

EPA has no authority to disapprove a 111(d)/129 plan submission for failure to use VCS. It would thus be inconsistent with applicable law for EPA, when it reviews a 111(d)/129 plan submission, to use VCS in place of a 111(d)/129 plan submission that otherwise satisfies the provisions of the Clean Air Act. Thus, the requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) do not apply. This rule does not impose an information collection burden under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

#### *B. Submission to Congress and the Comptroller General*

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This rule is not a "major rule" as defined by 5 U.S.C. 804(2).

#### *C. Petitions for Judicial Review*

Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by February 15, 2011. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this rule for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action approving the Commonwealth of Virginia section 111(d)/129 negative declaration and request for EPA withdrawal of the HMIWI plan approval may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2).)

#### **List of Subjects in 40 CFR Part 62**

Environmental protection, Administrative practice and procedure, Air pollution control, Aluminum, Fertilizers, Fluoride, Intergovernmental relations, Paper and paper products industry, Phosphate, Reporting and recordkeeping requirements, Sulfur

oxides, Sulfur acid plants, Waste treatment and disposal.

Dated: December 2, 2010.

**W.C. Early,**

*Acting Regional Administrator, Region III.*

■ 40 CFR Part 62, Subpart VV, is amended as follows:

#### **PART 62—[AMENDED]**

■ 1. The authority citation for part 62 continues to read as follows:

**Authority:** 42 U.S.C. 7401 *et seq.*

#### **Subpart VV—Virginia**

■ 2. Section 62.11625 is amended by revising the section heading, designating the existing paragraph as (a) and adding paragraph (b) to read as follows:

##### **§ 62.11625 Identification of plan—negative declaration.**

\* \* \* \* \*

(b) On September 13, 2010, the Commonwealth of Virginia, Department of Environmental Protection, submitted a negative declaration, and request for withdrawal of EPA's plan approval under paragraph (a).

■ 3. Section 62.11626 is removed.

■ 4. Section 62.11627 is revised to read as follows:

##### **§ 62.11627 Effective date.**

The effective date of the negative declaration and EPA withdrawal of the plan approval is February 15, 2011.

[FR Doc. 2010-31741 Filed 12-16-10; 8:45 am]

**BILLING CODE 6560-50-P**

#### **ENVIRONMENTAL PROTECTION AGENCY**

#### **40 CFR Parts 261, 268, and 302**

**[EPA-HQ-RCRA-2009-0310, FRL-9239-8]**

**RIN 2050-AG55**

#### **Hazardous Waste Management System; Identification and Listing of Hazardous Waste; Removal of Saccharin and Its Salts From the Lists of Hazardous Constituents, Hazardous Wastes, and Hazardous Substances**

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final Rule.

**SUMMARY:** The Environmental Protection Agency (EPA or the Agency) is amending its regulations under the Resource Conservation and Recovery Act (RCRA) to remove saccharin and its salts from the lists of hazardous constituents and commercial chemical products which are hazardous wastes

when discarded or intended to be discarded. EPA is also amending the regulations under the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) to remove saccharin and its salts from the list of hazardous substances. This final rule is in response to a petition submitted to EPA by the Calorie Control Council (CCC) to remove saccharin and its salts from the above lists. EPA is granting CCC's petition based on a review of the evaluations conducted by key public health agencies concerning the carcinogenic and other potential toxicological effects of saccharin and its salts, as well as EPA's own assessment of the waste generation and management information for saccharin and its salts. This review/assessment demonstrates that saccharin and its salts do not meet the criteria in the hazardous waste regulations for remaining on EPA's lists of hazardous constituents, hazardous wastes, and hazardous substances.

**DATES:** This final rule is effective on January 18, 2011.

**ADDRESSES:** EPA has established a docket for this action under Docket ID No. EPA-HQ-RCRA-2009-0310. All documents in the docket are listed in the <http://www.regulations.gov> index. Certain material, such as copyrighted material, will be publicly available only in hard copy. Publicly available docket materials are available either electronically in <http://www.regulations.gov> or in hard copy at the OSWER Docket in the EPA Docket Center (EPA/DC), EPA West, Room 3334, 1301 Constitution Avenue, NW., Washington, DC 20460. The Public Meeting Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the OSWER Docket and the Public Reading Room is (202) 566-1744.

