the statement "No U. S. Recommended Daily Allowance (U. S. RDA) has been established for this nutrient."

The regulations had barred addition of nutrients for which no RDAs had been established. The court, FDA said, "directed the Agency to consider whether there are other essential nutrients for which no U. S. RDAs have been established, which are unmentioned in the present regulations and which should be added," specifically mentioning cobalt and selenium.

The regulations, as amended, list the essential or "probably essential" nutrients for which no RDAs have been established for "informational" purposes, adding "all additional vitamins and minerals which the Food and Nutrition Board of the National Academy of Sciences-National Research Council has concluded are essential nutrients or probably essential nutrients for man but for which the NAS-NRC has established no recommended dietary allowances. . ."

The list now includes vitamin K, choline, chlorine, chromium, fluorine, manganese, molybdenum, nickel, potassium, selenium, silicon, sodium, tin and vanadium.

Cobalt, Sulfur Not Added to List of Non-Essential Nutrients

FDA did not add cobalt to the list, saying that it "is not an essential nutrient" and "its only known function is as an integral part of vitamin B_{12} (cobalamin), which is already included in the list of mandatory essential vitamins." Also, the agency said cobalt is not GRAS "and thus any food use is illegal in the absence of a supporting food additive regulation."

Because of toxicity, FDA said, food use of cobaltous salts already has been prohibited (See FOOD CHEMICAL NEWS, Sept. 23, SPECIAL SUPPLEMENT, Page 13).

Sulfur was deleted from the list because "sulfur per se is not an essential nutrient but rather an integral part of the molecular structure of several amino acids . . .," FDA said. "Sulfur may lawfully be sold as an ordinary food in any compound which is GRAS, if there is anyone interested in buying or selling such a product," the agency said, adding, "However, any representation that such sulfur is a dietary supplement or that it has special dietary properties would be false or misleading and unlawful."

For many of the substances listed, FDA said, "it is unlikely that . . . RDAs will ever be established." The agency said, for example, that while nickel "appears to be essential to good health as determined by experimental animal studies, the needed level of intake is so low and natural environmental availability is so pervasively abundant that there is no prospect of any dietary insufficiency and no need to divert research resources to determining a specific . . . RDA for humans."

Although FDA listed the essential nutrients for which RDAs have not been established in the §80.1 standard, the agency said the standard "does not properly encompass vitamins and minerals for which no NAS-NRC RDA nor any U. S. RDA has been established." While inviting applications to support inclusion of these nutrients in dietary supplements, FDA said:

"While there is evidence that these nutrients are 'essential,' there currently is no body of scientific evidence establishing that American diets are deficient in any of them. Accordingly, it would be wasteful and misleading to include them in standardized multi-component dietary supplements consumed by individuals who wish to assure themselves that they consume the range of vitamins and/or minerals important for good nutrition. Under these circumstances, the Commissioner concludes that it would not promote honesty and fair dealing in the interest of consumers for him on his own initiative to provide for the addition of such nutrients to multi-component supplements."

Limitation on Source Labeling Included in Regulations

The §125 regulations were tentatively amended last week to require "that whenever a representation is included in labeling concerning the source of a vitamin or mineral, the representation shall be accompanied, in type of at least equal size and prominence, by a statement of the percent of the vitamin or mineral content provided by the source."

For example, if 40% of the vitamin A content of a dietary supplement is derived from alfalfa, a statement "contains vitamin A derived from alfalfa" would be required to be accompanied, in type of equal size and prominence, by a statement such as "40 percent of the vitamin A content of this product is derived from alfalfa."

Saying this change would "help clarify this situation and prevent misleading labeling," FDA said that even a substance which may legally be included in a dietary supplement "may not be declared on the label in a manner which is false or misleading or otherwise in violation of the act or regulations."

Using the alfalfa example, FDA said a product could be labeled as a "Vitamin A supplement" and "alfalfa" could be included in the ingredient statement, but not in the listing of vitamins and minerals. It would be OK to include in the labeling the truthful statement that the vitamin A is "derived from alfalfa." However, the product could not be sold as a "vitamin A-alfalfa supplement."

FDA noted parenthetically that "powdered alfalfa" could be sold "as an ordinary food, rather than as a dietary supplement, with nutrition labeling . . ."

Any "unqualified representation in labeling" that a vitamin or mineral is derived from a particular source would be "misleading," FDA said, "unless that source provides a significant portion of the vitamin or mineral content of the product."

It would be misleading, FDA said, for a dietary supplement to bear the statement "vitamin A derived from alfalfa" or "vitamin C derived from rose hips" if only 2% of the vitamin were derived from the stated source. Therefore, the agency proposed the percentage labeling.

Noting that the Court said it should "articulate its intentions" with respect to non-essential ingredients, FDA said these "may not be added to vitamin-mineral supplements but they may be sold as ordinary foods by themselves or in combination with one another." For example, rutin tablets, or tablets containing a combination of rutin and para-amino-benzoic acid could be sold "provided no claims are made for such foods to the effect that they have special nutritional properties."

However, FDA warned that "one may not add rutin or para-amino-benzoic acid to a vitamin and/or mineral supplement because to do so would tend to mislead a consumer into believing that the additional ingredient makes the supplement more useful."

Noting that rutin and para-amino-benzoic acid are listed in §125 as specifically banned from dietary supplements, FDA said that addition of other substances to this black list would require the agency either to make a seizure action and "demonstrate . . . that the substance has been represented as having nutritional properties but has not been shown to be essential to human nutrition," or to issue a proposal to add the substance to the list.

Banned from inclusion in dietary supplements, FDA summarized, are any "substance which does not provide any vitamin or mineral and which is not a 'preservative, stabilizer, flavor, sweetener, color, seasoning, carrier, base, or vehicle' and which does not 'facilitate preparation' of the vitamin and mineral substances . . ."

Drug Issue Not Pursued "At This Time"

Regarding the elimination of the provision that high potency products are drugs, FDA confirmed its decision not to reopen the record for the taking of additional evidence on this point.

The agency said "the sole difference between the approach" taken in the regulations and that taken by the Court is that "these products will nowbe regulated under the law as foods rather than as over-the-counter (nonprescription) drugs . . ." FDA said "no useful purpose would be served by pursuing this point as a general rule at this time."

FDA noted that in "specific situations," such as with vitamins A and D, a nutrient can be placed on Rx legend where there are public health considerations.

FDA noted that a firm "may choose to offer a vitamin and/or mineral product as a drug rather than a food," in which case it must comply with the drug regulations rather than the dietary supplement regulations.

As directed by the Court, FDA amended §125 to permit representations "that infants, children, and women of childbearing age may not be receiving adequate amounts of iron in their daily diets."

Also as ordered, FDA exempted from §80.1 fresh fruits and vegetables, noting that the agency has proposed nutrition labeling regulations for fresh produce (See FOOD CHEMICAL NEWS, May 19, Page 14).

●

DIETARY HEARING CROSS-EXAMINATION OF HARPER OPENED UP

The reopened public hearing on special dietary foods may include cross-examination by more people than Dr. Miles Robinson, the Food and Drug Administration disclosed May 28 in publishing the tentative amendments to the §125 special dietary food regulations and the §80.1 dietary supplement standard (See preceding stories).

The Court remanded the regulations to FDA, with instructions to reopen the hearing for cross-examination of Dr. William H. Sebrell, who had been Chairman of the Committee on Dietary Allowances of the Food and Nutrition Board of the National Academy of Sciences, by Robinson, who had represented the National Health Federation.

Sebrell's successor as Committee Chairman, Dr. Alfred E. Harper, will be called to appear at the hearing, as expected (See FOOD CHEMICAL NEWS, March 17, Page 38).

In explaining that others in addition to Robinson may be allowed to cross-examine Harper, FDA said:

> "While the Court has required only that Dr. Robinson or counsel of some other similarly interested participant be allowed to engage in examination, the Commissioner intends that the examination be open to as many participants reflecting as many points of view as is reasonably possible. (Indeed, such open approach appears necessary to avoid a conflict concerning the person to conduct cross-examination. At the time of the hearing, Dr. Robinson was the official representative of the National Health Federation. It appears that Dr. Robinson is no longer acting for the NHF and that both Dr. Robinson and the NHF may assert a claim to conduct the cross-examination envisioned by the Court)."

FDA said it will direct the Administrative Law Judge, who is as yet unnamed to conduct the hearing, that "if requests to engage in examination are numerous and the participants cannot agree among themselves on apportionment of time or subject matter sufficient to accommodate all within a reasonable period of time, he should group participants with truly common interests and allow only one, or perhaps a few, qualified representative(s) from each group to examine Dr. Harper."

The agency said that the hearing officer "will be directed to expedite his report to the Commissioner upon concluding the hearing."

FDA noted that Harper served as chairman of the NAS/NRC Committee during development and publication of the eighth edition (1974) of the Recommended Dietary Allowances. The University of Wisconsin Professor "will not tender any direct testimony on behalf of the Government except to identify and provide for the record a copy of the eighth edition. . .," the preamble said. FDA added:

> ". . . He will be available . . . to respond to inquiry by those opposed to the regulations, concerning (1) the methodology employed in development of the recommended dietary allowances by the Board and the scientific foundation upon which these allowances are based, (2) the scientific appropriateness of the FDA's use of the Board's recommended dietary allowances, and (3) possible biases or conflicts of interest on the part of the Board, as well as other relevant subjects."

Saying that a notice stating the time and place of the hearing will be published soon, FDA said those who wish to participate must file new notices of appearance, since "it is likely that some of the participants of record may have changed their address or their counsel or may no longer wish to participate, and the Commissioner believes the proceeding should be open to new persons who are not presently participants of record."

FDA noted that its U. S. RDAs were based primarily on the seventh edition of the Board's recommended dietary allowances (1968), saying the changes made in the eighth edition "are not of sufficient magnitude as they relate to overall public health to warrant similar changes in the U. S. RDAs at this point in time."

However, the agency said that "U. S. RDAs may be proposed for additional nutrients over the next several years on the basis of accumulating scientific knowledge, and that it is reasonable to anticipate changes in existing U. S. RDAs to reflect changes in the NAS/NRC RDAs when the latter are next published, probably 1979."

FDA last week published tentative amendments to its regulations in line with a Court decision in the National Nutritional Foods Association case (See FOOD CHEMICAL NEWS, Aug. 19, Page 30). The agency allowed 45 days for the filing of exceptions.

Noting that the U. S. Supreme Court has denied certiorari in the case (See FOOD CHEMICAL NEWS, March 3, Page 8), FDA said, ". . . The Commissioner concludes that it is now appropriate to develop revised regulations, in compliance with the directions of the Court of Appeals, as expeditiously as is feasible."

In a news release, FDA said that the "final" revision of the regulations, which were issued in 1973 and which are now stayed, will be issued "after consideration of (1) the comments received in response to the tentative revisions, (2) the applications for additional formulations of vitamin-mineral combination products, (3) the record developed at the reopened hearing, and (4) final opinion of the Court. . ."

The agency noted that the "tentative revised regulations derived from 13 years of public proceedings. . .," recalling that they involved "the longest administrative hearing ever conducted by the agency, lasting from 1968 to 1970 and amassing 33,000 pages of testimony." In commenting on last week's publication, FDA Commissioner Schmidt said:

> "With this new proposal, the FDA is responding fully to the Court, and at the same time remaining faithful to our

three goals: (1) to provide consumers with more and better information about the vitamin-mineral products they buy; (2) to deter fraudulent and misleading claims; and (3) to eliminate nutritionally useless ingredients from dietary supplement products.

"The FDA does not argue with, nor will it interfere with, the consumer's right to use vitamins and minerals as 'nutritional insurance' against improper eating habits. We do seek to insure that consumers who elect to use vitamins and minerals will be able to buy products which are rationally formulated and honestly labeled.

"We believe that the revised regulations are a substantial improvement over the original approach because they will be less subject to misinterpretation and misrepresentation. They should, therefore, allow FDA to carry out a reasonable and effective program in an important area of consumer protection."

●

FOOD, ALLIED INDUSTRY JOINT TOXICOLOGICAL EFFORT URGED ✓

General Foods' Dr. John Kirschman has urged that a broad group representing the food, drug, cosmetic, petrochemical and other consumer product industries get together to tackle toxicological problems.

The proposal made at the recent convention of the Flavor and Extract Manufacturers' Association at Marco Island, Fla. (See FOOD CHEMICAL NEWS, May 26, Pages 36 and 40), would parallel the Chemical Industry Institute of Toxicology (CIIT) which was recently formed (See FOOD CHEMICAL NEWS, May 5, Page 25).

However, Kirschman said CIIT deals with large-volume heavy chemicals, whereas the consumer product group would emphasize toxicological evaluation of wide-exposure, low-poundage chemicals. Both groups, he said, would have "similar ends."

The General Foods' toxicologist said there must be a "move ahead" to establish closer coordination between safety evaluation groups in various industries.

McCormick's Dr. Richard L. Hall, who was part of an FEMA panel, noted that members of that panel represented half of the Grocery Manufacturers of America's toxicology committee and also half of the food industry members of the Society of Toxicology. The three are Kirschman, Hall, and International Flavors & Fragrances' Dr. Otho D. Easterday.

Hall noted that the food toxicology meeting planned for Aug. 17-23 in Aspen, Colo., is designed to pull together experts from around the world and to give the food industry a greater awareness of toxicology (See FOOD CHEMICAL NEWS, May 12, Page 11).

