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Sodium Hypochlorite, Calcium Hypochlorite, and Potassium Hypochlorite
Interim Registration Review Decision
Case Numbers: 0029 and 5076

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I. Introduction

This document is the Environmental Protection Agency's (EPA or the Agency) *Interim Registration Review Decision* for sodium hypochlorite, calcium hypochlorite, and potassium hypochlorite and is being issued pursuant to 40 CFR sections 155.56 and 155.58. A registration review decision is the Agency's determination whether a pesticide meets, or does not meet, the standard for registration in the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). The Agency may issue, when it determines it to be appropriate, an interim registration review decision before completing a registration review. Among other things, the interim registration review decision may require new risk mitigation measures, impose interim risk mitigation measures, identify data or information required to complete the review, and include schedules for submitting the required data, conducting the new risk assessment and completing the registration review. Initially, two separate registration review cases were scheduled to address sodium hypochlorite and calcium hypochlorite (Case 0029) and potassium hypochlorite (Case 5076). However, because of their similar use patterns, comparable chemical, physical, and environmental fate characteristics, these cases have been combined pursuant to 40 CFR Part 155.42 (b) (4), and this Interim Decision will address both cases. Further information and additional documents on sodium hypochlorite (PC Code 014703) and calcium hypochlorite (PC Code 014701), Case 0029, can be found in EPA's public docket (EPA-HQ-OPP-2012-0004) at www.regulations.gov. Potassium hypochlorite (PC code 129053), Case 5076, can be found in EPA's public docket (EPA-HQ-OPP-2014-0157) at www.regulations.gov.

FIFRA, as amended by the Food Quality Protection Act (FQPA) of 1996, mandated the continuous review of existing pesticides. All pesticides distributed or sold in the United States (U.S.) generally must be registered by the EPA based on scientific data showing that they will not cause unreasonable risks to human health or to the environment when used as directed on product labeling. The registration review program is intended to make sure that, as the ability to assess and reduce risk evolves and as policies and practices change, all registered pesticides continue to meet the statutory standard of no unreasonable adverse effects. Changes in science, public policy, and pesticide use practices will occur over time. Through the registration review program, the Agency periodically re-evaluates pesticides to make sure that as these changes occur, products in the marketplace can continue to be used safely. Information on this program is provided at http://www2.epa.gov/pesticide-reevaluation. In 2006, the Agency implemented the registration review program pursuant to FIFRA section 3(g) and will review each registered pesticide every 15 years to determine whether it continues to meet the FIFRA standard for registration.

Sodium Hypochlorite and Calcium Hypochlorite

Products containing sodium hypochlorite and calcium hypochlorite were first registered in the United States in 1957. A Reregistration Eligibility Decision (RED) was issued by the Agency for sodium hypochlorite and calcium hypochlorite in 1992. There are no outstanding Data Call-In (DCI) requirements for these active ingredients. Products containing calcium hypochlorite and/or sodium hypochlorite are often referred to as "bleach." Sodium hypochlorite is a liquid product, while calcium hypochlorite is a solid. There are currently 457 EPA-registered sodium hypochlorite products, and 129 EPA-registered calcium hypochlorite products. Registered uses for sodium hypochlorite and calcium hypochlorite include disinfectant, sanitizer, fungicide,

microbicide, bactericide, algaecide, and virucide uses. Sodium hypochlorite is used in irrigation water on agricultural premises.

Pursuant to 40 CFR section 155.50, EPA formally initiated registration review for sodium hypochlorite and calcium hypochlorite in 2012. The following timeline highlights significant events that have occurred during the registration review of sodium hypochlorite and calcium hypochlorite:

- Publication of Sodium Hypochlorite and Calcium Hypochlorite Preliminary Work Plan (PWP), in March 2012 for a 60-day public comment period.

- Comments received on the PWP were addressed in the Final Work Plan (FWP) for sodium hypochlorite and calcium hypochlorite. The publication of the FWP was in September 2012. No new data were determined to be needed and the Agency determined that updated risk assessments were not needed to support registration review.

- Publication of Sodium Hypochlorite, Calcium Hypochlorite, and Potassium Hypochlorite Proposed Interim Decision (PID), in September 2017 for a 60-day public comment period. The comment period ended on November 21, 2017. Comments received and the Agency's responses are presented in Appendix B.

Additional information on sodium hypochlorite and calcium hypochlorite can be found in EPA's public docket, which is accessible at www.regulations.gov in docket number EPA-HQ-OPP-2012-0004.

Potassium Hypochlorite

The first product containing potassium hypochlorite was registered in the United States in 1998. A Reregistration Eligibility Decision (RED) was not completed for potassium hypochlorite because it was registered after November 1, 1984. There are no outstanding Data Call-In (DCI) requirements for this active ingredient. Potassium hypochlorite is a liquid chlorine product, and there is only one EPA-registered potassium hypochlorite product, which is registered for use as a disinfectant, sanitizer, and algaecide.

Pursuant to 40 CFR section 155.50, EPA formally initiated registration review for potassium hypochlorite in 2014. The following timeline highlights significant events that have occurred during the registration review of potassium hypochlorite:

- Publication of the Potassium Hypochlorite Preliminary Work Plan (PWP), in March 2014 for a 60-day public comment period.

- No comments were received on the PWP. The Final Work Plan (FWP) for potassium hypochlorite was published in August 2014. No new data were determined to be needed and the Agency determined that updated risk assessments were not needed to support registration review.

- Publication of Sodium Hypochlorite, Calcium Hypochlorite, and Potassium Hypochlorite Proposed Interim Decision (PID), in September 2017 for a 60-day public comment period. The comment period ended on November 21, 2017. Comments received and the Agency's responses are presented in Appendix B.

During the development of the 2014 registration review PWP for potassium hypochlorite, the Agency conducted an in-depth review of the similarities between potassium hypochlorite and sodium hypochlorite and calcium hypochlorite, and determined that the data available to support the registrations of these active ingredients are also applicable to potassium hypochlorite.

Additional information on potassium hypochlorite can be found in EPA's public docket, which is accessible at www.regulations.gov in docket number EPA-HQ-OPP-2014-0157.

No updated risk assessments were conducted in support of the registration reviews of sodium hypochlorite, calcium hypochlorite, or potassium hypochlorite, as explained below.

II. Scientific Assessment

A. Human Health Assessment

EPA did not conduct an updated human health risk assessment for the registration reviews of sodium hypochlorite, calcium hypochlorite, or potassium hypochlorite.

The most recent human health risk assessments for sodium hypochlorite and calcium hypochlorite were completed, in support of the 1992 Reregistration Eligibility Decision (RED). The RED determined that the products containing these active ingredients were eligible for re-registration, except the uses on sugar syrup and raw sugar (the processed commodity), and consequently these products were not reregistered. In the Final Work Plan (FWP) for the registration review of sodium hypochlorite and calcium hypochlorite, the Agency decided that additional data or updated risk assessments would not be necessary.

For potassium hypochlorite, during the development of the 2014 registration review PWP for potassium hypochlorite, the Agency conducted an in-depth review of the similarities between potassium hypochlorite and sodium hypochlorite and calcium hypochlorite, and determined that the data available to support the registrations of those active ingredients are also applicable to potassium hypochlorite.

Although the Agency did not identify risk associated with these active ingredients in the Final Work Plan, EPA is requiring mitigation measures for stored hypochlorite solutions for drinking water disinfection. For discussion on possible chlorate and perchlorate formation, see section III.A.2. of this document. Products registered with the EPA that have surface disinfectant uses typically require inhalation toxicity data to quantitatively address risk as part of registration review. For bleach products, the Agency historically has not required these data, because the 1986 Standard, Guidance for Sodium and Calcium Hypochlorite Salts. Recently, open literature has identified risk concerns for the potential for asthma and other chronic respiratory illnesses from the use of cleaning products, including bleach, and as such, the Agency intends to further examine inhalation exposure and toxicity from all registered cleaning products. For further discussion on inhalation, see section III.A.4. of this document.