**FOR FURTHER INFORMATION CONTACT:** For general information, review our Web site at <http://www.epa.gov/epaoswer/hazwaste>. For information on specific aspects of the rule, contact Narendra Chaudhari of the Office of Resource Conservation and Recovery (5304P), U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue, NW., Washington, DC 20460; telephone number: 703-308-0454; e-mail address: [chaudhari.narendra@epa.gov](mailto:chaudhari.narendra@epa.gov).

#### **SUPPLEMENTARY INFORMATION:**

##### **I. General Information**

*A. Who is potentially affected by this final rule?*

This final rule could directly affect businesses that generate or manage

unused commercial products that contain saccharin or its salts. Specifically, the wastes affected by this final rule are unused commercial chemical products, manufacturing chemical intermediates, off-specification material, container residues, and spill residues that contain saccharin or its salts in a pure or technical grade form, or as the sole active ingredient and are listed as EPA Hazardous Waste No. U202 (see 40 CFR

261.33(f)). These wastes will no longer be subject to the U202 listing, provided the States adopt and seek authorization for this final rule. This action may also affect entities that need to respond to releases of these wastes as CERCLA hazardous substances, since saccharin and its salts will no longer be CERCLA hazardous substances. Persons in charge of vessels or facilities from which saccharin or its salts are released will no longer be required to immediately notify

the National Response Center of the release under section 103 of CERCLA and will not be subject to the liability provisions under section 107 of CERCLA. The table below provides a guide for readers regarding entities that likely would be directly or indirectly affected by this action, based on the information available from the 2007 Biennial Report.<sup>1</sup>

#### INDUSTRY SECTORS POTENTIALLY AFFECTED BY THE FINAL RULE

NAICS code	Industry description for NAICS code
31193 .....	Flavoring Syrup and Concentrate Manufacturing.
312111 .....	Soft Drink Manufacturing.
325199 .....	All Other Basic Organic Chemical Manufacturing [manufacturers of saccharin].
32541 .....	Pharmaceutical and Medicine Manufacturing.
325411 .....	Medicinal and Botanical Manufacturing.
325412 .....	Pharmaceutical Preparation Manufacturing.
32562 .....	Toilet Preparation Manufacturing. <sup>2</sup>
49311 .....	General Warehousing and Storage.
5417 .....	Scientific Research and Development Services.
54171 .....	Research and Development in the Physical, Engineering, and Life Sciences.
61131 .....	Colleges, Universities, and Professional Schools.

This action, however, may affect other entities not listed in the table. To determine whether your facility is affected by this action, you should examine 40 CFR parts 261, 268 and 302 carefully, along with the final regulatory language amending Chapter I of the Code of Federal Regulations (CFR). This language is found at the end of this **Federal Register** notice. If you have questions regarding the applicability of this action to a particular entity, consult the person listed in the preceding section entitled **FOR FURTHER INFORMATION CONTACT**.

#### Preamble Outline

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  - C. Regulatory Flexibility Act
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  - H. Executive Order 13211: Actions That Significantly Affect Energy Supply, Distribution, or Use
  - I. National Technology Transfer and Advancement Act
  - J. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations
  - K. Congressional Review Act

#### I. Statutory Authority

These regulations are being promulgated under the authority of sections 1006, 2002(a), 3001 and 3002 of the Solid Waste Disposal Act, as amended by the Resource Conservation and Recovery Act (RCRA), as amended, by the Hazardous and Solid Waste Amendments of 1984 (HSWA), 42 U.S.C. 6905, 6912(a), 6921, 6922, 6924, 6924(y), and 6938. These statutes combined are commonly referred to as the "Resource Conservation and Recovery Act" (RCRA) and will be referred to as such for the remainder of this action.

