To [illegible] file - [illegible]

W. A. K.

APR 19 1974

JOSEPH E. KELLER
JEROME H. HECKMAN
CHARLES M. MEEHAN
WILLIAM H. BORGHESANI, JR
ROBERT R. TIERNAN
WAYNE V. BLACK
DAVID L. HILL
MARTIN W. BERCOVICI
EDWIN B SPIEVACK
PETER M NEMKOV
JOSEPH E. HADLEY
CAROLE C. HARRIS
WILLIAM W. PUGH

LAW OFFICES
KELLER AND HECKMAN
1150 17TH STREET, N. W.
SUITE 1000
WASHINGTON, D. C. 20036

TELEPHONE
202 296-2700
CABLE ADDRESS "KELMAN"

April 16, 1974

Dr. Karl A. Hochschwender
American Hoechst Corporation
Route 202-206 North Bridgewater
Post Office Box 2500
Somerville, New Jersey 08876

Re: Proposed Regulation of Food-Contact Articles in the Household; 39 Fed. Reg. 13285, et seq.

Dear Karl:

We have reported several times recently that FDA was considering the revocation of the so-called "housewares exemption" under which utensils, dinnerware and similar articles used in the home were exempt from the Food Additives Amendment of 1958. The formal FDA action in this connection by means of a proposed Rule Making was published in the Federal Register on April 12, 1974. We are enclosing copies of the pertinent pages from the Federal Register for your ready reference. It will be apparent to you that in this proposed Rule Making the Food and Drug Administration is asserting jurisdiction over dinnerware, utensils and other housewares, but is also once again reaffirming that if a substance does not migrate under intended conditions of use, it is not a food additive.

As we see it, in its citation of legislative history in the preamble to this proposal, the Food and Drug Administration has gone to almost tortuous care to rationalize away and thereby minimize the significance of the explicit statements expressing Congressional intent to the effect that dinnerware or utensils were not intended to be the subject of coverage under the 1958 Food

Additives Amendment. Nevertheless, we believe that in light of recent Supreme Court decisions, it is not unreasonable to anticipate that the FDA position would be upheld by the courts should its jurisdiction be challenged in a case in which a health hazard was shown to exist.

Although the Food and Drug Administration refers to "no migration" in the preamble, and uses the statutory definition of a food additive in the proposed regulation which implies that a substance that does not migrate is not a food additive, FDA still has not defined "no migration" in operational terms. In following up on this, I discussed the situation in some detail and was advised by Peter B. Hutt, Assistant General Counsel of the Department of Health, Education and Welfare (in effect, General Counsel for FDA) that the time might be appropriate for filing a Food Additive Petition that would effectively define "zero migration" for indirect additives.

It is our intention to prepare such a Petition promptly to be able to circulate a draft along with draft Comments on the subject proposed Rule Making for your consideration. In this connection, we are requesting those receiving copies of this letter who wish to do so to submit to us your suggestions for the preparation of Comments. In order to circulate draft Comments and leave time to prepare final Comments within the permitted sixty day period, we are requesting your initial responses by May 1, 1974.

We plan to circulate draft Comments embodying any recommendations we might receive and a draft Petition to establish a "zero" standard for migration as close to May 15 as we can. In the meantime, as we await your suggestions, we hope that those of you who have any questions will not hesitate to contact us.

Cordially yours,

George A. Beckmann

Enclosures

cc: To All Members of SPI Food, Drug
and Cosmetic Packaging Materials Committee

in Puerto Rico, including Industry Committees Nos. 118, 119–A, 119–B, 120–A, 120–B, 121–A, 121–B, and 121–C and gave notice of dates of investigations and hearings.

The purpose of the hearings was to review the wage rates in those industries which were below $1.60, the then highest minimum rate under the Fair Labor Standards Act, except in agriculture where minimum rates below $1.30 were to be considered. Under section 5(d) of the Act, the Secretary is obliged to furnish to such committees such data as he has available on the matters referred to the committees. Section 511.6, Title 29, Code of Federal Regulations prescribes the use of surveys. As the result of the enactment of the Fair Labor Standards Amendments of 1974, Pub. L. No. 93–259, April 8, 1974, the data obtained in surveys in industries are now inadequate; the criteria for use in recommending wage rates are changed substantially, and the hotel and restaurant industries wage rates have been increased to those in the various States.

