

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Food and Drug Administration****21 CFR Part 189**

[Docket No. 91N-0326]

RIN 0910-AA06

Tin-Coated Lead Foil Capsules for Wine Bottles

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending its regulations to prohibit the use of tin-coated lead foil capsules (i.e., coverings for the cork and neck area) on wine bottles. Lead in these capsules may, as a result of their intended use, become a component of the wine. FDA is taking this action to reduce exposure to lead to the extent feasible.

DATES: Effective February 8, 1996. Wine is adulterated under the Federal Food, Drug, and Cosmetic Act (the act) if a tin-coated lead foil capsule is applied to the wine bottle on or after February 8, 1996.

FOR FURTHER INFORMATION CONTACT: Michael E. Kashtock, Center for Food Safety and Applied Nutrition (HFS-306), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-205-4681.

SUPPLEMENTARY INFORMATION:**I. Background**

In the Federal Register of November 25, 1992 (57 FR 55485), FDA published a proposed rule to prohibit the use of tin-coated lead foil capsules on wine bottles (hereinafter referred to as the 1992 proposal). The 1992 proposal was based on evidence from studies on bottled wine capped with tin-coated lead foil capsules that showed that the lead in the foil becomes a component of food. No food additive regulation exists for this use of tin-coated lead foil, nor is there a prior sanction for this use. Moreover, this use of tin-coated lead foil is not generally recognized as safe (GRAS). Therefore, FDA tentatively found that tin-coated lead foil capsules used on wine bottles are an unsafe food additive under section 409 of the act (21 U.S.C. 348), and wine is adulterated under section 402 (a)(2)(C) of the act (21 U.S.C. 342(a)(2)(C)), if a tin-coated lead foil capsule is applied to the wine bottle on or after February 8, 1996. Given the longstanding use of tin-coated lead foil capsules as a packaging material for wine, the agency proposed to prohibit use of this capsule by regulation to

make its regulatory status clear. FDA proposed to make any final rule that issued based upon the 1992 proposal effective on its date of publication.

II. Summary of and Response to Comments**A. Summary of Comments**

The agency received 16 comments in response to the 1992 proposal. Thirteen comments were from domestic and imported wine merchants, associations representing domestic winemakers, and a foreign national trade association representing exporters of wine. In addition, one comment was received from an international trade commission, and two were received from foreign governments.

All comments supported the proposal in principle. However, some comments sought clarification of what the proposal was intended to prohibit. Some comments raised issues concerning other types of capsules that may contain lead used on wine bottles. Some comments raised concerns about regulatory action by individual States concerning capsules used on wine bottles.

The majority of the comments reacted favorably to the proposed effective date, but two comments expressed the need for further clarification on this issue.

One comment asserted that the wine industry is being charged with an extraordinary share of the lead-reduction burden.

B. Responses to Comments

1. Several comments stated that the 1992 proposal did not clearly identify the specific type of capsule that FDA proposed to prohibit. One comment requested that the 1992 proposal be amended to provide a clearer definition of what is prohibited. The comment also stated that if the prohibition is to be based on the amount of lead that is present in the capsule, then fairness requires that reasonable notice be given of the precise requirement of the final rule before it becomes effective. Another comment stated that since some traces of lead may appear in alternative types of capsules, the final rule should be written in such a way that no ambiguity is possible concerning the amount of lead that the capsule may contain.

These comments apparently derive in large measure from the fact that the State of California has acted to prohibit the use of capsules that contain more than 0.3 percent lead. These comments are responding to the 1992 proposal's lack of a quantitative level of lead in a capsule that would subject it to

prohibition, inasmuch as the State's action included such a level.

In response to these comments, FDA emphasizes that the intent of the 1992 proposal was not to set a maximum permissible level of lead in a capsule. The intent was to prohibit the use of tin-coated lead foil capsules as a covering for the cork and neck areas of wine bottles. In the preamble to the 1992 proposed rule, FDA defined "tin-coated lead foil capsules" as "capsules composed of lead foil coated on both sides with a thin layer of tin." This identification is not ambiguous. It clearly differentiates between tin-coated lead foil capsules, in which lead is intentionally used, and other types of capsules known to be used in the bottling of wine (e.g., all tin capsules) that may unavoidably contain some lead as an impurity.

Nonetheless, given the concerns expressed by the comments, to eliminate the possibility of any ambiguity in the final regulation, the agency is modifying proposed § 189.301(a) to incorporate the definition of "tin-coated lead foil" as it appeared in the preamble of the 1992 proposal.

