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Robb MacKie <rmackie@americanbakers.org>
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To: OIRA_BC_RPT@omb.eop.gov

cc: 'Lee Sanders' <lsanders@americanbakers.org>
Subject: Comments on the OMB Draft 2004 Report to Congress on the Costs

Attached, please find the American Bakers Association submission of Comments on the OMB *Draft 2004 Report to Congress on the Costs and Benefits of Federal Regulations*, 69 Fed. Reg. 7987 (February 20, 2004). Thank you.

Robb MacKie
Vice President Government Relations
American Bakers Association
1350 I Street, NW Suite 1290
Washington, DC 20005
202-789-0300
202-898-1164fax
rmackie@americanbakers.org

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American Bakers Association

Serving the Baking Industry Since 1897

Robb MacKie, Vice President, Government Relations

May 20, 2004

Ms. Lorraine Hunt
Office of Information and Regulatory Affairs
Office of Management and Budget
NEOB, Room 10202
725 17th Street, NW.
Washington, DC 20503

Re: Comments on the OMB *Draft 2004 Report to Congress on the Costs and Benefits of Federal Regulations*, 69 Fed. Reg. 7987 (February 20, 2004)

Dear Ms. Hunt:

On behalf of the American Bakers Association (ABA), I am writing to respectfully submit for consideration by the Office of Information and Regulatory Affairs (OIRA) several federal regulations that have a significant negative impact on the wholesale baking industry. ABA applauds OIRA for its continuing efforts to reduce unnecessary and burdensome regulations and appreciates your favorable consideration of the comments below.

The American Bakers Association is the trade association that represents the nation's wholesale baking industry. Its membership consists of more than 200 wholesale bakery and allied services firms. These firms comprise companies of all sizes, ranging from family-owned enterprises to companies affiliated with Fortune 500 corporations. Together, these companies manufacture approximately 80 percent of the nation's baked goods. The members of the ABA collectively employ over one hundred thousand employees nationwide in their manufacturing, sales and distribution operations. ABA, therefore, serves as the principal voice of the American wholesale bakery industry.

The wholesale baking industry, like most manufacturing industries, has faced enormous challenges posed by the market place, capital and supply cost escalation, and the impact of government policies. Our comments are focused on the impact of federal regulations on the industry as a whole. As a 1996 survey of costs to the wholesale baking industry highlighted, the cost of government regulations is the single highest cost factor in the manufacturing of quality baked goods. At that time, Price-Waterhouse pegged the cost of government regulations at all levels to be 38% of the cost of producing a one pound loaf of bread.

Unfortunately, since 1996 the cost impact of government, particularly federal government regulations have grown dramatically. Just within the past two years, the wholesale baking industry has borne significant additional regulatory burdens of several major rulemakings such as Department of Transportation's revised Hours of Service regulations, Food and Drug Administration's food security regulations, Securities and Exchange Commission "Sarbanes-

1350 I Street, NW, Suite 1290 • Washington, DC 20005-3305 USA
Phone 202-789-0300 • Fax 202-898-1164 • rmackie@americanbakers.org

Oxley" regulations, and the Environmental Protection Agency activities under the Clean Air Act pertaining to refrigerants. Despite the best of intentions with these new regulations, the significant economic burden imposed can not be ignored.

Therefore, it is critically important for the federal government to take advantage at every opportunity to scale back or eliminate unnecessary or overly burdensome regulations. ABA appreciates this opportunity to offer the wholesale baking industry's suggestions for ways to achieve this goal. While ABA has a long list of potential contenders for review, we feet it most important to focus on those regulations with the strongest arguments for change while providing the industry with the maximum possible relief.

1. Food and Drug Administration Definition of "Fresh" 21 C.F.R. § 101.95

Currently, the Food and Drug Administration restricts use of the term "fresh" in food labeling. For many years, ABA has discussed the issue of "fresh" both internally within our industry and externally with FDA regarding the need for a redefinition or exemption for baked goods that is parallel to the exemptions currently given to both fresh pasteurized milk and fresh produce.

ABA has pushed for a redefinition of the term fresh, as it is unfair to discriminate against the use of preservatives, or other new technologies, thermal and non-thermal, since currently both fresh milk and fresh produce are preserved by various methods under the current regulations. ABA has repeatedly advised FDA that the situation should be remedied in one of two ways. Either the first paragraph of Section 101.95 should be amended to state that, like pasteurized milk, baked goods that are preserved with a safe and suitable preservative may also be called "fresh" because consumers commonly understand they are nearly always preserved. A second suggested alternative is to amend Section 101.95 (c) specifically to permit "the addition of safe and suitable preservatives to baked goods."