Section 102 of the Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (CERCLA), 42 U.S.C. 9602, as amended, is the authority under which the CERCLA aspects of this rule are promulgated.

#### II. List of Abbreviations and Acronyms

BRS Biennial Reporting System  
 CCC Calorie Control Council  
 CERCLA Comprehensive Environmental Response, Compensation, and Liability Act  
 CFR Code of Federal Regulations  
 EPA Environmental Protection Agency  
 EPCRA Emergency Planning and Community Right-to-Know Act  
 FDA Food and Drug Administration  
 HSWA Hazardous and Solid Waste Amendments of 1984

<sup>1</sup> EPA, in partnership with the States, biennially collects information regarding the generation, management, and final disposition of hazardous wastes regulated under RCRA. See the 2007

Biennial Report on the EPA Web site <http://www.epa.gov/epawaste/inforesources/data/index.htm>.

<sup>2</sup> Saccharin and its salts are used in personal-care products, such as mouthwash, dental cleaners, and lipstick, which come under Toilet Preparation Manufacturing (NAICS Code 32562).

IARC International Agency for Research on Cancer  
LD<sub>50</sub> Lethal Dose 50%  
LDRs Land Disposal Restrictions  
NAICS North American Industrial Classification System  
NOEL No Effect Level  
NTP National Toxicology Program  
OMB Office of Management and Budget  
ROC Report on Carcinogens  
RQ Reportable Quantity

### III. Summary of This Action

In this notice, EPA is finalizing regulations to remove saccharin and its salts from the lists of hazardous constituents (40 CFR part 261, Appendix VIII) and hazardous wastes (40 CFR 261.33 (f)) under RCRA and from the list of hazardous substances (40 CFR 302.4) under CERCLA. These final regulations are substantively the same as those that EPA proposed on April 22, 2010 (75 FR 20942).<sup>3</sup> This final rule is in response to a petition submitted to EPA by the Calorie Control Council (CCC),<sup>4</sup> under 40 CFR 260.20, to remove saccharin and its salts from its lists of hazardous constituents and hazardous wastes. In the same petition, CCC also requested removal of saccharin and its salts from the list of hazardous substances. EPA is granting CCC's petition based on a review of the evaluations conducted by key public health agencies concerning the carcinogenic and other potential toxicological effects of saccharin and its salts, as well as EPA's own assessment of the waste generation and management information for saccharin and its salts. This review/assessment demonstrates that saccharin and its salts do not meet the criteria in the hazardous waste regulations for remaining on EPA's lists of hazardous constituents, hazardous wastes, and hazardous substances.

### IV. Summary of the Proposed Action

On April 22, 2010, EPA issued a proposed rule (75 FR 20942) that would grant a petition submitted by CCC to remove saccharin and its salts from the lists of hazardous constituents (40 CFR part 261, Appendix VIII), hazardous wastes (40 CFR 261.33(f)), and hazardous substances (40 CFR 302.4). Under § 260.20, any person may petition the EPA Administrator to modify or revoke any provision in parts 260 through 266, 267, 268, and 273 of 40

CFR. The CCC argued in its petition (which is included in the docket for this final rule) that the current scientific evidence, as viewed by key public health agencies, such as the National Toxicology Program (NTP) and the International Agency for Research on Cancer (IARC), does not support classifying saccharin as a potential human carcinogen, which was EPA's original and only basis for placing saccharin and its salts on its lists of hazardous constituents, hazardous wastes, and hazardous substances. EPA's evaluation of this petition considered the original basis for the listing, NTP's and IARC's more recent conclusions about the risk of carcinogenicity of saccharin and its salts, as well as other factors or criteria required for making a listing determination. Based on this evaluation, EPA determined that saccharin and its salts do not present a significant risk to human health or the environment. Therefore, EPA proposed to grant CCC's petition by proposing to remove saccharin and its salts from the lists of hazardous constituents (40 CFR part 261, Appendix VIII), hazardous wastes (40 CFR 261.33(f)), and hazardous substances (40 CFR 302.4).