2. Several comments requested that the agency define "all tin-capsules" (an alternative to tin-coated lead foil capsules) to include the amount of lead that may be present in the capsule as an unintended impurity.

As stated above, this final rule is a prohibition of, and applies exclusively to, tin-coated lead foil capsules.

It is not FDA's intent in this rulemaking to address the regulatory status of any other type of capsule (e.g., tin, aluminum, or plastic). However, FDA recognizes that it is conceivable that materials, both metallic and nonmetallic, used in other types of capsules could become components of wine, thus subjecting these capsules to the provisions of the act. FDA provides the following guidance in response to the comments that sought an opinion on the status of various types of capsules that may be used in the bottling of wine.

If a substance, such as tin or aluminum, has a history of use as a capsule for wine bottles predating January 1, 1958, and the substance could become a component of food as a result of its intended use, the use may be GRAS based on common use in food or food contact. The criteria for determining whether the use is GRAS are described in § 170.30(c) (21 CFR 170.30(c)). Any substance whose use in capsules for wine bottles began after January 1, 1958, would either have to be GRAS for such use on the basis of scientific procedures described in

§ 170.30(b) or would be required to be used in accordance with a food additive regulation that prescribes safe conditions of use. In either case, the substance must be of a purity suitable for its intended use.

FDA is aware that the occurrence of some amount of lead in tin is unavoidable because lead is a naturally occurring impurity in tin ore. Manufacturers are expected to take steps to control this source of exposure to lead by securing raw materials of the highest purity practicable.

3. Several comments expressed concern that the States have or may enact inconsistent and conflicting laws that restrict the amount of lead that may be present in "all-tin capsules." Therefore, the comments requested that FDA establish a national definition of "all-tin capsules" based on the California definition¹ to eliminate inconsistencies and conflicts, to level the playing field among States, and to protect imported wine from State-imposed nontariff trade barriers.

The agency understands that some comments may wish to have a preemptive Federal regulation defining "all-tin capsules." However, this final rule is a prohibition of, and applies exclusively to, tin-coated lead foil capsules as defined by this agency.

It appears that the comments contemplate that some States may promulgate regulations that are different from, or more restrictive, than the "California definition" of "all-tin capsules." The agency recognizes that if individual States establish variable limits on the lead content of capsule materials, burdens on interstate commerce can result. However, the potential for such action by individual States, and the question of what would be an appropriate course of action by the Federal government in such a case, is outside the scope of this rulemaking. The prohibition of tin-coated lead foil capsules is absolute. More restrictive action by the States with respect to such capsules is not possible. As for other materials used to make wine capsules, interested persons may wish to petition the agency to establish limits on lead in such materials that have preemptive effect. Agency action on such petitions would be based on the merits of the

petition and the availability of agency resources.

4. One comment stated that it is unfair for FDA, and for other agencies of the United States, to place excessive responsibility on the wine industry to achieve lead reduction in food and not require similar efforts from other industries.

FDA disagrees with the comment's allegation that the agency is imposing excessive responsibility on the wine industry to achieve lead reduction. The prohibition on the use of tin-coated lead foil capsules is only one of the actions that the agency has taken to implement its policy to reduce exposure to lead in food to the maximum extent practicable. Other actions include a recently published final rule formally banning lead-soldered food cans (60 FR 33106, June 27, 1995), a final rule lowering the allowable level of lead in bottled water (59 FR 26933, May 25, 1994), the lowering of action guidelines for leachable lead from ceramicware (57 FR 29734, July 6, 1992), and a final rule requiring a warning label on decorative ceramicware, which could be mistakenly used to hold food, in order to exempt it from the action guidelines for leachable lead (59 FR 1638, January 12, 1994). FDA is also considering action to reduce the specifications for lead in food and color additives and in GRAS ingredients, as described in an advance notice of proposed rulemaking that was published in 1994 (59 FR 5363, February 4, 1994).

5. Several foreign comments sought assurance that wines capped with tin-coated lead foil capsules before January 1, 1993, will be permitted to enter the United States, and that marketing of wines capped with tin-coated lead foil capsules and imported before January 1, 1993, will be permitted.

FDA's 1992 proposal specifically stated that the prohibition on the use of tin-lead foil capsules is applicable to products capped after the effective date of this final rule. Thus, this prohibition will not be retroactively applied to any product capped before February 8, 1996, nor is any action required to recall and retrofit any product capped before that date. Consequently, European wines capped before the European Commission (EC) ban of January 1, 1993, will not be prohibited from being imported into the United States or marketed in the United States by this rule.