For an industry that serves consumers fresh products on a daily basis, it seems illogical that the result of the Nutrition Labeling and Education Act (NLEA) is to preclude freshly baked goods from being called "fresh". It is a common industry practice to replace (i.e. rotate) products on the shelf every three days to maintain freshness, before it becomes stale, as is the same practice with other fresh food items in retail facilities. This practice has served the industry well and meets the needs and demands of the consumer.

ABA believes that since the current regulation does not specify a time period during which pasteurized milk remains fresh or which preserved raw agricultural commodities remain fresh, it only logically follows that there is no need to establish specific time periods during which bread would remain "fresh" after baking. Current retail practices ensure proper rotation so that the freshest products are offered to consumers. "Use by" or "sell by" dating on bakery products provides additional clear label information for consumers.

Consideration of the First Amendment implications of restricting the use of a truthful labeling claim in the absence of evidence of consumer deception and assurance that the restriction will address the deception is critical. ABA and its members have a well-established commitment to ensuring that food labeling is truthful, not misleading, and substantiated by sound scientific evidence. ABA has already advised FDA of its general policy of supporting FDA requirements that are carefully tailored to address demonstrable consumer deception. ABA strongly opposes

restrictions based on an alleged risk of such deception and is strongly supported by case law in this area.

Since FDA established the basic food labeling requirements authorized by the NLEA, the Supreme Court and lower courts have repeatedly found that food labeling is subject to the same protections granted to other forms of commercial speech. As the D.C. Circuit made clear in Pearson v. Shalala, 164 F.3d 650 (D.C. Cir. 1999), FDA must assure that its food labeling policies do not unduly burden speech and are justified with reference to a defined harm that will be addressed by any speech restriction.

The existing ban of the term "fresh" impacts an entire category of food products, baked goods, despite the truthfulness of the claim and the lack of evidence that consumers would be misled by its use in labeling for those products. There is a lack of any evidentiary basis for the FDA determination that “fresh bread’ is misleading and upon the discriminatory handling of other preserved products. In the case of Ibanez versus Florida Department of Business and Professional Regulation, the Supreme Court ruled that government cannot restrict commercial speech on the mere assertion that is “potentially” misleading. The government must bear the burden of proving that the speech it objects to is actually/inherently misleading. FDA has clearly failed to meet this important threshold and therefore has placed the baking industry at a disadvantage in relation to other fresh foods.

In summary, the net effect of the ban of the term “fresh” creates the very confusion and misunderstanding in the minds of consumers that FDA claims to be trying to avoid. Forcing the baking industry to use other, less specific, descriptors only confuses its customers who see, smell and taste fresh bakery products but do not see the term “fresh” on the package or label. The confusion, however, is not limited to consumers but includes FDA staff:

During the FDA’s public hearings on food descriptors in Chicago, July 2000, many who offered testimony on the subject of "fresh", including an FDA representative, Christine Lewis, used "fresh bread" as an example of fresh, even though under current agency regulations, this term is disallowed on packaging. In an October 15, 2002 article in the Washington Post, FDA policy adviser and lawyer Sharon Lindan Mayl was quoted,

> "You can use the word 'fresh' on baked goods and bread. They [the bakers' comments] don't accurately reflect the state of the law."

To add further confusion the same article states:

> “another senior FDA official said the ‘fresh’ issue will probably be reevaluated in the agency's ongoing First Amendment proceeding after all. All this stuff is subject to reinterpretation. These definitions were not set in concrete," the official said.”

Despite these public assurances, the matter still remains unresolved by the FDA going on 15 years since the ABA first petitioned for the change. The time to eliminate consumer confusion and to allow bakers to market and label their products as they truly are is long overdue.

2. Internal Revenue Code Section 3121(d)(3)(A) Regulations Pertaining to Independent Distributors of Bakery Products

A substantial number of baking companies elect to utilize independent distributors for their products. This long standing business model is predicated on managements' belief that the best way to grow sales is through independent distributors having a vested financial and entrepreneurial incentive to grow their own businesses. Those ABA member companies contract with over 18,000 independent distributors - the vast majority being sole-proprietorships. The value of their geographic routes ranges from $30,000 to $150,000 with annual sales revenue ranging from $250,000 to $1.5 million. In addition, these distributors are responsible for all of their equipment, insurance, benefits and taxes.