### V. EPA's Evaluation of the Petition Based on the Available Toxicological Information and Waste Generation and Management Information for Saccharin and Its Salts

Saccharin is a white crystalline powder which is about 300 times sweeter than sucrose. It is typically available commercially either in the acid form (saccharin) or as salts (sodium saccharin or calcium saccharin). The use of the name saccharin has been applied to all three forms of this chemical. The chemical name for saccharin and its salts is "1,2-Benzisothiazol-3(2H)-one, 1,1-dioxide & salts." Saccharin and its salts are used primarily as non-nutritive sweeteners. The most common uses are in diet soft drinks, as a table-top sweetener, and in products, such as juices, sweets, chewing gum and jellies. They are also used in cosmetics (e.g., toothpaste, mouthwash, and lipstick), pharmaceuticals (e.g., for coatings on pills), and electroplating (e.g., as a brightener in nickel-plating baths).

As discussed in the proposed rule, EPA listed saccharin and its salts on the lists of hazardous constituents (40 CFR part 261, Appendix VIII), hazardous wastes (40 CFR 261.33(f)), and hazardous substances (40 CFR 302.4) based solely upon the evidence that it is a potential human carcinogen (75 FR 20945, April 22, 2010). EPA's evaluation

of CCC's petition includes consideration of the original basis for the listings in light of the most recent scientific evidence about the risk of carcinogenicity of saccharin and its salts. However, EPA has also evaluated the petitioner's requests against the listing criteria and factors that would need to be considered under the regulations.

#### A. Evaluation of Toxicological Information for Saccharin and Its Salts To Assess the Petition

There have been numerous scientific studies conducted over the past several decades for the purpose of determining the toxicological effects, in particular carcinogenic effects, from the use of saccharin and its salts. The NTP and IARC have recently re-evaluated the available scientific information on saccharin and its salts relevant to its carcinogenic and other toxicological effects. In 1996, CCC submitted a nomination to (or petitioned) the NTP to consider removing saccharin from its Report on Carcinogens (ROC) "based upon mechanistic data related to development of urinary bladder cancers in rats." NTP re-evaluated the available scientific information for saccharin and published its decision on CCC's petition in 2000, as part of its 9th ROC. In 1999, IARC published the results of its latest re-evaluation of the available scientific information for saccharin and its salts. The evaluations on the carcinogenicity and other toxicological effects of saccharin and its salts by NTP and IARC are summarized below. See the "NTP Report on Carcinogens Background Document for Saccharin" (which will now be referred to as NTP's Background Document) and part of the IARC Monographs Volume 73 concerning saccharin and its salts, which are included in the docket for this rulemaking. EPA believes it is appropriate to accept the saccharin evaluations performed by NTP and IARC. The NTP decision to delist saccharin from the ROC included scientific peer reviews, as well as public comment. IARC's evaluation on the carcinogenicity of saccharin and its salts provides additional support in EPA's assessment of CCC's petition.

#### 1. Evaluation of Information on the Carcinogenicity of Saccharin and Its Salts by NTP and IARC

NTP initially listed saccharin as "reasonably anticipated to be a human carcinogen" in its 2nd ROC, published in 1981, based on sufficient evidence, at that time, of carcinogenicity in experimental animals. Specifically, the listing was based on increased

<sup>3</sup> The regulations proposed by EPA on April 22, 2010 did not remove the chemical name of saccharin and its salts (1, 2-Benzisothiazol-3(2H)-one, 1, 1-dioxide, & salts) from 40 CFR 302.4. The final regulatory text corrects that inadvertent omission.

<sup>4</sup> To examine CCC's complete petition, see the docket for this final rule.

incidence of bladder tumors in experimental animals, especially male rats, when they were fed sodium saccharin. However, saccharin was removed, or delisted, by NTP in its 9th ROC, published in 2000. The delisting decision for saccharin was made on the basis of a formal review process adopted by NTP, which included two Federal and one non-governmental scientific peer review and public comment and review.

