FOOD CHEMICAL NEWS

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HIGHLIGHTS of the news

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CARAMEL produced by ammoniated processes may require the establishment of a temporary tolerance by FDA until tests recommended by the Joint FAO/WHO Expert Committee on Food Additives are completed (See FOOD CHEMICAL NEWS, July 4, Page 40). Adverse effects from studies in The Netherlands and Great Britain prompted a request from the Committee for additional tests on the safety of caramels produced by ammoniated processes, which are used to color soft drinks and beer.

DELANEY CLAUSE modification was proposed by former FDA Commissioner Dr. Alexander M. Schmidt in a speech to the Chicago Section of the Institute of Food Technologists. Calling for benefit-risk assessments, Schmidt said Congress could frame a narrow exemption for essential categories of additives, such as saccharin as a table top sweetener until a safer artificial sweetener becomes available; essential preservatives such as nitrite; and essential nutrients such as vitamins, minerals and certain amino acids. He said Americans would accept "certain finite, but very small, risks" in exchange for "important benefits of the use of chemicals in foods..."

FDA, FTC, and the regulatory activities of EPA would not be subject to program reevaluations until Jan. 1, 1987, under "sunset" legislation (S 2) reported recently by the Senate Governmental Affairs Committee (See FOOD CHEMICAL NEWS, July 4, Page 57). The Committee said the agencies were omitted from the process of review every five years because other regulatory reform and reorganization legislation is being considered for them by the Committee.

PEOPLES REPUBLIC OF CHINA, working through an intermediary in Hong Kong, has filed registrations for three canning plants covering about two dozen processes with FDA which meet the agency's low-acid canned food requirements and allow shipment of Chinese mainland products to the U. S. Washington negotiations were handled by the Council for U.S.-China Trade, marking the first time the Chinese have complied with U.S. government requirements.

VITAMIN K activity is not based solely on menadione content, a report submitted to FDA recently by Heterochemical Corp. concluded. The firm renewed its urging that menadione sodium bisulfite complex be declared GRAS for use in poultry feeds at up to 2 grams per ton, and that use of the food additives menadione and menadione sodium bisulfite be discontinued (See FOOD CHEMICAL NEWS, Jan. 10, Page 9).

FOOD ADDITIVE PETITION filed by Georgia-Pacific, and noted July 8, would amend §176.170 for components of paper and paperboard in contact with aqueous and fatty foods to clear polyamidol-epichlorohydrin resin, modified by reaction with formaldehyde, as a wet strength agent.

FDA'S RICHARD A. MERRIL, the outgoing Chief Counsel of the agency, will be honored at a dinner July 23 at the Sheraton-Silver Spring Motor Inn, Silver Spring, Md. Reservations at $14.50 may be made with Robert Bell, Room 7B-04, 5600 Fishers Lane, Rockville, Md. (Area code 301, 443-3290).

JAPANESE BEETLE spraying program with DDT and carbaryl being conducted by U.S. airlines on flights from East Coast cities to California to prevent crop infestations is being monitored by FDA. Inspection of spraying programs by FDA in 1976 found no evidence of residues in food, but there were residues detected on food-contact surfaces.

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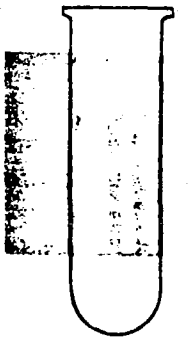

IBT STUDIES WERE USED TO SUPPORT 37 FOOD ADDITIVE PETITIONS

Industrial Bio-Test Laboratories has submitted studies in the past six years to the Food and Drug Administration in support of 37 Food Additive Petitions, according to a report of a Task Force in the Bureau of Foods which has reviewed IBT submissions made to the Bureau since 1971.

The review focused initially on studies submitted to FDA in the last two years. A report of the review indicated that no significant questions have been raised on the adequacy of the data submitted to the Bureau. Additional review of the submissions has been curtailed because of a hiring freeze.

The Bureau's report noted that additional review could uncover discrepancies that are not detectable from examination of submitted material, pointing out that a review of raw data would require extensive on-site work at IBT.

The Task Force broke down its review into studies conducted by IBT which constituted the entire Petition submission and other studies of major importance which were used to support the clearance of food or color additives.

The report noted that Petition submissions for five additives approved by the Bureau were based entirely on IBT studies, listing these as:

-- Brominated vegetable oil (interim regulation). Direct additive for use as a stabilizer for flavoring oils in beverages.

-- α-Hydro-omega-hydroxy-poly (oxyethylene) poly(oxypropylene) poly (oxyethylene) block polymer. Direct additive used as a dough conditioner in yeast leavened bakery products.

-- Nylon 6TA-66. Indirect additive for use as a food packaging material.

-- Poly (tetramethylene terephthalate). Indirect additive for use as articles or components of articles intended to contact non-alcoholic food.

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-- Modified hop extract. Direct additive used in beer.

Two other Petitions, in which part of the review was based on IBT submissions, were approved for:

-- Magnesium ricinoleate. Indirect additive used as an adjuvant in mineral oil lubricants.

-- $\alpha, \alpha', \alpha''$-(Propylidyne tris (methylene) tris (omega-hydroxypoly (oxypropylene)) (1.5 moles mininum) minimum molecular weight 400. Used in adhesives which are used in packaging material.

The report also listed the following seven submissions pending at the Bureau which were based entirely on IBT studies:

(1) Carboxyl terminated butadiene-nitrile copolymer (epoxy resin) and a heterocyclic aliphatic diamine (amine hardener). (2) Dimerized oleic acid. (3) 1,6-Hexanediamine tetramethylene phosphorous acid and formaldehyde. (4) Irradiated beef. (5) Irradiated papaya. (6) Syndiotactic 1,2-polybutadiene. (7) Poly (n-methylethylene)ammonium chloride.

Another 17 petitions pending at the Bureau were based partly on IBT studies. These are for:

(1) Azelaic acid. (2) Acrylonitrile/styrene. (3) Aminotri(methyl)phosphonic acid. (4) Butyl acrylate/styrene/methacrylic acid/methyl methacrylate/N-(isobutyl methyl) (acrylamide polymer). (5) Diiodomethyl p-tolylsulfone (Amical 48). (6) Dimethylpolysiloxane. (7) 3,5-Di-tert-butyl-4-hydroxy-hydrocinnamic acid triester. (8) Ethylene bis-stearamide (N,N-distearoylethylene diamine). (9) Fluorochemical L-2200. (10) Hydroxyethylidene-1,1-diphosphonic acid. (11) Poly(dimethyl-2-trihydroxypropylene)ammonium chloride. (12) Pellethane-apolyurethane polymer. (13) Starch-g-poly (acrylamide-co-β-methacryloyloxyloxyethyltri-methylammonium monomethyl sulfate). (14) Stroke Environ (a mixture of phenols, 2 -alkylomegahydroxypoly (oxyethylene, isopropanol and other minor substances. (15) Tetrahydrofurfuryl alcohol. (16) Trimellitic anhydride. (17) Urethane polymer.

IBT has informed some sponsors of tests at the laboratory that some of the studies conducted to support work submitted to the FDA may be faulty.

FDA to be Notified of Sponsor Responses by July 25

FDA-ers were told at a June 13 meeting with IBT's new management team that the firm's letters to test sponsors will request a response by July 18, and that it is hoped that FDA will be notified of the responses by July 25.

The agency itself has also written some firms for which IBT conducted tests to find out which tests were used to support petitions or applications (See FOOD CHEMICAL NEWS, June 27, Page 19).

According to a memo of the meeting written by Ernest L. Brisson, of FDA's Office of Compliance, the IBT officials told of plans "to involve sponsors in the follow-up on the possibly defective studies," with letters to be sent to the "sponsors of 56 studies asking them to identify the status of the study, i.e., whether it is supporting a product which is currently marketed, pending, or under investigation." In a June 28 letter to Brisson, IBT President Dr. Alvin Frisque said sponsors will be asked about 62 studies, since six 30-month studies were added to the list of fifty-six one- and two-year studies.

IBT officials told FDA-ers at the meeting that the firm will inform the agency of sponsor response, and "will advise the sponsors that these studies will have to be audited as they (IBT) feel that these studies may have some problems," the memo said, adding:

"IBT will supply the sponsors with copies of all records of each study. The list of studies to be audited to be sent to each sponsor may include some short-term studies when they were conducted in conjunction with a particular long-term study. Dr. Frisque indicated that the Federal agencies are invited to monitor the audits of the studies by the sponsors."

Frisque said that FDA "will be informed when the sponsors and IBT have identified a problem study (including potential problem studies)," the memo said, adding that "IBT will let us know when a sponsor wants to deal directly with us without involving IBT."

The IBT officials told the FDA-ers that approximately 80% of the toxicology studies which IBT conducts would be of interest to the Environmental Protection Agency, with the other 20% involving products regulated by FDA, the Agriculture Department, the National Institute of Occupational Safety and Health, and other agencies.

The June 13 progress report given by Frisque said current studies are being audited, and that 17 of the 34 studies lasting one year or longer conducted between 1969 and 1973 either have been or are being audited by a three-person team of scientists. The 17 studies were conducted for 7 clients, the memo said.

The IBT president stated that "he guesses that 90% of these studies probably have moderately serious to serious problems," Brisson wrote. In his letter, Frisque said that "even these deficient studies might have some redeemable features." One or two of the 17 studies are "almost entirely defendable," the letter said, but Frisque told the FDA-ers that "most of the others are seriously compromised."

Taking all of the IBT toxicology studies into consideration, Frisque said "less than 90% will have problems," the memo said.

The IBT president estimated "that it may require up to 200 man-years to review all of the studies ever conducted by IBT since Jan. 1, 1967," Brisson wrote, adding that the most serious problems were in the rodent department in the Northbrook, Ill., laboratories during the early 1970s. However, Frisque said he is not sure "whether this was the only problem area."

From Jan. 1, 1967, until April of this year, 56 studies of 12 months or longer were reported out of the IBT toxicology department, plus the 6 shorter studies. The memo said that 34 of the 56 studies were conducted during the period of 1969 to 1973, "which has been identified as the period of greatest activity and where most of the problems arose." The peak year, the memo said, was 1971, when 22 studies were started.

At the meeting, IBT attorney Merrill Thompson read a list of six items, asking "some response or at least an acknowledgement by FDA," the memo said. The items included:

"(1) Will FDA identify a senior agency coordinator on IBT matters with whom IBT can deal directly?

"(2) Is there some possibility for a single Federal agency to be designated as a lead agency among interested agencies for whom IBT studies were conducted?

"(3) Will IBT receive feed-back from FDA when decisions are made regarding particular studies or products so as to avoid needless duplication on data auditing and identification of studies which would require audit?

"(4) IBT has invited a re-inspection of its facilities to determine their current status for compliance with Good Laboratory Practices.

"(5) IBT has suggested additional meetings and periodical progress reports in order to assure expeditious resolution of any problems uncovered in these data audits.

"(6) IBT has requested that there be some joint participation in the establishment of priorities for identification as important studies to be audited."

Frisque told the FDA-ers that "survival of the firm is the largest issue facing IBT today," according to the memo. In his letter to Brisson, the IBT president added that "the larger issue was the public health."

Brisson's memo said Frisque "was very forthright in stating that their greatest sin was accepting more work than they had the capability of doing properly during the early 1970s, and that they are living with these problems now."