1. Risk Conclusions

EPA believes that risks to human health from the use of sodium hypochlorite, calcium hypochlorite, and potassium hypochlorite to be minimal when products are used according to directions for use and other labelling on product labels. According to the *Sodium Hypochlorite and Calcium Hypochlorite Human Health Risk Assessment Scoping Document in Support of Registration Review* (p. 2), [1] "Toxicity, exposure, and human health risk assessments for sodium and calcium hypochlorite were qualitatively assessed in the 1992 RED. […] As a result of the low toxicity of the breakdown product and low exposure, subchronic and chronic toxicity endpoints were waived in the RED; EPA reaffirmed this conclusion for registration review." Additionally, acute exposure is expected to be mitigated by precautionary labelling already on product labels. Conclusions made in support of the registrations of sodium hypochlorite and calcium hypochlorite are also applicable to potassium hypochlorite.

2. Human Incidents

Hypochlorite products are some of the most widely used EPA-registered products, particularly for residential end users. As such, these readily accessible products, mainly liquid bleach, have resulted in a variety of human incidents, and have been tracked though the Agency's Office of Pesticide Programs Incident Data System, with incidents dating back to 1973. Many of the incidents have been a result from the misuse of a product and/or not following registered label instructions.

There have been 4,581 reports of incidents associated with human exposure to sodium hypochlorite, calcium hypochlorite, or potassium hypochlorite reported in the OPP Incident Data System during the time period from 1973 to 2017. There were 29 reports of human related fatalities, including misuse of product, crime, and suicide-related fatalities. There were 157 reports of major human incidents, and 3,909 moderate human incidents. Finally, 173 domestic animal incidents were reported. The most recent report was generated on May 30, 2017. A summary of the reported human health incidents is presented below:

Routes of Exposure	Health Effects
Respiratory	Coughing, chest tightness, wheezing, dyspnea, bronchial hyper responsiveness, lung scar, and asthma like symptoms
Ocular	Eye irritation, red watery eyes, blurred vision, corneal abrasion, corneal epithelial erosions, conjunctivitis, and conjunctival chemosis
Dermal	Pain, itching, hive, burning sensation, generalized rash, irritation dermatitis,

[1] "Sodium Hypochlorite and Calcium Hypochlorite: Human Health Risk Assessment Scoping Document in Support of Registration Review" (2012) available at https://www.regulations.gov/docketBrowser?rpp=25&so=DESC&sb=commentDueDate&po=0&dct=SR&D=EPA-HQ-OPP-2012-0004

	acquired contact urticarial, erythema, blisters, and skin peeling
Oral	Oral irritation, gums numb, swollen tongue / throat, difficulty eating / drinking, abdominal cramp, and vomiting
Miscellaneous	Headache, dizziness, seizure, fainting, fever, swollen feet and arms, nausea, anaphylactic shock, miscarriage, and death

Although there have been a number of human health incidents from sodium hypochlorite, calcium hypochlorite, or potassium hypochlorite reported to the OPP Incident Data System since 1973, most of these incidents were due to misuse of the products, mainly liquid bleach. Based on this information, there does not appear to be a concern at this time.

3. Tolerances

There is an exemption from the requirement of a tolerance for sodium hypochlorite (40 CFR 180.1235). A food additive regulation permitting the use of sodium hypochlorite in washing or assisting in lye peeling of fruits and vegetables has been established (21 CFR 173.315). Additionally, sodium hypochlorite can be used as a component in paper in contact with aqueous and fatty foods (21 CFR 176.170), and in textiles fibers used for packing food (21 CFR 177.2800). Sodium hypochlorite has an exemption from tolerance for use in antimicrobial formulations (food-contact surface sanitizing solutions) in 40 CFR 180.940. It is listed as "hypochlorous acid, sodium salt" (CAS # 7681-52-9), with an upper limitation of 200 ppm total available chlorine as an end-use concentration.

Calcium hypochlorite is exempt from the requirement of a tolerance under FFDCA sec. 408 (40 CFR 180.1054) under the following circumstances: (a) when used preharvest or postharvest in a solution on all raw agricultural commodities, and (b) in or on grapes when used as a fumigant postharvest by means of a chlorine generator pad.

An exemption from the requirement of a tolerance is established for residues of potassium hypochlorite in or on all commodities [40 CFR § 180.1300].

4. Dietary Exposure

Food

Products containing sodium hypochlorite are registered for use as a sanitizer on food contact surfaces, and calcium hypochlorite products are registered for use as a sanitizer on food contact surfaces, as well as for pre-harvest and postharvest uses on agricultural commodities. Currently, there is only one registered product with the active ingredient potassium hypochlorite, and this is registered for use as a sanitizer on porous and non-porous food contact surfaces, as well as agricultural premises.

Although human dietary exposure via food contact to sodium hypochlorite, calcium hypochlorite, and potassium hypochlorite may occur as a result of the registered uses, there is no

risk of concern associated with these related compounds.[2] A dietary assessment was not performed for the RED for sodium hypochlorite and calcium hypochlorite based on the status of sodium hypochlorite being listed by the Food and Drug Administration (FDA) as Generally Recognized as Safe (GRAS), and calcium hypochlorite being listed as exempt from the requirement of a tolerance. Based on the 2014 Final Work Plan for potassium hypochlorite, there are no toxicological endpoints, therefore dietary exposures do not need to be assessed.

Drinking Water

Sodium hypochlorite, calcium hypochlorite, and potassium hypochlorite are all registered for use in drinking water disinfection. Although human dietary exposure via drinking water to sodium hypochlorite, calcium hypochlorite, and potassium hypochlorite may occur as a result of the registered uses, no risk was identified with these related compounds in the Final Work Plan.[3]

According to the *Sodium Hypochlorite and Calcium Hypochlorite: Human Health Risk Assessment Scoping Document in Support of Registration Review* (EPA, 2012, p. 5), "Residues of sodium hypochlorite in water are measured as available chlorine. In 1998, the Office of Water (OW) working with the Office of Pesticide Programs (OPP) established a maximum residual disinfectant level goal (MRDLG) of 4.0 mg/L (ppm) for chlorine (40 CFR 141.54) that is allowable in community water systems […] No adverse systemic effects are induced by sodium and calcium hypochlorite. As a result, EPA does not anticipate the need for a drinking water assessment at this time."

Based on the 2014 Final Work Plan for potassium hypochlorite, there are no toxicological endpoints, therefore drinking water exposures do not need to be assessed.

Although the Agency did not identify risk associated with these active ingredients in the Final Work Plan, EPA is requiring mitigation measures for stored hypochlorite solutions for drinking water disinfection. For discussion on possible chlorate and perchlorate formation, see section III-A-2 of this document.

5. Occupational and Residential Exposures

The Agency did not conduct new occupational and residential risk assessments. An occupational and/or residential exposure assessment is required for an active ingredient if (1) certain toxicological criteria are triggered, and (2) there is potential exposure to handlers (mixers, loaders, applicators, etc.) during use or to persons entering treated sites after application is complete. For sodium and calcium hypochlorite, there is potential exposure to occupational and

[2] "Registration Review Final Work Plan: Na & Ca Hypochlorite" (2012) and "Sodium Hypochlorite and Calcium Hypochlorite: Human Health Risk Assessment Scoping Document in Support of Registration Review" (2012) available at https://www.regulations.gov/docketBrowser?rpp=25&so=DESC&sb=commentDueDate&po=0&dct=SR&D=EPA-HQ-OPP-2012-0004

[3] "Registration Review Final Work Plan: Na & Ca Hypochlorite" (2012) and "Sodium Hypochlorite and Calcium Hypochlorite: Human Health Risk Assessment Scoping Document in Support of Registration Review" (2012) available in docket EPA-HQ-OPP-2012-0004 at www.regulations.gov

residential handlers, however, the toxicological criteria are not triggered, according to the *Sodium Hypochlorite and Calcium Hypochlorite: Human Health Risk Assessment Scoping Document in Support of Registration Review*. [4] Therefore, occupational and residential risk assessments are not required. Data available to support the registrations of sodium hypochlorite and calcium hypochlorite are also applicable to potassium hypochlorite.