In the ROC and its background document, NTP summarized its evaluation supporting the decision to remove saccharin as "reasonably anticipated to be a human carcinogen" as follows:

"There is evidence of the carcinogenicity of saccharin in rats but less convincing evidence in mice. Mechanistic studies indicate that the observed urinary bladder cancers in rat studies are related to urinary pH, osmolality, volume, presence of precipitate and urothelial damage with attendant hyperplasia following dietary concentrations of 3% or higher with inconsistent findings at lower dietary concentrations. The factors thought to contribute to tumor induction by sodium saccharin in rats would not be expected to occur in humans. The mouse data are inconsistent and require verification by additional studies. Results of several epidemiology studies indicate no clear association between saccharin consumption and urinary bladder cancer. Although it is impossible to absolutely conclude that it poses no threat to human health, sodium saccharin is not reasonably anticipated to be a human carcinogen under conditions of general usage as an artificial sweetener."

The available epidemiology studies, according to NTP, mostly examined associations between urinary bladder cancer and artificial sweeteners, rather than saccharin *per se*. The time trend data for bladder cancer from these studies were thought to be essentially noninformative with no clear indication that the increased use of saccharin or artificial sweeteners, beginning in the 1940's, was associated with any general increase in bladder cancer when controlled for confounding factors, mainly smoking. NTP's decision to delist saccharin, as stated in the ROC, was as follows:

"Saccharin will be delisted from the Report on Carcinogens, because the rodent cancer data are not sufficient to meet the current criteria to list this chemical as reasonably anticipated to be a human carcinogen. This is based on the perception that the observed bladder tumors in rats arise by mechanisms not relevant to humans, and the lack of data in humans suggesting a carcinogenic hazard."

IARC first evaluated saccharin in 1980 and concluded the following:

"There is sufficient evidence that saccharin alone, given at high doses, produces tumours of the urinary tract in male rats \* \* \*" (IARC, 1980).

In 1999, IARC presented its last re-evaluation, taking into consideration all new data on saccharin and its salts. It found that, based on a review of human studies on the carcinogenicity of artificial sweeteners, that there is "no consistent pattern of dose-response relationship between use of artificial sweeteners and cancers of the urinary bladder or lower urinary tract is apparent in the available literature." The animal studies in rats with sodium saccharin did show urinary bladder tumors in the 2-generation studies. However, the incidence of bladder tumors was significant only at higher doses (greater than 3% of the diet). Based on this re-evaluation, IARC concluded the following:

"There is inadequate evidence in humans for the carcinogenicity of saccharin salts used as sweeteners."

"There is sufficient evidence in experimental animals for the carcinogenicity of sodium saccharin."

"There is inadequate evidence in experimental animals for the carcinogenicity of saccharin (acid form) and calcium saccharin."

In making its overall evaluation of the carcinogenic risk from saccharin and its salts, IARC stated the following:

"In making its evaluation, the Working Group concluded that sodium saccharin produces urothelial bladder tumours in rats by a non-DNA-reactive mechanism that involves the formation of urinary calcium phosphate-containing precipitate, cytotoxicity and enhanced cell proliferation. This mechanism is not relevant to humans because of critical interspecies differences in urine composition."

"Saccharin and its salts are not classifiable as to their carcinogenicity to humans (Group 3)."

## 2. Evaluation of Information on Other Toxicological Effects of Saccharin and Its Salts by NTP and IARC

In addition to the evaluation of information on saccharin's carcinogenicity, NTP's Background Document and IARC's 1999 re-evaluation (as presented in IARC Monograph Volume 73) included information and analysis on other toxicological effects of saccharin and its salts. Specifically, saccharin, in the form of sodium saccharin, has generally been tested in rats by feeding the rats diets containing specified amounts of sodium saccharin. It has not been found to be acutely toxic in rats based on the criterion for listing hazardous wastes under § 261.11(a)(2). The LD<sub>50</sub> values for sodium saccharin by oral administration