The IBT president said that there are now 25 people employed at the Northbrook toxicology department, but that there were only 15 to 20 people during the early 1970s, "when the workload was two or three times greater than it is now ..." Frisque explained that IBT has been starting from 10 to 12 studies a year, and that, with the studies averaging about two years, there are now 22 on-going studies.

"Dr. Frisque stated that the firm will not begin any additional long-term rodent studies at Northbrook until the status of their capabilities has been further assessed," the memo said.

The IBT president told FDA-ers that "all the key people now employed by IBT in those critical areas regarding toxicology testing are new," and that the "previous staff has either been re-assigned or have resigned, some within the last eleven weeks, and some at their own request," Brisson wrote.

IBT Director of Research Dr. Barrie Phillips listed recent steps taken by IBT to improve toxicological testing practices. According to the Brisson memo, these were:

"(1) Initiation of a GLP manual including all standard operating procedures to be employed by IBT. (2) Rehabilitation of some of the facilities at Northbrook to improve conditions for its usefulness in conducting the animal studies, especially housing of

animals. (3) Consultation with two experts in animal husbandry and a concurrent inspection by AALAC. IBT will try to be certified by AALAC. (4) Personnel changes for important jobs in toxicology testing. (5) Production of a necropsy laboratory manual. (6) Production of clinical pathology and histopathology manuals is planned. (7) Necropsy technicians are now on duty seven days a week (only two or three hours per day on weekends). (8) A pathologist is always on call to necropsy technicians.

"(9) A quality assurance unit is now completely functional and is auditing studies upon completion. It will shortly begin auditing the studies during the course of the study. (10) New forms have been produced for coding data.. (11) A records archive is being developed but is not yet functional. (12) A new policy has been initiated where no study of greater than 90-days duration can be initiated without an approved protocol. (13) All dog studies will be conducted at the Wedges Creek Research Farm after July 1977. (14) Increased use of computer technology for records management. (15) Establishment of a log of protocol changes. (16) Initiation of new procedures for the receipt and handling of test materials. (17) Improved lines of communication within IBT for those involved in conduct of such studies."

The Brisson memo said that Phillips "further reviewed plans of additional factors regarding toxicology testing which IBT hopes to get into in the future including consideration of a new facility (to replace the Northbrook facilities which he considers antiquated), consideration of a functional re-organization of the scientific staff (the staff is now functioning in a parallel organization structure based upon a geographic location of three laboratories at Northbrook, Decatur, and Wedges Creek)."

In response to a question, Phillips told the FDA-ers that IBT "is no longer gang caging animals on chronic studies," the memo said, and he indicated that IBT is switching from ear notchings to metal ear tags for identification of rodents.

IBT had requested the June 13 meeting to acquaint the FDA-ers "with recent changes in management procedures ..." The FDA-ers "indicated that we would listen to IBT's presentation, however, we would not discuss any particulars relating to the current investigation of IBT," the memo said.

The IBT officials pledged cooperation with FDA, saying "there is now a new management team at IBT ..." with an "attitude ... of openness and cooperation with FDA ...," the memo said. It added that the visitors indicated "that IBT is not proud of the past."

Frisque described the Northbrook, Ill., facility as the firm's largest and oldest facility, employing 170 people. The newer Decatur, Ill., facility employs 120 people, and may be the largest inhalation facility in the world, he said. All dog, primate, and larger animal studies will be centralized at the Wedges Creek Research Farm in Neilsville, Wisc., which now employs 30 people, Frisque said.

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KOKOSKI SAYS THERE IS NO LEVEL OF "TOXICOLOGICAL INSIGNIFICANCE"

Dr. Charles J. Kokoski, Chief of the Food Additives Evaluation Branch of the Bureau of Foods' Division of Toxicology, testified recently that he does not believe that there is a level of "toxicological insignificance" for indirect food additives at which "the amount of the substance that may reasonably be expected to migrate to food is so small that, regardless of toxicity of the substance, it's safe to use."

In direct testimony prepared for the Food and Drug Administration's public hearing on use of acrylonitrile for beverage packaging (See FOOD CHEMICAL NEWS, July 4, Page 23), Kokoski described the considerations used by the Division of Toxicology to determine the types of tests required for indirect additives.

The Society of the Plastics Industry earlier this year (See FOOD CHEMICAL NEWS, April 4, Page 22) submitted a petition to FDA to redefine indirect food additives to incorporate the concept of "toxicological insignificance," a proposal which has been knocking around for a decade or so.

For most packaging materials, SPI's proposed redefinition would hold that they are non-migrants -- non-food additives -- if they migrate to food at a level lower than 50 p.p.b., the level of migration proposed for non-beverage bottle use of acrylonitrile (See FOOD CHEMICAL NEWS, March 14, Page 10).

SPI would apply FDA's use of the sensitivity-of-method approach to packaging materials which are carcinogenic or which are heavy metals.

Toxicological Insignificance Used as Shorthand For No (Nil) Migration: Kokoski

In his testimony, describing the principles used by FDA in evaluating the safety of indirect additives generally and acrylonitrile copolymers used to fabricate beverage containers specifically, Kokoski suggested the term "toxicological insignificance" may be a useful "shorthand" in cases when there is "virtually no (or nil) migration" of a substance to food and/or the food-contact article is in contact with the food for only a brief time.

"Whenever an article comes in contact with food and there is a recognized potential for migration to the food, that substance is a 'food additive' and a food additive petition must be filed with data to demonstrate the safety of the substance," he said. Kokoski explained:

"Where the anticipated migration of a substance is extremely low -- the phrase 'virtually nil' is sometimes used -- and where the substance is not a heavy metal, and where there is no reason to suspect that the substance is a carcinogen, or teratogen, we have required only acute toxicity data (i.e., LD50) to insure that the substance is not a highly acutely toxic chemical. As a benchmark we have, in the past, considered migration of a substance to food at less than 0.05 p.p.m. to be 'virtually nil.' Ordinarily 0.05 p.p.m. is the lowest limit of the analytical detection capability."

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If migration is over 0.05 p.p.m. but less than "about one part per million," he said, FDA refers to the migration as "negligible."

"The upper limit of migration for negligible is not a rigid, fixed point, but is a matter of scientific judgment based on an analysis of the individual food additive under consideration," Kokoski continued, commenting:

"A substance that migrates at negligible levels will require more extensive test data to establish its safety. We would ordinarily require short-term (i.e., subchronic or sub-acute or 90-day) feeding studies in test animals such as the rat and dog, usually divided into several groups for different test dose levels as compared with a control group not receiving the test material. We might also require tests to assess the teratogenic and reproductive effects of the substance if the data suggests that these tests should be undertaken."

Based on data from short-term studies, he said, FDA's determines the highest "no-adverse-effect" level in the most sensitive of the species tested.

"We then apply a safety factor of 1:1000 to that level to derive a maximum acceptable daily intake (ADI) for man, that is, the maximum amount that could safely be consumed on a daily basis by man," the FDA-er said. "The 1:1000 fold safety factor is the one employed when we see teratogenic effects in the test animals that are statistically significant," he testified, adding:

"If, based on the anticipated migration level it does not appear that the ADI will be exceeded, the substance would be considered to be safe, subject, of course, to limitations on use to insure that consumption does not exceed the ADI and that migration stays within the negligible range. Limitations on use could include the type of foods permitted to be placed in contact with the substance, restrictions on the temperatures to which the article will be exposed, restrictions on the amount of the residual monomer in the copolymer, etc."

Kokoski noted that if levels of anticipated migration are significant, and/or there is a suspicion the substance is cumulatively or chronically toxic, or is a carcinogen, then FDA would require lifetime animal feeding studies.

"If the results from these lifetime studies do <u>not</u> show the substance to be a carcinogen, we would determine the 'no-adverse-effect' level, if one can be determined from the data, and apply a safety factor to that level (usually 1:100) to derive an ADI for man," he said, noting that because lifetime studies give better data, FDA can estimate man's ADI more confidently than from subchronic animal studies.

If the potential migration is significant, or the substance is suspected of having toxicity potential upon reproductive physiology and/or teratology, he continued, FDA "also would require data from multigenerational reproduction and teratology studies. The results from these studies would be included in our determination of the ADI unless the substance is a carcinogen, in which case no level would be considered safe."

DSW 329726

If FDA finds it to be a teratogen, he said, then the agency applies the 1:1000 safety factor.

If teratogenicity is determined in one species, then FDA asks for studies in a second species, he noted.

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AFDO APPROVES COMMUNITY CANNERY REGULATION

The Association of Food and Drug Officials recently approved a draft regulation for States to use to regulate community canneries (See FOOD CHEMICAL NEWS, June 27, Page 36; and July 4, Pages 12 and 26).

The regulation is an outgrowth of an investigation conducted by FDA and several States into the operation of community canneries which uncovered equipment and operational deficiencies and raised the possibility that some products may be underprocessed by the canneries (See FOOD CHEMICAL NEWS, July 5, 1976, Page 11).

FDA had previously issued minimum guidelines for community cannery operations from which State and local agencies could build compliance programs. FDA had informed the States that it would be unable to assume regulatory responsibility for community canneries.

The community cannery regulation approved at AFDO's 81st annual conference in Portland, Ore., deals with:

(1) Preparation of product prior to canning; (2) Establishment of the scheduled processes; (3) Procedures which must be followed during processing; (4) Proper equipment, including installation and operating rules; (5) Container inspection; (6) Processing and production records; (7) Procedures for handling process deviations; (8) Qualifications of personnel; and (9) Licensing.

Although designed primarily for control of low-acid foods, the AFDO regulation can be applied to high-acid food as well.

AFDO's Laws and Regulations Committee has agreed to draft a position on implementation of uniform food and drug regulations by State legislative bodies. Heretofore, these regulations have been adopted, in many instances, without public notice by States as soon as they have been promulgated by federal agencies. Adversely affected persons were required to request hearings after determining the regulations were being implemented.

The Committee, in its report to the AFDO business session, noted that the automatic adoption provision is now "questionable" since an increasing number of States are adopting administrative practices which preclude adoption of any regulation without notice and hearing. As a result, the Committee observed, it has become "inadvisable" to recommend automatic adoption of federal regulations.

DSW 329727

AFDO Approves Regulation Opposing Sanctioning of Laetrile

AFDO approved a resolution encouraging State officials to participate in public proceedings, including legislative and executive branch activities, opposing sanctioning of laetrile. The AFDO resolution put the organization on record as opposed to legislation, State or federal, which undermines the consumer protection provided by laws that require that new drugs be demonstrated as safe and effective before they are made available to the public.

AFDO instructed its Executive Director to transmit copies of the resolution to governors of all States and chairmen of Congressional Committees dealing with laetrile legislation.

AFDO elected Norman E. Kirschbaum, Administrator of Wisconsin's Division of Food and Standards, as president.

Long-time Director of Tennessee's Food and Drug Division, Eugene H. Holeman, announced his retirement. He has agreed to continue as a consultant and to direct State participation for the Association of Official Analytical Chemists.

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FDA ADDS 6 MINERAL ANALYSES TO TOTAL DIET SAMPLE PROGRAMS

The Food and Drug Administration has asked its Kansas City laboratory, which analyzes Total Diet composites for Adults and similar samples for Infants and Toddlers, to determine levels of iron, potassium, calcium, phosphorus, sodium, and iodine in the consumer commodities collected for the programs for fiscal year 1978.