There are concerns for dermal and eye irritation. However, sodium hypochlorite, calcium hypochlorite, and potassium hypochlorite are subject to FIFRA registration requirements and labeling language. Existing label requirements effectively address any potential acute toxicity issues involving eye and skin irritation by requiring protection of eyes and skin while using the products.[5]

6. Aggregate Exposures

An aggregate assessment was not necessary for sodium hypochlorite, calcium hypochlorite, and potassium hypochlorite because there were no residential or dietary risks identified. In examining aggregate exposure, EPA takes into account the available and reliable information concerning exposures to pesticide residues in food and drinking water, and non-occupational pesticide exposures. Risks associated with these exposures are expected to be minimal based on limited evidence of any subchronic or chronic systemic effects through any route of exposure.

7. Cumulative Exposures

Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding as to sodium hypochlorite, calcium hypochlorite, and potassium hypochlorite. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the policy statements released by EPA's Office of Pesticide Programs concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism on EPA's website at http://www.epa.gov/pesticides/cumulative/.

B. Environmental Assessment

The Agency did not conduct an environmental risk assessment for sodium hypochlorite, calcium hypochlorite, or potassium hypochlorite. All environmental fate and ecological effects data requirements for sodium and calcium hypochlorite have been satisfied since the Registration Standard was issued in 1986. [6] Upon reevaluating these data for the registration review of these

[4] "Sodium Hypochlorite and Calcium Hypochlorite: Human Health Risk Assessment Scoping Document in Support of Registration Review" (2012) in docket EPA-HQ-OPP-2012-0004 at www.regulations.gov
[5] https://www.epa.gov/pesticide-registration/labeling-requirements
[6] "Guidance for the Reregistration of Pesticide Products Containing Sodium and Calcium Hypochlorite Salts as the Active Ingredient" can be found at https://nepis.epa.gov

active ingredients, EPA has concluded that the currently registered uses of these active ingredients will not result in unreasonable adverse effects to the environment.[7]

Sodium hypochlorite and calcium hypochlorite are very similar in their mode of action to potassium hypochlorite, and all three release chlorine as the active ingredient. No environmental fate and exposure assessment and ecological effects assessment have been conducted for potassium hypochlorite, and EPA has concluded that the currently registered uses of this active ingredient will not result in unreasonable adverse effects to the environment.[8]

Although the Agency did not identify risk associated with these active ingredients in the Final Work Plan, EPA is requiring mitigation measures for hypochlorite solutions in pools, spas, hot tubs, and fountains. For discussion on draining pools, spas, hot tubs, and fountains see section III-A-1 of this document.

1. Environmental Fate and Exposures

The Agency's current understanding of the environmental fate of sodium hypochlorite and calcium hypochlorite is based on previous scientific assessments. In 2012, the Agency issued the *Product Chemistry, Environmental Fate, and Ecological Effects Scoping Document* which concluded: "Sodium hypochlorite is a very active substance and dissociates immediately in water to produce hypochlorite. Depending on the pH of the medium, it has the capability to go through chemical transformation to chlorine dioxide, chlorine, chloride and under highly acidic and basic conditions it can chemically transform into chlorate and perchlorate, depending [on] the oxidizing or reducing conditions of the medium. Thus a conventional way of looking at the environmental data (hydrolysis, aquatic photolysis, aerobic/anaerobic aquatic metabolism) is not possible and therefore such data is not required. […] All environmental fate information requirements for sodium and calcium hypochlorite and reaction products have been satisfied." Data available to support the registrations of sodium hypochlorite and calcium hypochlorite are also applicable to potassium hypochlorite.

2. Ecological Effects Assessment

The Agency's current understanding of the environmental effects of sodium hypochlorite and calcium hypochlorite is based on previous scientific assessments. In 2012, the Agency issued the *Product Chemistry, Environmental Fate, and Ecological Effects Scoping Document* which concluded: The Ambient Water Quality Criteria for Chlorine – 1984 document contains a review of public literature on effects of chlorine (total residual chlorine) and based on the data derives freshwater and saltwater organism acute and chronic water quality criteria. Current ambient water quality criteria for chlorine are based on the data in the 1984 document and the method for deriving water quality standards discussed in a 1986 Water Quality Document. All ecological

[7] "Product Chemistry, Environmental Fate, and Ecological Effects Scoping Document in Support of Registration Review of Sodium & Calcium Hypochlorite Salts" (2012) available in docket EPA-HQ-OPP-2012-0004 at www.regulations.gov

[8] "Potassium Hypochlorite Final Work Plan, Registration Review, Case Number 5076" available at https://www.regulations.gov/document?D=EPA-HQ-OPP-2014-0157-0003

effects data requirements have been satisfied for the active ingredients sodium and calcium hypochlorite.[9] Data available to support the registrations of sodium hypochlorite and calcium hypochlorite are also applicable to potassium hypochlorite.

EPA believes that additional data may be necessary to fully evaluate risks to non-target terrestrial invertebrates, especially pollinators because sodium hypochlorite is used in irrigation water on agricultural premises. EPA issued the Guidance for Assessing Pesticide Risks to Bees in June 2014. Since the sodium hypochlorite, calcium hypochlorite, and potassium hypochlorite registration reviews did not include the issuance of a DCI, this 2014 guidance for pollinator studies were not included in the cases. Therefore, EPA is currently determining whether additional pollinator data are needed for these three active ingredients. If the Agency determines that additional pollinator exposure and effects data are necessary to help make a final registration review decision for sodium hypochlorite, calcium hypochlorite, and potassium hypochlorite, then EPA will issue a DCI to obtain these data.

3. Ecological Incidents

No ecological incidents were reported in OPP's Incident Data System (IDS) for calcium hypochlorite and potassium hypochlorite from 1994 until June 8, 2017, based on a search conducted on June 8, 2017. However, for sodium hypochlorite, two incidents were reported in the database. On July 18, 1994, at a filtration plant in Tomkins, New York, hundreds of fish from three species were killed: brown trout (*Salmo trutta*), smallmouth bass (*Micropterus dolomieu*) and trout (*Salmonidae*). In the second incident on July 25, 2008, at a building in Santa Clara, California, 49 rainbow trout (*Oncorhynchus mykiss*) were found dead. The New York incident was classified as misuse and the California incident was classified as undetermined.

C. Endangered Species Assessment

In November 2013, the EPA, along with the National Marine Fisheries Service and the Fish and Wildlife Service (the Services) and the USDA, released a summary of their joint Interim Approaches for assessing risks to endangered and threatened species from pesticides. The Interim Approaches were developed jointly by the agencies in response to the National Academy of Sciences' (NAS) recommendations and reflect a common approach to risk assessment shared by the agencies as a way of addressing scientific differences between the EPA and the Services. The NAS report outlines recommendations on specific scientific and technical issues related to the development of pesticide risk assessments that EPA and the Services must conduct in connection with their obligations under the Endangered Species Act (ESA) and Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA).

As part of a phased, iterative process for developing the Interim Approaches, the agencies will also consider public comments on the Interim Approaches in connection with the

[9] "Product Chemistry, Environmental Fate, and Ecological Effects Scoping Document in Support of Registration Review of Sodium & Calcium Hypochlorite Salts" (2012) available at https://www.regulations.gov/docketBrowser?rpp=25&so=DESC&sb=commentDueDate&po=0&dct=SR&D=EPA-HQ-OPP-2012-0004

development of upcoming Registration Review decisions. The details of the joint Interim Approaches are contained in the white paper *Interim Approaches for National-Level Pesticide Endangered Species Act (ESA) Assessments Based on the Recommendations of the National Academy of Sciences April 2013 Report*[10], dated November 1, 2013.

Given that the agencies are continuing to develop and work toward implementation of the Interim Approaches to assess the potential risks of pesticides to listed species and their designated critical habitat, the ecological risk assessment supporting this Interim Decision for sodium hypochlorite, calcium hypochlorite, and potassium hypochlorite does not contain a complete ESA analysis that includes effects determinations for specific listed species or critical habitat. Although EPA has not yet completed effects determinations for specific species or habitats, for this interim decision EPA's evaluation assumed, for all taxa of non-target wildlife and plants, that listed species and designated critical habitats may be present in the vicinity of the application of sodium hypochlorite, calcium hypochlorite, and potassium hypochlorite. This assessment will allow EPA to focus its future evaluations on the types of species where the potential for effects exists once the scientific methods being developed by the agencies have been fully vetted. Once the agencies have fully developed and implemented the scientific methodology for evaluating risks for listed species and their designated critical habitats, these methods will be applied to subsequent analyses for sodium hypochlorite, calcium hypochlorite, and potassium hypochlorite as part of completing this registration review.

