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SUPERIOR COURT OF CALIFORNIA

COUNTY OF LOS ANGELES

PHYSICIANS COMMITTEE FOR RESPONSIBLE MEDICINE, Plaintiff, v. **McDONALD'S CORPORATION, et al.,** Defendants.	Case No. BC 383722 **ATTORNEY GENERAL'S OBJECTIONS TO MOTION TO APPROVE PRIVATE PROPOSITION 65 SETTLEMENT WITH DEFENDANT BURGER KING CORPORATION** Date: November 17, 2008 Time: 10:30 a.m. Judge: Hon. Emilie Elias Dept.: 308

I. INTRODUCTION

In this case, the Physicians Committee for Responsible Medicine (PCRM) alleges that defendants should provide a cancer warning because a chemical called "PhIP," which is known to the state to cause cancer, is present in cooked chicken. But Proposition 65 expressly provides that no warning need be provided where the chemical poses no significant risk of cancer. Moreover, implementing regulations specifically provide that a less stringent "alternative risk" standard should be applied where a chemical that causes cancer is created by cooking food in a manner necessary to avoid microbiological contamination. In December of 2006, the Attorney General advised the parties that a review of the evidence showed not only that the level of PhIP present in chicken does not pose a significant risk of cancer, but that PhIP in chicken is created by cooking that reduces the risk of microbiological contamination by an amount greater than any risk created by PhIP itself. While the parties are not bound by that determination, they have provided little substantive response to the issue, and no evidence to the Court addressing it.

While parties ordinarily may resolve a case on nearly any agreeable terms, a private Proposition 65 case is brought "in the public interest," and may be settled only upon a judicial finding that the settlement meets specific statutory criteria and is itself "in the public interest." (*Consumer Advocacy Group v. Kintetsu Enterprises* (2006) 141 Cal.App.4th 46, 49 ["*Kintetsu I*"], Health & Saf. Code, § 25249.7, subd. (f).) At trial, defendants bear the burden of proving the "no significant risk" defense, but in seeking approval of a settlement, plaintiff bears the burden of introducing evidence to sustain findings necessary to obtain approval. In this instance, the evidence in the record contains no evidence to enable the Court to find that the settlement would be in the public interest, or to conclude that PCRM can properly claim an attorney fee for having accomplished a "public benefit."

II. PROPOSITION 65 SETTLEMENT APPROVAL REQUIREMENTS

In order to approve a private Proposition 65 settlement the Court must find that certain statutory criteria are satisfied *and* that the settlement is in the public interest.

Responding to a growing concern with private Proposition 65 enforcement actions that do "not provide any real protection to the public in the event of a violation, but do[] provide

compensation to the plaintiff's attorneys", the Legislature adopted settlement approval requirements. (*Kintetsu I, supra,* 141 Cal.App.4th at p. 49.) The requirements provide that settlements in private Proposition 65 cases must be submitted to the court by noticed motion, and may be approved only if the court makes the following findings:

> (A) Any warning that is required by the settlement complies with this chapter.
>
> (B) Any award of attorney's fees is reasonable under California law.
>
> (C) Any penalty amount is reasonable based on the criteria set forth [in the penalty provision].

(Health & Saf. Code, § 25249.7, subd. (f)(4).) The plaintiff must produce the evidence necessary to sustain the findings. (*Id.*, subd. (f)(5).) The Attorney General must be served with all moving papers, and is permitted to appear on the matter without intervening. (*Id.*)

Even where the specific statutory requirements are met, the Court is not required to approve the settlement, and indeed, *cannot* approve the settlement unless it is found to be consistent with the public interest. Thus, two courts of appeal have reversed trial court approvals of private Proposition 65 settlements that were not found to be consistent with the public interest. (*Consumer Defense Group v. Rental Housing Industry* (2006) 137 Cal.App.4th 1185, at pp. 1207-1208, *Kintetsu I, supra,* 141 Cal.App.4th at p. 59.)

III. PROCEDURAL HISTORY

PCRM provided its initial notice of intent to sue in 2006. In December of 2006, the Attorney General sent a letter to the U.S. Department of Agriculture addressing a number of related issues concerning this matter. Although the focus of the letter was to express the Attorney General's view that federal law does not preempt Proposition 65 in this instance, it also discussed whether there actually was a duty to warn for PhIP in chicken, because there could not be a conflict between state and federal law if Proposition 65 does not actually require a warning. (See Ex. A to Declaration of Edward G. Weil [Weil Dec.].)

As the letter points out, the statute establishes certain exemptions from its requirements, the most important of which is the "no significant risk" exemption. It provides that no warning is required for any exposure to a chemical known to cause cancer if "the person responsible can

show that the exposure poses no significant risk assuming lifetime exposure at the level in question[.]" (Health & Saf. Code, § 25249.10, subd. (c).) The "no significant risk" standard itself is set at a risk of 1 additional case of cancer per 100,000 exposed persons, which is less strict than the 1-in-1-million standard used by many regulatory agencies. (Cal. Code Regs., tit. 27, § 25703, subd. (b) [formerly tit. 22, § 12703(b)]; see *Ingredient Communication Council* v. *Lungren* (1992) 2 Cal.App.4th 1480, p. 1494, fn. 8.)

The regulations also provide, however, that the 1 in 100,000 risk level does not apply "where sound considerations of public health support an alternative level, as, for example: (1) where chemicals in food are produced by cooking necessary to render the food palatable or to avoid microbiological contamination[.]" The Final Statement of Reasons issued by the lead agency (now the Office of Environmental Health Hazard Assessment) in adopting this regulation sheds additional light on the full scope and meaning of the provision. As the agency noted:

> The public health benefits of cooking food are widely recognized. Cooking food significantly minimizes the possibility of food-borne infections and food intoxication. The high temperatures that foods are subject to during cooking are effective in killing pathogenic bacteria, helminths and other organisms[.]

(Statement of Reasons, at p. 4, Ex. B to Weil Dec.) The agency went on to note that a number of chemicals listed as carcinogens are by-products of the cooking process, and their concentrations vary depending on the cooking method, temperature, and duration. (*Id.*) It stated:

> The confusion which would result if all purveyors of cooked or heat-processed foods provide a warning with their product, to avoid any potential liability, could be enormous. If the warning were to specify that it is given for cooking, it could generate undue public fear about cooking food, leading some to undercook their food or avoid cooking altogether. This could result in an increase in the transmission of food-borne diseases. If the warning does not specify that it is given for cooking, consumers might avoid foods carrying the warning in favor of raw foods, which more likely would not carry a warning. Since most consumers cook raw food, they would expose themselves to the same listed chemicals anyway. Thus, consumers are likely to be exposed to these chemical by-products of cooking in any event. In light of the offsetting public health benefit that the cooking of food provides, the Agency takes the position that businesses which utilize cooking necessary for the processing or preparation of food should not be strictly held to the 10^{-5} standard.

