FINAL
STATEMENT OF REASONS
22 CALIFORNIA CODE OF REGULATIONS DIVISION 2

Article 4. Discharge

Section 12405. Discharge of An Economic Poison

The Safe Drinking Water and Toxic Enforcement Act of 1986 (Act) was adopted as an initiative measure (Proposition 65) by California voters on November 4, 1986. The Act imposed new restrictions on the use and disposal of chemicals which are known to the State to cause cancer or reproductive toxicity.

Part of the Act specifically prohibits persons in the course of doing business (as defined) from knowingly discharging or releasing such chemicals into the environment in a manner so that such chemicals pass or probably will pass into any source of drinking water (Health & Saf. Code, § 25249.5). (Unless otherwise specified, all statutory section references are from the Health and Safety Code.)

Violations of this prohibition can result in civil penalties of up to $2,500 per violation per day (§ 25249.7). Legal action to impose these penalties can be brought by the Attorney General, a district attorney, certain city attorneys or, under specified circumstances, any person "in the public interest" (§ 25249.7).

Chemicals subject to this discharge/release prohibition are set forth on a list which was first issued on February 27, 1987, and which is periodically revised (§ 25249.8). Since the discharge/release prohibition takes effect 20 months after the chemical involved first appears on the list, the initial list of chemicals became subject to this prohibition on October 27, 1988 (§ 25249.9).

Section 25249.12 authorizes agencies designated to implement the Act to adopt regulations as necessary to conform with and implement the provisions of the Act and to further its purpose. The Health and Welfare Agency (Agency) has been designated the lead agency for the implementation of the Act.

Procedural Background

Effective October 27, 1988, the Agency adopted on an emergency basis section 12405 of Title 22 of the California Code of Regulations. Pursuant to Government Code section 11346.1, that emergency regulation has been readopted three times so as to remain in effect.

On May 26, 1989, the Agency issued a notice of emergency rulemaking advising that the Agency intended to adopt permanently the version of section 12405 which had been in effect since 1988

(hereinafter "original version"). Notices were also issued that the Agency intended to adopt or amend two other regulations implementing the Act. Pursuant to such notices a public hearing was held on July 25, 1989, to receive public comments on the proposed regulations, including section 12405. Out of 18 pieces of correspondence received commenting on the regulations and 1 additional document submitted at the hearing, 10 contained comments regarding section 12405.

On October 13, 1989, the Agency issued a Notice of Public Availability of Changes to Proposed Regulations Regarding the Safe Drinking Water and Toxic Enforcement Act of 1986 (hereinafter the "October 13 version") The notice afforded interested parties the opportunity to comment on proposed modifications to the original version which were made in response to public comment. The comment period for the October 13 proposal closed October 30, 1989. Three pieces of correspondence were received.

In response to the comments received on the October 13 version, the Agency issued, on November 13, 1989, a second Notice of Public Availability of Changes to Proposed Regulations (hereinafter the "final version"). The comment period on the final version closed on November 30, 1989. Three pieces of correspondence were received. No changes were made to the regulation and the Agency's response to those three comments is contained in appropriate portions of this statement of reasons.

Purpose of Final Statement of Reasons

This final statement of reasons sets forth the reasons for the final language adopted by the Agency for section 12405 and responds to the objections and recommendations submitted regarding that section. 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 specifically 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 and 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 regulation or other regulations, sometimes in connection with their support of or decision not to object to the proposed action. 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 in this final statement of reasons to such remarks should not be construed to mean that the Agency agrees with them.

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 regulation was proposed, or would be as effective and less burdensome to affected private persons than the proposed regulation. 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 12405. However, because regulations other than section 12405 were also the topic of the public hearing on July 25, 1989, the rulemaking file contains some material not relevant to section 12405. This final statement of reasons cites only the relevant material. Comments regarding the regulations other than section 12405 discussed at the July 25, 1989, hearing have been discussed in separate final statements of reasons.