D. Endocrine Disruptor Screening Program

As required by FIFRA and FFDCA, EPA reviews numerous studies to assess potential adverse outcomes from exposure to chemicals. Collectively, these studies include acute, subchronic and chronic toxicity, including assessments of carcinogenicity, neurotoxicity, developmental, reproductive, and general or systemic toxicity. These studies include endpoints which may be susceptible to endocrine influence, including effects on endocrine target organ histopathology, organ weights, estrus cyclicity, sexual maturation, fertility, pregnancy rates, reproductive loss, and sex ratios in offspring. For ecological hazard assessments, EPA evaluates acute tests and chronic studies that assess growth, developmental and reproductive effects in different taxonomic groups. As part of its most recent registration decisions for sodium hypochlorite, calcium hypochlorite, and potassium hypochlorite, EPA did not identify endpoints for relevant risk assessment scenarios from the existing hazard database. However, as required by FFDCA section 408(p), sodium hypochlorite, calcium hypochlorite, and potassium hypochlorite are subject to the endocrine screening part of the Endocrine Disruptor Screening Program (EDSP).

EPA has developed the EDSP to determine whether certain substances (including pesticide active and other ingredients) may have an effect in humans or wildlife similar to an effect produced by a "naturally occurring estrogen, or other such endocrine effects as the Administrator may designate." The EDSP employs a two-tiered approach to making the statutorily required determinations. Tier 1 consists of a battery of 11 screening assays to identify the potential of a chemical substance to interact with the estrogen, androgen, or thyroid (E, A, or T) hormonal systems. Chemicals that go through Tier 1 screening and are found to have the potential to

[10] Available at http://www2.epa.gov/endangered-species/assessing-pesticides-under-endangered-species-act#report

interact with E, A, or T hormonal systems will proceed to the next stage of the EDSP where EPA will determine which, if any, of the Tier 2 tests are necessary based on the available data. Tier 2 testing is designed to identify any adverse endocrine-related effects caused by the substance, and establish a dose-response relationship between the dose and the E, A, or T effect.

Under FFDCA section 408(p), the Agency must screen all pesticide chemicals. Between October 2009 and February 2010, EPA issued test orders/data call-ins for the first group of 67 chemicals, which contains 58 pesticide active ingredients and 9 inert ingredients. The Agency has reviewed all of the assay data received for the List 1 chemicals and the conclusions of those reviews are available in the chemical-specific public dockets. A second list of chemicals identified for EDSP screening was published on June 14, 2013[11] and includes some pesticides scheduled for Registration Review and chemicals found in water. Neither of these lists should be construed as a list of known or likely endocrine disruptors. Sodium hypochlorite, calcium hypochlorite, and potassium hypochlorite are not on either list. For further information on the status of the EDSP, the policies and procedures, the lists of chemicals, future lists, the test guidelines and the Tier 1 screening battery, please visit our website.[12]

In this interim decision, EPA is making no human health or environmental safety findings associated with the EDSP screening of sodium hypochlorite, calcium hypochlorite, and potassium hypochlorite. Before completing this Registration Review, the agency will make an EDSP FFDCA section 408(p) determination.

III. Interim Registration Review Decision

A. Regulatory Rationale and Label Updates

Sodium hypochlorite, calcium hypochlorite, and potassium hypochlorite have played key roles in protecting public health through drinking water disinfection and are the most widely used chemicals for disinfecting public water supplies. Additionally, sodium hypochlorite, most well-known as “liquid bleach,” has been used as a disinfectant and sanitizer on surfaces for over a century.

At the final work plan stage, the Agency had identified no risks for the sodium hypochlorite, calcium hypochlorite, and potassium hypochlorite case beyond product specific acute risks, which are mitigated through precautionary statements and use directions on product labels. However, EPA recognizes that changes in science, public policy, and pesticide use practices will occur over time. As such, the Agency continuously re-evaluates pesticides to make sure that as these changes occur, products in the marketplace can continue to be used safely. Described below are four key topics related to sodium hypochlorite, calcium hypochlorite, and potassium hypochlorite that the Agency is currently addressing, some through label amendments, in registration review.

1. Discharge from Pool, Spa, Hot Tub, and Fountain Uses

[11] See http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPPT-2009-0477-0074 for the final second list of chemicals.
[12] http://www.epa.gov/endo/

Treated water from swimming pools, hot tubs, spas, and fountains can be discharged in various ways. However, product labels do not specify any means of discharge, other than any requirements imposed by the National Pollutant Discharge Elimination System (NPDES). Improper discharge into storm drains or surface water can lead to possible contamination of water bodies. There are no monitoring data for chlorine concentrations in receiving waters, and the Agency has no models to estimate such concentrations. Therefore, EPA is requiring advisory label statements.

There are four pathways pool or spa water may travel once discharged: (1) onto the surface of the land, (2) into a neighboring lake or stream, (3) into the municipal sewage system, or (4) into storm water drains. Most commonly, pools are drained directly onto the area immediately surrounding the pool or into municipal sewage systems. Both scenarios limit the exposure of the free residual chlorine, as soil naturally traps and removes impurities (i.e., chlorine) from water, and municipal sewage systems dechlorinate water before returning it back into the environment. Draining pools into a neighboring body of water or a storm drain is prohibited by many municipalities and discharge from waste water treatment plants is subject to National Pollutant Discharge Elimination System (NPDES) permits. The NPDES permit program controls water pollution by regulating point sources that discharge pollutants into waters of the US.

When properly disposed, the discharge of pool, spa, hot tub, or fountain water is not expected to disrupt wastewater treatment facilities or create adverse effects to aquatic and terrestrial organisms due to its extremely low use compared to other inputs. However, when improperly disposed, any chlorine residuals in pool, spa, hot tub, or fountain water have the potential to acutely adversely affect aquatic organisms.

Recognizing that states and local municipalities issue differing requirements and guidance for how to dispose of these treated waters and commercial discharges covered by the NPDES program, and that some states and local municipalities may not provide guidance, the Agency is requiring label amendments to mitigate risk to aquatic organisms. EPA consulted with stakeholders for the additional label mitigation below:

Label amendments for pool, spa, hot tub, and fountain products:

Add the following instructions to the Directions for Use section on applicable labels to not discharge treated water directly to bodies of water:

"Discharge Directions for [Commercial] and [Residential] [Pool,] [Spa,] [Hot Tub,] and [Fountain] Uses
Before draining a treated pool, spa, hot tub, or fountain, contact your local sanitary sewer and storm drain authorities and follow their discharge instructions. Do not discharge treated pool or spa water to any location that flows to a gutter, storm drain or natural water body unless discharge is allowed by state and local authorities."

For end-use products, NPDES permit language for pool, spa, hot tub, or fountain use is not required and must be removed if currently on the label.

For technical grade and manufacturing use products, the following NPDES statement must be included:

"Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA." (See Appendix A).

2. Possible Chlorate and Perchlorate Formation in Stored Hypochlorite Solutions

On July 31, 2014, the National Resource Defense Council (NRDC) wrote a letter to the Agency concerning a request to establish tolerances for sodium hypochlorite and calcium hypochlorite to minimize degeneration to perchlorate. While the letter fell outside of any currently open registration review comment period for the hypochlorites, EPA posted NRDC's comment letter, along with a formal response letter on January 25, 2017, to docket EPA-HQ-OPP-2012-0004 at www.regulations.gov.