Kare Stresses Benefits Derived from Flavors

In a keynote-type address that was discussed by many later speakers during the FEMA meeting, Dr. Morley R. Kare, director of the Monell Chemical Senses Center, stressed the positive functions of flavors, including the taste stimulus effect on the digestive tract. He emphasized the role of flavor in food consumption and nutrition.

The speaker discussed his tests which showed that newborn humans have a sense of taste, denying contentions that have been made that there is no need to flavor infant foods. Kare also said that infants have an early sweet perception.

The recent National Academy of Sciences symposium on sweeteners (See FOOD CHEMICAL NEWS, April 7, Pages 4 and 7), Kare said, centered almost completely on toxicology, with no discussion of the "functions of taste" and the positive aspects of sweeteners.

Hall, who is chairman of the FEMA Safety Evaluation Committee, said that "flavors are essential" and that they affect "proper dietary choices." He said the industry should start emphasizing these "positive aspects," commenting that industry has been preoccupied with toxicology and the "negative."

Unless industry "rouses itself" and begins to make consumers aware of the "positive aspect," Hall said, flavor use will be restricted "wholly unnecessarily." He urged industry not to devote all its efforts to fighting "brush fires." The concern has been centered, Hall said, "in trying to find something wrong," with no attention to benefits or giving a balanced picture.

IFF's Wallace G. Dempsey said it would be an "uphill battle" to convince consumer organizations. He noted that some European industry groups have held joint meetings with consumer organizations, and that the Common Market has representatives of both industry and consumer groups. Dempsey said the flavor industry does not have the resources for a large public relations campaign, and must work with the food processing industry. FEMA's outgoing president, Warner-Jenkinson's Oliver W. Hickel, Jr., also stressed FEMA's limited resources.

FEMA Attorney and Executive Secretary Daniel R. Thompson said industry should stress the "benefit" part of the "cost-benefit" equation for flavors.

Dempsey, who is chairman of FEMA's Government Relations committee, expressed concern about some food industry "abuse of the distinction between artificial and natural" which implies "superiority" of natural ingredients. He said food firms claiming "contains no artificial ingredients" play "up to an unfounded fear."

An effort should be made, Dempsey said, to convince both the food industry and consumers that the distinction between natural and artificial is "irrational."

Hall agreed that industry should avoid the "cannibalism with which we attack ourselves." He attributed the Food and Drug Administration's reluctance to re-clear cyclamates at least in part to consumer fears engendered by industry itself.

IFF's Eugene P. Grisanti said a first step in correcting the situation would be "selling" the marketing and advertising people in the food industry.

Legislation To Be Introduced To Amend BATF Law

Discussing the ingredient labeling proposals of the Bureau of Alcohol, Tobacco and Firearms (See FOOD CHEMICAL NEWS, May 19, Page 9), Robert G. Fries, Jr., of Mallinckrodt's Fries & Fries, revealed that legislation will be introduced soon to permit continued use in alcoholic beverages of 1/10 of 1% artificial flavors without "artificial" flavor labeling.

Without this provision to preserve the exemption for "top note" flavors, Fries said, firms will either shift their operations to foreign soil, or import the flavor mixtures used in alcoholic beverages. Either way, he added, jobs and money will be lost by the U. S.

Overseas, Fries said, many foreign firms replace natural flavors with artificial flavors which are difficult to detect and regulate. The U. S. cannot duplicate the European products without adding a trace amount of artificial flavor, he explained. Fries said that if this practice is followed in the U. S., under the new regulations there would be difficulties in selling because of "adverse" labeling. If this practice is not followed, he added, the U. S. products may be inferior to the European products.

BATF now permits the 1/10 of 1% "top note" without "artificial" labeling. However, this practice is threatened by the new ingredient labeling regulations, giving rise to the need for legislation, Fries said. If the BATF understanding on the wines and cordials containing "top notes" is lost, he added, a product might have to bear a name such as "Imitation Cherry Wine Specialty."

The BATF proposals pose a "serious problem," Fries said, alleging that the detailed labeling proposed would be "misleading and confusing" and would not help consumers. In line with FDA's flavor labeling regulations, he added, some "natural" flavors would become "natural and artificial."

Fries said that FEMA is now finalizing a statement to be submitted to BATF stressing the differences between nutritive foods and alcoholic beverages, and discussing the problem of regulating imported products.

Analytical Method for Ester Gum Submitted to FDA

Florasynth's Joseph J. Amento, chairman of FEMA's General Research Subcommittee, disclosed that a new analytical method for ester gum (glyceryl abietate) in soft drinks has been sent to FDA's Division of Food and Color Additives for evaluation. He said FDA "may require additional testing to define the precision and accuracy of the procedure."

Virginia Dare Extract's Anthony Filandro reported on continuing FEMA research on methods of analysis for vanilla. He said that Fitelson Laboratories has prepared a group of eight authentic vanilla extracts and analyzed them by the classical

procedures. ". . . We will soon have a large enough data foundation for making statistically sound conclusions with a greater degree of confidence than formerly possible," Filandro said.

Characterization of vanilla by gel permeation chromatography for non-volatiles has been conducted by Battelle Laboratories, he reported, saying this "revealed a potential for information rather than a readily usable procedure." If one or more of the aromatic acids and polyphenolic materials should prove to be unique to vanilla, he added, "it could give a new tool for authenticating vanilla."

Discussing the gas liquid chromatography test for vanilla, Filandro said it is "excellent" for the "detection of foreign acids in pure vanilla," but that it cannot be used as a "general yardstick of vanilla quality and strength."

Work in France on isotopic analysis of vanilla may be helpful, he reported, but the isotopic difference between vanilla and vanillin is small and difficult to measure. Filandro also said the procedure and apparatus are too complex for most laboratories.

The Wisconsin Alumni Research Foundation has analyzed vanilla for inorganic constituents, and Filandro said results "show that the metallic constituents of vanilla extract do not have any public health significance in the quantities present." He said that WARF will report next month about a test to determine the authenticity of vanilla extract through the potassium, phosphorus and nitrogen content. Filandro said more data is needed to "verify the validity of the proposed ratios."

●

FDA ISSUES RULES FOR SUBMITTING DATA TO OFFICE OF HEARING CLERK

The Food and Drug Administration has emphasized that material which anyone does not wish to become available to the public "should not be submitted to the Hearing Clerk with a petition or comment."

Provisions of the administrative practice and procedure regulations were published in the May 27 Federal Register (See FOOD CHEMICAL NEWS, May 19, Pages 27, 31 and 33; and May 26, Pages 3, 5, 8 and 9). Those dealing with submissions of documents to the Hearing Clerk covered much of the same ground on confidentiality and trade secrets with which the agency had dealt under the Freedom of Information regulations (See FOOD CHEMICAL NEWS, Dec. 16, Pages 3 and 4; Dec. 23, Pages 3 and 9; Dec. 30, Pages 3 and 6; Jan. 13, Pages 15 and 17; and Jan. 20, Pages 23 and 28).

The new administrative provisions attempt to bring all of the public disclosure regulations which deal with submissions to the Hearing Clerk into perspective.

All Data In Petitions and Comments Will Be Made Public, FDA Says

The FDA noted that all petitions and comments submitted to the Hearing Clerk must be available for public review and copying.

The regulations also noted that the rules of disclosure are applicable to all evidence and pleadings submitted in the course of a formal evidentiary public hearing, a public hearing before a Public Board of Inquiry (See FOOD CHEMICAL NEWS, Jan. 27, Page 46), a public hearing before the Commissioner, or any alternative form of public hearing used in lieu of a formal evidentiary hearing.

It is not applicable, FDA continued, to a public hearing before a public advisory committee or to a regulatory hearing before the FDA, explaining that these two do not provide for submission of material to the Hearing Clerk.

Separate provisions govern examination of the administrative record in these two proceedings, FDA explained.

Submissions to the Hearing Clerk are divided into the following three categories, FDA said:

(1) those that may be seen and copied by the public; (2) those that may be seen but not copied by the public; and (3) those that may neither be seen nor copied by the public.

Asserting that petitions and comments must be public because the Commissioner must publicly explain his action in accepting or rejecting these, the regulations emphasized that "material which any person does not wish to become available to the public should not be submitted to the Hearing Clerk with a petition or comment."

Since New Drug Applications and New Animal Drug Applications and petitions for biologics licenses are submitted directly to the Bureaus and not to the Hearing Clerk, FDA continued, their availability for public disclosure is governed by the FOI provisions.

Pointing out that issues of hearings before the Commissioner are likely to be similar to those considered in petitions and comments, FDA said all materials submitted by any person at this type of hearing "will also be fully available to the public," with one exception.

FDA said this would involve a public hearing before the Commissioner when a request is made for an alternative form of public hearing in lieu of a formal evidentiary public hearing.

In that situation, FDA said, the same rules on examination and copying of the administrative record will apply as if the proceeding were held pursuant to a formal evidentiary public hearing.

Objections and requests for hearings filed pursuant to the formal evidentiary hearing procedure as well as a hearing before a Public Board of Inquiry, FDA noted, will also be fully available to the public with some exceptions which limit public access to particular types of material.

"The Commissioner is of the opinion that public proceedings of any type should be held on the basis of publicly available data and information wherever possible," the regulations noted, explaining:

> "Unless this is true, participants in the proceeding may not be in a position to review and evaluate all relevant information, and thus to participate in a meaningful way. Accordingly, the Commissioner has concluded that all data and information submitted to the Hearing Clerk relating to such proceedings must be available for examination and copying by the public, with only very limited exceptions."

The exceptions to the general rule for public material relate solely to data and information which constitute trade secrets or which represent a clearly unwarranted invasion of personal privacy, FDA declared.

FDA noted that regulations dealing with privacy were enunciated in the FOI rules, and are similarly reflected in the provisions dealing with submission of documents, pointing out that even if it is submitted, this kind of information will not be available for public disclosure.

Saying that the same distinction the agency made under FOI on indirect competitive and direct competitive effects is reflected in the document's provisions, the agency noted, "Data and information relating to safety and effectiveness, which of course necessarily reveal the protocols involved, will be placed on public display in the Office of the Hearing Clerk, but will not be available for copying."

In contrast, FDA added, data and information relating to such trade secrets as manufacturing processes and quantitative formulas will not be available either for examination or for copying by the public.

FDA Re-States FOI Rules on Trade Secret Status of NADAs, Additive Petitions

The provisions relating to limited availability of safety and effectiveness information are applicable only to new drugs and new animal drugs, FDA said in re-stating the FOI rules, explaining that safety and effectiveness data relating to food additives, antibiotics, and biologics are available for public disclosure.

Any hearing which concerns the safety or effectiveness of a new drug or animal drug will permit full public participation, the agency said, since any participant will be able to obtain a copy of the summary of all of the relevant data and information and will then be able to check that summary against the full reports of the data and information contained in the Office of the Hearing Clerk.

At the same time, FDA said, providing the full reports only in the Office of the Hearing Clerk, and prohibiting their copying or, if they should be copied, subsequent submission to the FDA in support of any petition or application, "protects their commercial value to the maximum extent that is consistent with a public hearing."

FDA explained that the purpose of the provision was to protect the commercial value of the material by precluding submission of data in trade secret status with an NDA or NADA.

In noting the exclusion for manufacturing and similar data, FDA suggested that this data has not been relevant to any NDA or NADA hearing since 1938.

In order to reduce the possibility of damage to commercial interests, FDA said, the regulations provide access to the safety and effectiveness data which constitute trade secrets "only as long as is necessary for participation in a hearing and any subsequent judicial review," suggesting the procedure represents "a compromise between the need for public availability of information relevant to a public hearing, and the need for protection of trade secrets."

Recognizing that it would be a hardship to require a participant in a proceeding, who is located outside of the Rockville, Md., location of the Hearing Clerk, to review data available for examination but not for copying, the agency said it will entertain a petition requesting that the data and information involved be sent to the nearest FDA District Office where they may be examined.

Emphasizing that the provisions "will be strictly followed," FDA said if a person submits attachments marked "confidential," the papers will be placed on public display in accordance with both FOI and the administrative procedures "without consultation with the person who has submitted the information."

In some proceedings, FDA said, the new regulations require FDA to file the prior administrative record, which would include the relevant portions of an NDA or NADA. In performing this request, FDA continued, the agency may (1) either request that the holder of the NDA or NADA conduct the review and make an initial designation of those portions for which public disclosure is not warranted, after which the agency will make its final determination on the matter, or (2) the agency may itself make a determination and then consult with the holder of the NDA or NADA on any close questions pursuant to the FOI provisions.

FDA Requires Submission in Quintuplicate Except for Individuals

In general requirements for submission of documents to the Hearing Clerk, FDA pointed out that all submissions must be filed in quintuplicate, except for comments filed by individuals, and must include all data and information referred to or in any way relied upon unless the material has been previously submitted as part of the administrative file in the same proceeding. As an example, FDA said a petition for reconsideration may refer to the previously established administrative record without reproducing any portion of it.

All such documents, FDA noted, shall be considered as submitted on the date on which they are postmarked or delivered in person during regular business hours, unless an applicable regulation or the Federal Register notice specifies otherwise.

Actual copies of all documents to which reference is made are needed because of the Commissioner's experience that they are frequently hard to locate, the regulations

noted, adding that documents in a foreign language must be translated to avoid use of substantial agency resources.

