

review that would lead us to revise that position.

3. Impact of the Rule on Creditors

CUNA, the only creditor representative to discuss the subject, stated that "Generally, credit unions have not reported any significant economic or regulatory impact on their operations due to this rule."

4. Proposed Changes to the Rule to Benefit Creditors

The Missouri Bankers Association posited that the Rule provision prohibiting the pyramiding of late fees is not sufficiently clear as to what constitutes a late fee.²⁵ The Association questioned whether a returned check fee, for example, would be a late fee under the Rule, and, if so, whether the creditor would be permitted under the Rule to collect it.

This comment calls for an explanation of the Rule, rather than a modification to it.²⁶ The Rule does not prohibit a creditor from collecting a late fee, nor would it prohibit a creditor from collecting a returned check fee. The Rule states that, where a charge is assessed with respect to only one late payment and that charge remains unpaid, the creditor may not for that reason deem all subsequent payments to be late or incomplete and assess late charges with respect to those payments as well.

In the example provided by the commenter, if one check was returned for insufficient funds, the creditor could assess a returned check fee if permitted by state law and the terms of the contract to do so. What the creditor could not do, assuming the consumer did not promptly pay the returned check fee, is to declare all subsequent payments to be late or incomplete solely for that reason and assess fees on those payments.

5. Effect on Other Regulations

Except for the comparisons to the Federal Reserve Board and other agencies' versions of the Rule discussed above, no commenter discussed the Rule's effect on other federal, state or local laws or regulations.

²⁵ The three credit union-related associations asked that the Rule be amended to permit creditors to include the Notice in the documents evidencing the consumer credit obligation rather than requiring that it be a separate document, as discussed above.

²⁶ The Commission has handled inquiries of this nature through staff interpretation letters, which are placed on the public record. To date, more than 70 such letters interpreting the Rule have been issued.

6. Effect of Technology or Economic Conditions

No commenter discussed the effects, if any, of changes in relevant technology or economic conditions on the Rule.

7., 8., and 9. Effect on Small Businesses

According to CUNA, the Rule applies to 5,000 state-chartered credit unions.²⁷ CMIG states that the majority of those credit unions have assets of \$100 million or less. Thus, they are considered to be small entities for the purposes of the RFA.²⁸ The only burden that the commenters who claim to represent such entities identified as having been imposed by the Rule on small entities was the requirement discussed above of providing the cosigner notice as a separate document.

10. The Notice to Cosigner

No commenter discussed the wording of the notice.

11. Effect on the Cost and Availability of Credit

As mentioned above, CUNA stated that its members generally reported no significant economic impact on their operations due to the Rule. Williams & Eoannou stated that the Rule has had no negative impact on the cost or availability of credit and that the use of credit by consumers has increased since the Rule became effective. NCLC provided statistics purporting to show the increase in consumer debt in the years following the Rule's implementation. In its view, this increase can be explained in part by increased consumer demand for what became, as a result of the Rule, a more attractive type of credit. No commenter suggested any adverse economic impact from the Rule.

12. Disclosure Alternative to the Rule

No commenter addressed the question of an alternative Rule that would require disclosure of the existence of contract provisions that might cause injury to consumers, as opposed to restricting the use of such provisions.

III. Conclusion

The Notice attracted limited public interest. The discussion of issues relating to small entities, the parties protected by the RFA, was minimal. A number of varying suggestions were made to expand the Rule, but none of these had extensive support.

After carefully considering the comments, the Commission believes

²⁷ Federally-chartered credit unions are subject to the NCUA's version of the Rule.

²⁸ See Small Business Size Regulations, 13 CFR Part 121.601.

that they do not present a sufficient basis to conclude that the Rule has had a significant impact on a substantial number of small entities. Similarly, none of the other issues raised in the comments merits revision of the Rule at this time. The Commission is therefore terminating this review.

List of Subjects in 16 CFR Part 444

Federal Trade Commission, Consumer credit contracts, Cosigner disclosures, Trade practices, Truth in Lending.

Authority: The Regulatory Flexibility Act, 5 U.S.C. Section 601 (1980).

By direction of the Commission.

Donald S. Clark,
Secretary.