In 1991, the Internal Revenue Service (IRS) issued GCM 39853, which concluded that rights to distribute and sell baked goods do not constitute "facilities" under section 3121(d)(3)(A) of the Internal Revenue Code of 1986, as amended (the "IRC"), and that distributors of such baked goods are statutory employees. The GCM reversed long standing policy that ownership of distribution rights is an investment in facilities, which if substantial, precludes bakery distributors from being treated as statutory employees.

IRC § 3121(d)(3)(A) states that agent-drivers or commission-drivers engaged in distributing bakery products are statutory employees for FICA purposes if they meet certain requirements. IRC § 3121(d), however, provides that "an individual shall not be included in the term 'employee' under the provisions of this paragraph if such individual has a substantial investment in facilities used in connection with the performance of such services (other than in facilities for transportation)." Despite GCM 39853, a bakery distributor's substantial investment in distribution rights does constitute a "substantial investment in facilities used in connection with the performance of such services," within the meaning of IRC § 3121(d)(3)(A). Bakery distributors making such investments should therefore be excluded from statutory employee treatment under IRC § 3121(d)(3)(A) provided that their investments are substantial. Accordingly, the IRS should withdraw GCM 39853.

ABA and other organizations have sought the withdrawal of GCM 39853 since its inception in 1991 on the basis of case law and legislative history. Judicial opinions from the time period immediately prior to the 1950 enactment of IRC § 3121 indicate that the term "facilities" was generally used in its broadest sense and included both tangible and intangible assets. For example, in *Hartford Electric Light Co. v. Federal Power Commission*, 131 F.2d 953 (2d Cir. 1942), the Circuit Court held that the term "facilities" included items such as "petitioner's corporate organization, contracts, accounts, memoranda, papers and other records." The court explained that "the word 'facilities' is generally regarded as a widely inclusive term, embracing anything which aids or makes easier the performance of the activities involved in the business of a person or corporation."

By confirming that the term "facilities" is broad enough to include corporate organization, contracts, accounts, labor and capital, these court decisions demonstrate that the term "facilities" was used in its broadest sense in the time period leading up to the enactment of IRC § 3121 and included not only tangible structures and installations, but intangible assets as well.

Congressional concern was over the breadth of any exception to treating agent-drivers and commission-drivers as employees, not the breadth of the term 'facilities.' Any Congressional

concern regarding an overly broad application of the substantial investment exception was satisfied by means of the statutory requirement that the investment in facilities be substantial. These two requirements limit the breadth of the statutory employee exception exactly as Congress intended. It is wrong for the Service to superimpose a narrow construction of the term "facilities" on top of the restrictions already contemplated and set forth by Congress.

The administrative burdens on baking companies that utilize independent distributors are significant. It takes each baking company in excess of 2600 hours a year at a cost of $1.5 million to administer. In order to properly calculate, collect, match and remit the appropriate FICA and FUTA taxes, the companies must:

A. Receive financial statements from the distributors on a regular basis.
    1. Financial statements are required for each quarter, usually within 30 days after the end of the quarter.
    2. Many times baking companies must "chase" financial statements, meaning baking companies are constantly contacting its distributors about submitting the proper financial statements and on a timely basis.
    3. If financial statements are not received in a timely fashion, the FICA calculation must be based on gross income, not net income.
    4. A distributors' failure to provide the required financial information results in a higher FICA tax amount that must be matched by baking companies.
    5. In such cases, baking companies are unfairly assessed FICA tax when it has no control over whether a distributor turns in his financial information.

B. Manually analyze each financial statement and make necessary adjustments each quarter.
    1. Financial statements reflecting the distributors' earnings and expenses are the basis for the FICA and FUTA tax calculations.
    2. FICA tax is calculated on the prior quarter's earnings, and is collected over the course of the following quarter.
    3. Distributors submit updated financial statements each quarter, resulting in baking companies manually recalculating the distributors FICA liability each quarter.
    4. From these reported earnings, baking companies calculate the proper FICA tax and collects such amount from the distributor usually on a weekly basis.

C. Manually analyze each financial statement for deductible versus non-deductible expenses.
    1. The IRS disallows certain expenses in the FICA calculation. Accordingly, companies must train their accounting team to recognize allowable versus non-allowable expenses.

D. Amend W-2's for all distributors.
    1. Distributors receive a Form W-2 at the end of each year because the W-2 is the only form provided by the IRS where FICA earnings can be reported. FICA earnings cannot be reported on a Form 1099.
    2. The W-2s are due to distributors by January 31, but the final financial statement for the entire year that supports the W-2 is not received until after the W-2 deadline date.
    3. This results in amended/corrected W-2s (Form W-2c) being filed for every distributor
    4. Amended W-2s also results in amended Form 941s (Form 941c).