(*Id.*) Of course, this does not completely exempt all chemicals created by cooking food, because their creation may be avoidable, i.e., not "necessary," or because they could pose a cancer risk

greater than any countervailing health benefit. Thus, applying the regulation requires consideration of the nature of the food, the cooking process, and the relative health risks and benefits of cooking the products. Finally, in some instances, factual issues will exist as to whether the degree of cooking was necessary to avoid contamination or render the food palatable.

The letter then pointed out that the Attorney General had retained a qualified expert who reviewed the scientific issues associated with the claim, and had informally consulted with representatives of PCRM concerning this matter. (Weil Dec., Ex. B, pp. 6-7.) Based on that review, the Attorney General concluded that the level of PhIP present in cooked chicken falls far below the level that would require a warning under Proposition 65, even without addressing any concerns about risks associated with undercooking of chicken. The evidence also showed that PhIP in chicken is created by the process of cooking necessary to render the food safe from microbiological contamination, and that the reduction in hazard from microbiological contamination due to cooking is greater than the risk posed by the presence of PhIP, i.e., that the net effect of cooking is to reduce the health risk associated with the product. Thus, in applying the "no significant risk" standard under Proposition 65, the Attorney General concluded that PhIP created by cooking chicken would be deemed to pose no significant risk, and would not require a warning.[1/]

Of course, neither party was required to accept the Attorney General's conclusions, despite earlier requests during the initial consultations with PCRM, after the letter was sent neither PCRM nor defendants asked to review the scientific data upon which these conclusions were based. (Weil Dec., Par.2.)

In September of 2008, the Attorney General raised these issues in a communication with

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1. PCRM refers to another case in which a court permitted warnings concerning PhIP. (PCRM Memorandum at . p. 4.) In that case, which involved warnings for acrylamide in french fries, the Attorney General agreed that Burger King could have the option of providing a warning a warning about PhIP in chicken, along with warnings about acrylamide in french fries. This was done only because the Attorney General did not believe that, acting in another case, he could preclude Burger King from giving a warning about PhIP. It does not prejudice the Attorney General's ability to appear in this case and suggest that the warning is not in the public interest, because this is proper case in which to do so.

counsel for the settling parties. No substantive response was received until October 23, 2008. (Weil Dec., Par. 4.)

IV. ARGUMENT

A. PCRM Has Not Shown That Warnings for PhIP in Chicken Are In the Public Interest.

Under Proposition 65, the plaintiff seeking approval of a settlement has the burden of producing evidence necessary to sustain each finding that the Court must make. (Health & Saf. Code, § 25249.7, subd. (f)(5).) Ordinarily where a plaintiff establishes that a product contains a chemical known to the state to cause cancer, the defendant could simply agree to provide a warning, declining to proceed with its affirmative defense of "no significant risk." In this instance, however, there is a greater concern that a warning may run afoul of a "no significant risk" regulation that is specifically designed to assure that warnings need not be provided where the chemical in question is created by a process that actually has the net effect of making the food safer to eat, i.e., killing bacteria. Thus, the issue is not simply whether an unnecessary warning will be provided, but a warning that would actually be harmful and potentially create a conflict with federal law. This shows that provision of the warning would not be in the public interest, and at the very least that PCRM has not met its burden of producing evidence that the warning would be in the public interest.

B. No Attorney Fee is Appropriate Because the Settlement Does Not Confer a Significant Benefit on the Public.

To approve the settlement, the Court must find that "*any* award of attorney's fees is reasonable under California law." (Health & Saf. Code, § 25249.7, subd. (f)(4) [emphasis added].) In the Proposed Consent Judgment, Burger King agrees to pay PCRM $25,000 in attorney fees and costs. (Proposed Consent Judgment at ¶¶ 3.1.) The simple fact that Burger King agreed to pay does not automatically render the amount "reasonable," otherwise the requirement would be rendered meaningless. This would be especially inappropriate here, where the legislative history of Proposition 65 shows that unjustified attorney fees were a primary reason why the statute was adopted. (*Kintetsu I, supra,* 141 Cal.App.4th at p. 49.) Since the

statute addresses settlements, it presupposes that the defendant has agreed to pay attorney's fees, yet imposes the additional requirement that they be "reasonable under California law."

Thus, the Court of Appeal has required that any attorney fee award in a private Proposition 65 settlement be analyzed according to the criteria of Code of Civil Procedure 1021.5. In *Consumer Defense Group v. Rental Housing Industry, supra,* 137 Cal.App.4th at pp. 1219-1220, the court analyzed the attorney fee award (also agreed to by the defendants), by engaging in extensive analysis using the factors traditionally used under section 1021.5. It specifically found the fee unreasonable, based in part on its conclusion that the fees in that case were "earned at the *direct expense of the public interest.*" (*Id.*, at p. 1218 [emphasis in original].) The Court specifically noted that although one of the trial judges in that matter had substantially reduced the amount of the fee, "even that reduction was predicated on the idea that the settlement served a genuine public interest." (*Id.*, at p. 1219.)

The apparent basis for any fee in this case is the private attorney general statute, Code of Civil Procedure section 1021.5. Section 1021.5 allows fees only where the action "has resulted in the enforcement of an important right affecting the public interest," and where "a significant benefit ... has been conferred on the general public[.]" *(See Beach Colony II v. California Coastal Com.* (1985) 166 Cal.App.3d 106, 114.)

Following these principles, the Attorney General's settlement guidelines provide that where a settlement provides that a warning will be given "for an exposure that appears to require a warning, [it]is presumed to confer a significant benefit on the public." (Cal. Code Regs., tit. 11, § 3201, subd. (b)(1).) It cautions, however, that [i]f there is no evidence of an exposure for which a warning plausibly is required; there is no public benefit, even if a warning is given." (*Id.*) This is simply a specific application of the above-referenced case law to Proposition 65: if there is no plausible claim that a warning actually is required, there is no public benefit to support an award of fees.

In this instance, the plaintiff has submitted nothing to establish that there is any plausible claim that a warning is required, and therefore has not sustained its burden. In short, given the complete lack of evidence provided by PCRM of even a plausible claim that a warning is

required here, there is no showing of a public benefit, and there can be no award of attorney fees.

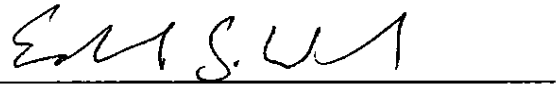
V. CONCLUSION

For the foregoing reasons, PCRM has failed to show that the settlement is in the public interest, or that its attorney fee is justified by any substantial public benefit. Accordingly, the motion should be denied.

DATED: November 4, 2008

Respectfully submitted,

EDMUND G. BROWN JR.
Attorney General of the State of California
J. MATTHEW RODRIQUEZ
Chief Assistant Attorney General
KEN ALEX
Senior Assistant Attorney General



EDWARD G. WEIL
Supervising Deputy Attorney General

Attorneys for Objector
Attorney General Edmund G. Brown Jr.