in rats ranged from 14 g/kg (14,000 mg/kg) to 17 g/kg (17,000 mg/kg) of body weight, which is significantly higher than the oral LD<sub>50</sub> value for rats of less than 50 mg/kg specified under the listing criterion. A 2-generation feeding study in rats that were given 1% to 7.5% sodium saccharin in their diet indicated that a 1% dietary level (500 mg/kg of body weight) of sodium saccharin represented a no-effect level (NOEL). There was also no significant increase in the incidence of urinary bladder tumors at the 3% dietary level of sodium saccharin. Generally, the studies on mutagenicity, genotoxicity, developmental and reproductive toxicity using saccharin and sodium saccharin have shown negative results. For more detailed information and analysis on other toxicological effects of saccharin and its salts, see NTP's Background Document and IARC's 1999 re-evaluation in the docket for this final rule.

## B. Evaluation of Waste Generation and Management Information for Saccharin and Its Salts To Assess the Petition

### 1. Quantity and Types of Wastes Generated

Saccharin and its salts are listed hazardous wastes, if the waste arises from the discard of commercial chemical products, manufacturing chemical intermediates, off-specification material, container residues or spill residues (EPA Hazardous Waste No. U202 in 40 CFR 261.33(f)). The U-waste code applies only if the chemical is present in a pure or technical grade form, or is the sole active ingredient in the chemical formulation; in addition, the chemical must be unused.

The U202 listing is narrow and does not apply to other discarded materials that merely contain saccharin or its salts, e.g., discarded products that contain saccharin as a sweetening agent. Nor does the listing apply to manufacturing process wastes that may contain saccharin or its salts, except for unused or off-specification saccharin or its salts that are discarded. Therefore, U202 is primarily generated by companies that manufacture saccharin or its salts, use saccharin or its salts in product formulations (e.g., soft drinks, cosmetics, pharmaceuticals), and by companies that are discarding small quantities of unused or off-specification saccharin or its salts, such as some laboratories.

Facilities are required by EPA to report the amount of hazardous waste, including U202 generated biennially (every two years) as part of the Biennial

Report System, or BRS. Based on the information available from the BRS for the years 2001, 2003, 2005, and 2007, generators reported a total of 123 specific wastes listed as U202 during this time period (some generators reported multiple U202 wastes over the years in question). The total amount of U202 waste generated over this time period was 20 tons for all industries/NAIC Codes; for 2007, there were 4.1 tons of U202 reported for 29 separate wastes.

Most of the U202 wastes appear to be discarded unused or off specification material and "lab packs," which package hazardous items for shipping and disposal. A limited number of other wastes are also reported, including contaminated debris/soil, organic and aqueous liquids, and other unidentified material. Although wastes were reported as "generated" by hazardous waste treatment, storage, and disposal facilities, the BRS data indicate that nearly all of these wastes were not generated on-site, but rather were received from off-site for storage/packing and subsequent transfer for treatment or disposal. To avoid counting these wastes twice (i.e., the reported wastes from the generator and again from the waste facility packing/transferring the waste), one can subtract out the amounts of waste reported by hazardous waste collection and treatment facilities. Removing the U202 wastes generated at these hazardous waste handling facilities from the 20 tons reported for all industries/NAIC Codes noted previously gives a total of 14.7 tons generated from 2001 through 2007; similarly, removing the double counting in the 2007 data from the 4.1 tons of U202 reported for all NAIC Codes gives 2.9 tons for 2007 alone. Therefore, the total quantity of U202 generated is quite small compared to the total volume of hazardous waste generated, both on an annual basis and over the course of four reporting years.<sup>5</sup>

## 2. Factors Considered for Waste Listing

Saccharin and its salts were listed as hazardous waste under the criterion for listing given in 40 CFR 261.11(a)(3). Under this criterion, the Agency can list a waste if it contains any of the toxic constituents identified in 40 CFR part 261, Appendix VIII and, after considering a number of factors, the