Stressing that submissions must be signed by the person making the submission or by an attorney or other authorized representative, FDA said the authorized representative or attorney may submit comments or other documents in his own name, without revealing that he is acting on behalf of a client.

If a submission reveals that an attorney or representative is not acting on his own behalf, the agency continued, there must be documentation verifying his authority to act in a representative capacity.

Failing to comply with the requirements, FDA said, will result in rejection of the submission for filing or, if it has been filed, in exclusion from consideration of the submission which fails to comply. The agency cited court precedents for rejecting a filing which is deficient.

Noting that the Hearing Clerk is not familiar with all of the technical requirements, FDA said the appropriate Bureau, Chief Counsel, and Associate Commissioner for Compliance may be called to advise whether or not a submission should be filed.

If a submission is erroneously filed, FDA observed that the regulations provide that an acceptance for filing "does not mean or imply that a document in fact meets all applicable requirements of the regulations."

Industry Comments Must Be Submitted to the Hearing Clerk in Quintuplicate

Additionally, FDA said, acceptance by the Hearing Clerk does not mean or imply anything with respect to the merits of the request, noting that some regulations allow acceptance for filing to mean a petition contains reasonable grounds for the action requested.

Noting the inconvenient location of the Hearing Clerk's Office in Rockville, FDA said any document delivered to Room 6819 of FDA's downtown headquarters building at 200 C. Street, SW., in Washington will be considered as having been received by the Hearing Clerk. FDA emphasized that this provision applies only to documents that are required to be received by the Hearing Clerk by a specific date, and not to documents that are required to be "mailed" to the Hearing Clerk by a specific date.

FDA warned that all submissions must be "true and accurate," and noted that "false reports" are considered felonies under the law.

In the past, FDA has accepted for filing comments which are not filed in quintuplicate -- a move which has tied the staff of the Hearing Clerk's Office up in work at the copying machine. Under the new rules, comments filed in fewer than five copies -- except those from individuals -- will be returned to the sender.

●

FDA SPELLS OUT METHODS FOR INITIATION OF ADMINISTRATIVE PROCEEDINGS

The Food and Drug Administration will ask courts requesting the initiation of administrative proceedings to leave with the agency discretion of how to tackle the problem.

Under the agency's new administrative procedure regulations (See preceding story), FDA said that an administrative proceeding may be initiated in any of the following three ways:

(1) on the initiative of an interested person outside the agency; (2) on the agency's initiative; or (3) at the request of a court.

Citing the Supreme Court decisions of 1973 dealing with FDA's regulation of new drugs, FDA said it has the primary jurisdiction to make the initial administrative determination on issues within its statutory mandate, and quoted the Court, as follows:

> "A decision that FDA lacks authority to determine in its own proceedings the coverage of the Act it administers, subject of course to judicial review, would seriously impair FDA's ability to discharge responsibility placed on it by Congress."

Accordingly, FDA said, the new Section 2.6(b) dealing with initiation of proceedings provides that the agency "will request a court to dismiss, or to hold in abeyance its determination of, or to refer to the agency for administrative determination, any issue within the agency's jurisdiction which has not previously been determined by the agency or which, if it has previously been so determined, the agency concludes should be reconsidered and subject to a new administrative determination."

In other provisions of the regulations dealing with referrals by the court, the agency acknowledged that any Federal, State, or local court may hold in abeyance, or refer to the Commissioner, any matter for an initial determination.

In such circumstances, FDA said, the Commissioner shall "promptly agree or decline to accept any such referral."

Under the provisions of Section 2.14, FDA said, the Commissioner will make "every reasonable effort to accept such referrals and to institute proceedings to determine the matters so referred, but must reserve the right to decline a referral in light of other agency priorities and the resources available to the agency."

"In handling such a matter," the agency continued, "the Commissioner may, in his discretion, utilize any of the various procedures established in the new regulations."

Saying it encourages the judiciary to use these provisions of the regulations, FDA suggested that "referral of complex and technical issues falling within the jurisdiction of the FDA to the agency for an initial administrative determination will promote consistent and fair interpretation and application of the law."

●

CITIZEN PETITIONS REQUIRE BALANCED PRESENTATION OF ISSUES

A balanced presentation, showing representative data on both sides of an issue, will be required under administrative procedures established by the Food and Drug Administration for the submission of a so-called citizen petition (See preceding stories).

FDA said the citizen petition is intended to cover every form of agency administrative activity, including a refusal to act, and may relate to factual, policy, or legal issues. The new Section 2.7 does not set out all of the possible activities involved, FDA noted.

FDA said the provisions do not cover, for example, referral of matters to United States attorneys for enforcement action in the courts and related regulatory activity.

The petition must state the action requested, the grounds, and the environmental impact, if any, of the action requested.

In addition to including all data, information and views on which the petition relies, FDA said, it must also include "representative data and information known to the petitioner that are unfavorable to the petition." FDA explained:

> "The Commissioner has found, in reviewing petitions submitted in the past, that adverse or unfavorable information is omitted and ignored, thus resulting in a very unbalanced and misleading presentation. It is for this reason that, in recent regulations, the Commissioner has required submission of representative unfavorable information in order to provide a more balanced and reasonable presentation ..."

Without such a requirement, FDA observed, a person submitting a petition could present only one side of the story and thus mislead the FDA and the public as to the true situation.

The provision, for example, FDA explained, will prevent a manufacturer from submitting only data showing the safety and utility of an ingredient or product, or a consumer advocate from submitting data showing only the hazards from an ingredient or product. Failure to include both sides, FDA emphasized, would constitute a violation of the False Reports to Government Act.

In distinguishing between petitions and regular correspondence with the agency, FDA noted that anyone may send a letter to the agency suggesting particular actions. Denial of an informal request or suggestion encompassed in routine correspondence will not be sufficient, however, FDA pointed out, to constitute a final agency action and to invoke the right of judicial review of administrative action.

Only those matters specifically raised in a formal petition will require a formal response by the Commissioner, which constitutes final agency action subject to court review, FDA observed.

The agency said the rules for citizen petitions were not meant to impede the normal flow of informal and routine correspondence.

If a petition meets the requirements of the regulations, FDA said it shall be filed by the Hearing Clerk and a docket number assigned which will be used to identify the administrative file established for all submissions relating to it. The Hearing Clerk is also required to keep a chronological list of all citizen petitions, showing the docket number, date of filing, name of petitioner and subject matter.

On occasion, FDA noted, the Commissioner receives petitions on which others wish to comment before the Commissioner takes action, pointing out that the new regulation provides that such comments may be submitted to the Hearing Clerk and included in the file.

Noting that the Commissioner will review and rule on every petition, the regulations emphasized that quite frequently a lack of resources requires priority setting by the agency, which may defer decision-making for "a substantial period of time."

FDA Says Delay in Responding May Be Due to FDA's Independent Action on Issue

An apparent delay in responding, the regulations observed, may also result from the fact that the agency is in the process of taking action of the type sought in the petition, but has not reached the point of implementation.

To grant relief sought in the petition in such instances, FDA continued, would be premature and to deny the petition would constitute final administrative action, possibly triggering the unnecessary initiation of judicial review by the petitioner.

FDA noted that a petitioner may supplement or amend his petition at any time, and may withdraw it without agency approval at any time before the Commissioner rules on it.

The regulations provide that the decision of the Commissioner shall be in writing and sent to the petitioner as well as being placed in the public file at the Office of the Hearing Clerk. FDA said the Commissioner has the "inherent discretionary power" to set any reasonable effective date relating to any decision resulting from a citizen petition.

Subsequent judicial review, the regulations noted, shall be based solely on the administrative record and the Commissioner's decision, suggesting that if the Commissioner or any interested person wishes to rely upon other data or information not included in the administrative record, the new information must be submitted with a new petition seeking to modify the decision.

●

FDA PLANS INCREASED USE OF INFORMAL PUBLIC MEETINGS

The Food and Drug Administration "anticipates increased use" of informal "public meetings to explore pending matters in the future," the agency disclosed in the administrative procedures published last week (See preceding stories).

Noting the need for "informal procedures ... to handle administrative determinations," FDA said that "without them, the entire administrative process would bog down in stifling formality."

Open public meetings "to discuss any matter pending before the agency" are provided in the new regulations, with public notice of the meetings to be given through FDA's public calendar. Depending on the time factor, FDA said, notice may also be published in the Federal Register.

Distinguishing the informal meetings from the various formal hearing procedures covered by the new regulations, FDA said that "any interested person may attend and participate ..." Although no transcript or recording of the meeting is required, the preamble to the regulations said, "one may be taken and in any event a written summary shall be prepared and retained in any relevant administrative file."

The meetings "are to be conducted informally, very much like a town meeting, and are not to be structured," FDA said, adding that "there is no fixed order in which persons may participate nor any advance notice required of those who intend to attend and participate." Examples of informal meetings given in the regulations dealt with non-food matters, specifically microwave ovens, digoxin, and high intensity mercury vapor discharge lamps.

Provision for "Private Meetings" Includes Requirement for Memos

The new regulations provide specifically for "private" meetings between individuals and FDA-ers, but require that memos be prepared summarizing the meetings. FDA said:

> "The Commissioner concludes that it is a fundamental right of every citizen to meet with his government in private. The Federal government is created by the people, and absent explicit statutory authority the government has no right to impose upon any citizen who requests an opportunity for a private meeting with a representative of the government a requirement that others outside of the government be present."

The regulations provide that "neither the FDA nor any other person may require the attendance of any person who is not a Federal government employee or consultant without the agreement of the person requesting such a private meeting."

However, FDA ruled that whenever a private meeting involves a pending case or other regulatory action or decision "or any other important matter, a decision on an issue, or statements or advice or conclusions to which future reference may be

required as part of the administrative record," a written memo summarizing "the substance of any private meeting shall be prepared by a representative of the agency."

"This will make certain that any matter which should be documented as part of the public record is in fact so recorded," FDA said, adding that the availability of the memo for public disclosure would be governed by the Freedom of Information regulations.

"The Commissioner believes that this will adequately protect the public interest, without infringing upon the citizen's right to a private meeting," the agency said.

FDA-ers may initiate meetings with individuals, and the agency provided that "any such meetings with one or two people, e.g., relating to a pending petition, may be held as a private meeting." These meetings would also be covered by the memo requirement.

FDA-ers Given Discretion In Participating In Outside Meetings

The agency said it "recognizes that agency employees have a responsibility to meet with all segments of the public in order to promote the objectives of the act and the agency."

The regulations provide that "where an agency representative is invited to attend an outside meeting, he may do so where he concludes that it is in the public interest and will promote the objectives of the act and the agency."

The FDA-er may "request that such meeting be an open meeting when he concludes that this would be in the public interest," and "he may agree or decline to participate in any such meeting which is held as a private meeting, depending upon which action he concludes will best serve the public interest."

All outside meetings are made subject to the memorandum preparation requirement.

The regulations make it clear that "in no event ... may an agency representative knowingly participate in any meeting which is closed on the basis of sex, race, or religion."

FDA-ers also may initiate meetings with people outside of the agency, and under the regulations "any such meeting with a large number of people ... shall be held as an open meeting ... and thus shall be publicly announced so that any person may attend and participate."

The new regulations provided that any meeting between an FDA-er and a representative of Congress, such as a committee staff member, which relates "to any pending or potential investigation, inquiry, or hearing shall be recorded in a written memorandum which shall be forwarded to the agency's Office of Legislative Services."

The preamble said "this provision does not restrict the right of any agency employee to participate in any such meeting, but guarantees that the agency will be aware of any congressional concern about agency activities and thus be in a position to respond in an adequate way."

MONS 028856

Any meetings between FDA-ers and representatives of other government agencies outside FDA's parent Department of Health, Education and Welfare which relate "to a pending case or other regulatory action or decision must be recorded in a written memorandum, and filed in the administrative file on the matter, unless it involves only a brief description of the matter provided for informational purposes," FDA said.

This policy, the preamble continued, "assures that an adequate administrative record will be maintained of all contacts outside the Department on any regulatory matter, to avoid the possibility or appearance of improper influence." FDA explained:

> "Thus, if a person in another government agency outside the Department, or in Congress, were to telephone any person in the FDA to make any suggestion about a pending regulatory decision, a memorandum will be prepared summarizing the discussion. Other meetings with persons within the Federal government, however, which do not involve a pending regulatory matter, are not subject to this requirement."

FDA reiterated its new policy that memos of conversations may be prepared by the non-FDA participant in the conversation. Conceding that "summaries of oral discussions, whether by telephone or in person, may differ depending upon the person who prepares the summary," the agency provided that "in addition to the agency summary, any outside person participating in such a meeting may prepare and submit to the agency for inclusion in the administrative record his own written memorandum recording the substance of the meeting." As provided in the FOI regulations, both summaries would be released whenever a public request is made for them.

●

ATTENTION AGAIN FOCUSED ON FDA/APHIS COMBINATION

A recurring discussion in Washington bureaucracy, the possible combination of the Food and Drug Administration and the Department of Agriculture's Animal and Plant Health Inspection Service into one food-safety agency, is again receiving attention.

As in the past, APHIS officials are firmly convinced that the agency should remain a part of the Agriculture Department rather than join the Department of Health, Education and Welfare, FDA's parent Department. Although noting that one agency designed to oversee all food safety activities sounds good in theory, APHIS representatives are wary of combining with FDA, an agency with a vastly different philosophy about enforcement.