DECLARATION OF SERVICE BY OVERNIGHT COURIER

Case Name: **Physicians Committee for Responsible Medicine v. Mcdonald's et al.**

Case No.: **BC 383722**

I declare:

I am employed in the Office of the Attorney General, which is the office of a member of the California State Bar, at which member's direction this service is made. I am 18 years of age or older and not a party to this matter; my business address is: 1515 Clay Street, 20th Floor, Oakland, CA 94612-0550.

On **November 4, 2008**, I served the attached **Attorney General's Objections to Motion to Approve Private Proposition 65 Settlement with Defendant Burger King Corporation** by placing a true copy thereof enclosed in a sealed envelope with the **Federal Express**, addressed as follows:

Trenton H. Norris, Esq.
Sarah Esmaili, Esq.
Arnold & Porter LLP - San Francisco
275 Battery Street, 27th Floor
San Francisco, CA 94111

Michele Corash, Esq.
Robin Stafford, Esq.
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Forrest A. Hainline, III, Esq.
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David G. Alderson, Esq.
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Richards, Watson & Gershon - Los Angeles
355 South Grand Avenue, 40th Floor
Los Angeles, CA 90071-3101

I declare under penalty of perjury under the laws of the State of California the foregoing is true and correct and that this declaration was executed on **November 4, 2008**, at Oakland, California.

SARAH L. ANDERSON
Declarant

Signature

90097288.wpd

EDMUND G. BROWN JR.
Attorney General of the State of California
J. MATTHEW RODRIQUEZ
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Attorneys for Objector
Attorney General Edmund G. Brown Jr.

SUPERIOR COURT OF CALIFORNIA

COUNTY OF LOS ANGELES

PHYCICIANS COMMITTEE FOR RESPONSIBLE MEDICINE, Plaintiff, v. **McDONALD'S CORPORATION, et al.,** Defendants.	Case No. BC383722 **DECLARATION OF EDWARD G. WEIL IN SUPPORT OF ATTORNEY GENERAL'S OBJECTIONS TO MOTION TO APPROVE PRIVATE PROPOSITION 65 SETTLEMENT WITH BURGER KING CORPORATION** Date: November 17, 2008 Time: 9:00 A.M. Judge: Hon. Emilie Elias Dept.: 308

I, Edward G. Weil, declare:

1. I am a Supervising Deputy Attorney General for the California Attorney General's Office, and am assigned to this matter.

2. Attached as Exhibit A is a letter dated December 6, 2008 from the Office of the Attorney General to the General Counsel of the U.S. Department of Agriculture. Copies also

were provided to counsel for defendants in this matter and to counsel for PCRM. Although representatives of PCRM asked for some of the Attorney General's underlying supporting evidence during preliminary discussions, since the letter was sent, neither representatives of PCRM or defendants have requested a copy of the consultant's scientific report that is discussed in the letter.

3. Attached as Exhibit B is a true and correct copy of the Final Statement of Reasons for California Code of Regulations, title 22, section 12703, as adopted by the Health and Welfare Agency when adopting that regulation. The regulation has since been recodified as title 27, section 25703, without change, and the "lead agency" that adopts Proposition 65 regulations is the Office of Environmental Health Hazard Assessment.

4. In late September of 2008, I inquired by electronic mail to the counsel in this case about the Attorney General's objections to this settlement. I received no response of any substance until October 23, 2008.

I declare under penalty of perjury under the laws of the State of California that the foregoing is true and correct.

DATED: November 4, 2008

EDWARD G. WEIL

EXHIBIT A

BILL LOCKYER
Attorney General

State of California
DEPARTMENT OF JUSTICE

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December 5, 2006

Richard A. Raymond, M.D.
Under Secretary
Office of Food Safety
United States Department of Agriculture
Office of the Secretary
Washington, DC 20250

Marc L. Kesselman
General Counsel
United States Department of Agriculture
Washington, DC 20250

RE: Proposition 65 and Federal Preemption

Dear Messrs. Raymond and Kesselman:

We have been provided with a copy of your letter of October 5, 2006 to Jeff Farrar, Chief of the Food Safety Section of the California Department of Health Services, concerning the Safe Drinking Water and Toxic Enforcement Act of 1986, commonly known as Proposition 65. Under California law, the Department of Health Services is not responsible for implementation or enforcement of Proposition 65. Since the Attorney General is the statewide official responsible for enforcement of Proposition 65, we are responding to your letter.

As you know, Proposition 65 requires that, under certain circumstances, businesses provide consumers with clear and reasonable warning of exposure to chemicals known to cause cancer, unless the exposure is shown to create no significant risk of cancer. In April of 2006, we received a Notice of Violation from the Physicians Committee for Responsible Medicine, in which that group alleged that grilled chicken contains a chemical commonly known as "PhIP" (2-amino-1-methyl-6-phenylimidazo[4,5-*b*] pyridine). This notice alleged that certain sellers of grilled chicken had violated Proposition 65 by failing to warn consumers of the presence of PhIP in grilled chicken. We investigated the matter thoroughly.

After a thorough review of the letter's contents, and minimal discussion with your staff, we have reached a number of conclusions on the matter.

First, the procedure by which the letter was developed and sent is contrary to the express provisions of an Executive Order and reflects a deliberate effort to avoid consulting the responsible state officials in order to ascertain the actual law and facts applicable to the matter.

Second, there is no conflict in this instance between Proposition 65 and federal law, because, based on our factual and legal analysis, Proposition 65 does not require a warning for PhIP in chicken.

Third, your letter can be read to assert that all Proposition 65 warnings would always be preempted by the Poultry Products Inspection Act ("PPIA"), an assertion that is contrary to law, and certainly is not supported by any of the authority set forth in the letter.

A. Process

On October 18, 2006, we received a copy of the letter, which was addressed to Jeff Farrar of the California Department of Health Services, Food and Drug Branch. Through a series of prior correspondence in 2005, the U.S. Department of Agriculture ("USDA") is well aware that the Attorney General is the state official with responsibility for enforcement of Proposition 65, and this correspondence should have been directed to him.

As we understand it, the USDA was approached by representatives of members of the regulated community, and the matter was the subject of a variety of communications between those entities and USDA. At no point was any public notice issued, nor were any members of the public or officials from the State of California consulted.

An Order of the President of the United States entitled "Federalism" directs federal agencies to consult with affected state officials in considering actions that could preempt state law. (Executive Order 13132 (August 4, 1999) [64 Fed.Reg. 43255].) Most on-point is the requirement that "[w]hen an agency foresees the possibility of a conflict between State law and Federally protected interests within its area of regulatory responsibility, the agency shall consult, to the extent practicable, with appropriate State and local officials in an effort to avoid such a conflict." (Executive Order, § 4(d).)[1] In this instance, the USDA has acted in direct defiance of

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[1]See also §2(i)["the national government should be deferential to the States when taking action that affects the policymaking discretion of the states and should act only with the greatest caution where State or local governments have identified uncertainties regarding the constitutional or statutory authority of the national government"]; § 3(b) ["[w]here there are significant uncertainties as to whether national action is authorized or appropriate, agencies shall

this Order. While we are aware that the Order is not actually enforceable by third parties (§ 11), we can think of no reason why USDA would deliberately avoid consulting state officials concerning a matter of potential conflict with state law.