[FR Doc. 95-11360 Filed 5-9-95; 8:45 am]

BILLING CODE 6750-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 500, 582, and 589

[Docket No. 94G-0239]

GRAS Status of Propylene Glycol; Exclusion of Use in Cat Food

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to amend its regulations to exclude from generally recognized as safe (GRAS) status the use of propylene glycol (PG) in or on cat food. This proposed action is based on FDA's review of currently available information which has raised significant questions about the safety of this use. Semimoist pet foods containing PG were not in existence when the GRAS status for use in animal feeds was established, thus this GRAS determination does not apply to the newly intended uses of PG. FDA is proposing that PG in or on cat food is a food additive and is not prior sanctioned for this use, and subject to certain provisions of the Federal Food, Drug, and Cosmetic Act (the act).

DATES: Written comments by July 24, 1995.

ADDRESSES: Written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: David A. Dzanis, Center for Veterinary Medicine (HFV-222), Food and Drug

Administration, 7500 Standish Pl., Rockville, MD 20855, 301-594-1728.

SUPPLEMENTARY INFORMATION:

I. Background

Propylene glycol has been used worldwide in the preparation of human foods, pet foods, pharmaceuticals, and cosmetics. It was first used in human foods in 1920, and in pet foods in the early 1960's. In pet foods, PG functions as a humectant, plasticizer, and microbiological preservative.

In the **Federal Register** of November 20, 1959 (24 FR 9368), the agency published a final rule establishing PG as generally recognized as safe (GRAS) in 21 CFR 121.101(h) as a general purpose food additive. PG's use in animal food and feed was recodified to 21 CFR 582.1666 in the **Federal Register** September 10, 1976 (41 FR 38618 at 38657).

In the **Federal Register** of June 17, 1977 (42 FR 30865), the agency proposed to affirm PG as GRAS as a direct and indirect human food ingredient. Subsequently, in the **Federal Register** of June 25, 1982 (47 FR 27810), a final rule was published affirming the GRAS status of PG. The agency's conclusions were based upon a review of scientific literature from 1920 to 1977. A total of 282 abstracts on the additive were reviewed and 68 particularly pertinent reports from the literature survey were summarized in a scientific literature review. The results of this scientific review were discussed in the June 17, 1977, document.

II. Prior Sanction

A substance that is added to food is not a food additive if it is the subject of a prior sanction (section 201(s)(4) of the act (21 U.S.C. 321(s)(4)). "Prior sanction" means an explicit approval granted with respect to use of a substance in food prior to September 6, 1958, by FDA or the United States Department of Agriculture (USDA) pursuant to the act, the Poultry Products Inspection Act, or the Meat Inspection Act (21 CFR 570.3(1)). A prior sanction applies to the specific use of a substance in food, i.e., the level, condition, product, etc., for which there was explicit approval by FDA or USDA. Moreover, the existence of a prior sanction exempts the sanctioned use from the food additive provisions of the act but not from the other adulteration or the misbranding provisions of the act (see 21 CFR 181.5(a) and (b)).

If, at the time that FDA proposes to determine that a substance is not GRAS and is a food additive under 21 CFR 570.38, the agency is aware of any prior

sanction for use of the substance, it will concurrently propose a separate regulation covering such use of the ingredient under part 582 (21 CFR part 582). If the agency is unaware of any such applicable prior sanction, the proposed regulation (as to the substances GRAS or food additive status) will so state and will require any person who intends to assert or rely on such sanction at any later time (21 CFR 570.38(d)).

FDA is not aware of any prior sanctions for the use of propylene glycol in or on cat food, that meet the criteria described above. No party has claimed a prior sanction for this use of propylene glycol in or on cat food. Accordingly, based on the information that is available to it, the agency concludes that no prior sanction exists for the use of propylene glycol in or on cat food.

III. FDA's Concerns

Following review of a number of studies conducted since 1982 concerning the use of PG in cat food, the agency has concluded that there are significant questions about the safety of PG in cat food. In 1976, because the safety of PG was being questioned, the European Economic Community (EEC) initiated a review of additives used in pet foods. In response to this initiative, studies were funded by several pet food companies to verify the safety of PG in semimoist dog and cat foods (these studies include Ref. 1). Clinical tests included the measurement of a blood parameter called Heinz bodies, a test which had not been performed in previous PG studies. Heinz bodies are small clumps of denatured protein in the red blood cells. Cats offered food containing PG at levels used in semimoist food were found to develop Heinz bodies. Although Heinz bodies were known to be indicative of red blood cell damage, the studies did not provide evidence that PG caused anemia or other adverse clinical effects in cats.

Because of the questions raised by the European cat studies, a U.S. pet food industry research group (IRG), composed of interested pet food companies and PG manufacturers, was formed in early 1978. The IRG's purpose was to investigate the significance of linking PG and Heinz body formation, especially PG's effect on the health of the cat. In August 1978, representatives of the IRG met with FDA to provide the results of the EEC tests and describe the research being conducted to determine the significance of Heinz body formation. Since this first meeting, additional pertinent research data have been provided to FDA.