EPA concurred with the observation in NRDC's letter that research by the American Water Works Association (AWWA) and the Water Research Foundation suggested the potential for perchlorate to form in stored hypochlorite solutions. As noted in the research, AWWA and the Water Research Foundation found hypochlorite concentration, pH, ionic strength, and temperature were major factors impacting perchlorate and chlorate formation in stored hypochlorite solutions at drinking water utilities. [13] Recent monitoring data included in the EPA Office of Water's Unregulated Contaminant Monitoring Rule (UCMR 3) found chlorate in finished drinking water.[14]

There have been reported improvements in industry practices to minimize chlorate and perchlorate formation in stored hypochlorite solutions for drinking water. [15] For example, the National Sanitation Foundation (NSF) / American National Standards Institute (ANSI) Standard 60: Drinking Water Treatment Chemicals implemented maximum levels of perchlorate in January 2013, and implemented maximum levels of chlorate in January 2015.[16, 17]

Further, EPA's Office of Water (OW) initiated the National Primary Drinking Water Regulation (NPDWR) process for perchlorate. In 2012, EPA sought recommendations from the Agency's Science Advisory Board (SAB) on how to derive a maximum contaminant level goal for perchlorate. To address SAB recommendations, EPA and Food and Drug Administration

[13] Reduction factors are from the 2011 American Water Works Association (AWWA) report, "Perchlorate, Bromate, and Chlorate in Hypochlorite Solutions: Guidelines for Utilities."
[14] "EPA Response to NRDC-Observations on Tolerances for Hypochlorite to Minimize Degeneration to Perchlorate, Correspondence" available in docket ID EPA-HQ-OPP-2012-0004 at www.regulations.gov
[15] Chlorine Institute Comment Letter to Rose Kyprianou on April 28, 2017, available in docket ID EPA-HQ-OPP-2012-0004 at www.regulations.gov
[16] www.nsf.org
[17] NSF International. March 9, 2016. "NSF/ANSI 60 – 2016 Drinking Water Treatment Chemicals – Health Effects."

scientists developed a Biologically Based Dose Response (BBDR) model to predict perchlorate's effects on thyroid hormones in pregnant women. EPA conducted an expert peer review of the BBDR model in January 2017. In January of 2018, EPA also conducted an expert peer review of approaches linking the BBDR model output to neurodevelopmental effects in offspring to inform the derivation of a maximum contaminant level goal (MCLG)[18] for perchlorate. The information obtained from these expert peer reviews will inform the Agency's Safe Drinking Water Act (SDWA) decision making for perchlorate. In light of this, the Office of Pesticide Programs (OPP) will continue to work with the OW on perchlorate issues during registration review of the hypochlorites.

Label amendments for drinking water disinfection products:

The Agency is requiring that advisory best management practices be added to hypochlorite drinking water disinfection product labels to minimize the potential for chlorate and perchlorate formation during storage. These best management practices can be used individually and in combination, and include storage time, pH, sunlight exposure, temperature, and dilution. See Appendix A for a table of the label language. EPA consulted with various stakeholders for label mitigation. Label amendments are to appear in the Precautionary Statements section of labels.[19] The practicality of these label amendments is based on the varying feasibility of different drinking water utilities to implement the suggested best management practices, such as geographic location and facility logistics; these label amendments are, therefore, advisory.

3. Residual Chlorine

EPA's OPP has specified label language allowing available chorine in public water systems to be in the 0.2-0.6 ppm range based on the 1986 Registration Standard for Sodium and Calcium Hypochlorite Salts. According to that document, levels within the 0.2 – 0.6 ppm range have been determined as safe, and may be referenced on labeling without the submission of additional data. Applicants may submit products with a higher residual chlorine level for registration, but this would require the submission of additional data and a resulting risk assessment.

In 1998, pursuant to the Safe Drinking Water Act, EPA's OW set a Maximum Residual Disinfectant Level Goal (MRDLG) of 4.0 mg/L and a Maximum Residual Disinfectant Level (MRDL) of 4.0 mg/L for chlorine based on a running annual mean for all measurements taken in the distribution system.

OPP is aware that utility companies may be using hypochlorite at higher rates than what pesticide labels permit, but within the MRDL limit. The use of EPA approved pesticides at levels higher than what is allowed on the label is considered to be a misuse (i.e., a FIFRA violation) and could lead to enforcement actions. Local health departments or other state-level agencies are not authorized to allow deviations from the EPA approved label without specific approval from

[18] The MCLG is a non-enforceable standard that is defined under SDWA (Section 1412.b.4.B) as the concentration of a contaminant in drinking water at which "no known or anticipated adverse effect would occur, allowing for an adequate margin of safety" [42 U.S.C. § 300g–1]

[19] Information for Precautionary Statements on EPA registered product labels can be found at https://www.epa.gov/sites/production/files/2015-03/documents/chap-07-jul-2014.pdf

the EPA. Therefore, OPP is working with the registrants and end users to revise the labels with rates that match the true use of the product. There are circumstances when a water system might have a higher distributed water residual chlorine level, and as such, label amendments would be needed. EPA has worked with AWWA (which represents many water treatment utilities) and the Chlorine Institute (which represents many hypochlorite manufacturers) in obtaining feedback, and the Agency will continue these collaborative efforts to ensure proper labeling and use of hypochlorite products. EPA does not anticipate any change in the supply chain based on suggested label amendments.

EPA is currently reviewing a proposal from industry for label amendments to address residual chlorine. Future updates about this issue will be placed in the public docket EPA-HQ-OPP-2012-0004. OPP will continue to work with EPA's OW and outside stakeholders on issues regarding residual chlorine, and the Agency will take into consideration all information provided by the commenters for future label changes. Any resulting label changes regarding residual chlorine will take place outside of this registration review process. Information on how FIFRA approval relates to SDWA can be found at https://www.epa.gov/pesticides/new-epa-quick-guide-registering-disinfectant-products-drinking-water-use .

4. Inhalation

Products registered with the EPA that have surface disinfectant uses typically require inhalation toxicity data to quantitatively address risk as part of registration review. For bleach products, the Agency historically has not required these data, because the 1986 Standard, Guidance for Sodium and Calcium Hypochlorite Salts, addresses risk concerns for inhalation: "The Agency has determined that the available acute toxicity data and fish and wildlife data are sufficient to address the acute toxicity risks to humans and the environment, and has concluded that there is no need for chronic or subchronic data to continue registering sodium and calcium hypochlorite products for the registered uses" (p. 7).[20]

Recently, open literature has identified risk concerns for the potential for asthma and other chronic respiratory illnesses from the use of cleaning products, including bleach, and as such, the Agency intends to further examine inhalation exposure and toxicity from all registered cleaning products. There have been a variety of human incidents that have been tracked though the Agency's Office of Pesticide Programs Incident Data System, with incidents dating back to 1973, as described in Section II.A.2. of this document. The first 15-year cycle of the registration review process concludes in 2022. As additional active ingredient risk assessments are completed on registered cleaning products, the Agency may refine risk mitigations in the sodium hypochlorite, calcium hypochlorite, and potassium hypochlorite final decision during this registration review cycle.

[20] "Guidance for the Reregistration of Pesticide Products Containing Sodium and Calcium Hypochlorite Salts as the Active Ingredient" can be found at https://nepis.epa.gov

B. Interim Registration Review Decision

In accordance with 40 CFR Sections 155.56 and 155.58, the Agency is issuing this Interim Registration Review Decision for sodium hypochlorite, calcium hypochlorite, and potassium hypochlorite. The Agency's interim decision is that (1) no additional data are needed at this time, and (2) certain labeling changes are needed. It does not cover either the ESA or EDSP component of this registration review case, and this interim decision is being issued pending their evaluation. EPA believes that additional data may be necessary to fully evaluate risks to non-target terrestrial invertebrates, especially pollinators, as described in Section III.B. of this document. If the Agency determines that additional pollinator exposure and effects data are necessary to help make a final registration review decision for sodium hypochlorite, calcium hypochlorite, and potassium hypochlorite, then EPA will issue a DCI to obtain these data.

IV. Next Steps and Timeline

A. Interim Registration Review Decision

A Federal Register Notice (FRN) will announce the availability of this interim registration review decision for sodium hypochlorite, calcium hypochlorite, and potassium hypochlorite in dockets EPA-HQ-OPP-2012-0004 and EPA-HQ-OPP-2014-0157 at www.regulations.gov. A final registration review decision for the sodium hypochlorite, calcium hypochlorite, and potassium hypochlorite cases will depend upon both the result of an ESA Section 7 Endangered Species assessment and consultation, if necessary, with the Services, and an EDSP FFDCA section 408(p) determination. EPA believes that additional data may be necessary to fully evaluate risks to non-target terrestrial invertebrates, especially pollinators, as described in Section III.B. of this document. If the Agency determines that additional pollinator exposure and effects data are necessary to help make a final registration review decision for sodium hypochlorite, calcium hypochlorite, and potassium hypochlorite, then EPA will issue a DCI to obtain these data.