In considering the process by which your letter was formulated, it would be helpful to clarify its actual status. At certain points, it asserts that the "the Agency has determined" that Proposition 65 warnings would conflict with federal law. (See page 1, 3rd paragraph; page 3, 1st full paragraph.) It appears to us that the letter simply expresses the informal view of USDA, and is not legally binding. If you contend that it constitutes some type of formal determination that has the force and effect of law, please let us know (1) the procedure by which it was adopted; (2) whether it is considered a "final agency action" subject to judicial review under the Administrative Procedure Act; and (3) the nature of the rulemaking record on which it is based.

Even when properly viewed only as the non-binding expression of the legal position of the USDA, we disagree with your assertion that the letter is entitled to substantial deference. While your letter provides authority that agency interpretations are entitled to deference from the courts under many circumstances, we think that under these circumstances such a letter would receive no significant deference from a court. In this instance, it appears that USDA reached its conclusions after discussion with interested parties from one side of the issue, deliberately avoiding any input from the public or the responsible state officials. While California courts typically defer to agency interpretations of statutes in a manner similar to that applied in the federal courts, our Supreme Court has held that "the views of an administrative agency that are 'the product of a nonadversarial, ex parte process, conducted at the request of an organization that exclusively represents the interests' of a private industry group are entitled to less deference than administrative decisions made after formal proceedings in which adversarial views are aired." (*People ex rel. Lungren v. Superior Court (American Standard)* (1996) 14 Cal.4th 294, 311.) We think that, given a similar set of facts, a federal court would reach a similar conclusion.

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consult with appropriate State and local officials to determine whether Federal objectives can be attained by other means"]; § 3(d)(3) [agencies shall "in determining whether to establish uniform national standards, consult with appropriate State and local officials as to the need for national standards and any alternative that would limit the scope of national standards or otherwise preserve State prerogatives and authority"].

B. Potential Conflict Between State and Federal Law

Of course, there is no dispute that where state and federal law conflict, federal law prevails. Such conflicts, however, must be "actual" and "irreconcilable." In order to determine whether such a conflict exists, one must ascertain the requirements of the federal law, the requirements of the state law, and how they apply to the current situation. From our reading of your letter, it appears that USDA misunderstood some of the requirements of Proposition 65.

1. Requirements of Proposition 65

The Safe Drinking Water and Toxic Enforcement Act of 1986 is an initiative statute passed as "Proposition 65" by a vote of the people in November of 1986. The warning requirement of the statute is contained in Health and Safety Code section 25249.6, which provides:

> No person in the course of doing business shall knowingly and intentionally expose any individual to a chemical known to the state to cause cancer or reproductive toxicity without first giving clear and reasonable warning to such individual, except as provided in Section 25249.10.

Proposition 65 establishes a procedure by which the state develops a list of chemicals "known to the state to cause cancer or reproductive toxicity." (Health & Saf. Code, § 25249.8.) "Listed" chemicals are then subject to the law. (Cal. Code Regs., tit. 22, § 12000.)

Implementing regulations allow a number of methods of providing warnings, including labels and other point-of-sale information, which are "deemed to be clear and reasonable," and therefore are often called "safe harbor" warnings.[2] These regulations also provide "safe harbor" warning language, which for chemicals known to cause cancer is "Warning: This Product Contains a Chemical Known to the State of California to Cause Cancer." (Cal.Code Regs., tit. 22, § 12601(b)(4)(A).) Contrary to the suggestion in your letter, this language is authorized, not required. A warning could be used that provided more balanced information concerning the nature of the product and the hazard. Many such warnings have been authorized by the Attorney General and approved by courts. If a warning were necessary in this case, we could work with

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[2]In previous correspondence, we have discussed our different views concerning whether point-of-sale warnings that do not move through commerce with the product constitute "labeling" within the scope of the express preemption provision of the PPIA. Since your letter indicates that it does not address that issue, we will not address it here.

USDA on the development of appropriate language, as we have with other federal agencies. Accordingly, the fact that USDA considers the use of the "safe-harbor" warning language inappropriate in this case does not establish an actual conflict between state and federal law.

Enforcement actions may be brought by the Attorney General or District Attorneys. (Health & Saf. Code, § 25249.7(c).) In addition, private parties may sue if they provide a "notice of violation" specifying the alleged violation and no public prosecutor commences an action within sixty days. (*Id.*, § 25249.7(d).) In 2001, the California Legislature amended the statute to provide that notices alleging violations of the warning requirement must include a Certificate of Merit attesting that the notifying party has consulted with appropriately knowledgeable persons and believes that the action has merit, and providing the supporting information upon which that belief is based to the Attorney General. (*Id.*, § 25249.7(d)(1).)

2. Significant Risk Standards

The statute establishes certain exemptions from its requirements, the most important of which is the "no significant risk" exemption. It provides that no warning is required for any exposure to a chemical known to cause cancer if "the person responsible can show that the exposure poses no significant risk assuming lifetime exposure at the level in question[.]" (Health & Saf. Code, § 25249.10(c).) The "no significant risk" standard itself is set at a risk of 1 additional case of cancer per 100,000 exposed persons, which is less strict than the "1 in 1 million" standard used by many regulatory agencies. (Cal. Code Regs., tit. 22, § 12703(b). See *Ingredient Communication Council* v. *Lungren* (1992) 2 Cal.App.4th 1480, 1494 n. 8.)

The regulations also provide, however, that the 1 in 100,000 risk level does not apply "where sound considerations of public health support an alternative level, as, for example: (1) where chemicals in food are produced by cooking necessary to render the food palatable or to avoid microbiological contamination[.]" The Final Statement of Reasons issued by the lead agency (now the Office of Environmental Health Hazard Assessment) in adopting this regulation sheds additional light on the full scope and meaning of the provision. As the agency noted:

> The public health benefits of cooking food are widely recognized. Cooking food significantly minimizes the possibility of food-borne infections and food intoxication. The high temperatures that foods are subject to during cooking are effective in killing pathogenic bacteria, helminths and other organisms[.] ... In addition to its anti-microbial benefits, cooking is often necessary to make foods palatable. Experience has shown that, when food isn't palatable, people tend not to eat. This can have health consequences as well.