The results of the IRG studies were published in peer-reviewed scientific journals (Refs. 2 and 3). In the first study, adult cats were fed diets containing 0, 6, or 12 percent PG on a dry matter basis over a 16-week period. Cats fed PG had a dose-related increase in Heinz bodies, and a dose-related decrease in mean red blood cell survival time. In the 12 percent group, there was also an increase in punctate reticulocytes, and slight changes in the packed cell volume, hemoglobin concentration, and red blood cell counts. These results indicate that red blood cells are more susceptible to destruction due to PG. Periportal liver glycogen accumulation, splenic nodules, and heart and kidney lesions were observed in some of the cats in the 12 percent group, and the same splenic lesions were seen in some cats in the 6 percent group. In the second study, 12- to 14-week-old kittens were fed diets containing 0, 6, or 12 percent PG on a dry matter basis for 13 weeks. Findings followed a pattern similar to those of the adult cat study, but the increase in reticulocyte count and reduction in red blood cell lifespan were greater in kittens than in adults. This difference was attributed to higher consumption of PG on a per weight basis in kittens.

Other reports in the scientific literature confirmed and expanded on the IRG findings. In a retrospective study, a direct relationship between Heinz body formation and lower packed cell volumes and lower erythrocyte reduced glutathione concentrations were found in cats (Ref. 4). Another study found dose-dependent increases in Heinz body formation and decreases in red blood cell lifespans in cats fed diets containing 12 and 41 percent PG (Ref. 5). A dose-dependent increase in iron pigment in liver and splenic tissue was also observed. Cats fed 41 percent PG diets had a significantly lower mean packed cell volumes, a decreased mean erythrocyte reduced glutathione concentration, punctate reticulocytosis, and bone marrow erythroid hyperplasia. This suggests that although the bone marrow was attempting to compensate for increased red blood cell destruction, the marrow could not produce enough red blood cells to compensate for the rate of destruction.

Increased Heinz body formation and decreased red blood cell survival time were observed in kittens fed diets containing 5 or 10 percent PG for 12 weeks in a study by Hickman and others (Ref. 6). Purified experimental diets containing nitrate, histamine, histamine plus nitrate, or vitamin A failed to induce Heinz body formation. After cessation of treatment with PG-

containing diets, the Heinz body percentage returned to pretreatment levels in 6 to 8 weeks. Thus, PG was identified as the causative factor, and these other possible components of cat food were ruled out as causes of Heinz body formation. Another study found cats fed a commercial diet containing 8.3 percent PG were more susceptible to red blood cell oxidant stress from acetaminophen administration than cats fed a control diet (Ref. 7). Thus, acetaminophen, a common pain reliever for human use but poisonous to cats, was even more dangerous if cats were fed diets containing PG.

Despite the lack of overt clinical anemia in cats in these studies, the data establishes clearly that PG taxes the red blood cell production system. The lack of reports from the veterinary profession of clinically obvious consequences of PG ingestion is an inappropriate criterion to judge the safety of PG, as the indirect impacts of a toxicant are not often readily associated with the compound. FDA believes that cats consuming PG-containing diets would be less able to compensate for other oxidative stresses, such as those induced by infections, drugs, or toxins. Heinz bodies induced by PG may interfere with the proper diagnosis of diabetes mellitus, hyperthyroidism, lymphoma, and other diseases in cats associated with Heinz body formation. Consumption of PG-containing diets may also contribute to the severity of anemia from a variety of causes. Thus, FDA concludes that the findings of the studies of IRG and others constitute adverse effects on the health of cats.

Based on data derived from the FDA master file on PG, the no-observed-effect-level (NOEL) in cats with respect to Heinz body formation is 80 milligrams (mg) PG per kilogram (/kg) body weight (Ref. 1). Assuming typical consumption rates, this level translates to approximately 4,900 to 5,700 mg PG/kg food dry matter (0.49 to 0.57 percent dry matter) for adult, nonreproducing cats, and 0.135 to 0.16 percent dry matter for growing kittens. These levels are far below what has historically been used as a humectant in semimoist cat foods (6 percent to 13 percent dry matter). At levels below 3 percent, PG no longer has any technical or functional effect in the food as a humectant. Effects are seen in adult as well as growing animals. Thus, FDA cannot conclude that a limited use of PG, e.g., a reduced level of use, or a diet intended for certain lifestages of cats only is GRAS.