Necessity for Adoption of Regulation

The Agency has determined that it is necessary to interpret, clarify, and make specific section 25249.5 of the Act with regard to persons in the course of doing business who use economic poisons (more commonly referred to as pesticides, herbicides, fungicides and so forth). The regulation adopted by the Agency provides a rebuttable presumption that, for purposes of section 25249.5, a discharge or release of a listed chemical resulting from the application of an economic poison probably will not pass into any source of drinking water.

To qualify for this presumption, the person responsible for the application must show that:

1. the registrant of the economic poison had provided all of the studies and other information required under the Pesticide Contamination Prevention Act of 1985 (the PCPA); and

2. the economic poison had not been placed on the Groundwater Protection List created by the PCPA; and

3. the application was otherwise in compliance with the PCPA and all regulations adopted under that Act.

The premise underlying the regulation is that an economic poison which has been studied under the PCPA and not been placed on the Groundwater Protection List established under that Act will probably not migrate to groundwater. Both the PCPA and section 25249.5 have as their goal the avoidance of contamination of drinking water. If persons who use economic poisons choose a product which meets the criteria in the regulation, then the intended result of avoiding such contamination will be presumed. However, if it can be shown that either surface or groundwater contamination nevertheless has occurred as a result of the application, then the presumption provided by the proposed regulation would not be available.

This regulation is necessary because businesses which use economic poisons are in need of increased clarity with regard to how Proposition 65 applies to their activities. Establishing uniform standards is also necessary since lawsuits under the Act may be brought by the Attorney General, district attorneys, certain city attorneys and, under certain circumstances, any person in the public interest. Setting uniform standards will avoid confusion so that prosecutors can more easily and consistently determine whether or not compliance has been achieved and businesses can limit changes to their business operations to those necessary to comply.

The final version of this regulation is similar to section 25249.9 of the Act which places upon a defendant in a Proposition 65 enforcement action the burden of showing that the use of a substance containing a listed chemical was done not only in compliance with all applicable laws, regulations, permits, requirements, and orders, but that its use would not cause any significant amount of a listed chemical to enter any source of drinking water.

This regulation is carefully and narrowly drafted so that affected businesses may meet this burden by relying upon appropriate standards developed by persons or agencies who are much better equipped to evaluate such risks than would be the average user. Without this regulation, a defendant would have to independently prove what experts have already proven.

Failure to adopt this regulation would put those businesses which use the types of economic poisons described in this regulation, primarily California agriculture, in the position of risking lawsuits and fines under circumstances which they are generally ill-equipped to fully evaluate on their own. The average farmer should not be expected to have or to develop the level of scientific expertise necessary to determine if significant

releases of a listed chemical would probably result from an appropriate application of an economic poison.

Failure to adopt this regulation could also have significant economic consequences for California. Businesses using economic poisons covered by this regulation would have to either accept the risk of legal action or forego the use of substances which have been found to be safe when properly used. Resorting to the use of inferior methods of pest control could have serious effects on crop quality, production, and cost.

This regulation would have the effect of encouraging the use of economic poisons which have been fully evaluated and found not to contaminate groundwater. This would further the purposes of the Act since businesses would have an incentive to use economic poisons which have been determined to pose little or no risk to groundwater under the PCPA.

Scope of Presumption

It is the intent of the Agency that the presumption set forth in this regulation be applied only within a very narrow set of circumstances. One way that the proposed regulation helps to ensure this narrow scope of application is by specific reference to the PCPA and by a description of what administrative determinations must have been made under that statutory/regulatory scheme. In addition, the Agency intends that the presumption of "probably will not pass" set forth in this regulation be available only if the person responsible for the application has complied with all other applicable requirements of law.

The original version of this regulation contained a presumption that, when an economic poison containing a listed chemical was used in compliance with all applicable laws, permits, requirements, and orders adopted for the purpose of avoiding surface or ground water contamination, no significant amount of that listed chemical would pass into a source of drinking water.

Four commentors, all representing either users or producers of economic poisons, approved of the original version in all significant respects. (Hearing Exhibit C; C-1; C-4; C-7.) No response to those remarks is necessary.