(Statement of Reasons, at 4.) The agency went on to note that a number of chemicals listed as carcinogens are by-products of the cooking process, and vary depending on the cooking method, temperature, and duration. (*Id.*) The agency went on to state:

> The confusion which would result if all purveyors of cooked or heat-processed foods provide a warning with their product, to avoid any potential liability, could be enormous. If the warning were to specify that it is given for cooking, it could generate undue public fear about cooking food, leading some to undercook their food or avoid cooking altogether. This could result in an increase in the transmission of food-borne diseases. If the warning does not specify that it is given for cooking, consumers might avoid foods carrying the warning in favor of raw foods, which more likely would not carry a warning. Since most consumers cook raw food, they would expose themselves to the same listed chemicals anyway. Thus, consumers are likely to be exposed to these chemical by-products of cooking in any event. In light of the offsetting public health benefit that the cooking of food provides, the Agency takes the position that businesses which utilize cooking necessary for the processing or preparation of food should not be strictly held to the 10^{-5} standard.

(*Id.*) Of course, this does not completely exempt all chemicals created by cooking food, because their creation may be avoidable, i.e., not necessary, or because they could pose a cancer risk greater than any countervailing health benefit. Thus, applying the regulation requires consideration of the nature of the food, the cooking process, and the relative health risks and benefits. Finally, in some instances, factual issues will exist as to whether certain cooking was necessary to avoid contamination or render the food palatable.

C. Application of Proposition 65 to PhIP in Chicken

In April of 2006, we received a Notice of Violation on this subject from the Physicians Committee for Responsible Medicine ("PCRM"), and investigated the matter throughly. Among other things, we retained a qualified expert who reviewed the scientific issues associated with the claim. In addition, we informally consulted with representatives of PCRM concerning this matter. We also received an inquiry from representatives of some of the alleged violators, and we advised them that we were reviewing the matter. They did not contact us again, however.

In reviewing the matter, we considered information about the concentration of PhIP in cooked chicken, the amount of chicken consumed by average users of the product, and the cancer potency of PhIP. Based on that review, we concluded that the level of PhIP present in cooked

chicken falls far below the level that would require a warning under Proposition 65, even without addressing any concerns about risks associated with undercooking of chicken.

In addition, we concluded that PhIP in chicken is created by the process of cooking necessary to render the food safe from microbiological contamination. We separately analyzed and quantified the health risks associated with undercooking chicken. Ultimately, our analysis showed that the reduction in hazard from microbiological contamination due to cooking is greater than the risk posed by the presence of PhIP, i.e., that the net effect of cooking is to reduce the health risk associated with the product. Thus, in applying the "no significant risk" standard under Proposition 65, it is clear that PhIP created by cooking chicken would be deemed to pose no significant risk, and would not require a warning.

Accordingly, in this respect, there is no conflict between Proposition 65 and the PPIA, because Proposition 65 does not require a warning for PhIP in cooked chicken.

D. Occupation of the Field by the PPIA

Most of your letter discusses whether warnings for PhIP in cooked chicken would conflict with USDA requirements concerning thorough cooking of meat. At certain points, however, the letter contains statements, which, taken by themselves, suggest that all Proposition 65 warnings for meat and poultry are always preempted by federal law, regardless of the circumstances. Such an assertion, which we are not certain you intended, amounts to an assertion that USDA has occupied the field of food safety. Such a contention is not supported in your letter, and cannot be sustained under existing law. Indeed, while there are many cases addressing preemption under the PPIA, and the similar Federal Meat Inspection Act, we are aware of none finding that those statutes automatically displace all state regulation.

As your letter indicates, it does not address the issue of whether point-of-sale warnings fall within the scope of "labeling" requirements, which are expressly preempted by the PPIA. The existence of that provision, however, is directly relevant to any claim that all Proposition 65 warnings are preempted by the PPIA. In *Cipollone v. Liggett Group*, 505 U.S. 504, 517 (1992), the Supreme Court held that the existence of an express preemption provision in a federal statute also should be viewed on a limit on the scope of preemption, such that federal "occupation of the field" can no longer be inferred.

Moreover, the relatively comprehensive nature of USDA regulatory requirements is not sufficient to either occupy the regulatory field or render all state-imposed warnings in conflict with federal law. This issue has been raised concerning other comprehensive federal regulatory

programs, including FIFRA and the Food, Drug and Cosmetic Act, yet no court has found that these requirements represent a scheme of federal regulation "so pervasive as to make reasonable the inference that Congress left no room for the states to supplement it." (*English v. General Electric* (1990) 496 U.S. 72, 79.) Indeed, the California Supreme Court recently considered conflict issues concerning Proposition 65 with respect to over-the-counter drugs, in *Dowhall v. SmithKline Beecham* (2004) 32 Cal. 4th 910. The court expressly found that the fact that regulation of over-the-counter drugs is comprehensive was not sufficient to create preemption. It also found that FDA's approval of a label without particular warnings could not be deemed to be a determination that no such warnings could be required by state law. Of course, that court did find that because the FDA had made a specific individual determination for the product in question by which it had formally and expressly forbidden the product manufacturer to provide the Proposition 65 warning, an irreconcilable conflict existed and federal law must prevail. As we discussed above, no such conflict exists here.

E. Conclusion

For the reasons set forth above, we do not think your claims as to preemption of Proposition 65 are legally correct, or are entitled to any significant deference from the courts. In this instance, there is no potential conflict between Proposition 65 and the PPIA because Proposition 65 does not require warnings for PhIP in cooked chicken.

With respect to our future practices, since the PPIA and FMIA do not occupy this field of health and safety regulation, we will continue to enforce Proposition 65 with respect to meat and poultry, although we will not require on-product labels. In addition, we are willing to consult with USDA in order to determine whether a given warning for a given product might be in conflict with federal law, and we would appreciate having the same courtesy extended to us.

Please do not hesitate to call me if you would like to discuss any of these issues.

Sincerely,

EDWARD G. WEIL
Supervising Deputy Attorney General

For BILL LOCKYER
Attorney General

EXHIBIT B

FINAL
STATEMENT OF REASONS
22 CALIFORNIA CODE OF REGULATIONS DIVISION 2

Section 12703 - Quantitative Risk Assessment

The Safe Drinking Water and Toxic Enforcement Act of 1986 (Health & Saf. Code, sec. 25249.5, et seq.) (henceforth referred to as the "Act") was adopted as an initiative statute at a general election on November 4, 1986. The Act prohibits any person in the course of doing business from knowingly discharging or releasing a chemical known to the state to cause cancer or reproductive toxicity into water or onto or into land where such chemical passes or probably will pass into a source of drinking water. (Health & Saf. Code, sec. 25249.5.) It further prohibits such persons from knowingly and intentionally exposing any individual to a chemical known to the state to cause cancer or reproductive toxicity without first giving a clear and reasonable warning. (Health & Saf. Code, sec. 25249.6.)

The Act also creates limited exceptions to these prohibitions. For chemicals known to the state to cause cancer, the Act provides that no warning is required if the person responsible for the exposure can show that the exposure would pose no significant risk assuming lifetime exposure at the level in question. (Health & Saf. Code, sec. 25249.10(c).) An exception to the discharge prohibition applies where the discharge or release complies with other legal requirements and does not cause a significant amount of the chemical to enter a source of drinking water. (Health & Saf. Code, sec. 25249.9.) A "significant amount" of a chemical is defined as a detectable amount or an amount which would not require a warning for an exposure in drinking water under section 25249.10(c).