In 1992, FDA informed industry through a letter to the IRG of its concern regarding the safety of PG in cat foods.

Subsequent to that action, the majority of cat food manufacturers removed PG from their formulations. However, a portion of the products on the market, including some imported products, continue to contain PG.

IV. Conclusions

On the basis of the foregoing, the agency has concluded that PG is not GRAS as an ingredient of cat food nor is this use subject to a prior sanction. Under these circumstances PG is deemed to be a food additive, subject to section 409 of the act (21 U.S.C. 348), and its use in cat food must be in accordance with a published food additive regulation.

V. Environmental Impact

The agency has carefully considered the potential environmental effects of this action. FDA has concluded that the action will not have a significant impact on the human environment, and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

VI. Analysis of Impacts

FDA has examined the impacts of this proposed rule under Executive Order 12866 and the Regulatory Flexibility Act (Pub. L. 96-354). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this proposed rule is consistent with the regulatory philosophy and principles identified in the Executive Order. In addition, the proposed rule is not a significant regulatory action as defined by the Executive Order and so is not subject to review under the Executive Order.

This assessment analyzes the economic effects of the proposed rule to exclude from GRAS status the use of PG in or on cat food. PG is used as a humectant, plasticizer, and microbiological preservative in semimoist cat food. Semimoist cat foods containing PG did not exist when the GRAS status for its use in animal feeds was established, and this GRAS determination does not apply to the newly intended use of PG. Currently available information on the effects of

PG demonstrates serious concerns about its safety in cats.

FDA requested that pet food manufacturers discontinue the use of PG as an ingredient in semimoist cat foods in 1992. The majority of manufacturers in the industry have complied with this request. Agency experts estimate that PG is currently used in at most 5 percent of semimoist cat foods and at most 10 percent of cat snacks, which are similar in texture and content to semimoist foods. These usage rates continue to decline.

FDA estimates of 1993 sales of semimoist cat foods and snacks to U.S. households are \$85,000,000 and \$53,000,000, respectively (Nielsen Marketing Research data). Those sales representing semimoist cat foods and cat snacks which contain PG are approximately \$9,550,000 (5 percent of \$85,000,000 plus 10 percent of \$53,000,000). The effect of the proposed rule would be to replace these sales with other cat foods and cat snacks not containing PG. Most of the industry has already substituted glycerin for PG in semimoist foods and snacks. It is likely that the remaining portion of the industry would make the substitution of glycerin for PG rather than surrender their share of the semimoist cat food and cat snack market. The cost of this substitution to the production process is expected to be small.

Purchases of PG by semimoist cat food and cat snack manufacturers represent a very small percentage of total PG sales, estimated at less than 1 percent. Demand for semimoist cat foods has declined considerably since 1987. Although demand for cat snacks continues to grow, its sales are still a small part of the total pet food industry. Thus, the effect of the proposed rule to PG manufacturers would also be small.

The effects of the proposed rule on small businesses would not be substantial. Although more small-sized companies are involved in manufacturing cat snack foods than in semimoist foods, their costs of compliance would not be significant.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. For the above reasons, the agency certifies that the proposed rule will not have a significant economic impact on a substantial number of small entities. Therefore, under the Regulatory Flexibility Act, no further analysis is required.

VII. References

The following references have been placed on display in the Dockets

Management Branch (address above) and may be seen by interested persons between 9 a.m. and 6 p.m., Monday through Friday.

1. Quast, J. F., C. G. Humiston, C. E. Wade, et al. Results of a Toxicology Study in Cats Fed Diets Containing Propylene Glycol for up to Three Months, *FDA Master File Report No. 12*, 1979.

2. Bauer, M. C., D. J. Weiss, V. Perman, "Hematologic Alterations in Adult Cats Fed 6 or 12% Propylene Glycol," *American Journal of Veterinary Research*, 53:69-72, 1991.

3. Bauer, M. C., D. J. Weiss, V. Perman, "Hematological Alterations in Kittens Induced by 6 and 12% Dietary Propylene Glycol," *Veterinary and Human Toxicology*, 34:127-130, 1992.

4. Christopher, M. M., "Relation of Endogenous Heinz Bodies to Disease and Anemia in Cats: 120 Cases (1978-1987)," *Journal of the American Veterinary Medical Association*, 194:1089-1095, 1989.

5. Christopher, M. M., V. Perman, J. W. Eaton, "Contribution of Propylene Glycol-Induced Heinz Body Formation to Anemia in Cats," *Journal of the American Veterinary Medical Association*, 194:1045-1055, 1989.