Six commentors felt that the presumption in the original version was not authorized under the Act and, as a result, the Agency lacked the legal authority to adopt such a presumption. (C-9 pages 1-3, 8-13, 25-27, tables 1-6; C-13 pages 1-2; C-14 page 2; C-15 page 1-; C-16 page 1-2; C-17 page 2.) These commentors felt that the Agency was basing the presumption upon pre-existing federal and state legal requirements which had proven to be inadequate and that this proven inadequacy had been the reason why the voters passed a more stringent law, Proposition 65.

These commentors appear to be mistakenly assuming that the presumption allowed by this regulation is available even when a person in the course of doing business has actually discharged a listed chemical into a source of drinking water. However, since the presumption is potentially available only when the chemical has not passed into a source of drinking water, the Agency decided to clarify this point by revising the presumption language (October 13 version) so that it expressly relates only to the question of whether a discharge or release "probably will pass" to a source of drinking water.

Similarly, the final version of this regulation requires that the listed chemical in question not have passed into a source of drinking water. If the chemical in question has "passed", then this regulation does not apply.

As mentioned above, there was concern about that portion of the original version which tied the presumption to other state or federal laws. Commentors felt that such laws were not adequate to meet the goals of Proposition 65. (C-9 pages 1-3, 8-13, 15-27, tables 1-6; C-13 page 4, incorporating by reference comments from page 3; C-14 page 2; C-15 page 1-2; C-16 page 1.)

One of these commentors suggested specific changes to this portion of the regulation. The commentor stated that the regulation should contain a specific requirement that the referenced federal or state laws be adequate (C-13 page 4). This commentor also stated that the reference in the regulation to "state or federal" should be changed to "state and federal" (C-13 page 4). This commentor also felt that this provision was ambiguous as to which state or federal requirements were involved because the definition depended upon whether the intent of the requirements was to avoid contamination of drinking water (C-13 page 4).

In light of these objections, it was apparent that the portion of the original version of the regulation which limited the presumption to applications of an economic poison which were in compliance with ". . . statutes, regulations, permits and orders adopted to avoid surface or groundwater contamination . . ." (emphasis added) was in need of clarification.

The Agency concluded that the reference to state or federal standards contained in the original version of the regulation should be clarified so that the Agency could better achieve its intended result of recognizing compliance with other appropriate laws which have the same goals as Proposition 65. The October 13 version changed this aspect of the regulation in three basic ways:

1. The general reference to other state or federal laws was eliminated.

2. The examples of state or federal laws which might be recognized under the regulation were eliminated.

3. A specific law, the PCPA, was referenced as the only law which this regulation would recognize as supporting a presumption of compliance with Proposition 65.

The Agency made the above described changes after reviewing the public comments from the July 25, 1989 hearing and determining that, with respect to the use of economic poisons, there was only one existing statutory scheme which justified the establishment of a presumption that chemicals in economic poisons probably would not pass into a source of drinking water. Furthermore, the Agency determined that only one aspect of the PCPA would be considered for the presumption, the portion which certifies that a particular economic poison has been carefully studied and found to not pass into groundwater when used as directed.

As evidenced by its introductory language, the PCPA is designed to protect that portion of the state's drinking water supply which is contained in aquifers (Food & Agr. Code §13141). The PCPA meets this goal through a series of administrative actions to study economic poisons and differentiate between those which do not pose a threat to groundwater and those for which such safety cannot be assured.

The Agency has decided that this regulation should apply to only those economic poisons which have undergone the full study and evaluation scheme described in the PCPA and been finally determined to not pose a threat to groundwater. In order to draw an easily recognizable "bright line" between those chemicals which are potentially subject to the presumption and those for which this presumption is not available, the Agency has decided to use the Groundwater Protection List described in the PCPA (Food & Agr. Code §13145).

The Groundwater Protection List is composed of economic poisons which have failed one or more of the criterion listed in Food and Agricultural Code section 13143(a). These criteria relate to a chemical's propensity to migrate into groundwater. An economic poison which has "passed" <u>all</u> of these criteria has undergone a significant amount of study and evaluation for the sole purpose of determining whether or not that substance has the propensity to move into ground based sources of drinking water. For economic poisons which have undergone that scrutiny and not been placed on the Groundwater Protection List, it is reasonable to conclude that they "probably will not pass" into groundwater and thus it is appropriate to apply the presumption established by this regulation.