The new assignment, which covers products to be analyzed over the next fiscal year, will also cover levels of fluoride in the products as soon as a method is validated for fluoride.

Due to changes in food technology and manufacturing practices, FDA observed in its notice to the field, many foods now vary significantly in composition from their counterparts of a few years ago.

FDA said additional data are needed on the levels of such essential minerals as iron, potassium, calcium, phosphorus, sodium, and iodine in both adult and infant and toddler populations. The updated information, FDA said, should help the agency make decisions concerning "the safety and food health impact of food additives which contain or affect these minerals."

The information will also be used in forming future policy on food fortification and enrichment policies, FDA pointed out.

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HEW TO AUDIT EPPLEY INSTITUTE HANDLING OF CONTRACT MONEYS

A Government Accounting Office (GAO) investigation of an Eppley Institute for Research in Cancer contract with the National Cancer Institute (NCI) has allegedly uncovered some questionable money practices, causing NCI to withhold payment on part of the contract (See FOOD CHEMICAL NEWS, June 20, Page 55).

Initiated by Rep. Obey (D-Wis.), the GAO audit reportedly turned up indications that the Eppley Institute was charging the government for research actually going to industry.

The GAO study found apparently improper listing of salaries, lack of inventory, and use of government contract supplies for industrial research.

In addition, "twelve projects under subject contract were never formally approved by the Contracting Officer," according to Joe Federline, the NCI Contracting Officer.

Negotiations with the Eppley Institute for renewal of its current $3.2 million NCI research contract are being postponed until August or September, when an audit, which will be conducted by the Department of Health, Education and Welfare, is finished.

The contract payment currently being withheld by NCI is for a $237,650 renovation of Eppley's animal breeding facility.

Although Eppley's contract expired June 30, it was extended administratively until Sept. 30, so that the audit can take place.

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FDA SEEKS ANIMAL FEED FORMULATION DISCLOSURE

Disclosure of the drug and non-drug ingredients in FD-1800 medicated animal feeds is required by the Food and Drug Administration, according to a June 17 Compliance Policy Guide (77-34).

Faced with refusual by some manufacturers to reveal information due to trade secrets, the bulletin noted that refusal to provide the following information would "warrant consideration of administrative/regulatory follow-up:

"1. Quantitative composition of active drug ingredients.

"2. Quantitative composition of non-drug ingredients when such information is essential for a determination as to compliance with a limitation established by regulation.

"3. Qualitative composition of all other non-drug ingredients."

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FDA noted in the policy statement that authority to inspect quantitative and qualitative formula statements is based on Section 512(m)(5) of the Act.

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NEW YORK SEEKS RETENTION OF CURRENT PCB LEVELS FOR FISH

The State of New York petitioned the Food and Drug Administration to reconsider its proposal to reduce acceptable levels for polychlorinated biphenyls in fish "and to delay implementation of any change pending further studies on the drastic and possibly tragic economic implications any change would instigate ..." in a resolution approved by the State Assembly May 26 and by the State Senate June 2.

Additionally, individual State Assembly members and Senators have written the agency urging that the lowering of the PCB levels be reconsidered (See FOOD CHEMICAL NEWS, July 4, Page 41).

FDA also received Congressional inquiries on the proposal from Sens. Proxmire (D-Wis.) and Griffin (R-Mich.), and from Reps. Ruppe (R-Mich.) and Vander Jagt (R-Mich.).

Rep. Lent (R-N.Y.) urged the agency to reconsider its proposed action "because of the possibility that FDA has underestimated the economic consequences ... and because of the continuing uncertainties associated with making precise determinations of the true health risks and benefits accruing for the proposed action, and in determining the level of equilibrium PCB concentrations once the relevant environments are allowed to adjust to a constant (non-increasing) ambient level of PCB concentrations." Lent suggested that:

"1. The current tolerances for PCBs in affected fisheries be maintained;

"2. The FDA require warnings to consumers of potential health risks associated with the consumption of these fish; and

"3. The FDA, in conjunction with the National Marine Fisheries Service and the Environmental Protection Agency, undertake to determine the equilibrium concentrations of the PCBs in these fisheries once the discharge of PCBs into the environment has been eliminate completely."

Lowering the PCB level from 5 p.p.m. to 2 p.p.m. was backed by Atom Manufacturing Co., producer of lures for saltwatergamefish, because lower hatches are being reported.

Individual comments on the proposal mostly support the FDA's proposed lowering of the action level.

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INCREASE IN MERCURY ACTION LEVEL FOR FISH AND SHELLFISH PETITIONED

A petition filed by AMR Biological Research has asked the Food and Drug Administration to increase the action level for mercury in fish and shellfish, both raw and processed, from 0.50 p.p.m. to 2.0 p.p.m.

The petition, filed on behalf of Captain Louis Puskas, Barnegat Light, N.J., noted that to accomplish the increased action level, "the Commissioner must establish or recognize official tests for determining the presence of methyl mercury and mercury in fish and shellfish."

"Since such tests have been clearly established by many laboratories, including those of FDA, the official approved tests should be included in the amendment to the action level," AMR wrote, adding that "The most recent gas chromatography methods should be included."

AMR explained that the petition was based "upon the excellent analytical methods now available, and upon the careful review of the publications which have appeared since 1970," pointing out that most of these "were not cited in the background for the action level published" by FDA in 1974.

Referral of the question of an appropriate action level for mercury in fish to the National Academy of Sciences was recently sought by the National Canners Association, which also cited recent information on the problem (See FOOD CHEMICAL NEWS, June 27, Page 15).

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LIMIT SPECIFICATIONS FOR BASIC INDIRECT ADDITIVES TO BE SET

The Food and Drug Administration plans "to contract to establish 'limit specifications' for basic resins and adjuvants used in containers," Ronald J. Wylie, Director of the Compliance Regulations Policy Staff in the Food and Drug Administration's Office of Compliance, revealed recently.

Wylie explained, at an Institute of Food Technologists short course held in conjunction with IFT's annual convention (See FOOD CHEMICAL NEWS, June 13, Pages 4, 7, 9, 12, and 15; and June 20, Pages 17, 19, 21, and 23), "Once the specifications are established, containers will be fabricated and then analyzed to determine migration into specific foods."

Noting that part of the "continuing public controversy about the safety of many widely-used substances and the lack of public acceptance of many recent toxicology decisions" is attributed by some "knowledgeable observers ... to the failure of government agencies to promulgate written rules governing toxicological evaluations of substances," Wylie pointed out that writing such rules is a difficult task.

DSW 329731

Written Toxicological Rules Will Force Resolution of Scientific Issues, Wylie Says

"An alternative ... is to require that all the judgmental factors in the decision be identified and the rationale for the judgment be explained in a written summary statement documenting the decision," he noted, explaining: "This approach would be similar to the written summary that is required for the safety decisions regarding new drugs for which raw safety data cannot be released." However, Wylie cautioned:

> "Without the accomplishment of the difficult task of codifying toxicological rules, each individual toxicologist has little choice but to make those decisions that he believes reflect the scientific policy of his agency. As a consequence, there is a high risk of different rules being applied both within and between agencies, of a deficiency of meaningful knowledge by the regulated industry of the requirements to be imposed, and a lack of understanding and confidence by the public and their representatives."

Also, Wylie pointed out, "By forcing more systematic thought and encouraging agreement on important points, the exercise could save or better direct scarce resources by resolving issues such as the validity of short-term tests as predictive tools for carcinogenicity and the type of animal tests which would be required to overcome positive results from a series of in vitro tests."

Written toxicological rules, Wylie said, "should undoubtedly be written with enough flexibility to allow the exercise of scientific judgment," adding that they "should be proposed with an opportunity for careful public scrutiny and comment, they should be subjected to judicial review, and the rules that survive this rigorous process should be religiously followed by the government in the same way that it is under an obligation to follow any written rule."

He suggested that "some thought should be given to substituting public educational campaigns for bans," urging that "Congress should consider formalizing FDA's educational role by defining it more specifically and by providing program direction and support."

"Under new Commissioner Kennedy, I would expect that the educational role of the FDA in general and nutrition education in particular would be given an added thrust," Wylie commented.

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DELANEY CLAUSE CHANGE LIMIT TO "FINE TUNING" SEEN BY KENNEDY

Food and Drugs Commissioner Kennedy has expressed the view that the Delaney anti-cancer clause "may need some fine tuning," but that there is "no real urgency to make sweeping revisions in the Delaney clause."

DSW 329732

He made the comments in reply to questions on the CBS Face the Nation TV show July 3. Kennedy is a member of a Department of Health, Education and Welfare panel considering whether legislative changes in the Delaney clause are needed. He said he has not yet "reached a final position."

However, the Commissioner said he would oppose "sweeping it away or revising it out of all recognition."

In recent Congressional testimony, Kennedy indicated he believes that technological advances may have made the Delaney clause outdated (See FOOD CHEMICAL NEWS, July 4, Page 47).

Kennedy said any effort to keep Congress from passing a moratorium on a saccharin ban (See FOOD CHEMICAL NEWS, July 4, Page 58) is a "losing battle at this point." He urged restrictions on saccharin to protect the public health during any moratorium period.

The Canadian epidemiology study upon which FDA appears to be relying (See FOOD CHEMICAL NEWS, July 4, Page 5) is more significant than other epidemiology studies involving saccharin because of the larger number of males involved, Kennedy said. However, he added that the Canadian study does not represent the "final word."

The Commissioner said the reopening of the comment period on saccharin by FDA will not prolong "our decision time by very much," because of the large number of comments already filed that will take time to evaluate.

Kennedy praised the FDA staff as "very, very good," saying there is some need to "upgrade" the agency so it can recruit for some "top science positions." Saying regulatory agencies are "at the confluence of great social pressures," Kennedy said FDA receives a great deal of criticism, including criticism for doing what it is supposed to do, as in the case of saccharin.

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VICHYSSOISE RECALLED BECAUSE OF UNDERPROCESSING

The Food and Drug Administration last week announced a Class II recall of condensed vichyssoise soup because "product was underprocessed which may cause a potential for bacterial outgrowth."

The products, some of which were labeled as condensed cream of potato soup, were being recalled by Specialty Foods Company, Inc., Johnson City, N. Y., from New York, New Jersey, Indiana, Illinois, Wisconsin, Michigan, Georgia, Florida, Colorado, California, South Dakota, and Ohio. The product was under recall under the following brand names:

(1) NIFDA (National Institutional Food Distributor Associates, Inc.); (2) Claybourne (Clayco Foods, Inc.); (3) Specialty Brand (Specialty Foods Corp); (4) Railton (B. A. Railton Co.); (5) Nugget (Nugget Distributors, Inc.); (6) Hudson Valley Brand (Catskill Grocery Co., Inc.); (7) Tartan (Alfred Lowry & Bros., Inc.); and (8) [illegible] (CFS Continental).

DSW 329733

A Class II recall was being made of frozen mahi mahi fish loins in 50-pound boxes because of high histamine levels. The importer, Sun Harbor Industries, San Diego, Calif., was recalling the fish from Florida. It was processed by Expromar, Manta, Ecuador.