The differing outlooks stem from different legislative mandates (See FOOD CHEMICAL NEWS, March 31, Page 32), but APHIS officials believe also that the differences reflect the different types of products which the two agencies oversee. They are firm in their belief that a sampling plan could not be substituted for the continuous antemortem and post-mortem inspection of animals to be used for food.

They are not as rigid when it comes to inspection of meat and poultry processing plants, however. APHIS officials themselves have been trying to cut down on the number of inspectors. But they are still hesitant to go to the much more limited FDA approach, which they feel is more oriented to after-the-fact checking.

APHIS staffers also believe that meat and poultry inspection activities are an integral part of the entire APHIS program. In their opinion, it should not be separated from the animal health programs of USDA and the states.

In addition, APHIS officials fear that if the two agencies were combined, the personnel problems would be difficult to overcome. Aside from the basic problem of deciding who would be in charge, it would be hard for good working relationships to develop between persons who were trained in different philosophies toward regulation.

One of the reasons why the discussion may be surfacing again is the section of Sen. Kennedy's (D-Mass.) bill (S 963) banning animal use of diethylstilbestrol, which would give the FDA independent status (See FOOD CHEMICAL NEWS, May 26, Page 2). Some APHIS officials see this as the first step in enlarging FDA's area of control.

●

SYMPOSIUM TOLD CURRENT STATUS OF MUTAGEN SCREENING TESTS FOR CARCINOGENS

The international symposium on "Health Effects of Chemicals in Food," sponsored by Canada's Department of Health and Welfare in Ottawa (See FOOD CHEMICAL NEWS, May 26, Pages 21 and 24; and May 19, Page 37), was told of the current status of mutagenic screening tests for carcinogenesis by Dr. Lionel A. Poirier, of the National Cancer Institute.

Explaining the basis for the screening tests (See FOOD CHEMICAL NEWS, May 19, Page 23), Poirier noted that direct-acting carcinogens are often directly mutagenic and procarcinogens manifest their mutagenic activities after metabolic activation either in vivo or in vitro.

"Thus, a good degree of correlation could be observed between mutagenesis and carcinogenesis," Poirier stated, adding: "This correlation held out the promise that chemical mutagenesis could serve as a rapid indicator of potential chemical carcinogens."

The NCI scientist pointed out that testing for mutagens is "far more rapid and cheaper than testing for chemical carcinogenesis." The "detector systems which appear to be most promising as a prescreen for chemical carcinogens are the microbial systems used in vitro with and without metabolic activation," he reported.

Reviewing results of tests conducted by NCI, Poirier stated that "approximately 72% of the carcinogens tested were mutagenic towards Salmonella in vitro; only 17% of the non-carcinogens were mutagenic to Salmonella. Yeast and pol A-deficient E. coli (polymerase A-deficient E. coli) each gave positive responses with about 50% of

the carcinogens tested, and with 25% of the non-carcinogens. When the in vitro results from Salmonella and from pol A(-) E. coli were combined, 86% of the carcinogens were detected; however, 29% of the non-carcinogenic structural analogues and mutagens showed mutagenic activity."

"All procarcinogens and ultimate carcinogens belonging to the 4 major classes of chemical carcinogens were mutagenic to the combined Salmonella and E. coli systems," Poirier reported, adding, "Of the 8 carcinogens which were not detected either by Salmonella or by E. coli, 7 required metabolic activation." He listed the "problem compounds," as follows:

"(1) Mutagenic non-carcinogens: 1-anthramine, 5-BUDR, 1,2-epoxybutane, glycidol, 7-hydroxy-N-2-fluorenylacetamide, hydroxylamine hydrochloride, and sodium nitrite.

"(2) Carcinogenic non-mutagens: acetamide, bis-(p-dimethyl)-aminodiphenylmethane 7,9-dimethylbenz(c)acridine, ethionine, thioacetamide, thiourea, and urethane.

"(3) The indeterminate compounds 5-FUDR and succinic anhydride."

Poirier acknowledged that many of the "problem compounds" might "not be true exceptions to the close correlation between mutagens and carcinogens."

He also noted that a study to be released by Dr. Bruce Ames, University of California (Berkeley), who developed the Salmonella strains used in the screening test, will report that 85% of carcinogens were found to be mutagenic and 10% of non-carcinogens were mutagens in Salmonella screening tests done by Ames and his colleagues.

While the screening tests have potential for the future, Poirier stressed that the tests are not yet ready to go, noting that the Ames test requires a screening system to fill in the gap so that carcinogens will not slip through the screen.

He reported that a hamster cell transformation system, being developed at Frederick, Md., test facilities, is testing about 50 compounds, including several carcinogens which were negative in the Ames test. Of seven carcinogens negative in the Ames test, two have tested as positive in the hamster cell transformation system, Poirier stated.

Use of mathematical models to extrapolate data so as to assess the degree of risk from carcinogens was discussed by University of California's (Berkeley) Dr. K. B. Jones. Jones stressed the need to consider time (latent period) in any risk assessment model, advancing a formula, which is a "general law," although with exceptions, governing relationship of latent period to dose.

However, Dr. Marvin Schneiderman, of the National Cancer Institute, speaking from the floor, attacked Jones' model, pointing out that Oxford University's Dr. Richard Peto had demonstrated that at low dose levels "the power function essentially disappears" (See FOOD CHEMICAL NEWS, Oct. 7, Page 20).

The consequence of this finding, Schneiderman stated, is that the time effect "also essentially disappears."

Jones discussed the need to consider the normal life-span of man and the potential risk during that period. However, Schneiderman pointed out that recent calculations have indicated that the average life-shortening effect of adding a new carcinogen to the environment would be eight years, although the average time to appearance of cancer would be 300 years.

The need to consider the "role that alterations of tissue architecture may play in determining the transformation of normal cells into cancer cells" was advanced by Dr. P. Grasso, of the British Industrial Biological Research Association. Grasso, a patholpgist, suggested:

> "If one can identify a particular lesion in animals that leads to malignancy and if one can demonstrate that malignancy does not arise at dose-levels in which this lesion is not induced then in my opinion one is justified in taking the view that the compound is unlikely to be a carcinogenic hazard to man unless the lesion seen in animals is likely to be induced also in man.
>
> "One is also justified, again in my view, in looking at the 'no-effect' level in a dose-response experiment, in the same way as one would look at a 'no-effect' level in a toxicity test and make the extrapolation to man in the accepted way.
>
> "In my view, this will take out of the category classed as carcinogens, those compounds in which the induction of cancer is purely the result of a particular set of experimental procedures (e.g. dose-levels, route of administration, length of time of administration) and will leave for a different sort of consideration those compounds which induce cancer in the absence of pronounced and long-standing pathological effects."

Dr. James R. Gillette, of the National Heart and Lung Institute, spoke on the need to apply pharmacokinetic principles such as rate of drug elimination or the pathways of drug metabolism, which may differ according to species, in extrapolating animal data to humans. Gillette commented:

> "The pharmacokinetic principles of irreversible reactions have ... played a valuable role toward our understanding of various toxicities of chemically reactive metabolites in animals.
>
> "Although similar studies for predicting the possible incidence of toxicities in man are not practical, studies of

urinary metabolites that arise from the formation of chemically reactive metabolites in man may be useful in evaluating potential toxicities."

Gillette warned, however, that "studies based solely on urinary metabolites should be interpreted with caution."

Dr. K. Khera, Canadian Health Protection Branch, suggested that metabolic factors play a role in teratogenic effects, and called for applied research conducted on a larger scale to generate information that would permit correlation of teratogenic to metabolic attributes of food additives.

"There appears to be some evidence that the parent compound should receive a careful scrutiny during metabolic investigation," Khera reported, suggesting: "the parent compound should be examined for its potential to hydrolyze spontaneously and distribution and elimination pattern."

Khera also reported that the Canadian agency "has spent large sums of money and efforts to explore the teratogenic sensitivity of the hitherto ignored species, the cat," adding "the results ... are very promising for further investigations."

The Canadian scientist reviewed results on several specific food additives, environmental contaminants, and pesticides, including methylmercury, in which he said:

"evidence to date suggests that fetal and neonatal developmental stages are most susceptible to mercury toxicity. In Iraq a study of infant-mother pairs revealed that in most of the pairs both the mother and the fetus got poisoned if heavily exposed. There were also cases in which the mother was poisoned but not the infant. The lowest blood level in a damaged infant was 560 ng/ml while adult subject could get poisoned at 200 ng/ml blood level. There is a consensus of opinion that abortion and stillbirth occurs in heavily exposed women but such data is not easily acquired."

Additionally, Khera noted that "methylmercury studies in the cat and monkey are complimentary and for safety evaluation, data from both the species should be considered."

Improved use of epidemiological studies was called for at the symposium by Dr. H. LeRiche, University of Toronto, and Dr. J. Higginson, of the International Agency for Research on Cancer, Lyon, France.

Both Higginson and LeRiche stressed the need to know the background level of environmental carcinogens present in the diet, in air and in water. Higginson further called for the setting up of cancer registries to trace patterns of cancers and any changes in incidence.

The need for scientific excellence in a food and drug regulatory agency was stressed by HPB's Dr. A. B. Morrison. Without scientific excellence "a regulatory agency in the food and drug area would be a lame duck, if not a dead duck," Morrison observed.

Other factors of importance in regulating chemicals in food, Morrison stated, include a responsible industry, inter-agency cooperation and consumer input.

Morrison noted that approximately one-half of the recalls in Canada result from consumer complaints. "The consumer is out there where the food is, and there are a lot more consumers than inspectors and analysts," Morrison pointed out, adding that HPB does not take consumer complaints "lightly."

●

FDA DETENTIONS OF BRAZILIAN COFFEE DISCUSSED AT MEETING

Representatives of the Brazilian Coffee Institute (IBC) recently met with Food and Drug Administration officials to express concern about FDA detentions of coffee because of insect contamination.

The IBC representatives detailed inspection of coffee in Brazil with additional fumigation in the warehouse if necessary, saying that the detentions must be caused either by insect infested holds of ships or the spread of insects from other commodities such as corn, soybeans, and peanuts.

FDA Associate Commissioner for Compliance Sam D. Fine offered his agency's help "in determining the causes of the problem and possible solutions," according to a memo of the May 19 meeting written by William V. Eisenberg, chief of the agency's Microanalytical Branch. Fine noted that on-site technical assistance was possible, recalling that this kind of service was provided to Iran on request of the Iranian government and industry relating to an aflatoxin problem (See story, Page 37).

The Brazilian representatives noted that detentions in the current fiscal year outnumber those in fiscal year 1974, and this was attributed "to withholding of coffee shipments during 1974 with build-up of insects in storage and/or to step-up of FDA import sampling during FY 1975."

The FDA-ers at the meeting noted that phostoxin and methyl bromide used as fumigants "did not offer any serious residue problem," but that use of malathion for control of the coffee berry borer might pose problems. It was recommended that the IBC officials "investigate the residue problem and check with the Environmental Protection Agency in the matter of any tolerance." The FDA-ers put the Brazilian visitors into contact with EPA and with the Agriculture Department's Tropical Products Division.

The need for "a supervised program of environmental control" for warehouses was discussed, with periodic sampling and inspection. The memo said, "It appeared very unlikely that any serious insect damage, relative to the defect action level, could develop during the approximately 11 days voyage to the United States if sampling and inspection at time of shipment assured a clean product with any insect damage well within the 10% action level."

●

QUARTERLY RESIDUE FINDINGS UP 1.3% IN MEAT AND POULTRY PRODUCTS

Chemical residue violations in meat and poultry products jumped from 1.6% of the samples tested during the last quarter reported to 2.9% for the first quarter of 1975 (See FOOD CHEMICAL NEWS, Feb. 17, Page 42).

USDA's Animal and Plant Health Inspection Service said the increase follows the pattern of first quarter violations reported in past years. The rate for the same quarter in 1974 was 2%, and for 1973 it was 3%. APHIS officials attributed the rise to the more frequent use of antibiotics to treat animals during the winter months and to spraying of interiors of barns and other shelters.

Calves rated the highest number of violations (57), reflecting the previously reported high number of antibiotics violations found in calves (See FOOD CHEMICAL NEWS, May 12, Page 40).

Cattle were next with 26 violations; swine, 20; turkeys, 11; ducks and geese, 8; horses, 7; chickens, 2; sheep and goats, 1; and rabbits, 1.

According to residue type, the violations were: antibiotics, 64; chlorinated hydrocarbons, 38; sulfonamides, 22; heavy metals, 7; and other drugs, 2.

The official USDA statement reported no violations involving growth hormones this quarter. However, APHIS does not report positive violations for diethylstilbestrol until all analyses are completed and the tests for DES this quarter are still being conducted.

APHIS officials also report that the special residue monitoring program for sulfaquinoxaline in ducks has shown that the birds are now clear of the drug (See FOOD CHEMICAL NEWS, April 21, Page 14). The residue was never found in the carcasses and most of the birds were sold minus the liver where the residues were found. The duck producers could have purchased livers from another source and sold them as part of the giblets pack in the ducks.

"Pass-Through" Docket Blamed for Unfair Competition

The proposal to exempt pre-packaged meat and poultry items which only "pass-through" retail stores from sales limits was hit in comments as promoting unfair competition (See FOOD CHEMICAL NEWS, May 26, Page 48).

Charging the Agriculture Department with "creating an unfair and discriminatory situation," H. Shenson, Inc., wrote, "A great deal of our business consists of buying and selling packaged meats that do not require any further processing, just as those you refer to in your proposal. This proposal creates unfair competition for us because the retailers do not have the added expense of maintaining USDA inspection."