The limited scope of this regulation does <u>not</u> mean that a person in the course of doing business who is responsible for applying an economic poison which <u>is</u> on the Groundwater Protection List is automatically violating Proposition 65. A plaintiff in an enforcement action under the Act must always prove that the chemical in question either passed or probably will pass into a source of drinking water. A defendant in such an action should

have an opportunity to produce evidence countering the plaintiff's case. A person who used an economic poison in a way that met the requirements of this regulation would be saved the time and expense of putting on the scientific evidence which, absent the presumption, would be normally produced by a defendant trying to counter a claim that the economic poison moved into groundwater. This point is discussed in more detail under "Burden of Proof," below.

Scope of Presumption- Comments On the October 13 Version

The three commentors who responded to the October 13 notice focused on the scope of the presumption set forth in that version.

One commentor objected to narrowing the presumption because it was felt that by doing so the regulation had eliminated from its coverage industrial biocide products (PH-1). Industrial biocides include preservatives, fungicides and algicides that protect substances from degradation or deterioration caused by microorganisms including bacteria and molds. Typical areas in which industrial biocides are used include: paints, coatings and adhesives manufacturing; clothing textile treatment; oil fields; fuel preservation; pulp and paper mill systems; cooling water systems; plastic preservation; metalworking fluid preservation; and disinfectants. According to the commentor, industrial biocides usage differs from agricultural pesticides in significant ways such as the fact that they are generally not broadcast into the environment and consequently are unlikely to pose hazards to groundwater.

As evidenced by the Initial Statement of Reasons for this regulation, as well as the examples set forth in the original version relating to "similar" applications and circumstances (see "Rebutting the Presumption" below), the Agency has always intended that this regulation apply to agricultural uses only. The Initial Statement of Reasons is replete with references to agriculture and the examples relating to rebutting the presumption which were in the original version of the regulation listed factors such as weather, soil, and crop type, all of which obviously relate to agriculture and not to the industrial uses described by this commentor.

The rationale behind this regulation simply does not apply to uses of industrial biocides. The presumption established by this regulation is designed in part to provide some protection for California agriculture against frivolous lawsuits which might otherwise be brought by those who mistakenly believe that any discharge of a chemical onto the ground will always result in a significant amount of a listed chemical reaching a ground-based source of drinking water. Although such a premise may be attractive to some, it is scientifically invalid. The same mistaken impression is not a potential problem for the industrial biocide uses mentioned above. Any discharges of industrial

biocides would be unusual events. Therefore, there is no compelling need for an evidentiary presumption related to such uses.

Finally, it appears that this commentor may be confusing the Act's discharge prohibition (§25249.5) with the separate provision relating to exposures (§25249.6). As discussed above, this regulation deals only with discharges.

The second commentor felt that although the October 13 version was an improvement over the original version, the regulation was still illegal because it continued to avoid the need for case-by-case determinations of levels of listed chemicals that "pass or probably will pass" into a source of drinking water (PH-2). This remark seems to treat equally two quite different situations. In an enforcement action under Proposition 65, determination of the level of chemical involved is relevant where the chemical has been found to have actually passed into a source of drinking water. The presumption in the October 13 version of the regulation applies only where there is a suspicion that a chemical will pass into a source of drinking water, not where it actually has passed.

This commentor also felt that the reference to the PCPA was incomplete because it needed to include a requirement that all provisions of the PCPA which were applicable to the chemical involved should be complied with before the presumption would be available. The Agency agreed with that recommendation and made several changes to accomplish that result. All of the changes made in the final version, except for the addition of the last sentence, were made for the express purpose of tightening the reference to the PCPA so that only those substances which "passed" the PCPA criteria and were not put on the Groundwater protection list are covered by the presumption.