Accordingly, pursuant to section 5 of the Fair Labor Standards Act of 1938 (29 U.S.C. 205) as amended, Reorganization Plan No. 6 of 1950 (3 CFR 1949–53 Comp. p. 1004), and 29 CFR Part 511, I postpone the meetings of Industry Committees Nos. 118, 119–A, 119–B, 120–A, 120–B, and 121–A. New dates for the convening of the postponed industry committees will be published in the FEDERAL REGISTER within the next few weeks. These industry committees will hold their meetings within the period between September 1, 1974 and December 15, 1974. Industry Committees Nos. 121–B and 121–C for the Hotels and Restaurant Industries are dissolved.

Signed at Washington, D.C., this 9th of April 1974.

PETER J. BRENNAN,
Secretary of Labor.

[FR Doc.74–8482 Filed 4–11–74;8:45 am]

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

[21 CFR Part 121]

SUBSTANCES IN FOOD-CONTACT ARTICLES IN THE HOUSEHOLD, FOOD SERVICE ESTABLISHMENTS, AND FOOD DISPENSING EQUIPMENT

Food Additive Status

Since enactment of the Food Additives Amendment of 1958 (September 6, 1958, Pub. L. 85–929, 72 Stat. 1784), letters and oral opinions have at times been issued by personnel of the Food and Drug Administration advising that ordinary houseware articles such as cutting boards, pots and pans, and eating utensils, as well as agents used to clean such housewares, are not subject to regulation under section 409 of the Federal Food, Drug, and Cosmetic Act (72 Stat. 1785; 21 U.S.C. 348). The FDA has also had a well-established regulatory policy that lead (or other heavy metals) in pottery dinnerware, in enamelware, or in pewter articles, which may migrate to food held in the dinnerware (or enamelware or pewter) and poison the consumer, is subject to regulation as a "food additive" within the meaning of section 201(s) of the act (21 U.S.C. 321). Food additive regulations have been promulgated governing numerous substances used in food-contact surfaces, and in sanitizing solutions for such food-contact surfaces, in 21 CFR Part 121, Subpart F.

Because of resulting confusion with regard to the applicability of the Federal Food, Drug, and Cosmetic Act to various houseware, food service, and food dispensing products, including cleaning agents, the Commissioner has determined that it is in the interest of efficient enforcement of the act to promulgate a regulation articulating the scope of the food additive provisions of the act with regard to such products.

The definition of a food additive is extremely broad and easily covers all substances which may reasonably be expected to migrate to food from food-contact articles. Section 201(s) provides that:

> The term "food additive" means any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food (including any substance intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food; * * *), if such substance is not generally recognized, among experts qualified by scientific training and experience to evaluate its safety, as having been adequately shown through scientific procedures * * * to be safe under the conditions of its intended use; * * *.

This statutory language provides no basis for an exemption for any houseware, food service, or food dispensing article or cleaning agent, and shows clearly that Congress meant to regulate all substances not generally recognized by experts as having been shown to be safe which become or which may reasonably be expected to become, directly or indirectly, a component of any food unless specifically exempted by section 201(s). (Although color additives are specifically exempted from the definition of food additives by section 201(s)(3), they are regulated by sections 706 and 402(c) of the act (21 U.S.C. 376, 342) regardless of intended use. See 21 CFR 8.1(f).)