B. Implementation of Mitigation Measures

Registrants will be required to submit amended labels that include the required mitigation to the Agency for approval within 60 days of the publication of this Interim Decision. Label changes are shown in Appendix A.

C. Labeling Clean-Up

As scientific findings and standards advance, the EPA seeks to ensure that all registered pesticide products are effective as claimed and are labeled in a manner that will prevent adverse effects to human health and the environment. Regulations and guidance may have been updated since products containing sodium hypochlorite, calcium hypochlorite, and potassium hypochlorite were previously registered.

In review of product labeling associated with these active ingredients, the EPA is concerned that the Storage and Disposal instructions and Precautionary Statements (which includes: Signal Word, Child Hazard Warning, Hazards to Humans and Domestic Animals, First Aid, Personal Protective Equipment, Physical or Chemical, and Environmental Hazards) for many of these products are outdated.[21] These products need to be accurately labeled. Therefore, the Agency is initiating this label cleanup of the active ingredients sodium hypochlorite, calcium hypochlorite, and potassium hypochlorite.

The Agency is making the request for companies to ensure their products' labeling language is correct based on 40 CFR PART 156—LABELING REQUIREMENTS FOR PESTICIDES AND DEVICES. Additional guidance and information regarding the precautionary language rules and regulations can be found online in the Agency's Label Review Manual (https://www.epa.gov/pesticide-registration/label-review-manual). As registrants update their labels to include the changes required under Registration Review, registrants must include any other labeling updates that may be needed to meet current labeling standards.

[21] For current label language, see the Agency's Label Review Manual (https://www.epa.gov/pesticide-registration/label-review-manual). Chapter 7: Toxicity Category, Child Hazard Warning, First Aid Statement, Precautionary Statements for Human Hazards, Personal Protective Equipment Statements; Chapter 8: Environmental Hazards; Chapter 9: Precautionary Statements for Physical or Chemical Hazards; Chapter 10: Signal Word; Chapter 13: Storage and Disposal.

Appendix A: Summary of Required Labeling Changes for Hypochlorites

Summary of Labeling Changes for Hypochlorites		
Description	**Labeling Language for Hypochlorites**	**Placement on Label**
Drinking Water Disinfection End Use Products		
For drinking water uses	"The following practices help to minimize degradant formation in drinking water disinfection: • It is recommended to minimize storage time. • It is recommended that the pH solution be in the range of 11-13. • It is recommended to minimize sunlight exposure by storing in opaque containers and / or in a covered area. Solutions should be stored at lower temperatures. Every 5^{o} C reduction in storage temperature will reduce degradant formation by a factor of two. • Dilution significantly reduces degradant formation. For products with higher concentrations, it is recommended to dilute hypochlorite solutions with cool, softened water upon delivery, if practical for the application."	Precautionary Statements, on applicable labels
Pool, Spa, Hot Tub, and Fountain End Use Products[1]		
For end use formulations used to treat commercial and residential swimming pools, hot tubs, spas, and fountains Note: Registrants must only include approved use sites in the Discharge Directions statement	**"Discharge Directions for [Commercial] and [Residential] [Pool,] [Spa,] [Hot Tub,] and [Fountain] Uses** Before draining a treated [pool,] [spa,] [hot tub,] or [fountain] contact your local sanitary sewer and storm drain authorities and follow their discharge instructions. Do not discharge treated pool or spa water to any location that flows to a gutter, storm drain or natural water body unless discharge is allowed by state and local authorities." For end-use products, NPDES permit language for pool, spa, hot tub, or fountain use is not required and must be removed if currently on the label associated with these uses.	Directions for Use, on applicable labels

Summary of Labeling Changes for Hypochlorites		
Description	**Labeling Language for Hypochlorites**	**Placement on Label**
Industrial Processes and Water Systems End Use Products, and All Technical Grade and Manufacturing Use Products[1, 2, 3]		
For technical and manufacturing use formulations used to formulate swimming pools, hot tubs, spas, and fountains and other approved use sites To clarify Environmental Hazards statements based on product category	"Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA."	Environmental Hazards, on applicable labels

[1] Note for Pool, Spa, Hot Tub, and Fountain Products: The Agency allows master labels to include multiple uses. Therefore, a label may include uses that would trigger the non-NPDES language (e.g. end use pool) and the NPDES language (e.g. industrial processes such as cooling tower use). For products whose uses trigger multiple discharge direction language, the label should indicate which uses the NPDES language applies to and which uses other discharge instructions apply to.
[2]See EPA's Antimicrobial Pesticides Use Site Index for a full description of use sites at https://www.epa.gov/sites/production/files/2016-10/documents/158w-usi.pdf
[3]Clarification on NPDES label language can be found in Pesticide Registration Notice (PRN) 95-1: Effluent Discharge Labeling Statements at https://www.epa.gov/pesticide-registration/prn-95-1-effluent-discharge-labeling-statements

Appendix B: Response to Comments Received on the Proposed Interim Decision

The Agency's Antimicrobials Division received comments from 11 submitters during the 60-day public comment period for the Proposed Interim Decision on the hypochlorites, which opened on September 22, 2017 and ended on November 21, 2017. Comments were submitted from a variety of stakeholder groups: Alexander & Baldwin, the American Water Works Association (AWWA), the California Storm Water Quality Association (CASQA), the California Water Board San Francisco Bay Regional Quality Control Board, the Chlorine Institute, the Clorox Company, the Environmental Defense Fund (EDF), the National Association of Clean Water Agencies (NACWA), New York City Department of Environmental Protection, the State of Hawaii, and the United States Department of Agriculture (USDA). Submissions can be found in dockets EPA-HQ-OPP-2012-0004 and EPA-HQ-OPP-2014-0157 at www.regulations.gov. Comments and responses below are organized by topic.

Residual Chlorine Levels: Regulations that Conflict with FIFRA Labels

The Proposed Interim Decision (PID) from June 2017 identified the differences between EPA's Office of Pesticides Program's (OPP) label and EPA's Office of Water (OW) Safe Drinking Water Act (SDWA) limits on residual chlorine (p. 18-19). According to OPP's approved bleach product labels, residual chlorine levels within the 0.2 - 0.6 ppm range have been determined as acceptable, and may be referenced on labeling without the submission of additional data. EPA's Office of Water set a Maximum Residual Disinfectant Level Goal (MRDLG) of 4.0 ppm and a Maximum Residual Disinfectant Level (MRDL) of 4.0 ppm for chlorine based on a running annual mean for all measurements taken in the distribution system. The Agency received many comments regarding the discrepancy between these two levels. Commenters stated that contradictory levels are confusing. Suggestions by commenters to remediate the discrepancy between OPP's label requirements and OW's SDWA levels were:

- Use chlorine gas label language, which is consistent with SDWA.
- If data collection is required to satisfy FIFRA requirements, then existing approval processes should be considered, such as NSF 60 certification of products for use in drinking water treatment.
- Replace OPP's 1986 Registration Standard for Sodium and Calcium Hypochlorite with SDWA requirements.

Agency Response: EPA is currently reviewing a proposal from industry for label amendments to address residual chlorine. Future updates about this issue will be placed in the public docket EPA-HQ-OPP-2012-0004.

OPP will continue to work with EPA's OW and outside stakeholders on issues regarding residual chlorine, and the Agency will take into consideration all information provided by the commenters for future label changes. Any resulting label changes regarding residual chlorine will take place outside of this registration review process. Information on how FIFRA approval relates to SDWA can be found at https://www.epa.gov/pesticides/new-epa-quick-guide-registering-disinfectant-products-drinking-water-use.