"Before the meat inspection regulations were issued in 1970," the firm continued, "this subject of retail exemption was thoroughly studied, with several different proposals being issued before the final regulation was issued. Nothing has changed since then."

Roberts Turkey Brand Corned Meats noted that "while rural retailers may be suffering a hardship, the proposed 'pass-through exemption' would affect all retail limits, rural, urban and suburban," adding, "The new methods of marketing boxed beef create far reaching implications when pre-packaged and pre-inspected meat is allowed to 'pass-through' the retail exemption."

"If rural retailers have enough non-household consumer business to require special consideration of the limits," Roberts wrote, "then clearly there exists a need for a change in operation to include Federal inspection."

Also complaining of unfair competition, Dixon's Wholesale Meats stated, "This revision would permit retail stores to sell local hospitals, schools, institutions and restaurants meat, without the labeling or inspection regulations which we must adhere to every day."

Asserting that there is no hardship on rural customers, Dixon's commented, "Rural areas in and around Des Moines are all supplied by at least three suppliers who come under the Wholesome Meat Act."

Becker Meat and Provision Co. made many of the same comments as earlier letters, claiming that the proposal is discriminatory and would be impossible to administer. However, the firm also provided a long list of reasons why consumer protection will be lessened if the proposal goes into effect, writing:

-- Product could not be traced through retail levels because retailers are not required to keep the detailed daily log of incoming products that inspected establishments are.

-- "All product at inspected establishments, bagged or unbagged, is subject to inspection on a daily basis," but retail stores see an inspector only occasionally.

-- "The pass-through type product in inspected establishments must be stored in an acceptable manner -- e.g. off the ground on racks, etc.," but in a retail store "the meat could even be piled on the floor."

-- The types of racks, dollies, and wagons must be approved for use in an inspected establishment, but there is no such approval for retail stores.

-- "Official establishments are required to maintain efficient refrigeration for storage of boxed product and good air circulation" but "no such controls exist for the retailer."

-- "If the pass-through type product becomes old but can be reworked, it is done under supervision in an official establishment" but not in a retail store. "Specifically, the trim would not be permitted into hamburger in the official establishment, but without supervision, there is no assurance that it will not go into human consumption channels at retail."

-- "Retailers are not known for their sophisticated record-keeping to segregate the pass-through product from that produced in the retail store."

-- The consumer protection controls which were given to the USDA under the Wholesome Meat Act cannot be exercised at retail by an inspector that comes by on an occasional basis.

-- "Operating hours over eight a day in an official establishment are at inspection overtime expense," but "no such surcharge is levied on a retailer."

-- "Delivery vehicles at inspected establishments (are inspected) for cleanliness and sanitation compared to no such inspection for delivery vehicles operated by retailers."

Becker agreed with other wholesalers that there is no hardship on rural retailers, noting it services rural areas as well as urban.

●

CANDY NET WEIGHT EXEMPTION OPPOSED BY FTC, NCWM, CMA

The proposal to exempt pieces of candy weighing less than 2 ounces from net weight labeling on the individual candies (See FOOD CHEMICAL NEWS, May 26, Page 17) was hit in comments from the Federal Trade Commission, the National Conference on Weights and Measures, Chocolate Manufacturers Association, and Association of General Merchandise Chains.

The proposal was also opposed by the California Department of Food and Agriculture, the Wisconsin Department of Agriculture, the Bucks County (Pa.) Department of Consumer Protection, the Philadelphia Bureau of Weights and Measures and the Santa Clara (Calif.) Board of Supervisors.

FTC described the proposal as "an unfortunate and inappropriate erosion of the established Congressional policy set forth in the Fair Packaging and Labeling Act," and said the shift of net weight labeling responsibility to the retailer from the packager is "unwarranted."

However, the Commission suggested that a "temporary exemption from the weight labeling requirements of the FPLA" might be justified because of economic considerations.

Others were not as gentle in their comments on the proposal. CMA noted that most of its members intended to continue to list weights on individually wrapped pieces of their chocolate products, and that two-thirds of its members opposed the proposal. CMA concluded:

> "the 'consumer's right to know' the weight of packages purchased outweighs any uncertain economic advantages of the exemption to the weight labeling requirements for individually wrapped pieces weighing between one-half ounce and 2 ounces."

NCWM opposition was based on several reasons, including increased potential for consumer deception and consumer confusion and inability to make value comparisons. Additionally, NCWM said, "the size of the proposed increase, 300 percent, is staggering and consumers should not be subject to such a shellacking. A one-half ounce exemption is enough."

The Conference commented, "since quantities are now less and costs are now more, it seems more logical that the one-half ounce exemption originally intended for 'penny candy' should be reduced."

State and local enforcement officials are already concerned about current exemptions, the Conference stated, adding: "State and local weights and measures officials take a dim view of such liberal exemptions by Federal rulemakers which preempt their efforts to provide equity in the marketplace."

The possibility of the exemption setting a "bad precedent" with other industries seeking similar exemptions "based on the questionable arguments presented by the petitioner" was seen by the Conference.

NCWM also warned that the proposal would result in increased costs for retailers, which would be passed on to consumers and in no protection for vending machine purchases, since "it would be virtually impossible to achieve suitable display methods for vending machines."

Increased retailer responsibility was also hit by the Association of General Merchandise Chains. The Association questioned "Why should retailers be responsible for the labeling of merchandise accounting for 47.2% of ... (manufacturer's) sales?"

●

NCA URGES STATE AGENCIES TO DOUBLE-CHECK RECALLS BEFORE TELLING PRESS

Noting that false positives for botulinum toxin are common "in the best of laboratories," the National Canners Association has urged that state agencies confirm the results before condemning canned food lots (See FOOD CHEMICAL NEWS, April 28, Page 2; and April 21, Page 40).

NCA wrote to State Health Departments and State Departments of Agriculture "to solicit your help in avoiding unnecessary publicity and recalls when the bacteriological examination of a container does not justify such actions." Diagnosis of botulinum toxin "requires a procedure that is extremely technical and exacting, and unless one is fairly familiar with all the techniques he can obtain false positives," NCA stated.

The group pointed out that many times mice have died from injection of food extracts but further tests showed these to be false positives. "What we're asking is that any group which makes the mouse test be extremely certain that they have a true positive," wrote NCA. It urged the state agencies to seek another test by a laboratory "that is continuously involved in this procedure," such as the Center for Disease Control in Atlanta, the Food and Drug Administration, or NCA's own labs.

The trade group noted there have been three recent instances where state agencies have condemned foods as containing botulinum toxin when later test results showed this was not the case. The packers involved suffered "very severe financial losses because of the wide publicity given their products," NCA asserted.

The Canners expressed confidence in FDA's low-acid canned food processing regulations. "With this kind of control," wrote NCA, "we feel confident that the likelihood of any spoiled cans of food being toxic is extremely rare and urge again the use of caution before a company is virtually ruined by a false diagnosis and its associated publicity."

Morey Questions FDA's Use of Publicity

Another attack on the use of the press in regulatory matters was made by Attorney Richard S. Morey of the Washington law firm of Kleinfeld, Kaplan & Becker, at the Food and Drug Law Institute's Pharmaceutical Update V in New York (See FOOD CHEMICAL NEWS, May 26, Page 59).

Morey, speaking on "Publicity as a Regulatory Tool," suggested that the FDA has at times abused its mandate, but he acknowledged that FDA is authorized to inform the public if a legal opinion is made or if there is gross deception or imminent danger to health and safety.

He cited the 1959 cranberry episode and the rescinded warning against Stokeley-Van Camp's string beans as two instances where the FDA overstepped statutory authority to issue public warnings.

This is not indicative of routine FDA procedure, Morey said, but he added that the two stories indicate that the agency carries with it the potential for great harm through adverse publicity.

Morey cited a recent Class III recall of some candy bars because of rancidity, a problem not regarded as a health hazard by FDA. The recall was printed in the Wall Street Journal, he noted.

"This kind of affirmative publicity does not come under the Freedom of Information Act," he said. Morey also complained that recall lists, which are subject to Freedom of Information release, are "out of date and too often confused rather than clarified."

The threat of adverse publicity is an effective persuader to a manufacturer in recall cases, Morey said. "The market may be permanently destroyed ... Few manufacturers are ready to stand up to the full FDA treatment."

●

FDA SEIZES MICHIGAN COHO SALMON WITH PCB RESIDUES ABOVE TOLERANCE

The Food and Drug Administration recently rejected a request from a Washington law firm to permit a food company to market or, in the alternative, export canned salmon containing polychlorinated biphenyls above the agency's temporary tolerance of 5 p.p.m. for food products.

In a letter to Paul M. Hyman, of the law firm of Kirkland, Ellis & Rowe, Taylor M. Quinn, Director of the FDA's Division of Regulatory Guidance in the Bureau of Foods, reported the agency's plans to go ahead and seize the products involved

Seizures were made last week of two lots held by the Point Adams Packing Co., Hammond, Ore., and another in possession of Sea Land Services, South San Francisco Calif., which was transporting the canned salmon to San Juan, Puerto Rico, after packing at Hammond.

The seizures involved products owned by Harrison Pierce & Co., Long Beach, Calif., which purchased Michigan salmon from Tempotech Industries, Inc., Holland, Mich.

Point Adams acted as a custom canner of the products for Harrison Pierce & Co.

"As you know," Quinn wrote, "we are considering a recommendation on the part of our Seattle field office to initiate seizure against those canned coho salmon, which are the subject of your letter."

He said analyses of the products showed a range of PCBs from 7.6 to 10.9 p.p.m., which he characterized "as well above the established temporary tolerance."

"As you indicated," he continued, "your client was well aware of this temporary tolerance and the general problem of PCB contamination in fish from the Great Lakes." He commented:

> "Hence, in our opinion, it would have been prudent on the part of your client to clearly establish the PCB content of these specific fish prior to accepting them for use as human food.
>
> "While we do not know the precise details of the arrangements of your client with Tempotech Industries and the Michigan Department of Agriculture, we do know that the FDA did not 'approve' or otherwise sanction the shipment of these salmon from Michigan to Point Adams Packing Company in Oregon for use as human food."

Under an agreement with the Michigan Department of Agriculture, Tempotech apparently was supplying female coho salmon, weighing less than eight pounds each, since these were expected to contain PCBs at levels less than the 5 p.p.m. tolerance.

Quinn said FDA strongly believes that human exposure to PCBs in any amount greater than the amount which can be avoided "is clearly unwarranted and illegal," saying:

> "Thus, we believe we would be remiss in our obligations and acting contrary to the public interest to permit the marketing of food bearing PCBs above temporary tolerances."

●

FDA IS REVIEWING PISTACHIO NUT CERTIFICATION PROGRAM

The Food and Drug Administration is currently reviewing the voluntary certification program operated by importers to detect aflatoxin in pistachio nuts.

MONS 028868

Increasing incidence of aflatoxin has prompted a reappraisal to determine whether the program may require adjustment.

A meeting recently with officials of CPC International indicated some concern by industry with the pistachio nuts shipped to the U. S. from Iran.

CPC officials reported, according to a memorandum of the meeting, that a number of lots offered since January, 1974, had been rejected by the firm after sampling and analyses by CPC's laboratories, even though the same lots had passed through the certification program.

FDA officials acknowledged this possibility because of difficulties in obtaining a sample which adequately represents an entire lot, since aflatoxin is usually localized within a lot.

CPC Reports High Rate of Rejection of Lots Beginning in Early 1975

Beginning in early 1975, CPC reported "a very high rejection" rate from its analyses, and pointed out that since no 1974 crop nuts have entered the U. S., the lots offered for sale have probably been in storage for a long time since original certification, giving rise to the speculation they may have been improperly stored.

FDA officials also noted that the 1973 crop year nuts from Iran showed a marked increase in the extent and incidence of aflatoxin contamination, and this increase was probably reflected in the results CPC was obtaining. As a result of an FDA visit to Iran, the Iranian government has instituted a number of the agency's recommendations for improving the handling of pistachio nuts, FDA reported.

The agency said it is hopeful that Iranian efforts will result in improvement of the crop, but plans have been made to reanalyze the certification program.

CPC International officials reported that the company has also instituted a more extensive plan for sampling and analyses because of the difficulties.

●

STUDIES SHOW HIGH CADMIUM CONTENT IN SLUDGE-TREATED SOY BEANS

Laboratory studies have shown that cadmium content in soy beans grown in some sludge-treated soils is substantially higher than in beans from similar soils not treated with the sludge, according to preliminary results released by the Food and Drug Administration's Dr. Robert M. Schaffner, Associate Director for Technology in the Bureau of Foods.

In a seminar presented at the Department of Agriculture's Northeastern Regional Laboratories in Philadelphia, Schaffner reported on developments in many of the agency's food programs.

Working in collaboration with both the USDA and the Environmental Protection Agency, he said FDA is attempting to set guidelines for the quality of sludge that will be

permitted for different crops, and, he added, studies will also monitor the incidence of pathogens in the sludges being used.

Schaffner also reported that FDA is in the process of setting up an aseptic canning system, which will be used to simulate industrial processes.

He said FDA hopes to have the system, which is being set up at the agency's pilot plant in Cincinnati, operational within the next six months to a year.

The pilot plant has recently initiated investigations into the vital area of thermal processing, Schaffner noted, pointing out that within the last year a steritort has been installed for such investigations.