The legislative history of the Food Additives Amendment of 1958 also shows that Congress recognized and intended that all substances which may reasonably be expected to become a component of any food are "food additives" (unless specifically exempt under section 201(s) of the act). Both the House and Senate Reports on the Food Additives Amendment of 1958 contain the following text (House Report No. 2284, 85th Cong., 2d sess., p. 3, July 28, 1958; Senate Report No. 2422, 85th Cong., 2d sess., p. 5, August 18, 1958):

> The legislation covers substances which are added intentionally to food. These additives are generally referred to as "intentional additives."
>
> The legislation also covers substances which may reasonably be expected to become a component of any food or to affect the characteristics of any food. These substances are generally referred to as "incidental additives."
>
> The principal examples of both intentional and incidental additives are substances intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food.
>
> On the other hand, substances which may accidentally get into a food, as for example paints or cleaning solutions used in food processing plants, are not covered by the legislation. These additives are generally referred to as "accidental additives," since these substances if properly used may not reasonably be expected to become a component of a food or otherwise to affect the characteristics of a food.

These statements make it clear that Congress intended to regulate all substances (except those generally recognized as safe or specifically exempted by section 201(s) of the act) which become or which may become a component of food by any means other than purely accidental contamination.

The House Select Committee to Investigate the Use of Chemicals in Food and Cosmetics which originally recommended a food additives amendment showed a similar desire for providing the strongest possible consumer protection through comprehensive food additive legislation. The committee's report to the Congress (House Report No. 2356, 85th Cong., 2d sess.), recommended:

> * * * the [food additive] legislation should provide that evidence that the chemical is safe, and does not produce harmful chemical reactions in the end food product, should be submitted to the Food and Drug Administration for clearance before the chemical is utilized.

Several manufacturers of food packaging and wrapping materials testified at the hearings on the Food Additive Amendment of 1958 and, while some favored and others opposed the legislation, it was generally recognized that substances used to package and hold food would be subject to the new legislation where migration occurred. See, for example, the statement by Frederick W. Leinbach, representing the American Paper & Pulp Association, "the overall national association of the paper and pulp industry," speaking with regard to packaging materials:

> If there are extractables, if those materials could reasonably be expected to become a component of the packaged food, they then become additives, and we feel they should be treated as additives. [Hearings Before a Subcommittee of the Committee on Interstate and Foreign Commerce, House of Representatives, Eighty-fifth Congress, on Bills To Amend the Federal Food, Drug, and Cosmetic Act with Respect to Chemical Additives in Food.]

Congressman John Bell Williams, the chairman of the subcommittee which prepared the food additive legislation reflected this understanding in the congressional debate on the bill:

> Since the food additive bill, H.R. 1321, passed the House, I have received an inquiry as to how this legislation affects the packaging industry. Of course, packaging

ASI-PR 0002085

ordinarily is not intended or reasonably expected to become a part of food and therefore would not come under the bill. The term "otherwise affecting the characteristics of any food" refers to an effect not generally recognized as safe among experts qualified by scientific training and experience to evaluate the safety of food additives; but innocuous effects of packaging, such as protection from dirt, retarding moisture loss, preserving shape, providing convenience in use, handling, and storage, and the like, would not be covered. [Congressional Record of August 23, 1958, 85th Cong., 2d sess.]

Similarly, Congressman Williams also stated that ordinary housewares would not be subject to the new law:

This bill is not intended, for example, to give the Food and Drug Administration authority to regulate the use of components in dinnerware or ordinary eating utensils. [Congressional Record, 104:17418.]

Thus, ordinary inert articles from which no migration to food occurs are clearly not subject to the act, but there was no congressional intent to exempt all food-contact articles used in the household, food service establishments, and food dispensing equipment.

Other provisions of section 409 of the act also manifest a strong congressional desire to regulate all intended uses of food additives. Section 409(a) provides that:

A food additive shall, with respect to any particular use or intended use of such additives, be deemed to be unsafe * * * unless—

(1) it and its use or intended use conform to the terms of an exemption * * * pursuant to subsection (i) [for investigational use] * * *; or

(2) there is in effect, and it and its use or intended use are in conformity with, a regulation issued under this section prescribing the conditions under which such additive may be safely used.

Section 409(b) provides that:

(1) Any person may, with respect to any intended use of a food additive, file with the Secretary a petition proposing the issuance of a regulation prescribing the conditions under which such additive may be safely used.