The third commentor objected to the portion of the regulation which excludes from the scope of the presumption economic poisons which have been placed on the Groundwater Protection List (PH-3). This commentor felt that the process used under the PCPA to decide whether or not an economic poison is placed on the Groundwater Protection List involves physical chemistry characteristics only and, thus, listing of a substance does not automatically mean that there is a problem. This commentor pointed out that the PCPA contains provisions which are designed to mitigate potential problems and that such controls justify use of the presumption established by this regulation. The Agency disagrees.

It is true that much of the PCPA deals with attempting to mitigate problems with economic poisons which have been placed on the Groundwater Protection List. However, the Agency intentionally restricted the scope of the presumption to those substances which "passed" the PCPA criteria without the need for mitigation. While such mitigation measures should prevent discharges into ground-based sources of drinking water, the

Agency felt that the presumption in the regulation should rest upon a firmer foundation, the use of economic poisons for which no mitigation is needed.

As stated earlier, use of an economic poison which is on the Groundwater Protection List does not automatically result in a violation of Proposition 65. It simply means that, in a Proposition 65 enforcement action, a defendant who used that type of economic poison might have to produce evidence to show that a chemical in the economic poison probably would not pass into a source of drinking water.

The commentor also was concerned about how farmers would be able to find out whether or not a particular economic poison met the requirements of the regulation (PH-3). The Agency shares this concern and added to the regulation a provision which designates each county agricultural commissioner's office as the source of this information. The regulation further provides that the State Department of Food and Agriculture will provide this information to each county office. The regulation further provides that a person in the course of doing business who obtains such information from a county agricultural commissioner may rely upon that information for purposes of Proposition 65.

This new provision will promote compliance with the Act because it establishes a source of official information about which economic poisons meet the definitions of the regulation. Such clarity will benefit not only persons who use agricultural economic poisons but also persons seeking to enforce the Act.

Scope of Presumption - Comments On the Final Version

Three commentors provided remarks concerning the final version of this regulation, all relating to the scope of the presumption.

One commentor felt that the reference in the regulation to the data submission requirements of Food and Agricultural Code section 13143(a) should be expanded to include all the provisions of that section (PH-2-1). The commentor felt that the reference to subsection (a) only precluded such factors as the manner of submission and the availability of extensions of time.

The Agency has not made any change in response to this comment because the final version of the regulation used broad terms such as ". . . completely and adequately satisfied all of the data submission requirements . . . ." Such wording clearly communicates that all of the applicable substantive and procedural requirements must be followed. Furthermore, the Agency intended that the available time extensions were not to be considered because the presumption is to be available only if the relevant data about the economic poison has actually been submitted and evaluated and found not to move to groundwater according to the criteria found in the referenced section 13143(a) and its implementing regulations.

This commentor also felt that the reference to the Groundwater Protection List should be dropped in favor of a provision that gives discretion to the Director of the Department of Food and Agriculture to cite to other scientific criteria and monitoring data as evidence that an economic poison which is on the Groundwater Protection List nevertheless does not move into groundwater. This commentor states that the Groundwater Protection List is based on a theory which is no longer used by those familiar with the subject. This commentor feels that, as a result, the criteria underlying that list ignore scientific advances which have occurred since the statute involved was passed in 1985. The Agency has decided to make no change in response to this comment because the purpose of the current statute is consistent with the application of the presumption in the regulation. If the methodology in the PCPA is outdated, it is up to the Legislature to make appropriate changes.

Another commentor (PH-2-2) also submitted comments on the October 13 version (see discussion regarding PH-1 under "Scope of Presumption- Comments on October 13 Version"). Although lengthier and more detailed than was the case for its earlier submission, this commentor raises the same objections and the Agency has the same response as for the first submission.

The third commentor raised the same concern as that stated by commentor PH-2-1 about the belief that the scientific criteria underlying the Groundwater Protection List was outdated and that the Director of the Department of Food and Agriculture should be given the discretion to consider other criteria (Ph-2-3). The Agency's response to this objection is the same as that indicated on those issues for commentor PH-2-1.