Archway Chocolate Chip Ice Box Cookies were undergoing Class III recall because of glass contamination. FDA also said the product contained nuts which were not declared on the label. Merit Baking Company, Boone, Iowa, was recalling the cookies from Iowa, Nebraska, Minnesota, Kansas, Missouri, and Arkansas.

A Class III recall was completed of Bumble Bee Brand Solid White Tuna in Water and Bumble Bee Brand Chunk Light Tuna because some labels of tuna for human consumption and tuna for catfood were mixed. FDA said the can codes were correct. Bumble Bee Seafoods, Astoria, Ore., a division of Castle & Cooke, San Francisco, Calif., recalled the product. Tuna processed by Pacific Fishing Company, Levuka, Fiji, was recalled from New York, Ohio, and Florida, and tuna processed by Hawaiian Tuna Packers, Honolulu, Hawaii, was recalled from Washington, Oregon, California, and Maryland.

Columbo Natural Yogurt, Unflavored, and Columbo Flavored Yogurt were recalled because of yeast contamination. The Class III recall from the Northeastern U. S. was completed by Columbo, Inc., Methuen, Mass.

FDA was seeking an injunction against H. W. Martin & Sons, Hebron, O., and two individual partners in the firm on charges that various grains for cattle and swine feed were held under insanitary conditions and contained pesticide chemicals.

The agency recently seized Carnation Flounder Fillets, shipped by Massachusetts Coastal Seafoods, Inc., Magnolia, Mass., on grounds turbot fillets were substituted for flounder fillets.

Alleging the product is a new animal drug marketed without an approved New Animal Drug Application, FDA seized Leg-Gel, in possession of Western Comfrey, Inc., Canby, Ore. FDA also seized Furazolidone Medicated Premix, shipped by the Hess & Clark division of Rhodia, Inc., Ashland, O., alleging that the product is a new animal drug which does not conform to an approved NADA because it contains furazolidone "which is not from a source approved in the application."

FDA seized potato flakes, in possession of Magic Valley Foods, Inc., Rupert, Idaho, on grounds the product was prepared, packed and held under insanitary conditions and contained E. coli, excessive coliform, and excessive total bacteria.

Conch meat, in possession of Merchants Refrigeration Company, Newark, N. J., was seized on grounds that it was decomposed. Whey solids were seized, in possession of Superior Bakers, also known as Ginsburg's Bakery, Atlantic City, N. J., on grounds it was held under insanitary conditions and was rodent contaminated.

FDA seized Hi Nucli Tablets on the ground that it contained the unsafe food additive ribonucleic acid, and Sel-E-Chrom II Tablets on the ground that it contained the

unsafe food additive selenium. The products were seized in possession of Alacer Corporation, Buena Park, Calif.

Regulatory Letters Hit Labeling of Food Products

A June 23 regulatory letter to Meinerz Creamery Co., New Berlin, Wisc., said the firm's Salami Cheese for Pizza was misbranded "since it is represented as and purports to be provolone cheese, ... but fails to comply with the fat and moisture requirements of the (food) standard." Copies of the letter were sent to Beatrice Foods, Chicago, and the Meinerz Creamery at Preston, Iowa.

The letter said that "other brand labels for this type of cheese were also noted which are misbranded and do not conform to the standard of identity in the same respect ..." These included Salami Type Cheese under the Meinerz Creamery brand, Giovacci Salame Style Cheese under the brand name of Continental Specialty Foods, Inc., Quality Brand Salami Cheese for Pizza, Lipco Brand Salami Style Cheese, Party Pak Pizza Brand Salami Cheese for Pizza, Barone Brand Salami Style Cheese, Sun-Re Salami Style Cheese, and Angilo's Brand Salame Cheese for Pizza. FDA also said the label for the Salami Cheese for Pizza failed to bear a net quantity of contents statement.

A regulatory letter sent June 24 to Tarlas Meat Company, Madison, Ill., said that paper bags of flour found at Gus' Pretzel Shop, St. Louis, Mo., were being sold as 100 pounds of flour but failed to bear "an accurate statement of the quantity of contents in terms of weight." The label also failed to identify the product as flour.

The agency explained that if flour is treated or contains additional ingredients, it is subject to food standard requirements for label statements regarding the type or composition of the flour.

FDA sent a letter June 24 to Don's Chuck Wagon Products, Inc., East Detroit, Mich., taking issue with labeling for buttermilk pancake and waffle mix and buckwheat pancake and waffle mix. The agency said the name and address do not appear properly on the labels. The letter also said the net contents statements for Golden Mushroom Batter Mix, Onion Ring Mix, and Tempura Fruit Cantonese Batter Mix appeared in a type insufficiently large. FDA said some ingredients were not declared by their common or usual names, as with "soda leavening." The letter added that enriched flour was not declared properly for non-standardized food labels.

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ADULTERATION PREDOMINANT AS CAUSE OF MEAT AND POULTRY DETENTIONS

Nine of the detentions of meat or poultry by Agriculture Department compliance officers for which releases were made in early June involved adulteration problems.

Three of these cases involved horsemeat or trimmings owned by LDC Limited, Rutledge, Ga., which were being held at Commercial Cold Storage, Atlanta. Of a total of 77,640 lbs. of meat involved, 24,540 lbs. were voluntarily destroyed and 53,100 lbs. were released for reinspection.

DSW 329735

At Columbia, S.C., 25,620 lbs. of pork skins being held at Capitol City Cold Storage and owned by Lumberjack Meats, Birmingham, Ala., were released for reinspection.

Truck wrecks led to two of the adulteration cases. In one of these, 22,533 lbs. of pork loins owned by Goehring Meat, Lodi, Calif., and Harry Krantz, Encino, Calif. -- and listed as being at U. S. Growers Cold Storage, Los Angeles -- were released after reinspection of part of the product. In the other, 8,400 lbs. of chicken legs in a shipment of 35,520 lbs. were voluntarily destroyed for human food purposes. The product was at Pacific Cold Storage, Los Angeles, and was owned by Union Packing, Omaha, Neb. The other three adulteration cases involved:

(1) 3,000 lbs. of pork legs owned by Pierce Packing, Billings, Mont., and being held at United States Cold Storage, Oakland, Calif., released for reinspection; (2) 3,000 lbs. of various beef cuts owned by and being held at Sandy Lockers, Sandy, Ore., part condemned and removed from the premises and part released for reinspection; and (3) 15,524 lbs. of pork snouts and skins, owned by Coloidales Duche S A, Laredo, Texas, and being held at Laredo Cold Storage, voluntarily destroyed for human food purposes.

Other detentions for which releases were made during early June were for failure to denature and misbranding or lack of identification of product. The one denaturing problem concerned 15,000 lbs. of beef fat tissue owned by Bay Meat Products, Boston, being held at Girard Freezer of that city, which were released to a pet food manufacturer.

In the misbranding cases, failure to identify a product led to detention of 48,100 lbs. of ground chicken owned by Ottawa Fur Farm, Le Sueur, Minn., which were being held at Newport-St. Paul Cold Storage, Newport, Minn. The product was brought into compliance. At Crete, Neb., 3,417 lbs. of mixed poultry being held at Allen Products there and owned by O'Brien Produce No. 3, Southwest, Mo., were voluntarily destroyed for human food purposes. At San Antonio, Texas, 40,000 lbs. of "inedible mechanically deboned meat" owned by L&H Packing and being held at Loop Cold Storage, both in San Antonio, were released for reinspection.

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TWO CITIZEN ACTIONS AGAINST COMMUNICATIONS COMMISSION FAIL

The Federal Communications Commission last week turned down one citizen group complaint concerning children's television and got help from an Appeals Court in denying another group's petition on the same subject.

In the first action, FCC denied a complaint against ABC and CBS from the Council on Children, Media and Merchandising, which had asked the agency to direct the networks to present "instructional programming to educate children on television advertising techniques."

DSW 329736

Turning down the proposal, FCC said it "would not take any step that would deprive broadcasters of the right to select the means of serving their communities" and that requiring networks to "present specific programming would constitute such a step."

In the other action, the U. S. Court of Appeals for the District of Columbia turned down an appeal by Action for Children's Television against a 1974 policy ruling of FCC which called for limiting commercial content of children's shows and adopted other guidelines for children's programming (See FOOD CHEMICAL NEWS, July 1, 1974, Page 40.)

The ruling by FCC is not in final form, the agency noted, and has been kept open "to evaluate the anticipated improvement in children's programming and advertising" from a voluntary code drawn up by the National Association of Broadcasters.

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KENNEDY RESPONDS TO KELLEN'S "REMARKABLE" SACCHARIN LETTER

Food and Drugs Commissioner Kennedy on June 28 responded to what he termed a "remarkable letter" written by Calorie Control Council's Robert H. Kellen regarding saccharin.

The Kellen letter urged Kennedy to "desist from any further irresponsible statements" about the Canadian epidemiology study on saccharin (See FOOD CHEMICAL NEWS, June 27, Page 39).

The Commissioner replied, in part: "As you know perfectly well, the decrease in risk for women was noted in a small sample, and did not meet the tests of statistical significance applied by the authors. In other words, it cannot be asserted that the depression of risk among female controls is attributable to saccharin use rather than to chance. By contrast, the increased male risk was highly significant statistically. This is the reason--and the only reason--that we reported it."

"As to decency," Kennedy continued, "I am happy to leave it to history to decide whether my statements, which I regard as scientifically based and carefully made in the interests of public health, display more or less of that virtue than the Calorie Control Council's own efforts to continue to profit from the sale of saccharin-containing soft drinks."

Kellen had included a list of questions about the Canadian study posed by Harvard University's Dr. Phillip Cole. Kennedy said Cole's "comments appear to be thoughtful and professional inquiries about the study in question." He continued:

> "Most of them have also been asked by the group of epidemiologists in the FDA who have been helping me

> review the study. As you must know, we have decided to extend the comment period by filing a supplemental Federal Register notice and placing both of the new epidemiological studies on public display. Dr. Cole and other epidemiologists whom you may care to have comment on these studies will be welcome to put their views on file..."

However, the Commissioner wrote, "So that we may have the record clear, I hope you will tell me whether Dr. Cole's analysis was subsidized in any way by the Calorie Control Council." Kennedy said "it would be appropriate if that information could be supplied for any other comments in this rulemaking proceeding whose sponsorship might otherwise not be known to the public."

In a separate letter to Cole written on June 29, Kennedy noted that he raised the question of whether the Professor's analysis was subsidized by CCC, and said, "I want you to understand that this question is not motivated by any assumptions of impropriety." However, he added that "it is an important part of the process of public evaluation that any sponsorship by an interested party that is not readily apparent to the public be identified."

Saying that he will "welcome" Cole's views, Kennedy invited the epidemiologist to submit his analysis "or an expanded version" during the extended comment period.

Calling the Cole analysis "exactly the kind of thoughtful, critical comments I would expect from a good scientific referee," Kennedy said, "The annoyance you will detect in the tone of my letter to Mr. Kellen obviously relates to the extraordinary material in his letter, and not to the analysis you provided."

Many of the questions raised by Cole and by FDA-ers, the Commissioner said, probably "can be dealt with by the Canadian group."