Some commenters stated that in order to achieve certain disinfection goals (e.g., *Giardia* control), some drinking water systems are required to exceed pesticide labels' approved residual chlorine levels. Additionally, chlorine residuals in water systems vary by location in system and time of treatment. Commenters offered the following suggestions for instances when the residual chlorine level exceeds OPP's approved label levels of 0.2 - 0.6 ppm

- End users of EPA registered hypochlorite products should check with their local Health Department, and primacy agency, which would allow them to use in excess of the label's 0.6 ppm limit.
- When end users must perform corrective checks of residual chlorine levels above 0.6 ppm, these should not be seen as violation of the label.
- The American Water Works Association (AWWA) suggested that EPA OPP should not create a data collection requirement for disinfectant registrants and their supply chain that has the net effect of constraining the supply and delivery of hypochlorite products for drinking water treatment at public water systems.
- EPA OPP should not impede conventional drinking water treatment approaches to assure SDWA compliance under 40 CFR 141.72 and 40 CFR 141.403.

Agency Response: EPA is currently reviewing a proposal from industry for label amendments to address residual chlorine. Future updates about this issue will be placed in the public docket EPA-HQ-OPP-2012-0004.

The use of EPA approved pesticides at levels higher than what is allowed on the label is considered to be a misuse (i.e., a FIFRA violation) and could lead to enforcement actions. Local health departments or other state-level agencies are not authorized to allow deviations from the EPA approved label without specific approval from the EPA. Therefore, EPA is working with the registrants and end users to revise the labels with rates that match the true use of the product.

The Agency concurs with AWWA that under SDWA (40 CFR 141.130) there are circumstances when a water system might have a higher distributed water residual chlorine level, and as such, label amendments are needed. EPA has worked with AWWA (which represents many water treatment utilities) and the Chlorine Institute (which represents many hypochlorite manufacturers) in obtaining feedback, and the Agency will continue these collaborative efforts to ensure proper labeling and use of hypochlorite products.

EPA does not anticipate any change in the supply chain based on suggested label amendments.

EPA received comments that the State of Hawaii is concerned that the current labeling language for sodium and calcium hypochlorite products conflicts with other drinking water regulations, specifically:

- Disinfection requirements under the Surface Water Treatment Rule (40 CFR §141.72)

- Maximum residual disinfectant levels for disinfectants under the Stage 1 Disinfectants and Disinfection Byproducts Rule (40 CFR §141.65)
- Treatment technique requirements for ground water systems under the Ground Water Rule (40 CFR §141.403(b))

The State of Hawaii suggested that EPA use chlorine gas label language for sodium and calcium hypochlorite.

> **Agency Response:** EPA is currently reviewing a proposal from industry for label amendments to address residual chlorine. Future updates about this issue will be placed in the public docket EPA-HQ-OPP-2012-0004.
>
> Hawaii cited the existence of an "OPP level." However, OPP accepts chlorine levels on an individual product basis. Label changes, such as changing the maximum residual rate, require a label amendment process initiated by a pesticide company, and would not require rulemaking. Regarding chlorine gas label language, EPA will consider whether or not it is acceptable to use on sodium, calcium, and potassium hypochlorite labels. Any resulting label changes regarding residual chlorine will take place outside of this registration review process.

1986 Registration Standard for Sodium and Calcium Hypochlorite

Commenters stated that the 1986 Registration Standard for Sodium and Calcium Hypochlorite is outdated, since there have been significant revisions to regulations in the past 30 years. One suggestion by a commenter was to replace the 1986 Registration Standard with SDWA requirements. Other commenters agreed with the Preliminary Interim Decisions statements that no data are needed, but label amendments are needed to address degradant formation in stored hypochlorite solutions used for drinking water. USDA submitted a comment stating that they agreed that human health and ecological risks are minimal when current labels are followed.

> **Agency Response:** EPA is reviewing options for how to address the issues with the 1986 Standard outside of the registration review program. The 1986 Standard addresses additional use patterns outside of drinking water use.

NSF/ANSI 60 – 2016 Drinking Water Treatment Chemicals

The Environmental Defense Fund (EDF) suggested that the label should require compliance with the National Sanitation Foundation / American National Standards Institute (NSF/ANSI) 60 2016 Standard for Drinking Water. The Clorox company suggested that utilities must meet NSF/ANSI Standard 60 requirements.

> **Agency Response:** The NSF/ANSI – 2016 Drinking Water Treatment Chemicals guidance document was developed by an international, independent, not-for-profit, non-governmental organization. Participation of EPA's representatives in the standard's development or implementation activities do not necessarily constitute EPA's

endorsement of the standard. Although third party certification is permitted on OPP labels, the Agency would have to identify the specific sections of the standard that may be applicable to the circumstances on the product, since the standard covers a wide array of topics. The Agency would not cite the entire NSF/ANSI 60 – 2016 Drinking Water Treatment Chemicals guidance document on registered labels. However, information contained within the NSF/ANSI 60 – 2016 Drinking Water Treatment Chemicals guidance document may be considered in registration review decisions.

Agreement with Proposed Label Language for Minimizing Perchlorate Formation

Many submitters of comments agree with the Agency's proposed label language for minimizing perchlorate formation. There are available data about degradant formation to support changes to the hypochlorite product labels, the bulk of which are based on sodium hypochlorite. Comments stated that the recommended practices will substantially reduce chlorate and perchlorate formation. Additionally, another commenter agreed that the Precautionary Statements section is the most suitable place for perchlorate language. USDA reaffirmed that EPA took correct actions in seeking public input for perchlorate minimization label language.

Agency Response: The Agency thanks the submitters for their comments. EPA-OPP has worked with EPA's Office of Water, AWWA and the Chlorine Institute in obtaining data regarding chlorate and perchlorate formation in stored drinking water, and the Agency will continue these collaborative efforts.

Human Health Concerns for Perchlorate Formation

The Agency received comments from the Environmental Defense Fund (EDF) that listed concerns for children's health and brain development, as it relates to perchlorate in drinking water. EDF suggested that the proposed label language to minimize perchlorate formation be made mandatory, rather than advisory. Additionally, EDF urged that the maximum pH should be less than 12.5. EDF cited EPA and FDA's Biologically Based Dose Response (BBDR) model, which examines the effects of perchlorate in drinking water on thyroid hormones in pregnant women and in young children. EDF suggested that when the BBDR is finalized, OPP should incorporate these findings into registration review decisions. Finally, EDF stated that there is also concern about pesticides that are used to treat food, just as drinking water, and cited FDA's Total Diet Study's results for processed meat and its levels of perchlorate.

Agency Response: EPA has kept the label language for minimizing perchlorate formation advisory because the practicality of applying this label language is based on the varying feasibility of different drinking water utilities to implement the suggested best management practices, such as geographic location and facility logistics. However, this advisory label language will be subject to future reevaluation.

EPA chose to keep the pH range of 11 to 13 for the best management practices for maintaining the stability of hypochlorite solutions. This pH range is recommended in AWWA's report, "Perchlorate, Bromate, and Chlorate in Hypochlorite Solutions:

Guidelines for Utilities." A lower pH range may be acceptable depending on manufacturing process and the storage time. However, below a certain pH, the rate of decomposition begins to increase significantly, and decomposition also begins to increase at a higher pH.[22] The Agency welcomes submissions of data for further information on pH levels of stored hypochlorite solutions.

The Agency concurs with EDF that results from EPA and FDA's BDDR will inform future registration review decisions. At this time, the BBDR model is not complete.

Finally, EPA does not possess data that show significant concern for hypochlorite solutions that are used to treat food handling equipment when products are used according to their registered labels. The Agency welcomes submissions of such information.

Industry Concerns About Proposed Label Language for Minimizing Perchlorate Formation

The Clorox Company stated that proposed best practices for degradant minimization should be placed under the labels' Directions for Use section, rather than in the Precautionary Statements section. Clorox stated that this mitigation only applies to drinking water disinfection, and not to all uses. Further Clorox suggested that the marketing label for products with no drinking water use should not be required to have storage recommendation statements. Clorox also expressed concern that the registrants of hypochlorite products would not have knowledge of how end users are applying the product, and that it is likely that utilities follow SDWA, not the FIFRA label. Further, Clorox stated that dosing is climate, temperature, location and storage dependent.

Agency Response: The Agency is coordinating efforts with registrants to update labels so that utilities are in compliance with the label. The Agency recognizes that the proposed label language for minimizing perchlorate formation is only for drinking water uses. The label example in the PID[23] and Appendix A (p. 23) of this document states clearly that these statements only apply to drinking water uses. Further, the label language is advisory but will be subject to future reevaluation. Best management practices for degradant minimization must be located in the Precautionary Statements section of the labels. For detailed information on precautionary statements, see EPA-OPP's Label Review Manual, Chapter 7: Precautionary Statements at https://www.epa.gov/sites/production/files/2015-03/documents/chap-07-jul-2014.pdf.