The Act neither defines the phrase "no significant risk" nor provides any guidance on how to determine whether an exposure poses a significant risk. Health and Safety Code section 25249.12 gives agencies designated to implement the Act authority to adopt regulations as necessary to conform with and implement the provisions of the Act and to further its purposes. The Health and Welfare Agency ("Agency") has been designated the lead agency for the implementation of the Act.

By regulation, the Agency established a methodology for quantifying the risk from daily exposure to chemicals. (Cal. Code Regs., tit. 22, sec. 12703.) Subsection (b) of that regulation provides that daily exposure to a chemical over a lifetime poses no significant risk if the risk of cancer does not exceed one excess case in a population of 100,000 exposed persons, except where sound considerations of public health support an alternative level. As an example of a public health consideration, the regulation referred to cleanups and resulting

discharges ordered and supervised by an appropriate governmental agency or court of competent jurisdiction. No further examples were provided.

This regulatory action amends subsection (b) of section 12703 to add two additional examples of public health considerations: (1) Where chemicals in food are produced by cooking necessary to render the food palatable or to avoid microbiological contamination; and (2) where chlorine disinfection in compliance with all applicable state and federal safety standards is necessary to comply with sanitation requirements.

Procedural Background

The version of section 12703 which this regulatory action amends was adopted finally on June 9, 1989. On October 13, 1989, the Agency issued a Notice of Proposed Rulemaking which scheduled a public hearing for November 28, 1989, to consider proposed amendments to section 12703, and to amend or add two other regulations. Two comments were presented at the public hearing, and 23 other persons or organizations provided comments before the close of the comment period. Of these commentors, 17 commented on the proposed amendment to section 12703(b).

By notice dated March 19, 1990, the Agency made changes to the proposed regulation (March 19 version) and provided a 15-day period in which interested persons could comment on the changes. No comments were received.

Purpose of Final Statement of Reasons

This final statement of reasons sets forth the reasons for the final language adopted by the Agency in section 12703(b), and responds to the objections and recommendations submitted regarding that section as originally proposed in the October 13 proposal and modified by the March 19 proposal. Government Code section 11346.7, subsection (b)(3) requires that the final statement of reasons submitted with an amended or adopted regulation contain a summary of each objection or recommendation made regarding the adoption or amendment, together with an explanation of how the proposed action has been changed to accommodate each objection or recommendation, or the reasons for making no change. It provides that this requirement applies only to objections or recommendations specifically directed at the Agency's proposed action, or to the procedures followed by the Agency in proposing or adopting the action.

Some parties included in their written or oral comments remarks or observations about these regulations or other regulations which do not constitute an objection or recommendation directed at the proposed action or the procedures followed. Also, some parties offered their interpretation of the intent or meaning of the proposed regulations or other regulations, sometimes in

connection with their support of or decision not to object to the October 13 proposal. Again, this does not constitute an objection or recommendation directed at the proposed action or the procedures followed. Accordingly, the Agency is not obligated under Government Code section 11346.7 to respond to such remarks in this final statement of reasons. Since the Agency is constrained by limitations upon its time and resources, and is not obligated by law to respond to such remarks, the Agency has not responded to these remarks in this final statement of reasons. The absence of response should not be construed to mean that the Agency agrees with the remarks.

Specific Findings

Throughout the adoption process of this regulation, the Agency has considered the alternatives available to determine which would be more effective in carrying out the purpose for which the regulations were proposed, or would be as effective and less burdensome to affected private persons than the proposed regulations. The Agency has determined that no alternative considered would be more effective than, or as effective and less burdensome to affected persons than, the adopted regulation.

The Agency has determined that the regulation imposes no mandate on local agencies or school districts.

Rulemaking File

The rulemaking file submitted with the final regulation and this final statement of reasons is the complete rulemaking file for section 12703. However, because regulations other than section 12703 were also the topic of the public hearing on November 28, 1990, the rulemaking file contains some material not relevant to section 12703. This final statement of reasons cites only the relevant material. Comments regarding regulations other than section 12703 have been or will be discussed in separate final statements of reason.

Necessity for the Regulation

The Agency has determined that the adoption of this amendment to section 12703 is necessary. The Act exempts discharges, releases and exposures which pose no significant risk of cancer assuming lifetime exposure at the level in question, based upon scientifically valid evidence and standards. However, the Act provides no guidance on what exposures are "significant," including where the exposure is the consequence of practices motivated by competing considerations of public health, such as the avoidance of disease. Section 12703 provides that a chemical risk is significant if daily exposure to the chemical over a 70-year lifetime will produce more than one excess case of cancer in a population of 100,000 exposed persons (1×10^{-5}).

The Agency made an exception where sound considerations of public health support an alternative level of risk. To illustrate what constitutes a sound consideration of public health, the existing regulation provides a single example. The Agency believes that additional examples will better serve to illustrate what kinds of public health considerations warrant special treatment.

The public health exception is justified because the Act was intended by the voters as a measure to protect the public health and well-being. (Ballot pamphlet, Safe Drinking Water and Toxic Enforcement Act of 1986, Section 1.) It might contravene this intent if the Act were construed to prohibit activities which protect the public health. It would be ironic and counterproductive if, as the result of warnings, the public avoided practices which protect the public health.

SECTION 12703

Cooking

The public health benefits of cooking food are widely recognized. Cooking food significantly minimizes the possibility of food-borne infections and food intoxication. The high temperatures that foods are subjected to during cooking are effective in killing pathogenic bacteria, helminths and other organisms (e.g., Salmonella, Shigella, Campylobacter, and Trichinella), and, in most cases, breaking down their toxins. (See Manual for Control of Communicable Diseases in California, California State Department of Health, 1977, pp. 160-165, 370-377, 384-388, 441-444.) State and federal laws require that food establishments ensure that certain foods be thoroughly cooked prior to serving. (21 C.F.R. sec. 110.80; Health & Saf. Code, secs. 26209, 27591, 27601.)

In addition to its anti-microbial benefits, cooking is often necessary to make foods palatable. Experience has shown that, when food is not palatable, people tend not to eat. This can have health consequences as well.

On the other hand, there is extensive information in the scientific literature which indicates that chemicals having mutagenic and/or carcinogenic properties are formed as a result of cooking food. The chemicals formed and their amounts vary with such factors as the method of cooking (e.g., boiling, pan frying, grilling, etc.), the temperature and duration of cooking, and the type of food. Chemicals that have been found in cooked food include benzo[a]pyrene and other polycyclic aromatic hydrocarbons, tryptophan-P-1 and other amino acid pyrolysates, nitrosamines, and aldehydes. A number of these chemicals have been listed as known to the state to cause cancer.