However, Kennedy said "one of the problems about their manuscript...is that because it is not a full-length manuscript it lacks some information about the selection of controls and other details." The Commissioner added:

> "Because of its preliminary nature, I was not anxious to initiate a round of public discussion. The opportunity to deal with the problem in a more leisurely fashion was foreclosed when, on June 16, Toronto newspapers carried an account of the main results. Washington newspapers pieced together a more complete story from a number of sources unknown to me; FDA shared its copy of the document in confidence with the Chairmen of the relevant Senate and House Subcommittees, and only with them.
>
> "My own public statements since that time, seldom quoted in full, have emphasized the preliminary nature of the findings,

but have noted that in terms of sample size and control selection procedures the Canadian study is distinctively superior to previous and contemporary case-control studies of the same issue."

Saccharin Epidemiology Papers Raise New Questions

FDA last week made available the two recent epidemiology studies on saccharin, their contrasting conclusions giving ammunition to both sides in the controversy. In addition, both papers leave room for additional questions.

The Canadian study on which FDA apparently is relying notes that the numbers in the group of interviewees who used saccharin or other artificial sweeteners were small. Diabetics, who consumed "considerably more artificial sweeteners than the general population," were found to have a reduced risk in the other study by Ernst L. Wynder and Robert Goldsmith of the American Health Foundation. The authors of the Canadian study concluded:

"It appears that although for males, all types of users (of saccharin) are at risk compared to non-users, those with a frequency of use greater than 2,500 tablets per year (approximately 7 per day) for more than three years are at substantially increased risk (5.3).

"Similar significant dose response relationships were seen in males for frequency and duration of use when all artificial sweeteners were considered, rather than just saccharin."

The nine researchers associated with the Canadian study said the "failure to detect increased mortality from bladder cancer in diabetics could be explained by the reduced risk for diabetics observed in the present study when artificial sweetener use was controlled for." They continued, "This in turn could be associated with reduced exposure to bladder carcinogens among diabetics, though we have no evidence in the present study as to the source of any such reduction."

Wynder and Goldsmith concluded, "No association of bladder cancer with artificial sweetener use was found," but added:

"The epidemiologic pattern of bladder cancer cannot be entirely explained on the basis of smoking habits and occupational exposure. It is likely that additional factors such as diet -- possibly in terms of a high intake of protein, fat and/or cholesterol -- are of etiologic significance."

Wynder and Goldsmith said they did find differences between diabetic and non-diabetic populations, but that these differences were not significant. They also

noted, "Among users, cases and controls differed very little in general consumption of artificial sweeteners."

A total of 574 males and 158 females, with an equal number of controls, were interviewed in the Wynder and Goldsmith study, while 632 persons, plus an equal number of controls, were interviewed in the Canadian study.

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NO URGENT NECESSITY FOR COLOR LABELING, HYPERKINESIS COMMITTEE SAYS

The Nutrition Foundation's National Advisory Committee on Hyperkinesis and Food Additives, in a summary of recent work released last week, noted that there are limitations on current evidence but emphasized, "...There are presently no data to suggest that initiation of major changes in food manufacture or labeling is urgently needed."

The report, noting that research had been triggered by the work of Dr. Ben Feingold at Kaiser-Permanente (See FOOD CHEMICAL NEWS, June 27, Page 34), concluded that Feingold's hypothesis of decreased hypertension when color additives were removed from the food of children "was, in general, incorrect, but there might be an occasional young child who genuinely reacts adversely to food colorings in the manner predicted by Dr. Feingold."

A study, by Drs. Keith Connors and Charles Goyette at the University of Pittsburgh, was described in the summary as having been generally negative. However, the summary continued:

> "...An interesting new observation was made on the children who were examined using special tests for attention and distractability one to two hours after ingestion of the challenge materials. Transient increments in attention lasting a few hours were noted with the additive-containing substances but not with the placebo."

The summary also described work at the University of Wisconsin (See FOOD CHEMICAL NEWS, Feb. 9, 1976, Page 5), where investigators found "no difference in behavior between additive-free and additive-containing food bars...except in one child."

A third study by Dr. Ivan Williams and colleagues at the University of Western Ontario and the London Health Unit in Ontario, Canada, was described as having compared both the effects of an additive-free diet and the effectiveness of such a diet in connection with stimulants commonly used for treatment of the children. The summary continued:

"There were some diet effects noted in parent ratings. When the children were on medication, the parent ratings were worse when the children were eating cookies with

artificial food coloring than when they were eating cookies without artificial food coloring.

"The teacher ratings showed strong diet effects. Contrasted with parent ratings, the diet effects for teachers were most marked when the children were on placebo medication. The children ate cookies in the morning and in the afternoon, and the ratings were worse when they were eating the cookies with artificial food coloring than when they were eating cookies free of artificial food coloring. While there are some inconsistencies in the findings, the results based on the teacher ratings suggest the need for further studies for verification."

The summary noted that Feingold "has yet to report the results of blind challenge tests" in his clinic (See FOOD CHEMICAL NEWS, Oct. 4, Page 2) and called this "especially regretful." The summary also noted:

> "It is apparent that what seems on the surface to be a simple research problem, namely the rigorous testing of the Feingold hypothesis to yield a clean yes or no answer, has turned out to be more subtle and complex."

In the long run, the variations in the types of tests being conducted "will help to give better answers," the summary said, but continued that at present comparisons are made more difficult.

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FDA REFUSES ACRYLONITRILE STUDY, QUESTIONS LAB PRACTICES

The Food and Drug Administration has refused to accept a study on the synergistic toxic effects of acrylonitrile and cyanide ion because of deficiencies in laboratory practices detected by agency inspectors.

The study was submitted by Monsanto and concerned work at Younger Laboratories, St. Louis.

Providing a close look at what FDA is searching for in its inspections of labs under the Good Laboratory Practices program, FDA told the lab in a June letter that the agency is "particularly concerned" about the following:

"(1) The lack of documentation of the procedure for dilution of test substances, the lack of documentation of the weighing out of test substances, and the lack of calibration of balances used for weighing compounds.

"(2) Inadequate recording of data.

"(3) The reporting of only 'meaningful' data.

"(4) The use of a pest control substance in the animal rooms, the identity of which is unknown."

The lab was requested to inform FDA within 30 days of the corrections it plans to make. The inspection of the lab was said to have taken place April 4-6.

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AFFI PROPOSES STANDARDS OF IDENTITY, QUALITY FOR FROZEN RASPBERRIES

The American Frozen Food Institute has submitted proposed standards of identity and quality, with provision for label statement of optional ingredients, for frozen raspberries to the Food and Drug Administration.

AFFI explained that the proposal is based on the Recommended Standard for Quick Frozen Raspberries, adopted by the Codex Alimentarius Commission in 1974, with modifications reflecting domestic practices. The standard of quality proposed reflects the U. S. Department of Agriculture's U. S. Grade B standards, AFFI said, explaining, "This level of quality is designed to represent general consumer acceptance

Contrasting the proposed standards with the Codex standard, AFFI said the proposed standard would:

Refer to three varietal types -- Rubus idaeus L. (red or yellow varietal types); Rubus occidentalis (black varietal types); and Rubus neglectus (purple varietal types) rather than just to Rubus idaeus L. (red varietal types);

Apply to all frozen raspberries rather than just those intended for direct consumption without further processing except for repacking, but the quality standard would not apply to "raspberries for manufacturing;"

Exclude provisions for mineral impurities, since these are covered by FDA's unavoidable defects provisions;

Adopt different provisions for color defects and differing tolerances for other defects.

As proposed by AFFI, frozen raspberries would be defined as the "round, properly ripened whole fruit" of one of the three varieties, prepared directly from fresh raspberries or from individually quick frozen raspberries which are stemmed, washed, drained and packed either without a packing medium or with one of the optional packing media specified -- dry or liquid safe and suitable nutritive carbohydrate sweeteners singly or in combination, with water as the liquid ingredient in the liquid sweeteners.

If a dry sweetener or combination of sweeteners is used, "the total soluble solids content of the liquid extracted from the thawed comminuted sample" would be not "more than 35 percent nor less than 18 percent, by weight," as determined by a

procedure specified; for liquid sweeteners the total soluble solids content of the liquid could be not more than 30 percent nor less than 15 percent.

The raspberries could also contain safe and suitable antioxidants as an optional ingredient.

They "are preserved by freezing in such a way that the range of temperature of maximum crystallization is passed quickly. The freezing process shall not be regarded as complete until the product temperature has reached -18° C. (0° F.) or lower at the thermal center of the package."

When packed in "packaged" form, the food would be labeled as "raspberries," preceded or followed by the varietal type, if other than red, such as "yellow," "purple," or "black;" in other forms of packaging, the name is "raspberries for manufacturing," with the name of the food, in each case, to also contain the words "frozen" or "quick frozen."

The standard of quality would provide:

"(1) Stems. Not more than 5 attached or detached stems (stocks) each longer than three mm (0.1 in.) in one dimension per sample unit.

"(2) Extraneous Vegetable Material Measurable by Area. Not more than 4 cm^2 (0.62 sq. in.) of extraneous vegetable material (calyces and leaves or portions thereof), per sample unit.

"(3) Extraneous Vegetable Material Not Measurable by Area. Not more than one piece of extraneous vegetable material not measurable by area (such as grass or weeds) per sample unit.

"(4) Not Well Colored: Minor Blemished: Undeveloped. There may be present per sample unit not more than 15 berries that are not well-colored for the varietal type (the berries are excessively light in color, but not green, due to immaturity or in the case of varietal types other than black raspberries, the berries are excessively dark due to over maturity); that are minor blemished berries (blemishes not exceeding an area of a circle having a diameter of 5 mm (.20 in.) and/or that are undeveloped berries (berries containing shriveled parts in the fruit flesh or drupelets).

"(5) Major Blemished: Dissimilar Varieties. There may be present per sample unit not more than 5 berries that are major blemished (blemishes that exceed the area of a circle having a diameter of 5 mm (0.20 in.); and/or that are of dissimilar varieties (berries that are significantly different in color or shape due to varietal characteristics).

"(6) Completely Uncolored. There may be present per sample unit not more than 1 berry that is completely uncolored (green or whitish in color).

"(7) Disintegrated or Not Intact. There may be present per sample unit not more than 25 percent, by weight, in the case of red, yellow, and purple varietal types and not more

than 20 percent, by weight, of black varietal types, of the drained berries that are disintegrated or not intact (berries in which more than 25 percent of the berry is missing or berries that are crushed, broken, or smashed into small pieces or flattened into a pulpy mass)."

Where the quality falls below the standard of quality, the label could either bear a general statement of substandard quality or, if the raspberries are below standard in only one aspect, the statement "Below Standard in Quality _____," with the blank filled in with the specific reason.

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BATF SPELLS OUT METRIC REQUIREMENTS FOR WINE, SPIRITS

United States measures will be required to be on labels with metric standards of fill until Jan. 1, 1979 for wine, and until January 1, 1980 for distilled spirits, according to a recent Bureau of Alcohol, Tobacco and Firearms (BATF) bulletin (See FOOD CHEMICAL NEWS, March 28, Page 34).

The ATF Industry Circular 77-15 stated that equivalent U.S. measures must be shown on wine bottle labels as follows: "3 liters (101 fl. oz.), 1.5 liters (50.7 fl. oz.), 1 liter (33.8 fl. oz.), 750 milliliters (25.5 fl. oz.), 375 milliliters (12.7 fl. oz.), 187 milliliters (6.3 fl. oz.) and 100 milliliters (3.4 fl. oz.)."