6. Hickman, M. A., Q. R. Rogers, J. G. Morris, "Effect of Diet on Heinz Body Formation in Kittens," *American Journal of Veterinary Research*, 50:475-478, 1990.

7. Weiss, D. J., C. B. McClay, M. M. Christopher, M. Murphy, V. Perman, "Effects of Propylene Glycol-Containing Diets on Acetaminophen-Induced Methemoglobinemia in Cats," *Journal of the American Veterinary Medical Association*, 196:1816-1819, 1990.

VIII. Comments

Interested persons may, on or before July 24, 1995, submit to the Dockets Management Branch (address above) written comments regarding this proposal. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects

21 CFR Part 500

Animal drugs, Animal feeds, Cancer, Labeling, Polychlorinated biphenyl's (PCB's).

21 CFR Parts 582 and 589

Animal feeds, Animal foods, Food additives.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR parts 500, 582, and 589 be amended as follows:

PART 500—GENERAL

1. The authority citation for 21 CFR part 500 continues to read as follows:

Authority: Secs. 201, 301, 402, 403, 409, 501, 502, 503, 512, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 342, 343, 348, 351, 352, 353, 360b, 371).

2. New § 500.50 is added to subpart B to read as follows:

§ 500.50 Propylene glycol in or on cat food.

The Food and Drug Administration has determined that propylene glycol in or on cat food is not generally recognized as safe and is a food additive subject to section 409 of the Federal Food, Drug, and Cosmetic Act (the act). The Food and Drug Administration also has determined that this use of propylene glycol is not prior sanctioned.

PART 582—SUBSTANCES GENERALLY RECOGNIZED AS SAFE

3. The authority citation for 21 CFR part 582 continues to read as follows:

Authority: Secs. 201, 402, 409, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 342, 348, 371).

4. Section 582.1666 is amended by revising paragraph (b) to read as follows:

§ 582.1666 Propylene glycol.

* * * * *

(b) *Conditions of use.* This substance is generally recognized as safe (except in cat food) when used in accordance with good manufacturing or feeding practice.

PART 589—SUBSTANCES PROHIBITED FROM USE IN ANIMAL FOOD OR FEED

5. The authority citation for 21 CFR part 589 continues to read as follows:

Authority: Secs. 201, 402, 409, 701, of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 342, 348, 371).

6. New § 589.1001 is added to subpart B to read as follows:

§ 589.1001 Propylene glycol in or on cat food.

The Food and Drug Administration has determined that propylene glycol in or on cat food has not been shown by adequate scientific data to be safe for use. Use of propylene glycol in or on cat food causes the feed to be adulterated and in violation of the Federal Food, Drug, and Cosmetic Act (the act), in the absence of a regulation providing for its safe use as a food additive under section 409 of the act, unless it is subject to an effective notice of claimed investigational exemption for a food additive under § 570.17 of this chapter, or unless the substance is intended for

use as a new animal drug and is subject to an approved application under section 512 of the act or an effective notice of claimed investigational exemption for a new animal drug under part 511 of this chapter.

Dated: May 2, 1995.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 95-11526 Filed 5-9-95; 8:45 am]

BILLING CODE 4160-01-F

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 301

[IA-007-95]

RIN 1545-AT21

Authority of the Secretary of Agriculture to Share Employer Identification Numbers Collected From Retail Food Stores and Wholesale Food Concerns

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of proposed rulemaking.

SUMMARY: This document contains proposed regulations relating to the authority of the Secretary of Agriculture to share employer identification numbers collected from retail food stores and wholesale food concerns with other agencies or instrumentalities of the United States. These proposed regulations reflect changes to the law made by section 316(b) of the Social Security Independence and Program Improvements Act of 1994 and affect retail food stores and wholesale food concerns.

DATES: Written comments and requests for a public hearing must be received by June 9, 1995.

ADDRESSES: Send submissions to: CC:DOM:CORP:T:R (IA-007-95), room 5228, Internal Revenue Service, POB 7604, Ben Franklin Station, Washington, DC 20044. In the alternative, submissions may be hand delivered between the hours of 8 a.m. and 5 p.m. to: CC:DOM:CORP:T:R (IA-007-95), Courier's Desk, Internal Revenue Service, 1111 Constitution Avenue NW, Washington, DC.

FOR FURTHER INFORMATION CONTACT: Robert J. Basso (202) 622-6232 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

This document contains proposed amendments to the Procedure and