In the 1992 proposal, FDA proposed that the effective date of this final rule be the date that it is published in the Federal Register. In the 1992 proposal, the agency stated that information that it had already received indicated that

the industry anticipated the availability of adequate supplies of alternative capsules by no later than November 1992. The industry desired that the prohibition of the use of tin-coated capsules not precede the availability of adequate supplies of alternative capsules. No comments indicating that the industry would not be able to comply with the effective date were received.

III. Conclusions

After review and consideration of the comments received in response to the 1992 proposal, FDA concludes that no evidence or information has been presented that would cause the agency not to adopt § 189.301, which prohibits the capping of bottled wine with "tin-coated lead foil capsules."

Therefore, FDA is amending 21 CFR part 189 as proposed with the exception that the agency has modified § 189.301 to include the definition of "Tin-coated lead foil capsules" as discussed in comment 1 of this document and made minor editorial changes.

IV. Environmental Impact

The agency has previously considered the environmental effects of this rule as announced in the proposed rule (57 FR 55485, November 25, 1992). No new information or comments have been received that would affect the agency's previous determination that there is no significant impact on the human environment and that an environmental impact statement is not required.

V. Economic Impact

FDA has examined the impacts of this final rule to prohibit the use of tin-coated lead foil capsules for wine bottles as required by 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 Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. FDA finds that this final rule is not a significant regulatory action as defined by Executive Order 12866. In compliance with the Regulatory Flexibility Act, the agency certifies that the final rule will not have a significant economic impact on a substantial number of small entities.

¹ The "California definition" refers to a definition agreed to by the State of California and several wine producers and importers in a December 6, 1991, consent decree (*People of the State of California v. Gallo Vineyards, Inc. et al.*, No. 640951, San Diego County Superior Court). This decree states in part that "lead foil" or "tin-lead foil" capsules are " * * * any foil capsules * * * containing lead as an intended constituent at concentrations greater than .3% by dry weight."

On November 25, 1992, FDA published an analysis of the economic impacts of the proposed requirements under the previous Executive Order (Executive Order 12291). In that analysis the agency stated that banning the use of tin-lead capsules for wine bottles would require the wine industry to use other materials for capsules, such as polyvinylchloride (PVC), aluminum, or tin. The cost estimates reported in this regulation did not include costs to the wine industry in California because

California State law already prohibited the use of these capsules in wine bottles.

The impact of the proposed regulation was expected to be an increase in the cost of capsule material and bottling equipment to the portion of the industry that still used tin-lead capsules. At the time of publication of the proposal it was assumed that the most likely alternative to tin-lead foil capsules to be used was tin capsules at a total cost to the industry of \$4.5 million annually.

A. Costs

Since the publication of the 1992 proposal to ban tin-lead foil capsules, several new alternatives have emerged and existing ones have been improved through better quality, lower prices, or both. According to a recent trade publication, there are four basic capsules that may be used, which are listed in the chart below (Ref. 1).

PVC (polyvinylchloride)	\$40 per 1,000 capsules
Polylam (aluminum/plastic laminate)	\$60 per 1,000 capsules
Aluminum	\$85 per 1,000 capsules
Tin	\$90 per 1,000 capsules

It is assumed in this analysis that only imported wines still continue to use tin-lead foil capsules, not including those imported from the European Union (EU). Approximately 15 percent of wines consumed in the United States are imported and 5 percent of all wines are from countries other than the EU. Thus, if all such wines used tin-lead foil capsules, 8.6 million bottles of imported wine would be expected to be converted away from tin-lead foil capsules as a result of this final rule. Since tin-lead foil capsules cost the same as polylam capsules, only those wineries who

choose tin or aluminum will incur additional costs. Assuming that all conversions will be evenly distributed between the four options above, costs of using different capsules are expected to be approximately \$90,000 per year.

B. Benefits

Benefits of this regulation will be realized in reduced exposure to lead by children and pregnant women (fetuses), groups that are particularly sensitive to exposure to lead. Adverse health effects of lead exposure in these population groups occur at lower blood lead levels

than in adults. Exposure to very low levels of lead can adversely affect the production of the iron-containing component of hemoglobin in children and can cause neurobehavioral and growth deficits at prenatal (maternal) stages. The agency has previously stated that for infants and children, the lowest observed effect level of lead in blood is 10 micrograms per deciliter (µg/dL) (57 FR 55485 at 55487, November 25, 1992).