Prior to this regulatory action, interested parties have expressed their concern that the Act would impact upon the practice of cooking. (See Cal. Code Regs., tit. 22, sec. 12501, Final Statement of Reasons, June 9, 1989, p. 9.) They have variously requested that the Agency prevent the potential of liability under the Act as the result of the cooking of food. A petition from 13 food, drug, cosmetic and medical device organizations requested that the Agency provide that exposure to chemicals which result from cooking pose no significant risk. (See Exh. 1, p. 1.) This proposal was not adopted, however, because the Agency could not be certain that all exposures which result from all manner of cooking in fact pose no significant risk.

Several commentors to section 12501 of the regulations recommended that chemicals formed by cooking be considered as "naturally occurring" chemicals which do not cause an exposure under the Act. (See Cal. Code Regs., tit. 22, sec. 12501, Final Statement of Reasons, June 9, 1989, p. 9.) This recommendation was also not adopted, since the definition of "naturally-occurring," which was derived from federal regulation (Id.), requires an absence of human activity, and cooking is a human activity.

Nevertheless, the Agency believes that some relief from a strict 10^{-5} standard is indicated for necessary cooking. Strict compliance with the 10^{-5} standard may not be possible where necessary cooking takes place. The concentration of chemical by-product may vary with each item prepared. Businesses may have considerable difficulty determining in any particular case whether cooking has resulted in the concentrations of listed chemicals which meet the 10^{-5} standard. Thus, businesses may feel compelled to provide a warning to protect them from liability in the event the level of risk does exceed 10^{-5}.

The confusion which would result if all purveyors of cooked or heat-processed foods provide a warning with their product, to avoid any potential liability, could be enormous. If the warning were to specify that it is given for cooking, it could generate undue public fear about cooking food, leading some to undercook their food or avoid cooking altogether. This could result in an increase in the transmission of food-borne diseases. If the warning did not specify that it is given for cooking, consumers might avoid foods carrying the warning in favor of raw foods, which more likely would not carry a warning. Since most consumers cook raw food, they would expose themselves to the same listed chemicals anyway. Thus, consumers are likely to be exposed to these chemical by-products of cooking in any event. In light of the offsetting public health benefit that the cooking of food provides, the Agency takes the position that businesses which utilize cooking necessary for the processing or preparation of food should not be strictly held to the 10^{-5} standard.

Subsection (b)(1) of this regulation specifically includes cooking necessary to avoid microbiological contamination or to make food palatable as an example of a public health consideration which supports the use of a no significant risk level other than 1×10^{-5}. Under the previous version of the regulation, cooking was arguably an example of a public health consideration. Specifically including necessary cooking as an example dispenses with the need for argument.

This approach has the advantage of flexibility. It does not establish a rigid line with which businesses must comply or face liability. Necessary cooking may result in varying amounts of chemical by-products. To the extent that the cooking is necessary to avoid contamination or to render the food palatable, the level which is considered to pose no significant risk should vary with the level of chemical by-product, and the public health benefit to be obtained.

One commentor objected that the proposal does not draw a specific dividing line. (Exh. 1, p. 4.) However, as indicated above, necessary cooking will produce varying amounts of chemical by-products, which makes the establishment of a dividing line difficult. Further, the public health exception to the 1×10^{-5} dividing line was created due to dissatisfaction with an absolute dividing line. There is no indication that the establishment of a different fixed dividing line will prove to be any more satisfactory.

This same commentor recommended that the Agency instead provide that chemical by-products of cooking do not result in an "exposure" pursuant to the Act, similar to the treatment given to "naturally-occurring" chemicals under section 12501 of the regulations. (Exh. 4, p. 3.) However, unlike "naturally-occurring" chemicals in food, chemical by-products of cooking are arguably "put out into the environment." (See Ballot pamphlet, Argument in Favor of Proposition 65, as presented to the voters, Nov. 4, 1986.) The "naturally-occurring" chemicals regulation is currently under judicial review. (Nicolle-Wagner v. Deukmejian, Los Angeles County Superior Court, Case No. 0689725.) Including chemical by-products of cooking in section 12501 would likely generate additional litigation. Accordingly, this recommendation was not adopted.

One commentor objected that the word "cooking" is unclear, since it can apply arguably to any manner of operation which involves the application of heat. (C-22, p.2.) The word was selected for its broad applicability to domestic and commercial food processing and preparation. Therefore, it represents an accurate expression of the Agency's intention.

The word "necessary" is not intended to favor one cooking practice over another. If a food could be boiled or broiled to avoid contamination or render the food palatable, but broiling

produces more chemical by-products than boiling, broiling does not become unnecessary. The Agency's intention is that, whatever method of cooking is chosen, the amount of cooking which is necessary to avoid bacterial contamination or to render the food palatable should provide a basis for the application of a risk level other than a risk of 1×10^{-5}.

One commentor objected that the phrase "necessary to avoid" is susceptible to different interpretations, and pointed out that cooking may not be necessary to avoid contamination where preservatives have been added to food. (C-22, p. 2.) The Agency agrees that different circumstances will raise questions of fact as to whether cooking is necessary to avoid contamination and, if the cooking is not also necessary to make the food palatable, whether warnings should be provided. This does not render the regulation unclear, or provide any other valid basis for objection. Since there was no recommendation of more appropriate language, the phrase has been retained.

As originally proposed, subsection (b)(1) would have applied only to cooking necessary to avoid bacterial or microbial contamination. Upon further review, it was determined that the words "bacterial or microbial" could be replaced by the word "microbiological," which covers the whole spectrum of parasitical, bacterial, viral and other microbial contamination. Accordingly, the March 19 proposal made this replacement. No objections were received.

Two commentors observed that cooking is performed to make food edible and palatable, as well as to avoid microbiological contamination, objected that the regulation as proposed would apply only to cooking necessary to avoid contamination, and recommended that it be expanded to include cooking necessary to render food edible, palatable, or otherwise fit for consumption. (Exh. 1, pp. 4-5; C-3, pp. 3-4.) Fitness for consumption arguably occurs when the cooking eliminates any microbiological contamination. Thus, reference to fitness for consumption appears duplicative. Food which is "palatable" appears to include that which is "edible," since food which is palatable due to cooking is usually edible, though not all food which is edible is palatable. Accordingly, the Agency determined that the needs of these commentors would be satisfied by the phrase "to render the food palatable." This language was included in the March 19 proposal. No objections were received.

The word "palatable" means "acceptable to the taste; sufficiently agreeable in flavor to be eaten." (American Heritage Dictionary, 2d Ed., Houghton Mifflin, "palatable," p. 893.) This raises the question of whose taste provides the standard of palatability. Cooking may render a food palatable to one person, but not to another. It is the Agency's intention that the word "palatable" refer to the taste of an ordinary person. This is consistent with the treatment of other elements of risk assessment. For

example, exposure to consumer products is based upon the average rate of exposure to the average consumer.

Chlorine Disinfection

According to the U.S. Environmental Protection Agency:

> "Chlorination is the most widely used method of disinfecting drinking water in the United States. It is convenient to use, effective in destroying or inactivating pathogens, and continues to disinfect in the distribution system. Chlorination is the standard against which all other disinfection techniques and disinfectants are compared." (52 Fed.Reg. 25728, July 8, 1987.)