"We are investigating critical control points such as variation in head space, fill-in weight, initial temperature, and reel speed," he explained.

In another area, Schaffner disclosed that the agency is conducting studies for the development of improved construction and operational criteria for shellfish processing plants and waste treatment facilities discharging to shellfish growing areas.

Noting the agency's efforts toward developing a data base for the establishment of environmental index levels for determining chemical and microbiological contamination of growing areas, Schaffner said the information will allow FDA to set federal standards or tolerances for shellfish and shellfish growing areas.

Schaffner Outlines FDA Projects to Improve Shellfish Harvesting

The FDA is also investigating the possibility of using relaying and depuration as a means of improving the quality of shellfish, the FDA-er continued, explaining that relaying is a procedure in which shellfish are moved from contaminated or semi-contaminated waters to acceptable waters.

"These shellfish are left in clean waters for various periods of time during which they cleanse themselves of microbiological contamination," he said.

Depuration on the other hand, he continued, is a process in which the shellfish are placed into tanks where the water quality, temperature and salinity are controlled so that the cleansing of the shellfish may be accelerated.

Schaffner said the depuration studies are being conducted under contract with the Virginia Institute of Marine Science while the relaying experiments are being done by FDA's Dauphin Island facility in Alabama.

Oyster pasteurization is being investigated by FDA as a means of adding a further safeguard against infectious diseases such as hepatitis and typhoid, Schaffner said.

●

LSRO FINDS IODINE DIETARY INTAKE INCREASED

Two studies prepared by the Life Sciences Research Office of the Federation of American Societies for Experimental Biology, under contract to the Food and Drug Administration's Division of Nutrition, have concluded that dietary intake of iodine "has increased to levels above that amount considered necessary to meet nutritional needs."

However, the studies, "Iodine in Foods: Chemical Methodology and Sources of Iodine in the Human Diet," and "A Review of the Significance of Untoward Reactions to Iodine in Foods," concluded mainly that further studies are required to develop methods to determine iodine content of foods and to define what impact increased dietary iodine has on such conditions as toxic goiters, thyrotoxicosis, acne, iododerma, or iodine-induced hypersensitivity or idiosyncratic reactions.

The studies pointed out that increased dietary intake of iodine can be traced to increased intake by food-producing animals in the form of mineral feed supplements, iodized salt blocks and veterinary medications, and to intentional and accidental sources of iodine, such as iodized salt, food additives, food coloring substances, medicinals, and sanitizing agents.

Iodine was included by FDA in its 1974 market basket survey, the report on iodine in food noted. Among additional studies called for by the report were:

(1) additional data on carry-over from iodine in milk (which is increasing in quantity) to other dairy products; (2) investigation of the effects of cooking and preparation on iodine content of food items; (3) definitive data on the source and quantity of iodine in bread and bakery products throughout the United States; and (4) further data on iodine content of iodine-containing additives such as the alginates, agar-agar and carrageenan.

Mean adult intake levels of iodine "currently range from 380 to 450 microgram (mcg) per person per day," LSRO calculated, noting that daily intakes of 100 to 300 mcg "are recommended as adequate to meet the known nutritional needs" of most adults, although the National Research Council's Food and Nutrition Board has indicated that levels between 100 and 1000 mcg are considered safe.

"Despite the evidence for increasing amounts of dietary iodine consumption," LSRO concluded: "there are no current reports that document an increase in the incidence of iodine toxicity or hypersensitivity. Similarly, the frequency of reports of metabolic disorders induced by excess iodine is relatively stable . . ."

●

FASEB TABLE SIRUP SWEETENER REPORT CONTAINS LITTLE DATA

A report by the Life Sciences Research Office of the Federation of American Societies for Experimental Biology on the allergenic potential of sweeteners in table sirups came up with almost no data and no definitive conclusions.

MONS 028871

But the report recommended source labeling for sweeteners in table sirup anyway.

In finalizing the food standard for Table Sirup, FDA referred to the FASEB report, saying that it "finds that it is appropriate to give further consideration to the matter of requiring labeling that identifies the source of nutritive sweeteners" (See FOOD CHEMICAL NEWS, May 26, Page 53). However, the agency declined to include a provision for source labeling in the new food standard.

The FASEB report, which was written under an FDA contract, said in part:

> "While there is little conclusive proof of hypersensitivity to nutritive sweeteners in blended table syrups, the evidence uncovered in this study suggests that it would be prudent to provide source labeling for those individuals who desire to avoid these nutritive sweeteners in their diet.
>
> "First, there are a limited number of sources of nutritive sweeteners (corn sugar or syrup, cane sugar, beet sugar, honey, or maple syrup). Second, the treatment of food allergy involves primarily elimination or avoidance of foods or food constituents that induce symptoms. Third, the diagnosis and therapy of food allergies are basically specific treatment on an individual basis."

The authors of the report, Drs. Kenneth D. Fisher and C. Jelleff Carr, who is Director of the FASEB Life Sciences Office, noted that FDA in proposing source labeling for fats and oils has provided that these would not have to be listed on food product labels in descending order of predominance (See FOOD CHEMICAL NEWS, June 14 SPECIAL SUPPLEMENT, Page 16).

"It is suggested that similar language may be appropriate on label panels of table syrups containing blends of nutritive sweeteners," the report said, adding: "Labels could indicate that in addition to the major source ingredient, the product may contain nutritive sweeteners derived from other sources, specifically corn, sugar cane, sugar beets, or sorghum."

Noting that in the case of maple, cane, and sorghum sirups, the source of the saccharides used in addition to the main ingredient would be declared on the label, the report said, ". . . the major issue of allergy or hypersensitivity is associated with table syrups which may not be source labeled."

The FASEB report said, "The existence of allergy or hypersensitivity to table syrups per se could not be documented; but based on clinical experience, the nutritive sweeteners in table syrups are the most likely substances that could induce allergic or hypersensitivity reactions in sensitive individuals."

The authors said "the extent to which corn sensitivity reactions may be evoked by consumption of table syrups containing saccharides from corn starch is uncertain,"

adding: "While a majority of allergists would agree that the probability of evoking allergic reactions is remote, some hold that sugars derived from corn starch hydrolysis are allergenic."

Stating that "no reports of hypersensitivity to maple syrup, maple sugar, sorghum syrup, or sorghum sugar were found," the report continued:

> "Despite clinical evidence for allergenicity of corn syrup, corn sugar, cane sugar, and beet sugar, there are no studies that demonstrate chemically pure sucrose, glucose, or fructose can function as a hapten or allergen in individuals known to be sensitive to corn, beets, or sugar cane. Similarly, there is no evidence that the other constituents or trace contaminants in nutritive sweeteners are not the allergenic substances."

The report also noted that "there is little or no active research on this subject."

Noting that "there is no unanimity of opinion among allergists as to the basic mechanism involved in food allergy," the authors said "no published reports were found that clearly indicate the fundamental nature of possible reactions to table syrups and other ingredients." Published reports were found which indicated reactions of 19 patients to ingestion of beet sugar and ingestion or injection of cane or corn sugars.

Calling the scientific literature on the subject "scant," FASEB said the Scientific Literature Reviews which are part of the "generally recognized as safe" review program were consulted. A monograph on corn sugar, which contained 4,925 references, contained only two references dealing with allergy. Of 1,980 references in the sucrose monograph, only two related to allergy. The monograph on dextrin and corn dextrin, the report said, yielded four references to anaphylactoid reactions in rats and one to a nonallergenic dermatitic effect, out of 305 references.

A bibliography prepared by the International Sugar Research Foundation contained no references to allergy, hypersensitivity, or table syrups, the FASEB report said. The National Library of Medicine's computerized literature retrieval systems showed that of 5,555 citations about carbohydrates and 3,827 about hypersensitivity, only eight "appeared to be related to allergy of table sirups and their ingredients." The FASEB report said only two of these eight turned out to be "indirectly relevant . . ."

"It is recognized that the paucity of literature citations may reflect either a lack of current scientific investigations or a lack of interest in publication of clinical reports of phenomena that have been documented previously," the report said.

The authors noted that FASEB last year held a meeting on allergic reactions to iodine (See preceding story), and said "the attendees at this meeting provided their opinions and experience with respect to allergy and hypersensitivity of table syrups."

The report said that consumption estimates "suggest that the sugars in table syrups per se are less than 3% of the average daily intake of sucrose, corn syrup, or glucose, and therefore constitute a minor dietary source of these nutritive sweeteners."

●

FDA SUPPLIES CANADA WITH RESULTS OF FISCAL 1974 FOOD ADDITIVE SURVEY

The Food and Drug Administration has supplied the Canadian Health Protection Branch with results of its fiscal year 1974 survey of food additives to determine compliance with Food Chemicals Codex specifications (See FOOD CHEMICAL NEWS, March 17, Page 48).

The information lists 93 samples of 45 different food chemicals, of which most were violative in at least one specification, although only seven samples were recommended for seizure. The seven involved only two substances: calcium lactate powder and calcium lactobionate.

Reported violations for the calcium lactate powder included high heavy metal and alkali salt content and low assay for calcium lactate, while the calcium lactobionate samples reportedly contained high amounts of calcium and/or bromide.

High heavy metal content, arsenic content or ash content were frequent findings, the results indicate. Other frequent findings included low aldehydes assays for citrus oils and low pH for papain.

The results indicate that in close to a third of the samples, at least some of the tests were not completed, due to lack of equipment or reagents, or to interference.

●

FCC MAY REQUIRE "PACKED IN FLORIDA" ON CITRUS JUICE LABELS

The Florida Citrus Commission may impose a mandatory requirement that 100% citrus juices processed in Florida bear the declaration "Packed in Florida" on the label, the Food and Drug Administration agreed recently.

However, it "clarified" its position by stating that two other terms considered by the Commission: "Florida" or "from Florida" could be considered misleading, if juice from citrus grown outside Florida was included in the product.

Earlier FDA correspondence with the FCC had indicated that the latter terms would be acceptable, "if most of the juices are from Florida and the product is packed in Florida ... as long as the label does not imply that all the juice in the consumer package is from oranges grown in Florida, when that is not the case."

However, the Coca Cola company had protested that FDA "approval" of the terminology "packed in Florida," "from Florida," or "Florida" "under the conditions proposed would constitute government acquiescence in a potentially deceptive and misleading labeling practice," since "under any of the proposed label formats there is a strong implication, if not an outright affirmation that the labeled product consists entirely of Florida juice."

"The intent is not," Coca Cola argued, "to have an innocuous 'packed in Florida' label statement but to promote the word 'Florida' which suggests to the consumer that she is in fact purchasing a container of Florida-grown and processed citrus juice."

The firm expressed the fear that the labeling will be extended to "product repacked outside the state of Florida since it will, in fact, have originated and have been a part of the Florida regulated product in the first instance," and warned:

> "It is our company's position that a mandatory labeling regulation regarding a Florida designation on citrus juices packed in Florida is illegal, and our company plans to vigorously contest such a regulation, if it is proposed by the Commission. Meanwhile, we feel that the entire matter, including the appropriateness of a Florida designation should not have any implied approval or sanction by the FDA."

Designation May Trigger Nutrition Labeling, if Used in Conjunction with Advertising

FCC had also asked if use of the proposed terms on the label of citrus juice products would trigger nutritional labeling, if the Commission used nutritional advertising for the commodities.

FDA indicated that while it could not respond definitely without specific examples of both labeling and advertisements, it felt "that the use of a trademark or symbol which had been featured in nutrition advertising on a label of a packer's product could trigger the requirement for nutrition labeling."

●

METHOPRENE CLEARED FOR USE IN CATTLE FEED

A Food Additive Order was issued May 28 to clear use of methoprene in feed for cattle for prevention of the breeding of hornflies in the manure of treated cattle, as had been Petitioned by Zoecon (See FOOD CHEMICAL NEWS, Jan. 13, Page 47).

The new §561.282 permits use of isopropyl (E,E)-11-methoxy-3,7,11-trimethyl-2,4-dodecadienoate in feed at the rate of 0.375 to 0.750 mg per 100 pounds of body weight per month. The label and labeling of pesticide formulations containing methoprene must conform to that registered by the Environmental Protection Agency. On the same day, EPA established pesticide tolerances for residues of methoprene of 0.1 p.p.m. in meat, fat and meat byproducts of cattle, and 0.01 p.p.m. in milk.

On May 28, the Food and Drug Administration amended the New Animal Drug regulation for tylosin (§558.625) to grant Kerber Milling a premix level for the manufacture of swine feed of 5 grams per pound.

FDA on May 27 withdrew New Animal Drug Applications for two phenothiazine-containing oral anthelmintics, noting that Pitman-Moore has indicated that it no longer makes or markets the products and has requested the withdrawal. FDA had asked for submission of information about Phenazoid and Phenazoid Compound,

●

MONS 028875

SMOKED PHEASANT, QUAIL SEIZED BECAUSE OF NITRITE, NITRATE USE

The Food and Drug Administration recently seized canned smoked quail and canned and frozen smoked pheasant on grounds that the products contained sodium nitrite and sodium nitrate, which do not have food additive clearance for these uses.

The quail was shipped by High Valley Farm, Inc., Colorado Springs, Colo., and the pheasant was seized in possession of the company. FDA also charged that the quantity of contents statement for the quail did not appear on the principal display panel.