(2) Such petition shall * * * contain—

* * * * *

(B) a statement of the conditions of the proposed use of such additive * * *

* * * * * *

(D) a description of practicable methods for determining the quantity of such additive in or on food, and any substance formed in or on food, because of its use; * * *

These sections are clear. They give no indication that some intended uses are to be regulated while others are not. To the contrary, they show a definite Congressional concern for additives in or on food regardless of how they got there.

When Congress intended to exempt certain substances from the coverage of the act it had no difficulty making such intent readily apparent. Thus, in section 201(s) of the act it specifically provided that the term "food additive" does not include:

(1) a pesticide chemical in or on a raw agricultural commodity; or

(2) a pesticide chemical to the extent that it is intended for use or is used in the production, storage, or transportation of any raw agricultural commodity; or

(3) a color additive; or

(4) any substance used in accordance with a sanction or approval granted prior to * * * [September 6, 1958] pursuant to this Act, the Poultry Products Inspection Act * * * or the Meat Inspection Act * * *; or

(5) a new animal drug.

Had Congress meant to exempt specific articles such as dinnerware and cooking utensils from the coverage of the act, therefore, it would have been a simple matter for it to do so.

Finally, section 409(c)(5) of the act provides that:

In determining * * * whether a proposed use of a food additive is safe, the Secretary shall consider among other relevant factors—

* * * * *

(B) the cumulative effect of such additive in the diet of man * * *

It is not possible to make an accurate determination of the cumulative effect of an additive without taking into account all means by which that additive may reasonably be expected to enter man's diet. Any reports of adverse effects resulting from migration of unsafe chemical additives from articles such as dinnerware and eating utensils would require prompt regulatory action. Therefore, to exempt dinnerware, eating utensils and other houseware, food service, and food dispensing articles which may reasonably be expected to contribute significant amounts of harmful additives at the final and, arguably, most critical stage of food processing (i.e., immediately before being ingested by the consumer) at the very time when technological advancements have vastly improved methods of detection and evaluation of their effect in man, would be in direct conflict with the express mandate of section 409(c)(5)(B) of the act.

On January 17, 1974, Judge John Feikens of the United States District Court for the Eastern District of Michigan handed down an opinion in *United States* v. *Articles of food * * * pottery*, holding that pottery dinnerware is subject to the food additive and food requirements of the act:

The legislative history leading to the Food Additives Amendment of the Act shows a clear Congressional intent that substances which are subject to being ingested by human beings be cause of migration are "food additives" and thus "foods" within the meaning of the Act. * * * It is likewise clear that ordinary packaging or food holding devices from which there is no migration are not subject to the Act.

For these reasons, and in the interest of public health, the Commissioner of Food and Drugs has concluded that any prior statements by FDA which conflict with this notice are erroneous and contrary to the Congressional intent as plainly expressed in the act, and any such statements are hereby withdrawn.

The Commissioner recognizes that as a matter of fairness, transitional provisions to implement this proposed regulation are appropriate, since members of industry may presently be marketing certain products bearing migratory substances without an applicable food additive regulation, in reliance upon a prior statement from FDA that the act was not applicable to the product. The proposal therefore provides that by December 31, 1974, manufacturers must either be in compliance with existing regulations or have filed a food additive petition covering the use of a given substance or article. Of course, if there is no migration of a substance to food, or if the substance is generally recognized as safe at the level of migration under the conditions of use involved, the substance is not a food additive and no petition is required. An opinion with respect to migration or GRAS status may be obtained from the Food and Drug Administration upon request.

No transition period is justified, however, for migratory substances in pottery dinnerware, enamelware, or pewter. FDA has for several years conducted a widely publicized regulatory program against such products. Accordingly, the proposal explicitly states that there is no moratorium on food additive charges where migratory substances are found in pottery dinnerware, enamelware, or pewter.

Therefore, pursuant to provisions of the Federal Food, Drug, and Cosmetic Act (secs. 201(s), 409, 701(a), 72 Stat. 1784–1788, 52 Stat. 1055–1056; 21 U.S.C. 321(s), 348, 371(a)), and under authority delegated to him (21 CFR 2.120), the Commissioner proposes to amend 21 CFR Part 121 by adding a new § 121.14, as follows:

§ 121.14 Food additive status of food-contact articles intended for use in the household, food service establishments, and food dispensing equipment.