The distilled spirit labelings required were: "1.75 liters (59.2 fl. oz.), 1.00 liter (33.8 fl. oz.), 750 milliliters (25.4 fl. oz.), 500 milliliters (16.9 fl. oz.), 200 milliliters (6.8 fl. oz.), 50 milliliters (1.7 fl. oz)."

The dual labeling can appear either on the bottle ("legally blown, etched, sand-blasted, marked by underglaze coloring...") or on the label, according to the circular. The milliliter is the only metric measurement which may be abbreviated--to "ml." BATF also advised:

--"Informative statements comparing a metric size to the former standard of fill size which will be replaced by it are permissable.

--"The terms 'Magnum' or 'Metric Magnum' may be used in reference to wine when the statement of net contents '1.5 liters (50.7 fl. oz.)' appears on the labels or in the glass.

--"Individual coverings, cartons and other containers of readily removable bottles used for sale at retail (other than shipping container) may display a statement of metric measure without the United States measure."

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PROBABLE BOTULISM RISK FROM LOW NITRITE USE CALLED "UNDERESTIMATED"

The probable toxicity of 0 to 50 parts per million nitrite in cured meat -- because of the formation of C. botulinum spores at those lower levels -- has been "grossly

underestimated," according to researchers at the Swift & Co. Research and Development Center.

Writing in the July-August issue of the Journal of Food Science, R. B. Tompkin and colleagues at the center described a series of seven tests in which varying levels of nitrite were used in the inhibition of deliberately-added C. botulinum in a perishable canned meat product. The issue of how much nitrite is enough is central to current consideration of proposed Agriculture Department regulations (See FOOD CHEMICAL NEWS, July 4, Page 3).

The researchers also said that addition of nitrite at levels greater than 150 p.p.m. "would not appreciably increase the degree of botulinal inhibition under the conditions described." The cans of comminuted meat were subjected to a temperature of 27 degrees Centigrade for more than 100 days.

The Swift & Co. researchers cautioned that there was considerable variation in the tests and that the reasons were unknown.

Two other articles on nitrite appeared in the same issue of the Journal. J. G. Sebranek and colleagues at Iowa State University concluded as a result of taste tests using nitrite and erythorbate:

> "Thus, the effect of various nitrite concentrations was as expected, with significant improvements in color, flavor and overall acceptability as nitrite increased from 0 to 156 p.p.m. The influence of erythorbate on color, flavor or acceptability does not seem to be significant at either 156 p.p.m. nitrite or 52 p.p.m. nitrite."

Below that level, however, the investigators reported, erythorbate did seem to have an effect.

J. I. Gray and colleagues at the University of Guelph, Canada, reported that proline was more important as a precursor of N-nitrosopyrrolidine in cooked pork with nitrite than putrescine. Approximately 27-49% of the N-nitrosopyrrolidine produced by nitrite and the precursors was volatilized during the cooking process, they said.

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COMMISSIONER KENNEDY GIVES FDA "B" IN MANAGEMENT

Food and Drugs Commissioner Dr. Donald Kennedy said he found after three months that the agency is "being managed in a more than acceptable manner," but that some administrative and management changes will be needed.

The Commissioner reported, in a message on "FDA Goals and Priorities" in the July 1977 issue of FDA Today, that he has formed "a small task force to report to

me by August on their examination of our organizational structure and policy-making procedures, looking especially at ways to ensure maximum responsiveness and flexibility and at an optimal division of labor between the Deputy Commissioner and myself" (See FOOD CHEMICAL NEWS, July 4, Page 26).

Any reorganization would be geared to improving "FDA's ability to respond quickly to legitimate demands for change," he said in his message. He said the changes will insure that the agency is responsive to the Commissioner "and that it is generally perceived that the Commissioner does in fact direct the Food and Drug Administration."

He commented, "I am not certain that our present organizational arrangement provides the best possible system to ensure that matters that should be brought to my attention do in fact reach me."

Additionally, he said, bureau directors have been asked "to list projects that are near decision and have the greatest potential for public controversy or agency embarrassment." The lists will be used to assign priorities.

Kennedy noted the need for FDA to establish priorities, and to announce publicly "not only what we will do, but also what we will not do," suggesting: "In the long run, we will be less criticized if we confess the inadequacy of our resources to do everything expected of us, and say flatly where we draw the line."

Although Kennedy had questioned the assertion that the Department of Agriculture is best suited to represent the United States in the Codex Alimentarius Commission (See FOOD CHEMICAL NEWS, May 16, Page 5), in his message Kennedy declared that he supports the Carter Administration's opposition to "turf battles," explaining:

> "We may find that giving away an assignment or responsibility is the best way to deal with it, and I will -- as a matter of policy -- sit down with other agencies as necessary to determine where a certain function fits best, rather than automatically defend historic territory."

Kennedy stressed the need in FDA "of the best science we can find to justify and support sound regulatory decisions," continuing: "I presuppose -- based partially on observation -- that substantial in-house research will be required to get the scientific answers that we need and that are not available from other sources."

"To meet our research and other scientific needs," the Commissioner said, "it seems to me that we must establish positions -- through upgrading and other means -- at intermediate and higher levels, and we must recruit aggressively at major universities for full-time appointees and mid-career fellows."

Additionally, Kennedy said, a single locale for FDA's science laboratories to "bring together laboratories whose scattered locations impede the Agency's scientific efforts" must be sought (See FOOD CHEMICAL NEWS, July 4, Page 21).

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Regulatory procedures must be improved in addition to improving science, Kennedy declared. Noting the recommendations of the Secretary's Review Panel on New Drug Regulation (See FOOD CHEMICAL NEWS, June 6, Page 20), Kennedy commented, "Although I cannot agree with every recommendation of the panel, their reports provide a basis for sensible revisions in FDA new drug procedures that should receive strong political support."

There is a need for "procedural excellence in all areas of FDA responsibility," Kennedy said. However, in his "message" he concentrated on drug procedures "because of the immediate focus placed on that matter by the Secretary's Panel."

Several of the features listed by Kennedy as necessary to an efficient drug approval process could also carry over to any revamping of the food additive approval process, including: limited and formalized contact between agency personnel and industry representatives; clear identification of agency requirements; full public disclosure of safety and efficacy data; and participation of advisory committees -- including public members -- in decision making by the agency.

In the area of FDA personnel, Kennedy noted his earlier memorandum to employees "should help define relationships between FDA and regulated industry as well as lead to sensible guidelines that ensure an employee's right to address the Commissioner or other agency officials on matters of policy outside the purview of Departmental or Civil Service procedures (See FOOD CHEMICAL NEWS, July 4, Page 46).

Kennedy also pledged "an aggressive affirmative action program to achieve better representation of women and members of minority groups."

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FDA STAYS PARTS OF FROZEN DESSERTS STANDARDS; ASKS DATA

The Food and Drug Administration on July 8 stayed the portions of the frozen dessert standards which would permit increased use of casein, caseinates and whey, calling for submission of data within 60 days.

As expected (See FOOD CHEMICAL NEWS, June 13, Page 46), FDA did not promise a public hearing, but said that the additional information is needed for a decision to be made about a hearing.

Publication of the stay late last week may have an effect on the expected effort by Rep. Rose (D-N.C.) this week to tack a statutory standard for ice cream onto the farm bill (See FOOD CHEMICAL NEWS, June 27, Page 48).

The non-controversial parts of the frozen dessert standards (See FOOD CHEMICAL NEWS, April 18, Page 5) were confirmed as effective.

Regarding the controversial "safe and suitable" provision under which additional milk-derived ingredients could be used, FDA concluded "that insufficient data

and information have been made available to make a final decision on the merits of granting the requested hearing..." The agency invited submission of "specific data and information" regarding:

"(a) The asserted effect on the physical and nutritional characteristics of ice cream, frozen custard, ice milk and sherbet that would result from the amended regulations;

"(b) Parameters of the nutritional value variations of milk-derived ingredients allowable under both the current and amended regulations for ice cream, frozen custard, ice milk, and sherbet;

"(c) Parameters of the nutritional value variations of ice cream, frozen custard, ice milk and sherbet made in accordance with the minimum requirements of the current and amended applicable regulations;

"(d) The feasible, practical and most commonly acceptable combinations or blends of nonfat milk solids and/or other milk-derived ingredients that are or could be used to fabricate ice cream, frozen custard, ice milk and sherbet meeting the applicable regulation;

"(e) Nutritional value data and information specifically for calcium, phosphorus, zinc, sodium, protein, vitamins B_{12}, B_6, A, thiamine, riboflavin, and pantothenic acid; and

"(f) Any other pertinent data or information."

Regarding the objections to utilization of a minimum milk protein requirement in lieu of the current minimum nonfat milk solids requirement for ice cream and frozen custard, FDA also concluded that there is insufficient information on which to base a decision about a hearing, inviting "information pertaining to the applicability of the minimum milk protein quantity and quality requirements of the amended regulations."

Also tied in with the casein-caseinate-whey issue is the use by FDA of the term "nonfat milk-derived solids" instead of the term "nonfat milk solids," as well as use of the term "milk-derived solids" in the sherbet standard. These provisions were also stayed pending a "decision on the merits of granting a hearing..."

Ice Milk Provisions on Bulky Flavors Stayed

FDA also stayed the provision of the ice milk standard providing for reduction in milk fat and milk protein when bulky flavors are added. In preparation for ruling on a hearing on this issue, the agency invited "additional data and information about (a) the changes in physical and nutritional characteristics in bulky flavored ice milk as a result of providing for a decrease in milk solids when bulky flavors are used, and (b) why ice milk should not have the same provisions for bulky flavors as ice cream."

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An objection noted that the current ice milk standard does not provide for the reduction when bulky flavors are used. However, FDA said that except for stating this fact, "no additional information was provided in opposition to providing such a decrease."

Without the reduction provisions for bulky flavors, the agency said, "an ice milk manufacturer must (a) formulate and process a different batch of ice milk mix for each variation in kind and quantity of bulky flavor used, or (b) formulate and process an ice milk mix high enough in milk solids so that in no case will the minimum milk solids requirement for the food not be met."

Noting that the current standard for ice cream provides for a decrease in milk solids content when bulky flavors are used, FDA said the change in the ice milk standard would make the standards "uniform."

In discussing the casein-caseinate issue, FDA rejected as a basis for a hearing an alleged potential decrease in the use of domestic milk solids as frozen dessert ingredients. The agency said:

> "The Commissioner agrees that if, due to technological advances, certain components or combinations of components derived from the milk of cows were allowed to compete with historical ingredients such as nonfat dry milk or condensed skim milk, there would be an economic impact on the producers, sellers, and buyers of those ingredients. The Commissioner, however, does not believe that this impact is an issue that can legally be considered in deciding upon the merits of a standard of identity."

In staying the "safe and suitable" provision, FDA noted that implementation of the provision would:

"(a) Remove the current restriction on the use of sweet cheese whey; (b) allow the use of acid cheese whey; (c) provide for the use of modified sweet and acid whey products such as concentrated whey protein, delactosed whey, and demineralized whey; (d) remove the current restrictions on when casein and caseinates may be used; (e) provide for the use of coprecipitates of casein, lactalbumins, and lactoglobulins; (f) allow individual components derived from milk, nonfat milk, sweet or acid cheese whey, and whey from the manufacture of casein to be blended together as a substitute for nonfat milk solids from milk, nonfat milk, or nonfat dry milk, and ... allow the use of any form of butterfat or milk fat, including milk fat from whey cream extracted from cheese whey."