The following table shows estimates of the current blood lead incidence levels in the two population groups predicted to exceed 10 µg/dL (Ref. 2).

TABLE 1.—BACKGROUND INCIDENCE OF BLOOD LEAD LEVELS >10 µg/DL

Population Group	Estimated Incidence
Children, age 2 years	10%
Women of child-bearing age	1%

1. Benefit Estimation for Children Ages 3 through 6

Using the estimates in Table 1 and assuming that the same incidence levels apply for children ages 3 through 6 as for 2-year olds, then approximately 1.4 million children between the ages of 3 and 6 have blood lead levels greater than 10 µg/dL.

Wine consumption data were obtained from the United States Department of Agriculture (USDA) Nationwide Consumption Survey. This survey provided the percentage of children who consumed wine at least once in a 3-day period and the daily consumption distribution (in grams (g)) for each group. Approximately 0.12 percent of the children ages 3 through 6 in this survey, or 1,680 children (1.4 million x 0.0012 = 1,680), consumed

wine once in 3 days. The average daily consumption of wine for children ages 3 through 6 is 51 g/day per child.

Assuming that children who consume imported wine do so in the same proportion as national consumption (e.g., 5 percent of the total wine consumed is imported from non-EU countries), then an estimated 84 children (5 percent of 1,680) may be at risk.

The capsule contribution of lead from imported wine is, on average, 6 µg lead (Pb)/day (120 parts per billion (ppb)). By using an absorption rate factor of 0.16 for children, the blood lead level increase attributable to the consumption of imported wine by these children is estimated to be 1 µg Pb/dL (Ref. 3).

To assess monetary benefits from reducing this lead intake, this analysis

uses a study by the Centers for Disease Control (CDC) that looked at the effect of lead reduction on the lifetime earnings of consumers. The CDC study used three "pathways" with associated parameter estimates to measure the change in lifetime earnings that would result from a change in 1 µg Pb/dL blood. Each pathway included an estimate of a quarter of an intelligence quotient (IQ) point decrease for each 1 µg Pb/dL of blood increase.

The CDC study measured the impacts of a change in blood lead on IQ through changes in wages, educational attainment, and labor force participation rates. Because each of these effects are highly correlated (wages, education, and labor force participation), FDA will conservatively use only the strongest effect, education. FDA used a similar

approach in the economic impact analysis of the proposed rule to ban lead soldered food cans (58 FR 33860, June 21, 1993). For this factor, it is estimated that an increment of 1 µg Pb/dL blood decreases lifetime earning levels by approximately 0.2 percent.

Starting from an average expected lifetime earnings rate of \$260,000, the decrease in the net present value of lifetime earnings from a 1 µg/dL change in blood lead levels will be \$512 (.00197 x 260,000). For the 84 children estimated to be at risk, the lower bound annual benefit of reducing blood lead levels by 1 µg Pb/dL from domestic wine consumption is estimated to be \$43,000 (512 per child). It should be noted that the amount may be understated to the extent that this estimate, a human capital approach, does not represent utility from a higher IQ in nonlabor activities which would be included in a willingness-to-pay estimate.

The above calculations are also considered to be lower bound, as they

only estimate benefits for children with blood lead levels above 10 µg/dL. Using the same wine consumption levels as above (51 g/day), but allowing for effects (linear) below 10 µg Pb/dL blood, the annual benefit of reducing blood lead levels by 1 µg/dL would be \$4.6 million.

Assuming that half the problem is solved each year, over the next 20 years total discounted benefits may range between \$81,000 and \$5.7 million.

2. Benefit Estimation for Fetuses

There are approximately 58 million women between the ages of childbearing age (15 to 44 years). Each year, approximately 3 million (6 percent) are pregnant at any given time. Using the incidence estimates in Table 1 (1 percent of 3 million), 30,000 of these women (pregnancies) are estimated to have blood lead levels above 10 µg/dL.

Dietary exposure to lead (from tin-lead foil capsules) for pregnant women has been evaluated in a manner similar to that used for children. The USDA food consumption survey (1977-1978) reported average wine intake per day for individuals who drank wine on 1, 2,

and 3 days over a 3-day period. It also provided the wine consumption data for women of different age groups, including those of childbearing age (15 to 44 years). After eliminating the tin-lead capsules in wine bottles, the lead levels in imported wine would be reduced by an average of 120 ppb. A 120 ppb reduction is equivalent to 120 µg/kilogram of wine. Thus, if a pregnant woman consumes 100 g of wine per day, the lead intake from wine will be reduced by 12 µg Pb/day. Using the maternal (adult) absorption rate of 0.04, the blood lead level in the fetus would be reduced by 0.50 µg Pb/dL blood (Ref. 3).