(a) Any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food is subject to the food provisions of the Federal Food, Drug, and Cosmetic Act and, if it is not generally recognized as safe or exempt under section 201(s)(1)–(4) of the act, to the food additive provisions of the act. This includes any substance in food-contact articles whether intended for use in the household, food service establishments, or food dispensing equipment.

(b) Except as provided in paragraphs (c) and (d) of this section, a food additive in a food-contact article intended for any of the uses referred to in paragraph (a) of this section shall, not later than December 31, 1974, be the subject of a food additive regulation or a food additive petition filed with the Food and Drug Administration covering such use. The filing of such a food additive petition shall stay the effective date of this section until the petition is granted or denied.

(c) The transitional provisions in paragraph (b) of this section shall not apply to:

(1) Migratory substances in pottery dinnerware, enamelware, or pewter;

(2) Any migrating substance which is a poisonous or deleterious substance under section 402(a)(1) of the act; or

ASI-PR 0002086

(3) Food additives in food packaging and wrapping materials used to package, hold, or otherwise contain food prior to ultimate purchase by the consumer.

(d) Any oral or written opinions contrary to this section are hereby revoked and superseded.

Interested persons may, on or before June , 1974, file with the Hearing Clerk, Food and Drug Administration, Rm. 6-86, 5600 Fishers Lane, Rockville, MD 20852, written comments (preferably in quintuplicate) regarding this proposal. Comments may be accompanied by a memorandum or brief in support thereof. Received comments may be seen in the above office during working hours, Monday through Friday.

Dated: April 5, 1974.

SAM D. FINE,
Associate Commissioner for Compliance.

[FR Doc.74-8424 Filed 4-11-74;8:45 am]

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

[49 CFR Part 571]

[Docket No. 74-16; Notice 1]

MOTOR VEHICLE SAFETY STANDARDS

Proposed Modification of Requirements for Motor-Driven Cycles

This notice proposes amendments of 49 CFR 571.108, 571.122, and 571.123, Motor Vehicle Safety Standards Nos. 108, 122, and 123, that would modify current requirements applicable to motor-driven cycles.

The National Highway Traffic Safety Administration has been petitioned by Cycles Peugeot, Ateliers de la Motobecane, and S.I.N.F.A.C. for "(1) recognition of the power-assisted bicycle as a separate category of motor vehicle and (2) promulgation of safety standards for the bicycle appropriate to its low power and speed." Similar petitions have been filed by Bermuda Bikes, Inc. and Robert F. Smith, who are retail dealers of low-powered two-wheeled vehicles.

These vehicles are currently classified as "motor-driven cycles", a subcategory of "motorcycle" that is defined by 49 CFR 571.3(b) as "a motorcycle with a motor that produces 5-brake horsepower or less". As such they are required to meet Federal motor vehicle safety standards, most importantly the ones covering lights (No. 108), hydraulic brake systems (No. 122) and controls and displays (No. 123). Petitioners contend that vehicles which produce no more than 1.5 horsepower deserve a separate classification, and that existing standards applicable to motor-driven cycles are not reasonable, practicable, and appropriate for them.

This agency has decided not to establish a separate category of motor vehicle. The problems of conforming to the standards encountered by vehicles with 1.5 horsepower or less do not appear to be sufficiently different from those of vehicles between 1.5 and 5 horsepower to justify a separate category. However, this agency has reviewed the requirements applicable to motor-driven cycles in light of the petitions and the renewed public interest in this type of vehicle, and has found that certain minor modifications in the standards may ease the burden of compliance without jeopardizing basic safety performance.

With respect to Standard No. 108, this agency has tentatively determined that in view of the speed and weight characteristics of motor-driven cycles, the problems associated with hand signaling and the lack of turn signal lamps are not as significant as they are with the larger motorcycles. It is therefore proposed that the requirement for turn signals be deleted for motor-driven cycles with a top-speed capability of 30 mph or less. Also, it has been found that low-powered cycle motors may have some difficulty in providing the full required illumination. It is proposed that the required stop-lamp photometric output for low top-speed motor-driven cycles be reduced to one-half that for motorcycles generally. It should be noted that Standard 108 already contains reduced photometric output requirements for motor-driven cycle headlamps.