Alleging labeling violations, FDA recently seized black pepper, imitation vanilla, and instant minced onion, shipped by Tone Bros., Des Moines, Iowa. The agency said the labels had inadequate type size, improper separation of type, and lack of the dual declaration of contents.

FDA seized bulk wheat, in possession of Potter Co-op Grain Co., Potter, Nebr., on grounds the product was contaminated with sodium tripolyphosphate and was held under insanitary conditions. Sugar, in possession of Amalgamated Sugar Company, Nyssa, Ore., was seized because of an "objectionable odor" and because it was held under insanitary conditions. Other recent seizures on insanitation grounds involved:

(1) Celery seeds, in possession of Schiff Food Products, Brooklyn, N. Y., on grounds they were insect contaminated. (2) Split peas and whole wheat flour, in possession of House of Spices, Corona, N. Y., on grounds they were rodent contaminated. (3) Sweet rice and yellow beans, in possession of Quong Yuen Shing & Co., New York, N. Y., on grounds they were held under insanitary conditions and were rodent contaminated.

FDA last week disclosed a Class III "routine" recall of Hyde Park Brand Sweet Cream Butter because blue ink from the parchment wrapper was bleeding onto the surface of the butter. The recall was conducted by Kraftco's Breakstone Sugar Creek Division, Russellville, Ark., from Arkansas, Louisiana, Mississippi, and Missouri. The firm estimated that little, if any, of the affected product remained on the market.

A Class III recall was made of Mary Ellen Brand apple jelly because 18-ounce jars were mislabeled as 32-ounce jars. The recall, which was completed in November, was conducted by J. M. Smucker Co., Salinas, Calif., from the San Francisco Bay area.

Diet-Tru Low Sodium Shrimp Deveined were under Class III recall because of short net drained weight. The canned shrimp were recalled by General Nutrition Corporation Pittsburgh, Pa., nationwide, and the firm estimated that approximately 10 cases of 25/5 ounce cans each remained on the market. The product was manufactured by Robinson Canning Co., Inc., Westwago, La.

A Class III recall because of "false and misleading" labeling was made of Iron Supplement Elemental Iron 4% and Vet Gro Vet Ferrous Elemental Iron 4.50%. FDA said approximately 6 tons were recalled by M&M Livestock Co., Eagle Grove, Iowa, from Iowa and South Dakota.

Another regulatory letter was sent by FDA concerning low-acid canned foods. Indicating prior correspondence, the agency told Knapp Sherrill Company, Donna, Tex., that two letters from the firm concerning carrot chips did not "fully" answer the points raised previously.

FDA said a review of production records and other observations "revealed that control was not maintained over the critical factor (i.e., maximum drained weight) specified in the scheduled process for chipped carrots and chipped beets in 603 x 700 cans, and that drained weights were found to exceed the maximum drained weight of 73 ounces specified for chipped carrots."

Noting that records were not found that indicate that the portions of the production involved had been reprocessed or evaluated, FDA advised the company to quickly obtain an evaluation for potential public health significance.

A regulatory letter went to Sunshine Pecan Company, San Antonio, Tex., saying that Home Delight Pecans were misbranded "in that the quantity of contents is less than that stated on the label."

Purification Systems Incorporated, Buchannon, W. Va., was told that its Collard System 1 Water Purifier was misbranded because of the label statement, "Save Your Life, Avoid Cancer; Kills and removes all water-borne disease-carrying bacteria such as those producing typhoid, paratyphoid, cholera, bacillary dysentery, and others; Kills dangerous bacteria, removes harmful, poisonous, bad-tasting substances, takes out foreign substances such as insecticides like DDT, pesticides, algae."

●

CODEX GROUP WEIGHS MICROBIOLOGICAL LIMITS FOR MILK PRODUCTS

The FAO/WHO Committee of Government Experts on the Code of Principles Concerning Milk and Milk Products, which met in Rome, Italy, last month, has stressed the need for microbiological end product specifications in international codes and standards.

The Joint Committee, which is part of the Codex Alimentarius operation, accepted a U. S. proposal that work on microbiological standards should proceed on the basis of need and demonstrated health hazards, plus the availability of expert recommendations on specifications and methodology. The Australian delegation will prepare a draft code of practice for dried milk to set a pattern for future codes.

The current Code of Principles for Milk and Milk Products permits either full acceptance or acceptance with deviations specifying more rigorous requirements. However, the Codex Alimentarius now provides for acceptance of standards "with specified deviations." The Joint Committee will discuss revising the milk code acceptance procedures at its next meeting.

The General Standard for Cheese was revised by the group by incorporating a food additive section linking the use of additives with types of cheese. This standard is being held at Step 5 of the Codex acceptance procedure for comments from

governments. Also at Step 5 is the U. S.-proposed standard for hard-grating cheese, which was worked out in cooperation with Italy. Draft standards for Edible Acid Casein and Edible Caseinate are also at Step 5, as is a draft standard for Cream. A Flavored Yogurt standard was retained at Step 5 for additional comments. Advanced to Step 7 were draft standards for Yogurt.

●

FDA'S PBB GUIDELINES PROVIDE MARGIN FOR HUMAN SAFETY: KOLBYE

The Food and Drug Administration's present guidelines for residues of polybrominated biphenyls provide the necessary margin for human safety, FDA's Dr. Albert C. Kolbye, Associate Director for Sciences in the Bureau of Foods, told a Michigan hearing May 29 in Lansing, Mich. (See FOOD CHEMICAL NEWS, April 21, Page 27).

He said the guidelines, which were revised downward after re-analysis (See FOOD CHEMICAL NEWS, Nov. 11, Page 2), follow the same criteria used in setting limits for polychlorinated biphenyls, but the agency used an additional safety factor of 10 to compensate for the fact there seems to be a five-fold greater degree of biological activity associated with the PBBs as compared to the PCBs.

Kolbye testified that it is unlikely that Michigan residents would exceed acceptable exposure levels, based on FDA's guidelines for meat and milk.

In the case of meat, he estimated exposure at 18 mcg per day, if a person ate meat three times a day, and every portion were contaminated at the guideline level. FDA's guideline for PBB in milk and meat on a fat basis is 0.3 p.p.m.

Using a 1,000 day exposure limit of 20 mg for PBBs, Kolbye said this translates to a limit average exposure of 20 mcg per individual per day or approximately 0.3 mcg/kg body weight per day. For infants and young children, he explained, FDA would recommend lesser exposures.

For milk, Kolbye suggested that 40 gm of fat in one liter of milk would not contain more than 0.02 p.p.m. or 0.8 mcg of PBB and thus not contribute residues to humans for all practical purposes.

Additionally, he pointed out, milk is pasteurized and bottled at dairies where significant dilution with milk from non-affected dairy farms occurs.

In fact, he added, a recent Michigan survey performed on commercial dairy milk has shown no residues detectable by a method sensitive to 0.02 p.p.m.

Observation of Exposed Persons Recommended

Saying that approximately 8,000 Michigan residents were exposed to food contaminated with PBB in 1973 and 1974, Kolbye recommended medical observation of the people who had been exposed. He said that, "Based on information available to FDA from the Michigan Health Department survey of farm families, no human disease has been identified as a direct result of PBB contamination."

However, he added that FDA and the Center for Disease Control have proposed a long-term evaluation of exposed persons, and that, "Additional recommendations have been made to the Michigan Department of Public Health concerning the importance of having all practicing physicians in Michigan alerted to identify all individuals who are known to have been substantially exposed to PBB contamination." He said MDs should take the following steps:

"(1) Patients should be observed for any adverse drug effects and alteration in drug metabolism.

"(2) Patients should be observed for any indication of alterations in liver function.

"(3) Patients should be observed for any alterations in the immune mechanism.

"(4) Mothers should be cautioned about breast-feeding infants.

"(5) Patients should be advised to avoid all weight reduction programs unless under the guidance of a physician.

"(6) Patients should be advised to exercise caution in using alcoholic beverages.

"(7) Diabetic patients should be observed carefully in light of items 1-3 above.

"(8) Patients who are scheduled for surgery should have a fat biopsy done and a blood sample collected at the time of surgery."

Kolbye unveiled FDA's work comparing animal toxicity of PBB as compared with PCB. He said the results "indicate that both PCB and PBB cause dramatic alterations in normal biochemical and physiological processes," at many "levels of biological organization, from macroscopic retardation of growth to submicroscopic changes in the relationships between cellular molecules." The new study, the FDA-er said, "substantiated" previous findings on PCB effects, "extended them to include PBB," and "added new knowledge concerning additional effects."

The "most grossly obvious effect" was growth retardation at high levels of exposure, Kolbye said. Growth depression in rats fed PCB and in farm animals ingesting PBB contaminated feed "was due primarily to decreased food efficiency and secondarily to decreased food consumption ...," he explained.

"Disruptions in the energy metabolism of the cell were produced by even three weeks of dietary exposure to PCB and PBB," the witness stated. In studies using isolated mitochondria, Kolbye said "PBB caused greater disruption of mitochondrial energy production than PCB." Studies measuring the in vivo concentration of the components of intermediary metabolism in livers of rats fed PCB or PBB "indicated a perturbation of the redox state of the cell," he said, adding that this state "is intimately related to cellular energy production."

"Increased cell size and resultant liver enlargement were more marked with PBB than PCB," Kolbye reported, adding that the changes in liver composition associated with

this hepatomegaly were "also greater in the animals fed PBB." The changes included increased percent dry weight and increased percent liver lipid.

The FDA-er said that pathological analysis has not yet been completed on the liver and other tissues from the study, but that "the changes seen in the liver composition with PBB are a well established part of the now classical response to PCB." This, he said, includes proliferation and concentric array formation of the smooth endoplasmic reticulum, fatty liver degeneration, and induction of microsomal mixed function oxidase activity.

Regarding this microsomal mixed function oxidase activity, Kolbye said, "On a molar or per molecule basis, PBB was about 5 times more potent than PCB in both studies."

Analysis of plasma and serum components of the rats showed the only significant effects were a change in blood glucose and cholesterol levels. Kolbye said PCB caused a decreased blood glucose level at the 50 p.p.m. and 500 p.p.m. levels, while PBB caused a slight decrease only at 50 p.p.m. However, cholesterol, he said, was increased by 5 p.p.m. PBB and only by 500 p.p.m. PCB.

He said, "No chemical related effects were observed on testes weight, on the incidence of chromosome abnormalities, or the number of cells in mitosis from bone marrow or spermagonia of rats fed PCB or PBB for five weeks."

Kolbye concluded that "although the mechanism of all the effects is not understood, at present, the weight of evidence at this time indicates that PBB caused greater responses at lower levels than PCB and supports the evaluation of the greater potential toxicity of the polybrominated biphenyl which may be up to 5 times that of the polychlorinated biphenyl."

Dr. H. Dwight Mercer, of FDA's Bureau of Veterinary Medicine, testified at the Michigan hearing about the results of his agency's investigation which indicated no pattern of illness in the animals fed products contaminated with PBB.

Meanwhile, Michigan Farm Bureau Services and two of its insurance companies filed a $200 million suit in Federal court in Grand Rapids against the Michigan Chemical Company and three of its subsidiaries. The PBB incident reportedly has led to approximately 40 suits and more than 600 claims on Michigan Farm Bureau Services for livestock losses. The PBB incident was caused by 'accidental' use of the flame retardant instead of a feed ingredient.

●

OCA STUDY RECOMMENDS COORDINATED, CONSISTENT FEDERAL COMPLAINT HANDLING

A coordinated complaint-handling system among federal agencies, including clear and uniform definitions, a consistent complaint classification scheme, and standards for appropriate responses, was called for in a study released today (June 2) by the Federal Office of Consumer Affairs.

The report, conducted by Technical Assistance Research Programs (TARP), Inc., under contract to OCA, evaluated the responsiveness to complaints of 15 governmental agencies, including the Food and Drug Administration, the Agriculture Department, the Environmental Protection Agency, and the Federal Trade Commission. TARP evaluated complaint-handling performance on such criteria as internal follow-up, referral follow-up, statistical reporting, evaluation and input into agency policy.

The researchers pointed out that the results and conclusions drawn from the evaluation are tentative and preliminary. A more extensive evaluation will follow the second phase of the study during which TARP will survey consumers' reactions to the responses they have received from federal agencies and will sample consumers across the country to learn what steps they usually take to resolve complaints. The second report, to be completed in November 1975, will also examine several additional service-oriented federal agencies.

Evaluating the effectiveness of the complaint-handling process by rating such functions as logging, classification, and internal follow-up, the report noted very different results for the three sections of FDA surveyed. The Office of Legislative Services and the Bureau of Drugs received generally high marks, while the Office of Professional and Consumer Programs was rated "unsatisfactory" in many areas. USDA's performance was satisfactory for the most part, as was the FTC's. However, EPA received an extremely low rating, largely because many of the tasks were not performed.

Evaluating the speed of complaint handling, Agriculture was rated "excellent" in almost every category. FDA, this time rated as a whole, received mostly "satisfactory" grades, as did the FTC. Figures for EPA were not available.

FDA has budgeted $636,000 for complaint-handling in fiscal 1976 and had the highest budget of the four agencies for fiscal 1975, with $583,000. EPA, the only other agency providing a figure for fiscal 1976, allotted the same amount as for 1975 -- $298,000. USDA budgeted $336,000 for 1975 and FTC budgeted $377,000.

The study recommended greater consistency in the federal complaint-handling system, and suggested use of a uniform complaint classification scheme for all federal agencies, as well as uniform federal standards for appropriate responses to given complaints.