Listing the dairy ingredients permitted under the current standard, FDA noted that these include whey, casein, and caseinates.

The proposed amendment would not set specific limits on use of nonfat milk solids and other milk-derived ingredients, leaving the option to the manufacturer so long

as the minimum requirements of the standards are met and "the basic physical and nutritional characteristics are not changed," FDA said. The agency also said the amendment would not set specific limitations that would prevent all of the nonfat milk solids and/or other milk-derived ingredients from being obtained from a single safe and suitable substance derived from milk.

The current standards allow nonfat milk solids to be obtained from buttermilk, delactosed nonfat milk, or nonfat milk treated with sodium hydroxide and disodium phosphate, so long as requirements of the standards are met, FDA said, noting that these practices "may not be feasible or practical" because of physical or nutritional characteristics.

The present standard limits cheese whey to 25% of the nonfat milk solids, and provides for use of casein and caseinates after the minimum requirements for milk solids have been met. FDA said these restrictions "were primarily based on previous technological inabilities to (a) utilize more cheese whey, (b) produce modified whey products, and (c) formulate blends of milk-derived ingredients utilizing casein or caseinates."

FDA said that milk varies in composition and nutritional value so that "ingredients obtained from milk also vary in composition and nutritional value."

"The physical and nutritional characteristics of ice cream, frozen custard, ice milk and sherbet vary depending on the ingredients or blend of ingredients used to fabricate a food meeting the minimum requirements of the applicable regulation," FDA said, adding, "This would be so whether the minimum requirement of the current or amended regulations were met."

Discussing the objection to use of the minimum milk protein requirement, FDA said the objection was based on "recognition and acceptance...given to ingredients from the nonfat milk ingredient category as well as those from the milk-derived ingredient category as a means of meeting one of the minimum compositional requirements..."

The agency explained that the minimum milk protein level was used in lieu of the minimum nonfat milk solids requirement "to provide an analytical means to enforce the nonfat milk solids and/or other milk-derived ingredients requirement..." FDA said the minimum milk protein requirements were established "so as to be equal to the average minimum milk protein present when all of the other minimum requirements... were met."

Conceding that there is controversy over the use of the Protein Efficiency Ratio (PER), FDA said it is used comparatively in the standards, explaining, "Whatever the value of PER, its use is relative, e.g., PER of whole milk protein (which is 108% that of casein) versus any blend of proteins of nonfat milk and other milk-derived ingredients (which must also equal 108% of that of casein)."

FDA promised to "give appropriate consideration to any formal proposals suggesting more meaningful methods and procedures to evaluate relative protein quality."

Calling for data within 60 days on the "safe and suitable" provision, use of the minimum milk protein requirement, use of the term "nonfat milk-derived solids," and the ice milk reduction provision when bulky flavors are used, FDA stayed the applicable portions of the revised standards. Meanwhile, the nonfat milk solids requirements and the limitations on use of whey and caseinates remain in effect.

July 1, 1979, Effective Date Confirmed

Confirmed as effective were the revised standard for water ices, and the noncontroversial portions of the revised standards for ice cream, frozen custard, ice milk, and sherbet. FDA said compliance may have begun on June 13, 1977, and that it is mandatory for products initially introduced into interstate commerce on or after July 1, 1979.

Noting that it received 34 responses to the amended standards (See FOOD CHEMICAL NEWS, May 16, Page 25; May 30, Page 35; June 6, Page 13; and June 20, Page 49), FDA said that 6 were comments, 14 raised objections but failed to request a hearing, and 14 contained both objections and hearing requests. One of the 34 responses contained all of the objections, and hearing requests, and FDA said this response was supported by 30 interested parties.

In response to an objection to amending the standard without issuing an Economic Impact Statement, FDA said the proposal to amend the standard was published July 25, 1974, while the Executive Order and Office of Management and Budget circular require Impact Statements only for agency proposals published after Nov. 27, 1974. The agency said "all proposals, as well as final regulations based on proposals, published before Nov. 27, 1974, are exempt from economic impact evaluation."

FDA also rejected an objection to the ingredient declaration requirements, saying it "was based on a misunderstanding of the regulations and does not raise an issue of fact that warrants a hearing." The objector apparently believed that such ingredients as casein, caseinates, and modified whey would not have to be declared in the ingredient statement. The letter also alleged an error in the omission of buttermilk from the list of ingredients allowed to be declared as "milk fat and nonfat milk."

FDA said that all the ingredients in the frozen desserts are "optional," and that all of them must be declared, with use of common or usual names unless ingredients fall into the "milkfat and nonfat milk" category. The agency said that casein, caseinates and other milk-derived ingredients would have to be "declared by their common or usual name since they would not be entitled to the alternative labeling..."

Buttermilk was purposefully omitted from the list of ingredients which can be declared as "milkfat and nonfat milk," FDA said, since the agency does not consider liquid, concentrated or dried buttermilk to fit into that ingredient category.

Firm Given Temporary Permit for Chunky Pears

Meanwhile, FDA on July 8 granted to Libby, McNeill and Libby a temporary permit for test marketing "chunky" canned pears. The permit runs for 15 months beginning no later than 90 days after the July 8 Federal Register publication.

The product would deviate from the food standard in that pears would be cut into units predominantly greater than 1/2 inch and less than 1-3/4 inches in the longest dimension. As currently permitted by the canned pear standard, the product would be packed in heavy syrup and would contain artificial strawberry flavor.

Under the permit, 50,000 cases of 24 16-ounce cans would be produced by the firm at Sunnyvale, Calif., and test marketed in Western New York, Iowa, and Nebraska, and in Erie, Pa., and Moline and Rock Island, Ill. The product would be labeled "Chunky Pears," and the prinicipal display panel would bear the statement "In heavy syrup" (See FOOD CHEMICAL NEWS, March 7, Page 48).

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FAO/WHO TO COLLECT MONITORING DATA ON FOOD CONTAMINANTS

The Joint FAO/WHO Food and Animal Feed Contamination Monitoring Programme has asked 13 countries with national monitoring programs for chemical contaminants to submit data from their studies.

The monitoring data from the national programs will then be utilized to estimate intakes of specific chemical contaminants from food and to provide Codex Alimentarius committees with information on which to base maximum limits for specific contaminants in the development of international food standards.

Thirteen countries including the United States are participating in the pilot program at present, with the possibility of other countries joining the program as their monitoring programs are established.

Contaminants on which data will be submitted in the first phase of the program are the organochlorine pesticides DDT and its breakdown products DDE and TDE, BHC, heptachlor/betaheptachlor epoxide, aldrin/dieldrin, and HCB, as well as PCBs (polychlorinated biphenyls) and lead.

Initially, monitoring data for the organochlorine pesticides and PCBs will be submitted only for whole fluid milk, whole dried milk, butter and human milk, and data for lead only for canned fruit, canned fruit juice including concentrates, canned vegetables and canned milk (in cans with lead soldered seams).

It is expected that the program will be expanded to include data on cadmium and data on more products for the pesticides, PCB and lead.

DSW 329752

Collaborating Centers for food contamination monitoring have been designated in all thirteen participating countries -- Austria, Canada, Denmark, Federal Republic of Germany, Hungary, Ireland, Japan, Netherlands, Poland, Sweden, Switzerland, United Kingdom and U. S. The Food and Drug Administration's Bureau of Foods has been designated as the official U. S. center.

Dr. Charles Jelinek, Deputy Associate Director for Technology in FDA's Bureau of Foods, attended the FAO/WHO meeting in Geneva in June.

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EFFECTIVE DATE FOR DIETARY SUPPLEMENT REGULATIONS POSTPONED

The Food and Drug Administration on July 8 postponed the effective date of the regulations governing dietary supplements (See FOOD CHEMICAL NEWS, April 25, Page 45) from Jan. 1, 1978, to July 1, 1979.

The National Nutritional Foods Association, the National Association of Pharmaceutical Manufacturers, and Solgar Co. had petitioned for a stay of the regulations (See FOOD CHEMICAL NEWS, June 6, Page 41), asking that the effective date be dependent on completion of judicial review.

The three parties, represented by the New York law firm of Bass, Ullman & Lustigman, have asked the U. S. Court of Appeals for the Second Circuit to review the regulations (See FOOD CHEMICAL NEWS, May 16, Page 2).

Adopting the July 1, 1979, deadline for products introduced into commerce, FDA noted that this is the uniform effective date for food labeling regulations issued after April 1, 1977. The agency said the new deadline should provide time for judicial review and for compliance.

However, if the judicial review is still pending after July 1, 1978, FDA said it will entertain petitions for more time.

As it did previously, the agency said voluntary compliance with the requirements could begin immediately.

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FDA EXTENDS HEARING REQUEST TIME ON REVOCATION OF PEN-STREP PREMIXES

The Food and Drug Administration's proposal for revocation of penicillin-streptomycin premix clearances will be open for hearing requests until Aug. 10.

Pfizer had requested the 30-day extension (See FOOD CHEMICAL NEWS, June 27, Page 2).

DSW 329753

Meanwhile, in case the revocation goes to a hearing, FDA has designated two sets of government attorneys as advisors: (1) Advisors to the Commissioner -- Chief Counsel Richard Merrill, Tom Scarlett, Margaret Gilhooley, Jess Stribling, Don Beers, Edward Basile and Fred Degnan; (2) Advisors to the Bureau of Veterinary Medicine -- Jeff Springer, Edward Allera and Richard Geyer. Designation of the advisors is necessary under rules of practice which forbid consultation between the two groups on matters concerned with the possible hearing.

Gentian Violet Mail Campaign Urged

Meanwhile, FDA was receiving a storm of Congressional mail on one veterinary drug matter, and another mail campaign to Congress was being urged.

On the latter issue, Naremco was asking industry to write FDA and Congress urging the agency to issue a regulation permitting continued use of gentian violet.

The firm made the appeal after a U. S. District Court issued a final ruling that two Naremco products are "new animal drugs" and may not be marketed without approved New Animal Drug Applications.

The Court had ruled after the U.S. Court of Appeals for the 8th Circuit upheld FDA in an injunction action against the firm and remanded the case to the lower court (See FOOD CHEMICAL NEWS, May 9, Page 45).

The Congressional storm of letters concerned FDA's decision to ban feed uses of penicillin and tetracyclines (See FOOD CHEMICAL NEWS, May 30, Page 38 and 55, and June 20, Page 28). "Inquiries" have been received from at least 77 legislators.

Dr. Mercer to Leave Bureau of Veterinary Medicine

In another development, Dr. H. Dwight Mercer, Deputy Director of the Division of Veterinary Medical Research, is leaving FDA's Bureau of Veterinary Medicine to become a professor of pharmacology and toxicilogy at Mississippi State University' College of Veterinary Medicine. He has been with FDA 11 years.

Under the proposed BVM reorganization (See FOOD CHEMICAL NEWS, June 7, 1976, Page 37), Mercer was slated to be director of the Division of Drugs for Swine and Minor Species in the new Office of Scientific Evaluation. The new positions in the reorganized BVM were formally published in the July 8 Federal Register.