The figures in the following table were derived from the USDA food consumption survey data utilizing data on lead levels in imported wine attributable to the use of tin-lead foil capsules and the maternal absorption rate factor just noted. Blood lead level reductions for each group of wine consumers are the result of eliminating the capsule's lead contribution.

TABLE 2.—BLOOD LEAD LEVEL REDUCTIONS AFTER ELIMINATING TIN-LEAD CAPSULES (PREGNANT WOMEN WHO CONSUME WINE AND ARE AT RISK OF REACHING BLOOD LEAD LEVELS OVER 10 µG/DL)

Age females	Number of wine consumers	Number of imported wine consumers ¹	Blood Pb level reduction (µg/dL blood)
Drink once in 3 days			
15-18	37	1.8	0.29
19-34	1,542	77	0.37
35-44	74	3.7	
Drink two of 3 days			
15-18	3	1.4	0.37
19-34	411	20	0.70
35-44	28	1.4	0.54
Drink all 3 days			
15-18	0	0	0
19-34	179	8.9	1.34
35-44	26	1.3	0.94
TOTAL	2,300	115 ²	

¹ Excludes consumers of wine imported from the EC.

² Pregnancies resulted in live births only.

Assuming 115 fetuses have their blood lead levels reduced by the amounts shown in Table 2 above, the increase in the value of lifetime earnings is estimated to be \$16,000.

Again, assuming the relationship between IQ and income is linear benefits are estimated for all fetuses with nonzero blood lead levels. The annual upper bound benefit in terms of an increase in the value of lifetime earnings is estimated to be \$1.6 million.

Thus, the benefit of reducing maternal blood lead levels ranges from \$16,000 to \$1.6 million.

Assuming half of the lead problem is solved each year, the total discounted benefits (at 6 percent) to pregnant

women (fetuses) is estimated to be \$30,000 to \$3 million.

C. Summary

For this analysis, FDA has assumed that only imported wines still continue to use tin-lead foil capsules, excluding those imported from the EU. Costs of conversion are expected to be approximately \$90,000 annually. Total discounted costs (6 percent) are estimated to be \$1.2 million.

Assuming that, (1) the population growth rate in the United States continues to be near the replacement rate, and (2) half of the lead problem is reduced each year, the reduction of blood lead levels due to ingestion of

wine is expected to result in discounted benefits ranging from \$97,000 to \$8.7 million.

VI. References

The following references have been placed on display in the Dockets Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1-23, Rockville, MD 20857.

1. Walker, L., "What's Next in the Wine Capsule Department?," *Wine & Vines*, 74(3):20(3), March 1993.

2. Carrington, C., P. M. Bolger, and R. J. Scheupleia, "Risk Analysis of Dietary Lead Exposure," in press.

3. FDA memorandum, "Provisional Tolerable Exposure Levels for Lead," Clark D. Carrington, Division of Toxicological Review and Evaluation, to Elizabeth Campbell, Division of Regulatory Guidance, November 16, 1990.

List of Subjects in 21 CFR Part 189

Food ingredients, Food packaging. Therefore, under the Federal Food, Drug, and Cosmetic Act, as amended, and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 189 is amended as follows:

PART 189—SUBSTANCES PROHIBITED FROM USE IN HUMAN FOOD

1. The authority citation for 21 CFR part 189 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).

2. New § 189.301 is added to subpart C to read as follows:

§ 189.301 Tin-coated lead foil capsules for wine bottles.

(a) Tin-coated lead foil is composed of a lead foil coated on one or both sides with a thin layer of tin. Tin-coated lead foil has been used as a capsule (i.e., as a covering applied over the cork and neck areas) on wine bottles to prevent insect infestation, as a barrier to oxygen, and for decorative purposes. Information received by the Food and Drug Administration establishes that the use of such a capsule on wine bottles

may reasonably be expected to result in lead becoming a component of the wine.

(b) The capping of any bottles of wine after February 8, 1996, with a tin-coated lead foil capsule renders the wine adulterated and in violation of section 402(a)(2)(C) of the Federal Food, Drug, and Cosmetic Act because lead from the capsule, which is an unsafe food additive within the meaning of section 409 of the act, may reasonably be expected to become a component of the wine.

Dated: January 29, 1996.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

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