The federal agencies are not adequately evaluating their own complaint-handling systems, the report concluded. Urging that the evaluation be conducted out of the agency if funds are available, the study said that if it is conducted in-house, it should be supervised "by a senior agency official who is not connected with the complaint-handling system on a day-to-day basis."

The study also recommended that a concerted effort be made to increase public awareness of the complaint-handling systems, part of which would be a special effort to elicit comments from the disadvantaged.

As coordinator of the complaint-handling effort, OCA would have several functions, including responsibility for evaluating the procedures of the various agencies and for making sure that the systems effectively address all consumer problems

FTC REISSUES FOOD AD TRR; EMPHASIZES FLEXIBILITY

The Federal Trade Commission, as expected, reissued its proposed Trade Regulation Rule on Food Advertising May 28,including a new "Statement of Reasons for the Proposed Rule," which emphasized that the Commission intends to carefully consider the comments received (See FOOD CHEMICAL NEWS, May 26, Page 2).

The Statement stressed that neither the staff statement nor the issues set out in the material accompanying the proposed rule (See FOOD CHEMICAL NEWS, Nov. 11, Page 23) are to be considered the designated "disputed issues of specific fact" -- which means they are not necessarily the issues to be subject to cross-examination at the hearing. The Commission will be accepting recommendations for what these issues should be until July 28.

The republication noted that in addition to comments on all the issues raised by the proposed rule and the accompanying material, "the Commission also seeks comments evaluating the economic impact of the rule on small businesses."

The May 28 publication reprinted only the proposed rule and included the other material in the Nov. 11 issuance "through incorporation by reference." The Statement of Reasons summarized the in-depth justification for the proposal provided in the earlier staff statement, adding:

> "The Commission has determined that it has reasons to believe (these) statements on the basis of a staff review of food advertising which was aimed at identifying patterns of misleading nutritional claims. The staff's examination of food advertising has included consultations with experts from a variety of disciplines whose expertise bears upon the issues raised in this proposal. The Commission has not adopted any findings or conclusions of the staff. All findings in this proceeding shall be based solely on matter in the rulemaking record."

The Statement noted that in addition to the rules setting uniform definitions for terms used in affirmative nutritional claims, the Commission published the staff recommendation for affirmative disclosure of nutrition information in all food advertising. "The Commission is extremely concerned about the considerations in the staff statement, including the implications for food advertising raised by the Food and Drug Administration's nutrient labeling program," the Federal Register notice said, concluding that it is therefore "in the public interest" to solicit comments on the staff statement.

The Commission asserted that past experience has shown "that adjudication alone is inadequate to establish well-defined legal standards for the guidance of consumers and food advertisers." In the past four years the Commission issued approximately 20 consent orders relating to misleading nutrition claims, the notice reported.

The comment period will remain open until 10 days before the hearing, which has not yet been scheduled. Comments will be accepted at least until July 28 and must be submitted in only five copies, rather than the 20 called for in the original proposal.

FTC Hires Staff Nutritionist

The Federal Trade Commission recently hired a staff nutritionist for the Bureau of Consumer Protection's Division of National Advertising. Arlene R. Howard is completing work on her doctorate in Food Science at the University of Maryland and has a B.S. and M.S. in Foods and Nutrition from the University of California at Berkeley.

Howard taught for several years at the Universities of Maryland and California in the field of foods and nutrition. She also worked as a chemist at the Agriculture Department's Carbohydrate Nutrition Lab in Beltsville, Md.

There has not been a nutritionist on the FTC staff since Judy Cooke was killed in an auto accident in November 1973 (See FOOD CHEMICAL NEWS, Nov. 26, 1973, Page 2).

●

CANNED CHICKEN RECALLED BECAUSE OF UNDERPROCESSING

Swift Dairy & Poultry Co., a division of Esmark, Inc., is voluntarily recalling 147 cases of canned whole chicken because of underprocessing at its Clinton, Iowa, plant.

The product was distributed in Iowa, Nebraska, Texas, South Dakota and Kansas. The firm learned of the problem when cases unpacked at a retail outlet contained swollen and leaking cans.

The problem involved 3 lb. cans of Swift's Premium Brand Whole Chickens, with the code EO 55 stamped on the top or bottom of the can. The establishment number in the official inspection mark is P 76.

The U. S. Agriculture Department is monitoring the recall. All but 29 of the 147 cases, each containing 12 canned chickens, have been accounted for.

Beef Grading Rules Halted

A federal judge in Omaha, Neb., issued a permanent injunction against the USDA's new beef-grading standards. U. S. District Judge Robert V. Deney ruled that compulsory grading of beef carcasses for yield is not necessary and that the USDA's economic impact statement was inadequate.

USDA has not yet decided whether to appeal the decision to the Eighth Circuit Court of Appeals in St. Louis.

●

BVM IS REASSESSING NEED FOR SHELL TO SUBMIT EIAR WITH NADA

The Food and Drug Administration's Bureau of Veterinary Medicine is reassessing the need for the Shell Chemical Company to submit an Environmental Impact Analysis Report (EIAR) for a long-pending New Animal Drug Application.

According to a memorandum of a meeting with Shell officials, prepared by BVM Director Dr. C. D. Van Houweling, the company had asked to be relieved from the EIAR requirement. An NADA for Atgard C for swine production improvement had been submitted in 1971, and subsequently supplemented after being declared incomplete.

BVM had established a policy that NADAs submitted prior to March 15, 1973, the date of the first proposal by FDA to implement the requirements of the National Environmental Protection Act, would not require EIARs or Environmental Impact Statements (EIS).

This policy, according to Van Houweling, had been agreed to by the Office of General Counsel. Several applications have been handled in accordance with this policy. He said the Shell application differed in the following two respects:

> "(1) there are concerns about the environmental effects from use of the drug and (2) the amended regulations in regard to NEPA will provide for retroactive actions (including prior approvals of drugs)."

FDA is preparing a new proposal to provide additional exemptions for new animal drugs and food additives from EIAR and EIS requirements. A number of exemptions had been provided for in the previous NEPA amendments published by FDA (See FOOD CHEMICAL NEWS, April 22, 1974, Page 3).

The discussion with Shell indicated that FDA's environmental concerns centered largely on bird toxicity. Shell officials said "they had submitted sufficient material on that matter to answer any questions."

Van Houweling said FDA officials agreed that BVM would check the file, determine what questions had been raised, and arrange a compilation of those for transmission to the company or arrange for another meeting at which time Shell would submit again all the material it has concerning bird toxicity.

If the sole environmental problem involves bird toxicity, Van Houweling said BVM will evaluate the data to determine whether or not the Shell submissions satisfied the agency.

"If so," he wrote, "then a complete EIAR would not be required," adding: "If there are other issues that must be dealt with, the firm will submit a complete EIAR."

He promised the Shell officials a prompt review so that the firm will know whether or not a complete EIAR will be required.

●

CANDY GMPS TO BECOME EFFECTIVE IN 60 DAYS

The Food and Drug Administration on Wednesday (June 4) will finalize its proposed Good Manufacturing Practice appendix for cacao products and confectionery, with the new GMPs to become effective in 60 days.

However, the agency has provided for extensions to 180 days "when certain significant problems in implementation exist." FDA explained that it would be "reasonable to extend the effective date in those instances where compliance with particular provisions requires the installation of equipment or facilities which are in short supply and where the manufacturer is able to demonstrate that this is causing significant problems to the extent he needs additional time for complete compliance."

The GMP proposal for candy (See FOOD CHEMICAL NEWS, Dec. 3, 1973, Page 12) inspired 18 comments (See FOOD CHEMICAL NEWS, Jan. 28, 1974, Page 14; Feb. 4, 1974, Page 36; Feb. 11, 1974, Page 6; March 4, 1974, Page 32; March 11, 1974, Page 16; and March 25, 1974, Page 2).

Raw Bean, Extract, Flavors Excluded from Cacao Product GMP

A major change in the GMP for cacao products excluded raw cacao beans, flavorings and extracts. FDA said the raw agricultural commodity is not "within the scope of the definition of cacao products." The agency also said that "the manufacture of chocolate extracts and of flavorings derived from them represents a technology unlike the manufacture of other cacao products, and that the GMP requirements are different."

Also excluded from the cacao products definition were "most chocolate- or cocoa-flavored foods," and FDA said, "Products such as cake mixes and chocolate- or cocoa-flavored milk for which separate GMPs are appropriate are among these exclusions."

A revised definition of "cacao products" explained that covered foods "include but are not limited to cacao nibs, sweet chocolate, milk chocolate, other foods standardized by Part 14 of this chapter, and chocolate sirup."

The agency also revised the definitions of "confectionery," but did not agree with suggestions that toppings, frostings, and cake decorations should be excluded. As revised, the definition provides:

> "'Confectionery' means candy and other food products made with sweeteners, and frequently prepared with colorings, flavorings, milk products, cacao products, nuts, fruits, starches, and other materials. Such foods include but are not limited to frostings, toppings, and cake decorations. They do not include chewing gum, sauces, sirups, jellies, jams, preserves, cakes, or cookies."

Concluding that "there yet may be uncertainties regarding the applicability of the regulation to specific products," FDA said it "will be glad to offer an opinion in answer to individual inquiries."

Because the proposed definition for products "made basically from sweeteners" would not cover nut products, this was changed in the finalized definition.

Deleted from the definition was the phrase "and often fashioned into attractive shapes or forms." FDA had previously made it clear that the GMP does not cover chewing gum.

The definition of "lot" was revised to make it clear that it is "intended to refer only to lots of finished product." In comments, it was pointed out that the proposed definition would not be applicable for materials such as chocolate liquor, liquid sugar, or corn sirup which may be used for periods longer than one day's production.

FDA revised the definition of "waste" to make it clear that the product is rejected because of adulteration. Thus, the definition was broadened to cover more than "filth."

In the section on plants and grounds, FDA deleted the phrase "whenever necessary," making it clear that there are mandatory requirements for measures to be taken to prevent contamination of products, raw materials, or packaging materials. Saying in the preamble that the requirement "allows individual judgments by manufacturers," FDA offered to "cooperate with industry in exercising judgment on these matters."

Equipment, Utensil Provisions Revised

In the controversial section on equipment and utensils, FDA made a number of changes as a result of comments filed.

Instead of requiring "corrosion-resistant" food-contact surfaces, FDA is requiring that the surfaces be "maintained in a corrosion-free condition." Noting that use of the word "nonabsorbent" would eliminate the use of wooden starch molding boards and paddles, FDA revised the section "to allow for their use."

The agency also deleted its requirement for "smooth material," so that equipment designed for abrasive action can continue to be used. FDA said:

> "The Commissioner agrees that provisions should be made for food-contact surfaces that are, of necessity, not smooth. Upon reconsideration, he also realizes that there are appropriate food-contact surfaces in addition to those intended for abrasive actions, such as conveyor belts, which are neither smooth nor nonabsorbent. He has therefore deleted the requirement for smooth and nonabsorbent food-contact surface materials. The Commissioner has, however, added a requirement that all food-contact surfaces shall be maintained so as to prevent product contamination."

There were a number of objections in the comments to the tone of FDA's preamble to the GMP proposal. FDA responded last week that it "did not intend to imply that cacao products and confectionery are or are not high risk products, but rather that special considerations must be given to their processing in order to accommodate any unique properties and to eliminate potential hazards."

One "important unique" property "is the necessity for maintaining dry conditions in cacao product operations," FDA said, explaining that water "must be restricted in the production and cleaning operations associated with chocolate manufacture" because "its presence may create conditions conducive to the growth of microorganisms." On the other hand, the agency pointed out, "because of the low moisture environment, microorganisms which may be present are more resistant to destruction by heat."

FDA said that the absence from the preamble to the proposal of a direct reference to microbial contamination "was not meant to infer that cacao products and confectionery are free of the possibility of its occurrence." Since the proposal was issued, the agency said, there have been three occurrences of salmonella in confectionery items containing milk chocolates which necessitated recalls. One of the incidents involved a domestic product and two were of imports.

"These occurrences point up the fact that continued surveillance is necessary in the production of cacao products and confectionery to maintaining the GMPs that ensure the safety, cleanliness, and wholesomeness of these products," FDA added.

Some of the comments alleged that statistics on compliance presented in the preamble to the proposal were misleading. Saying that the information was "presented in summary fashion," FDA explained:

> "The data were presented to point out that insanitary conditions do exist and to demonstrate the need for a GMP ... The legal actions cited in the preamble to the proposal covered a 13-month period which ended February 1973. During the ensuing period ending in April 1974, there were an additional 5 legal actions ... involving manufacturers and dealers of confectionery and a dealer of cacao beans as a raw material. These violations involved storage under insanitary conditions, or adulteration by filth or extraneous matter."

FDA said that comments indicated there is "some confusion" between the terms "critical control points" and "good manufacturing practice." The agency emphasized "that there is basically no distinction between them," adding:

> "Critical control points identify processes, practices, or conditions that present a potential for causing a food to be dangerous, filthy, or otherwise unsuitable for food use. GMPs represent a code of procedures designed to control these points. The GMP regulations are intended to implement certain provisions of the act relating to adulterated food, and the failure of a manufacturer to identify critical control points and to adopt GMPs which control these points may result in violations ... Moreover, ... the scope of GMP regulations is not restricted to aesthetic or nonsafety factors as implied by some of the comments but also related to safety."

●