Agency concludes that the waste poses a "substantial present or potential hazard to human health or the environment" when improperly managed. The nature of the toxicity of a chemical contained in a waste is one of the factors to be considered in listing a waste as "toxic" (see § 261.11(a)(3)(i)). The Agency cited toxicity as the "decisive" factor in listing commercial chemical products under § 261.33(f), because the waste is typically the chemical itself (see EPA's Background Document for § 261.33, April 1981). Saccharin and its salts were listed as toxic constituents on Appendix VIII of part 261 and subsequently identified as hazardous wastes in § 261.33(f) based solely on their potential for carcinogenic effect in humans. Therefore, if the toxicological basis for listing saccharin and its salts on Appendix VIII of part 261 is removed, then the basis for listing in § 261.33(f) no longer exists.

Other factors considered in listing a waste under § 261.11(a)(3) are related to the potential of the chemical to migrate if improperly managed, and include the chemical's persistence and accumulation potential. However, these other factors are not critical in a listing evaluation for commercial chemical products containing saccharin and its salts, because the low toxicity of these chemicals revealed in scientific studies, including a lack of potential carcinogenic effect in humans, means that any risk from a plausible management scenario (e.g., disposal in a landfill) would not be sufficient to cause a substantial present or potential hazard to human health or the environment. In addition, the quantity of waste generated from the discard of saccharin and its salts by individual facilities and on a nationwide basis (§ 261.11(a)(3)(viii)) is relatively small, as described previously, which further reduces any potential hazard that might arise from disposal of the waste. The generators are distributed across the nation, located in 42 different counties according to BRS data, reducing the likelihood of significant co-disposal in the same landfill.

Additionally, one of the other factors for EPA to consider is action taken by other governmental agencies and regulatory programs (§ 261.11(a)(3)(x)). These actions also demonstrate that saccharin and its salts do not present a substantial hazard to human health or the environment. These actions include: (1) The determinations by NTP and IARC that saccharin is not a potential human carcinogen, as discussed previously; (2) the State of California's removal of saccharin and its salts from its list of chemicals known to cause

cancer or reproductive toxicity (under its Safe Drinking Water and Toxic Enforcement Act of 1986, known as "proposition 65");<sup>6</sup> and (3) the FDA's approval of a variety of uses of saccharin in food, cosmetics, and drugs, and the elimination of the warning label on food containing saccharin.<sup>7</sup> Saccharin and its salts continue to be used widely as a non-nutritive sweetener in food products and are also used in products, such as toothpaste, mouthwash, chewing gum, confections, and pharmaceuticals.

Furthermore, as noted previously in section V.A.2., the information reviewed indicates that saccharin and its salts are not acutely toxic, and as such, they would not meet the criterion for listing hazardous wastes under § 261.11(a)(2). Moreover, saccharin and its salts do not meet the criterion under § 261.11(a)(1), because saccharin and its salts are not expected to exhibit any of the characteristics of hazardous waste, i.e., ignitability, corrosivity, reactivity, and toxicity, as described in 40 CFR 261.21 through 261.24.

Finally, the Agency needed to consider only one factor in listing saccharin and its salts as hazardous substances under CERCLA. Under the statutory provisions of section 101(14)(C) of CERCLA, a hazardous waste that exhibits one or more of the hazardous waste characteristics or specifically is listed as a hazardous waste under RCRA becomes a hazardous substance under CERCLA.<sup>8</sup> As a result, saccharin and its salts were listed in 40 CFR 302.4 and designated as hazardous substances under section 102(a) of CERCLA. The Agency no longer has an independent basis upon which to retain saccharin and its salts as CERCLA hazardous substances and is taking action to remove saccharin and its salts

<sup>6</sup> California EPA, Office of Environmental Health Hazard Assessment, Notice to Interested Parties for Chemical Delisted Effective April 6, 2001 and Notice to Interested Parties for Chemical Delisted Effective January 17, 2003 (available in the docket for this proposed rulemaking).

<sup>7</sup> Section 517, Title V, Appendix A, Consolidated Appropriations Act of 2001 (Pub. L. 106-554, 114 Stat. 2763), repealed 21 U.S.C. 343(o), the saccharin warning statement requirement.