Finally, as was stated in the response to the comments received regarding discrepancies in OPP label limits and SDWA guidance, OPP will continue to work with OW on issues regarding residual chlorine. Information on how FIFRA approval relates to SDWA can

[22] 2011 American Water Works Association (AWWA) report, "Perchlorate, Bromate, and Chlorate in Hypochlorite Solutions: Guidelines for Utilities."
[23] The label example can be found on page 21 in Appendix A in the Sodium Hypochlorite, Calcium Hypochlorite, and Potassium Hypochlorite Proposed Interim Decision in dockets EPA-HQ-OPP-2012-0004 and EPA-HQ-OPP-2014-0157 at www.regulations.gov

be found at https://www.epa.gov/pesticides/new-epa-quick-guide-registering-disinfectant-products-drinking-water-use.

Agreement with Label Language for Swimming Pools, Hot Tubs, and Spa Discharge

Many submitters of comments agreed with the Agency's proposed label language for Swimming Pools, Hot Tubs, Spa, and Fountains discharge. Submitters supported EPA's clarification that OPP standard NPDES permit label language is only for manufacturing-use products and is not suitable for end-use products.

Agency Response: The Agency thanks the submitters for their comments. Similar label language can be found in the Boric Acid (Case 0024), Lithium Hypochlorite (Case 3084), and Copper (Case 0649) cases. AD is making efforts towards implementing this unified label language.

Industry Concerns About Label Language for Swimming Pools, Hot Tubs, Spa, and Fountains Discharge

The Chlorine Institute suggested that pool, spa, hot tub, and fountain end use products labels that have multiple approved uses should not be required to have multiple labels because of NPDES language. Specifically, several industry members have the NPDES permit language on their labels because their labels do not just have pool and spa uses on them, rather they have all the other approved uses. The Chlorine Institute is concerned that this change would require these registrants to create separate labels when selling to the swimming pool industry so that their label would not have the NPDES language on them.

Agency Response: The Agency allows master labels to include multiple uses. Therefore, a label may include uses that would trigger the non-NPDES language (e.g. end use pool) and the NPDES language (e.g. industrial processes such as cooling tower use). For products whose uses trigger multiple discharge direction language, the label should indicate which uses the NPDES language applies to and which uses other discharge instructions apply to.

Clarification on NPDES label language can be found in Pesticide Registration Notice (PRN) 95-1: Effluent Discharge Labeling Statements.[24] This notice exempts certain products from bearing effluent discharge labeling statements specified by PRN 93-10 for manufacturing use products and end use products that may be discharged to waters of the United States or municipal sewer systems.[25] The purpose of these statements is to remind manufacturers, formulators, and facilities which may use and discharge pesticides of their obligations under the Clean Water Act or to local Publicly Owned Treatment Works (POTW). OPP believes that these parties may be already aware of their obligations via

[24] https://www.epa.gov/pesticide-registration/prn-95-1-effluent-discharge-labeling-statements
[25] https://www.epa.gov/pesticide-registration/prn-93-10-effluent-discharge-labeling-statements

other mechanisms at the state and local level. While OPP has required variations of the labeling statements since the late 1970's, the purpose of these statements has been to simply augment other mechanisms used by OW, the states, and local POTWs to inform pesticide producers and users of their obligations under the CWA or local authorities. Accordingly, by PRN 95-1, OPP revised the scope of PRN 93-10 to exclude products in certain end-use containers.[19] However, PRN 93-10 still applies to end-use products in large containers and to all technical grade and manufacturing-use products.

Use of the Term "Liquid Chlorine"

The Chlorine Institute noted that the term "liquid chlorine" should not have been used on page 6 of the PID, since liquid chlorine refers to the element chlorine in a liquid state, and not as the form of the product itself.

Agency Response: EPA acknowledges the confusion that may be caused by the use of the term "liquid chlorine." Page 6 of the PID should read, "Sodium hypochlorite is a liquid product, while calcium hypochlorite is a solid." This change is reflected in this document, the Interim Decision.

Industry Concerns About Labelling Clean Up

The Chlorine Institute was concerned that the 60 days proposed in the PID for labelling amendments is not an adequate timeframe, and instead proposed 180 days to comply. Alternatively, the Chlorine Institute proposed that the group, which represents industry, be able to come up with a precautionary label for all registrants. Additionally, the Chlorine Institute suggested that EPA should approve primary registrants' labels, and then allow supplemental registrants to update their labels. Further, the Chlorine Institute proposed that old labels should have three years to be out of circulation. Finally, the industry group urged EPA to do a cost analysis for label clean up.

Agency Response: At a February 8, 2018 meeting with the EPA, the Chlorine Institute explained that their concern about the 60-day deadline was based on distributor product labels. The EPA clarified that the 60-day deadline only applies to primary registrants (i.e., labels that are reviewed and accepted by the EPA) and that distributor product labels are not reviewed by the EPA. Therefore, the Agency will keep the deadline at 60 days for submission of amended labels for changes outlined in Appendix A of this document. General labelling cleanup for Storage and Disposal instructions and Precautionary Statements label changes will be done as labels are amended per changes in Appendix A to optimize the label amendment process.

For residual chlorine label changes, OPP will continue to work with EPA's OW and outside stakeholders, and any resulting label changes regarding residual chlorine will take place outside of this registration review process.

OPP has previously analyzed the cost of labelling amendments for registered pesticides. Registrants at times become subject to regulations or guidance which necessitate or involve labeling revisions. EPA's Biological and Economic Analysis Division (BEAD) conducted an analysis in May 2016 for label amendments to determine the costs per registration. [26]

Tolerance Missing in PID

The Clorox Company notified the Agency that there was a tolerance for sodium hypochlorite missing from the listing in the Tolerances section (p. 9 – 10) of the PID.

Agency Response: EPA concurs that a tolerance exemption was missing. The following has been added to this document: Sodium hypochlorite has an exemption from tolerance for use in antimicrobial formulations (food-contact surface sanitizing solutions) in 40 CFR 180.940. It is listed as "hypochlorous acid, sodium salt" (CAS # 7681-52-9), with an upper limitation of 200 ppm total available chlorine as an end-use concentration.

Emergency Drinking Water

Commenters suggested that label changes should also be consistent with EPA guidance for emergency disinfection of drinking water, including the Quick Guide for Homeowners.[27] For certain stakeholders, in the event of loss of primary water supply, emergency backup water supply could be in excess of permitted pesticide label residual levels.

Agency Response: OPP intends to coordinate efforts with OW for emergency drinking water guidance for sodium, calcium, and potassium hypochlorite. The Agency acknowledges that there are circumstances when a water supply might have a higher distributed water residual chlorine level, and as such, label amendments are needed. The Agency will continue these collaborative efforts to ensure proper labeling and use of hypochlorite products. Any resulting label changes regarding emergency drinking water will take place outside of this registration review process.

Inhalation Study for Cleaning Products

The Clorox Company submitted a comment that stated there is an inhalation study for cleaning products currently available. The study is listed as MRID 48017502.

Agency Response: EPA thanks Clorox for the information. MRID 48017502 was reviewed in March 2016, and the Agency will consider this information moving forward

[26] https://www.reginfo.gov/public/do/PRAViewDocument?ref_nbr=201606-2070-001
[27] https://www.epa.gov/ground-water-and-drinking-water/emergency-disinfection-drinking-water

in the reevaluation of this case. As EPA looks into inhalation issues for cleaning products, updates will be placed in the public docket EPA-HQ-OPP-2012-0004.

Safe and Economical Food Supply

USDA stated that the use of sodium, calcium, and potassium hypochlorite are critical for a safe and economical food supply in the United States.

Agency Response: EPA thanks USDA for their comment.

Regulatory Timeline

The American Water Works Association (AWWA) stated that they support the proposal to make an interim decision rather than postponing regulatory action for several years.

Agency Response: EPA thanks AWWA for their comment.