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FDA TO CONTRACT FOR 120 MORE MUTAGENICITY TESTS

A request for proposal (RFP) for mutagenicity tests on 120 food chemicals, most of which are included in the Food and Drug Administration's review of "generally recognized as safe" substances, has been issued by the agency. The contract,

which will test chemicals for "mutagenic potential in bacteria and yeast," will bring the total number of Tier 1 tests in the review for mutagenicity to approximately 320.

To date, 25 substances have been selected for Tier 2 tests in Drosophila. These were selected because of positive responses in Tier 1 or because of widespread use. Some chemicals with negative results were thrown in to check for false negatives.

With most of the reports back on the Tier 2 tests, only FD&C Red 2 has had a positive result.

Tier 2 dominant lethal testing is currently being done on another nine chemicals, which had unclear results in Tier 1. These are ammoniated glycyrrhizin, sodium carrageenan, gum arabic, potassium nitrate, potassium nitrite, sodium bisulphite, sodium metabisulphite, ferrous sulfate and butylated hydroxytoluene.

Heritable translocation testing is underway for six substances in Tier 3 tests selected for either ambiguous results or heavy use. These chemicals are: FD&C Red 40, ammonium saccharin, calcium saccharin, Red 2, oil of mustard and oil of nutmeg.

Previous heritable translocation tests on manganese sulphate, sodium erythorbate, sodium acid pyrophosphate, and sodium saccharin were all negative.

FDA Negotiating Contract to Distribute Information on Saccharin

FDA is currently negotiating a contract with Supermarket Communications Systems, Inc., for distributing information on saccharin in grocery market displays as an addition to an earlier contract. FDA plans to distribute reprints on saccharin from its magazine FDA Consumer.

The agency has also proposed continuation of a study on the pathogenicity of Escherichia coli isolated from foods, by the New England Medical Center Hospital.

A $35,000 contract has been let by FDA to the University of Wisconsin to study mechanisms of asborption of lead.

FDA has also announced a request for proposal for analysis of frozen homogenized shellfish meats for 11 trace metals: antimony, arsenic, cadmium, copper, lead, manganese, mercury, molybdenum, selenium, tin and zinc.

The National Cancer Institute has issued RFPs for a laboratory animal study on the effects of protein types on carcinogenesis and a survey of cancer incidence among U. S. vegetarians.

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DSW 329755

FOUR MORE PESTICIDE ADJUVANTS EXEMPTED

The Environmental Protection Agency on July 8 finalized its proposal to exempt four more inert (or occasionally active) adjuvants for pesticide formulations from tolerance requirements (See FOOD CHEMICAL NEWS, March 21, Page 2).

By cross-reference the adjuvants are exempted from food additive tolerance requirements under §182.99 for adjuvants for pesticide chemicals.

Exempted when applied to growing crops or to raw agricultural commodities after harvest was monoammonium phosphate, when used at not more than 3.75% by weight in formulations with aluminum phosphide for postharvest fumigation. The exemption was requested by Research Products, and EPA noted that it is considered "generally recognized as safe" by the Food and Drug Administration as a miscellaneous food substance.

Also exempted when used in formulations applied to growing crops or to commodities after harvest was sodium α-olefin sulfonate (sodium (C_{14}-C_{16}) olefin sulfonate), when used as a surfactant or related adjuvant of surfactants. The exemption was requested by Lakeway Chemicals. EPA said it was determined to be safe on the basis of 2-year rat-feeding studies, noting that the sulfonate constituent was previously cleared.

Exempted from tolerance requirements when applied to growing crops only was α-alkyl(C_{10}-C_{12})-omega-hydroxypoly(oxyethylene)poly(oxypropylene) copolymer with a poly(oxyethylene) content of 11-15 moles, and a poly(oxypropylene) content of 1-3 moles. The adjuvant is to be used as a surfactant and related adjuvant of surfactants. The exemption was requested by BASF Wyandotte. EPA said the substance was determined to be safe on the basis of long term studies, and added that there is no hazard from breakdown products.

Proposal on Adjuvant Related to Saccharin Withdrawn

(Phthalocyaninato)(2-))copper -- C. I. Pigment Blue No. 15 -- was also exempted when used in formulations applied to growing crops as a coloring agent or pigment when used in low-density plastic films. Dow Chemical requested the exemption. EPA said there is no reasonable expectation of residues on raw agricultural commodities.

The agency also revised the exemption previously granted for polyoxyethylated primary amine (C_{14}-C_{18}) where the fatty amine is derived from animal sources, the adjuvant contains 3% water, and the poly(oxyethylated) content averages 20 moles. The limits on use of the adjuvant as a surfactant were revised to permit it to be applied prior to planting of any crop, or as a directed spray around the base of any crop.

The exemption for use on growing crops had previously limited use as a directed spray to the base of citrus, pome fruit, small fruit and berries, tropical fruits with inedible peel, tree nut crops, leafy beverage crops, and seed beverage crops.

The change in the exemption was requested by ICI United States. EPA said safety was established in 90-day dog and rat feeding studies.

However, EPA withdrew its proposal to exempt from tolerance requirements 1,2-benzisothiazolin-3-one used as a preservative at 1% of formulations applied to growing crops. A comment had said the adjuvant is related to saccharin, which is now suspect as a possible carcinogen, urging that the exemption not be granted until the saccharin situation is settled. EPA apparently agreed. The exemption had been requested by ICI United States, and EPA had said that no mammalian toxicity was shown in subacute rat and dog feeding studies.

Feed Additive Tolerance Extended

The Food Additive Order for 0-ethyl S,S-diphenyl phosphorothioate was amended July 8 to extend a tolerance of 0.3 p.p.m. in rice hulls used for feed from May 13, 1977, to June 20, 1978. The §561.231 clearance is tied to an experimental use permit.

The food additive tolerance for residues of the fungicide -- which is known as edifenphos -- had been Petitioned by Mobay Chemical's Chemagro, which requested the extension. At the same time, EPA extended a temporary pesticide tolerance for residues of the fungicide of 0.1 p.p.m. in or on rice grain.

EPA on July 8 proposed setting a food additive tolerance for residues of dalapon of 0.2 p.p.m. in potable water when it is present from application of dalapon sodium-magnesium salt mixtures to irrigation canals and ditch banks in the Western U. S. in Bureau of Reclamation projects. The agency proposal, which is open for comments and/or advisory committee requests for 30 days, was based on a Food Additive Petition filed by the U. S. Department of Interior (See FOOD CHEMICAL NEWS, June 25, 1973, Page 45). The Petition had been amended on July 26, 1976.

The herbicide is 2,2-dichloropropionic acid. At the same time it proposed the food additive tolerance, EPA also proposed a number of pesticide tolerances for residues in or on raw agricultural commodities.

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FTC SAID TO HAVE IGNORED POWERS ON AD SUBSTANTIATION, CORRECTIVE ADS

The Federal Trade Commission has failed to use effectively its powers to require ad substantiation and corrective advertising, the House Committee on Government Operations said in a critical report released today (July 11).

The report, based on an investigation by the Consumer Affairs subcommittee of Rep. Rosenthal (D-N.Y.), also made a series of recommendations for speeding FTC procedures and making the agency more responsive to consumer petitions. At the same time, the Committee chided the ad review program of the Council of Better Business Bureaus.

DSW 329757

"Additional views" from Rep. Brown (R-Mich.) voiced strong objections to the agency's pending Trade Regulation Rule on nutrition (See FOOD CHEMICAL NEWS, May 9, Page 40; and July 4, Page 26).

FTC is using an internal standard on corrective advertising that is too strict, the report said, noting that the remedy has been sought in only five cases since 1974 and stating:

> "The requirement that advertising play a substantial role in creating the false belief (in the minds of consumers) imposes a significantly higher burden in establishing the relationship between the ad and consumer beliefs than is required by the law.
>
> "If affirmative relief is warranted to correct false impressions for which a respondent is only in part responsible, there is no reason why corrective advertising orders should be issued only when a respondent has substantially contributed to a false impression."

The selectivity of FTC in asking for substantiation of material in ads has led, the report said, to a weakening of the "deterrent" value of the program.

The report saw another problem, the lack of availability to the public of substantiation data. "The problem of putting the substantiating data in a form which would be usable to examiners has plagued the program since it began," the report said, "and yet there has been no effort to solve it."

Without offering a "solution," the report noted that the complex nature of the ad substantiation program makes it a time-consuming one. "This means that the ads have stopped well before the decision is made to sue the advertiser," the report noted.

FTC's "affirmative disclosure" program also "has been floundering since its inception," said the report, although the subcommittee saw the program as "among the most valuable and effective" tools available to the Commission. "Yet," the report continued, "aside from a large amount of resources devoted to the food nutrition rule, little has been done to make affirmative disclosure truly effective."

In its section on FTC's advertising programs, the report also took a look at the voluntary program of the Council of Better Business Bureau National Advertising Division's National Advertising Review Board, questioning "whether competitor inspired complaints should be taking up so much of the NAD's very limited resources" and stating:

> "... Of 902 complaints received over four years, 564 were found to be adequately substantiated or administratively dismissed. In addition, another 256 cases were dismissed

> because advertisers agreed to the NAD requested modification or because the advertising was discontinued anyway. The numbers indicate that the chances of an advertiser having to change advertising as a result of an NAD investigation are very slim."

Another section of the report addressed "delays in rulemaking" and called for Congressional action on HR 3816 (See FOOD CHEMICAL NEWS, Feb. 28, Page 34), which, among other things, would, the report said, "help to reduce investigatory delays in the rulemaking process by providing civil penalties for failure to comply with Commission subpoenas and more carefully define the criteria for review of such subpoenas."

Characterizing the present FTC time lags between announcement of investigations and the promulgation of rules as "excessive," the report recommended that:

"The Commission take immediate action to reduce delays associated with the rulemaking process in the following ways -- (a) The wide discretion to extend comment time and postpone hearing dates should be narrowed, extensions and postponements should be permitted only when hardship to participants can be demonstrated; (b) Commissioners should be required to vote on rulemaking proposals within 30 days after submission by the staff; (c) Rulemaking investigations should be limited to one year...; (d) Make greater use of outside petitioners in the investigatory process."

In its relationships with consumers, FTC was said to be like many other agencies -- "overgrown, insular, and ill-equipped to respond to active outside participation in their work."

The subcommittee recommended that FTC's responses to citizen petitions always provide reasons for denials and that FTC should have an appeals process for individuals or groups who feel their petitions have been wrongly denied.

"It is very difficult to locate petitions at the Commission once they are received," the report said, adding, "An internal procedure for keeping track of petitions is essential." The report continued:

"With respect to organized public interest organizations who regularly petition the FTC, it would seem that greater advantage could be taken of their investigatory effort and their direct relationship to consumers and consumer problems. By instituting a formal petition framework which requires some of the kinds of preparation that the Commission staff would have to do anyway, access would be improved, staff time could be saved and rulemaking would address specific consumer complaints as well as staff proposals."

The "additional views" of subcommittee member Brown noted that FTC's proposed nutrition rule "would require all food manufacturers who advertise their product as having nutritional value to spell out the nutrition content in the ad." Brown said he doubted that FTC's jurisdiction would stretch that far and said, "It would be far more efficient if the FTC simply required advertisers making nutritional claims to direct consumers to read the labels on the product."

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