Commentor PH-2-3 included with its remarks a copy of its letter dated October 27, 1989, in which it commented on the October 13 version of the regulation. That correspondence was received by the Agency after the deadline for the submission of comments on the October 13 version and was therefore not considered at that time. However, of the two comments contained in that letter, one was also raised in this commentor's timely submission to the final version and is discussed in the preceding paragraph. The other comment contained in the October 27 letter was the same as that which was made by commentor PH-3 relative to how a farmer is supposed to find out what economic poisons satisfy the requirements of the regulation. (See discussion of commentor PH-3 under "Scope of Presumption- Comments on October 13 Version".)

<u>Burden of Proof</u>

Three commentors felt that the presumption allowed by this regulation violated the Act because it shifted the burden of proof from dischargers back to persons who file Proposition 65 enforcement actions. (C-9 pages 3, 14-15; C-13 second of two

unnumbered cover letter pages, attachment pages 1-4; C-14 page 2.) These commentors apparently misunderstand how the Act is structured.

The plaintiff in an enforcement action involving a discharge or release under the Act must prove that the defendant discharged a listed chemical and that it either passed or probably will pass into a source of drinking water. The only burden of proof which the defendant in a Proposition 65 case must carry is on the issue of whether a discharge, release, or exposure poses no significant risk from a listed chemical (§ 25249.10(c)).

This regulation does nothing more than describe a situation which, if proven, would give the defendant the benefit of a rebuttable presumption on the issue of whether a chemical "probably will pass" into a source of drinking water for purposes of § 25249.5. The defendant in such an enforcement action has the option of introducing evidence to counter any or all elements of the plaintiff's case. For example, the defendant could admit that a discharge occurred involving a listed chemical but argue that the chemical would not get into drinking water. The defendant does not have the burden of proof on that issue. He or she merely has the option of introducing evidence to counter the plaintiff's case. The defendant has the option of not introducing <u>any</u> evidence while the plaintiff has the burden to provide sufficient evidence to prove all of the above stated elements of the case, not to merely allege them.

<u>Rebutting the Presumption</u>

In the original version, the presumption was not available to a person who actually knew that, despite compliance with applicable laws and standards, a similar application under similar circumstances had resulted in significant amounts of a listed chemical passing into a source of drinking water.

In order to help define what was meant by "similar," the original version listed several factors of comparison (soil conditions, crop type, weather conditions, location and proximity to a source of drinking water). The listed factors were intended to serve as examples of what could differentiate one application from another. It was intended that other such factors of comparison could be considered when determining if "similar circumstances" existed.

Two commentors specifically expressed their disagreement with the requirement of showing the "actual knowledge" of the person responsible for the application relative to his or her awareness of prior contamination resulting from "similar" applications and circumstances. (C-13 pages 3-5; C-16 page 1.) First, it was pointed out that proving the actual knowledge of the person responsible for the application would be so difficult that rebutting the presumption was, for all practical purposes, impossible. Secondly, it was felt that the requirement of showing similarity of application and circumstances, especially

in light of the examples set forth in the original version, would also be next to impossible. The commentors felt that "similar" was defined so narrowly that it would be impossible as a practical matter to prove that two separate applications were similar enough to rebut the presumption. Lastly, one of these commentors went on to state that the definition of a "similar" application and circumstances was problematic and would lead to considerable ambiguity and litigation (C-13 page 3-4).

When drafting the October 13 version, the Agency decided to eliminate any reference to overcoming the presumption. Therefore, the objectionable provisions about proving actual knowledge about similarity of application and circumstances is eliminated from the regulation.

Once the Agency had decided to narrow the presumption, it no longer was appropriate to retain the provisions concerning actual knowledge and similar circumstances. Those provisions were designed for the more generally worded original version of the regulation and are not needed to clarify the more specifically worded version.

The absence of any specific reference to overcoming the presumption should not be interpreted as implying that the presumption in the final version cannot be rebutted. The plaintiff in a Proposition 65 enforcement action can introduce evidence to counter the defendant's case on any of the elements of the presumption. Also, the plaintiff could attempt to counter the defendant's claim that the economic poison was applied in compliance with all other requirements of law.

Conclusion

The final version of the regulation reflects a consideration of all the comments received during the adoption process and of the circumstances under which a presumption of the type proposed is appropriate. The Agency believes that this final version is a necessary and helpful clarification of the requirements of the Act.