Following the introduction of gaseous-feed chlorination systems in 1912, the death rate from typhoid fever and paratyphoid dropped from 25 in every 100,000 persons to fewer than 10 waterborne outbreak cases annually in the U.S. at large. (See Sawyer and McCarty, Chemistry for Environmental Engineering, 3d Ed., McGraw-Hill, 1978, pp. 385-388.) The public health benefits of water chlorination are considerable. Chlorine disinfection is also routinely employed in food processing plants, barns and dairies to disinfect equipment, tools and surfaces of organisms which may contaminate food. Food establishments are required to disinfect reusable eating and serving utensils with chlorine in order to prevent the transmission of certain infectious diseases through these items. (Health & Saf. Code, sec. 27613.) Swimming pool water must contain adequate amount of chlorine to minimize the growth of, or kill, microorganisms which may cause disease. (Cal. Code Regs., tit. 17, sec. 65529.)

Chlorine is also a highly reactive substance. Reactions between chlorine and various organics may result in the formation of chlorinated compounds which may be listed as known to the state to cause cancer, such as chloroform. Chlorine disinfection may, therefore, result in exposures to listed carcinogens via contact with food or other media. Wastewater discharged from facilities that disinfect with chlorine may likewise contain listed carcinogens.

The drafters of the Act were apparently aware of the problems surrounding chlorination. The Act specifically exempts any entity in its operation of a public water system, as defined in Health and Safety Code section 4010.1, most of which utilize chlorination, as indicated by the EPA (supra). Consistent with this exemption, the regulations adopted by this Agency provide that the discharge or release of water received from a public water system and other sources of drinking water is not a "discharge or release" of a listed chemical within the meaning of the Act to the extent that chemicals were contained in the water

received. (Cal. Code Regs., tit. 22, sec. 12401(a).) Similarly, the use of water containing listed chemicals received from these sources of drinking water does not cause an exposure within the meaning of the Act to the extent that chemicals were contained in the water received. (Cal. Code Regs., tit. 22, sec. 12502.) Thus, exposures to chlorination by-products in drinking water are generally exempt from the Act.

The exemption of drinking water suggests an intent on the part of the voters that chlorine disinfection practices not be disrupted at the expense of the public's health. In keeping with this intent, the Agency believes that some specific relief from a strict 10^{-5} standard is necessary for chlorine disinfection.

Prior to this regulatory action, interested parties have expressed their concern that the Act would impact upon the practice of chlorine disinfection. (See Cal. Code Regs., tit. 22, sec. 12401, Final Statement of Reasons, October 6, 1988, pp. 8-9.) Strict compliance with the 10^{-5} standard may not be possible where chlorine disinfection is required. The concentration of chemical by-product may vary with the situation. Businesses may have considerable difficulty of determining in any particular case whether chlorination has resulted in the concentrations of listed chemicals which meet the 10^{-5} standard. Thus, businesses may feel compelled to provide a warning to protect them from liability in the event the level of risk does exceed 10^{-5}, or to minimize their disinfection practices. In light of the offsetting public health benefit that the chlorine disinfection provides, the Agency takes the position that chlorine disinfection is a consideration of public health which should not be strictly held to the 10^{-5} standard.

Subsection (b)(2) of this regulation specifically includes chlorine disinfection necessary to comply with sanitation requirements and in compliance with all applicable state and federal safety standards as an example of a public health consideration which supports the use of a no significant risk level other than 1×10^{-5}. Previously, chlorine disinfection was arguably an example of a public health consideration. Specifically including safe and necessary chlorine disinfection as an example dispenses with the need for argument.

Addressing chlorination by this approach has the advantage of flexibility. It does not establish a rigid line with which businesses must comply or face liability. Necessary chlorination may result in varying amounts of chemical by-products. To the extent that chlorine disinfection is necessary, and is in compliance with all applicable state and federal safety standards, the level which is considered to pose no significant risk should vary with the level of chemical by-product, and the public health benefit to be obtained.

One commentor objected to the reference to state and federal safety standards on the ground that it is unauthorized, and cited AFL-CIO, et al. v. Deukmejian, et al., Sacramento County Superior Court, Case No. 502541, in support of this position. The Agency maintains that section 12713, the regulation which is the subject of that action, is consistent with the Act and valid as construed by the Agency. Therefore, even if this regulation accomplished the same result as section 12713, it would be valid and consistent with the Act.

In addition, the references to state and federal safety standards in section 12713 and section 12703 are distinguishable. Section 12713 provides that foods, drugs, cosmetics and medical devices which comply with specific safety standards and which, in addition, are safe, should be deemed to pose no significant risk. Thus, the safety standards referred to can provide a basis for exemption from the Act. The reference to safety standards in section 12703, on the other hand, requires compliance with state and federal standards in the practice of chlorine disinfection before an exception to the 10^{-5} no significant risk standard may be taken. The references, therefore, do not accomplish the same result.

ADDENDUM TO THE
FINAL STATEMENT OF REASONS
22 CALIFORNIA CODE OF REGULATIONS

Section 12703 - Quantitative Risk Assessment

On page 7, insert the following paragraph after the existing first paragraph:

The commentor also stated that "Chemicals formed generically by the ordinary process of cooking should be distinguished from chemicals formed (or formed in much greater quantities) when specific precursor chemicals are intentionally added to a food product, which are known to form potent listed carcinogens or reproductive toxins under predictable and commonly occurring conditions of cooking." The commentor appears to believe that this regulation provides an exemption for listed chemicals formed as a result of cooking. This is not the case. A person responsible for an exposure to a listed chemical formed as a result of cooking has the burden of proving that "sound considerations of public health support an alternative level" (sec. 12703(b)). For example, in the situation described by the commentor, the person responsible for the exposure must be able to show that the beneficial health effects of the additive outweigh the risks. If the proposed alternative level cannot be so supported, then subsection (b)(1) is not available and the 10^{-5} standard applies.

DECLARATION OF SERVICE BY OVERNIGHT COURIER

Case Name: **Physicians Committee for Responsible Medicine v. Mcdonald's et al.**

Case No.: **BC 383722**

I declare:

I am employed in the Office of the Attorney General, which is the office of a member of the California State Bar, at which member's direction this service is made. I am 18 years of age or older and not a party to this matter; my business address is: 1515 Clay Street, 20th Floor, Oakland, CA 94612-0550.

On November 4, 2008, I served the attached **Declaration of Edward G. Weil in Support of Attorney General's Objections to Motion to Approve Private Proposition 65 Settlement with Burger King Corporation** by placing a true copy thereof enclosed in a sealed envelope with the **Federal Express**, addressed as follows:

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I declare under penalty of perjury under the laws of the State of California the foregoing is true and correct and that this declaration was executed on November 4, 2008, at Oakland, California.

SARAH L. ANDERSON
Declarant

Signature

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