Because of the low speed of these vehicles, it appears that some modification of Standard No. 122, Motorcycle Braking, would be appropriate. Since fade recovery is not a safety-critical requirement for vehicles with low top speeds, it is proposed that a motorcycle be exempted from the fade requirements of S5.4 if the speed it attains in 1 mile is 30 mi/h or less. Further, since Table I provides no maximum stopping distances below 30 mi/h, values for stops from 25, 20, and 15 mi/h are proposed, maintaining the same deceleration values as required of higher speed stops. For example, a stop from 25 mi/h in the total system effectiveness test would have to be made in not more than 19 feet.

Finally, the NHTSA is proposing an amendment to the Motorcycle Controls and Displays standard, No. 123. Manufacturers of lightweight motor-driven cycles have petitioned that placement of the rear brake control on the left handlebar, rather than at the right foot, be allowed. This deviation from the standardized position for motorcycles would appear to have a minimal detrimental effect, and it is therefore proposed by this notice.

In consideration of the foregoing, it is proposed that 49 CFR Part 571 be amended as follows:

§ 571.108 [Amended]

1. In § 571.108 the following definition would be added to paragraph S3:

"Speed attainable in 1 mile" means the speed attainable by accelerating at maximum rate from a standing start for 1 mile on a level surface.

2. In § 571.108 the following two subparagraphs would be added to paragraph S4:

S4.1.1.— A motor-driven cycle whose speed attainable in 1 mile is 30 mi/h or less need not be equipped with turn signal lamps.

S4.1.1.— A motor-driven cycle whose speed attainable in 1 mile is 30 mi/h or less may be equipped with a stop lamp whose photometric output for the groups of test points specified in Figure 1 is at least one-half of the minimum values set forth in that figure.

§ 571.122 [Amended]

3. In § 571.122, the following sentence would be added to S5.4: "These requirements do not apply to a motorcycle whose speed attainable in 1 mile is 30 mi/h or less."

4. In § 571.122, Table I would be amended to add the following values:

Vehicle test speed miles per hour	Preburnish effectiveness total system (S5.2.1)	Preburnish effectiveness partial mechanical systems (S5.2.2)	Effectiveness total system (S5.4)	Effectiveness partial hydraulic systems (S5.7.2)
	I	II	III	IV
15	13	30	11	2
20	24	54	19	4
25	37	84	30	6

§ 571.123 [Amended]

5. In § 571.123, Table I would be amended by revising Item 11, Column 2 to read:

"Right foot control.[1] Left handlebar permissible for motor-driven cycles."

Interested persons are invited to submit comments on the proposal. Comments should refer to the docket number and be submitted to: Docket Section, National Highway Traffic Safety Administration, Room 5108, 400 Seventh Street SW., Washington, D.C. 20590. It is requested but not required that 10 copies be submitted.

All comments received before the close of business on the comment closing date indicated below will be considered, and will be available for examination in the docket at the above address both before and after that date. To the extent possible, comments filed after the closing date will also be considered. However, the rulemaking action may proceed at any time after that date, and comments received after the closing date and too late for consideration in regard to the action will be treated as suggestions for future rulemaking. The NHTSA will continue to file relevant material as it becomes available in the docket after the closing date and it is recommended that interested persons continue to examine the docket for new material.

Comment closing date: May 13, 1974

Proposed effective date: 30 days after publication of final rule in FEDERAL REGISTER.

(Sec. 103, 119, Pub. L. 89-563, 80 Stat. 718, 15 U.S.C. 1392, 1407; delegations of authority at 49 CFR 1.51 and 49 CFR 501.8.)

Issued on April 9, 1974.

ROBERT L. CARTER,
Associate Administrator, Motor Vehicle Programs.

[FR Doc.74-8461 Filed 4-11-74;8:45 am]

ASI-PR 0002087