5. The amended Form W-2 and Form 941 process takes several months, and many man-hours, to complete.
6. Once the W-2c is completed, they must then be sorted and mailed to the distributors. This process also takes many hours.
7. Once the W-2c and 941c are filed, it usually takes 6-12 months for the IRS to process any FICA refunds that are due.
8. FICA tax refunds due are sent to baking companies in a lump sum payment, which baking companies must process individual checks for and mail to any distributors that are due FICA tax refunds.

E. Design accounting systems to calculate, track and report the correct FICA amounts to the IRS and the appropriate states.

Clearly the IRS should relieve independent distributors and wholesale baking companies from this unnecessary, costly and extremely burdensome regulations. A simple reversion to the pre-1991 GCM 39853 interpretation of IRC Section 3121(d)(3)(A) or modifying the Section would resolve this long vexing issue.

3. OSHA Reliance upon ACGIH TLVs

In the past several years, the wholesale baking industry has become acutely concerned about a so-called consensus organization – the American Conference of Governmental Industrial Hygienists (ACGIH) and its close ties to the Occupational Safety and Health Administration (OSHA). ACGIH develops Threshold Limit Values (TLVs) on a variety of potentially harmful substances in the workplace. While ACGIH's TLVs are technically considered to be exposure guidelines and not have the weight of law, they are frequently used by OSHA as a foundation for Permissible Exposure Limits (PELs) and could be used by OSHA for so-called "general duty clause", Section 5(a)(1) violations.

In addition, the 23 states that have adopted their own safety and health programs in lieu of the federal OSHA program rely heavily upon the TLVs that ACGIH develops. These states have a charter obligation to provide safety and health protection equal to or greater than the federal program. These states need to have confidence in the procedures and results of the consensus standard setting organizations upon which they rely in developing their own standards and enforcement proceedings. In the case of ACGIH, in ABA's and other organizations experiences, they have been found woefully lacking as a so-called consensus organization.

In September 1999, the ACGIH began the process of developing for the first time a threshold limit value for flour dust. ACGIH announced that it was looking at establishing a level of .5 milligrams per cubic meter (mg/m^3) of inhalable dust. By way of comparison, the current ACGIH TLV for grain dust is 4 mg/m^3 and the OSHA PEL for grain dust is 10 mg/m^3 as an eight hour Time Weighted Average (TWA). This is the standard as it applies to grain silos, grain mills and related industries. OSHA's current PEL for nuisance dust, which flour dust is considered, is 15 mg/m^3.

ABA and its Safety Committee were obviously concerned that there might be new evidence showing that employees in the baking industry were being exposed to conditions that could lead to serious adverse health conditions. ABA attempted to contact ACGIH for a better

understanding of the science supporting their proposal and what opportunities there were to open a dialogue to discuss this important issue. ABA was informed that ACGIH does not provide affected industries with an opportunity to discuss TLVs under consideration or have a voice in their development. Over the course of two years, ABA and the North American Millers Association (NAMA) were informed that ACGIH did not want to even meet to discuss the TLV for flour dust.

In the spring of 2000, our organizations and the Canadian National Millers Association (CNMA) contracted with Sandler Occupational Medicine Associates (SOMA) to conduct a literature review of the documentation ACGIH was relying upon to determine whether to issue a TLV. In addition, we asked SOMA to determine if there was additional research material that could be helpful in determining whether a health risk existed.

The findings of the SOMA review were clear and startling: the scientific evidence does not support the ACGIH TLV. In fact, the SOMA study concludes:

> "Research in this area as reported by many independent studies has found that sensitization to flour dust does not account for a majority of reported symptoms in flour workers. This is based on the absence of evidence of flour sensitization in most symptomatic workers. Research findings support the conclusion that symptoms in flour workers are primarily *non-allergic* and that flour dust primarily acts as a *non-specific irritant* rather than as a sensitizer or allergy- causing substance."
>
> "Published data pertaining to exposure thresholds for flour-related effects, including sensitization and irritant effects are very limited. Furthermore, the data that serves as the basis for the TLV-TWA for flour sensitization *were not intended to be definitive for identifying exposure thresholds and do not provide confirmation* of the appropriateness of the TLV-TWA."
>
> "In conclusion, the TLV-TWA provided in the ACGIH document is based upon *very limited, indefinite and unconfirmed information and is not substantiated* by the accumulated scientific evidence regarding flour dust exposure. From a scientific and occupational medical perspective it is surprising that a TLV-TWA would be developed based upon such limited data. *The scientific evidence does not provide a basis for control of exposure at specific thresholds,* particularly exposure to flour dust for purposes of preventing or limiting flour allergen sensitization and other work-related effects. The … accumulated research does not provide scientifically-based, appropriately-derived support in the areas relevant to exposure threshold determination as provided in the ACGIH document."

On September 1, 2000, the ABA, NAMA and CNMA submitted the SOMA study to the ACGIH Chemical Substances/Threshold Limit Value Committee for their review with a request that the ACGIH should withdraw the proposed TLV on flour dust. Later that month, ACGIH issued the final TLV on flour dust. Calls from our organizations were ignored. Not until almost six months later did we receive a summary dismissal of our request that the TLV be withdrawn. In fact, the February 21, 2001, response failed to address the very serious issues raised in our letter and in the SOMA study. It merely stated that "ACGIH received no substantive comments on the

proposal during the year it was on the NIC. ACGIH believes that the *Documentation* for the flour dust TLV and the research cited therein adequately support the TLV."

To further illustrate how out of touch the ACGIH is with our concerns about the lack of scientific evidence, our organizations received a letter date June 14, 2001 stating that they "have carefully reviewed the critique of the Documentation …" and that "Review and evaluation of these reports has, in the Committee's opinion, strengthened the support for the TLV-TWA of .5 mg/m^3 as inhalable dust". It is inconceivable that even a cursory review of the SOMA study would lead to such conclusions.

All of this illustrates that a so-called "consensus organization" is conducting its scientific evaluations and decision making completely in private, with no outside input or oversight, and thus no true public consensus or confidence in the final work product. It is no wonder that ACGIH has found itself battling numerous lawsuits and may continue to face legal action in the future. Their work product – not just in the case of flour dust - is unsubstantiated, unreliable, and completely without merit.

Were it a mere "academic" exercise, ABA would not be concerned, however as one baking company in Kentucky found out, there are real consequences to these TLVs. Kentucky OSHA cited the company with a serious violation of the General Duty Clause and Respiratory Protection Standards. Kentucky OSHA had adopted the ACGIH TLV as a consensus standard on the belief that it was developed by a reputable resource in cooperation with the wholesale baking industry. This came as a great shock to the ABA.

The citation presented by Kentucky OSHA required that the company take immediate steps to abate employee's exposure to flour dust above the ACGIH TLV. This would result in baking personnel, who previously had not been required to wear respiratory protection under OSHA exposure standards, to start wearing full face mask respirators like those worn by hazardous materials workers. This would represent an extraordinary leap in hazard management for bakery facilities of any size. It is likely that few in the baking industry could ever meet the excessive engineering and respiratory requirements that would be required under this flawed an unnecessary TLV.

Kentucky OSHA formally dropped their citation in this matter when its review of the scientific foundation of the TLV and the SOMA critique conducted for the wholesale baking industry came to the same conclusion of the industry - that it is based on bad science. While this is only citation issued thus far, several other states have conducted inspections using the ACGIH TLV for flour dust.

We strongly urge OIRA to insist that OSHA utilize only data and consensus standards that meet minimum requirements for openness and participation. In addition, we urge OIRA to add further confidence in the regulatory process by requiring OSHA to utilize scientific data and economic impact analysis that has been independently peer-reviewed. OSHA reliance upon ACGIH standards clearly violates its own data quality guidelines.

ABA also urges OIRA to insist that OSHA avoid using ACGIH's TLVs as the basis for regulations and enforcement proceedings in accordance to ACGIH's own policy statement:

> *"Regulatory agencies should not assume that it is economically or technically feasible to meet established TLVs or BEIs (Biological Exposure Indices). ACGIH believes that TLVs and BEIs should NOT be adopted as standards without an analysis of other factors necessary to make appropriate risk management decisions."*

OSHA should be required to instruct the state OSHA plans that, given the controversies involving ACGIH standards, states also should refrain from utilizing the TLVs for enforcement and standard setting. Anything less creates a serious lack of integrity in OSHA's rulemaking and enforcement procedures.

In conclusion, ABA greatly appreciates the opportunity to submit all of these onerous regulations for serious consideration for reform. We applaud OIRA's diligence in pursuing more reasonable and less burdensome government regulations and suggest that OIRA provide aggressive and vigorous oversight to the respective agencies ensuring successful reforms. Please feel free to contact the ABA with any questions, or for additional information on any of these issues of interest.

Respectfully,

Robb MacKie
Vice President Government Relations
American Bakers Association