<sup>8</sup> In addition, hazardous substances include: (1) Any substance designated pursuant to section 311(b)(2)(A) of the Federal Water Pollution Control Act; (2) any element, compound, mixture, solution, or substance designated pursuant to section 102 of the Comprehensive Environmental Response, Compensation, and Liability Act; (3) any toxic pollutant listed under section 307(a) of the Federal Water Pollution Control Act; (4) any hazardous air pollutant listed under section 112 of the Clean Air Act; and (5) any imminently hazardous chemical substance or mixture with respect to which the Administrator has taken action pursuant to section 7 of the Toxic Substances Control Act. Saccharin and its salts are not included on any of these lists.

<sup>5</sup> For comparison, BRS shows that approximately 47 million tons of hazardous waste was generated in 2007 (see <http://www.epa.gov/osw/inforesources/data/br07/national07.pdf>). Also in 2007, approximately 137 million tons of municipal waste went to landfills and other disposal (see <http://www.epa.gov/epawaste/nonhaz/municipal/msw99.htm>).

from the list of CERCLA hazardous substances.

## VI. Response to Comments and Rationale for the Final Rule

### A. Response to Comments

EPA received comments from the CCC and the New York State Department of Environmental Conservation (NYSDEC) in response to the proposed rule. The CCC supported EPA's proposal, which responded to CCC's April 30, 2003 petition, to remove saccharin and its salts from the lists of hazardous constituents, hazardous wastes and hazardous substances. In its comments, CCC stated that the current scientific evidence for saccharin and EPA's own assessment supports the Agency's proposed decision to remove saccharin and its salts from its lists. NYSDEC's comments do not present any concerns about EPA's proposal to remove saccharin and its salts from its lists. Instead, NYSDEC's comments request clarification regarding the regulatory status of a discarded unused chemical product containing multiple ingredients (*i.e.*, saccharin-containing nicotine gum) under 40 CFR 261.33. Since EPA's proposal was for removing saccharin and its salts from its lists, the Agency does not consider NYSDEC's comments to be within the scope of the rule and therefore, not relevant to its decision on finalizing the proposal. The entire comments submitted by CCC and NYSDEC in response to the proposed rule are available in the docket for this rulemaking.

### B. EPA's Rationale for Granting the Petition

In summary, the comments on the proposed rule were either supportive or requested clarification on an issue that is not relevant to EPA's proposed decision; the Agency received no comments that disagreed with EPA's proposal to remove saccharin and its salts from the lists of hazardous constituents (40 CFR part 261, Appendix VIII), hazardous wastes (40 CFR 261.33(f)), and hazardous substances (40 CFR 302.4). EPA believes that saccharin and its salts, based on the results of the latest reviews of the available scientific information performed by NTP and IARC, do not pose a present or potential risk of causing toxic, carcinogenic, mutagenic or teratogenic effects on humans or other life forms. This is because saccharin and its salts: (1) Are not found to be highly toxic in scientific studies; (2) are not reasonably expected to have carcinogenic effects in humans and carcinogenic effects in experimental

animals (*i.e.*, rats) have been observed mainly at higher doses (greater than 3% of the diet) and effect mechanisms that are not relevant to humans; and (3) are not reasonably expected to be mutagenic or teratogenic. Therefore, there is no basis for retaining saccharin and its salts as a hazardous constituent listed on Appendix VIII of Part 261.

EPA also believes that saccharin and its salts, based on a review of the evaluations conducted by NTP and IARC concerning the carcinogenic and other potential toxicological effects of saccharin and its salts, as well as EPA's own assessment of waste generation and management information for saccharin and its salts, do not meet the criteria for listing as hazardous wastes under 40 CFR 261.11. This is because saccharin and its salts: (1) Are not known to exhibit any of the characteristics of hazardous wastes identified in 40 CFR 261.21 through 261.24; (2) are not found to be acutely toxic in studies with animals; (3) are not found to be highly toxic in non-acute (longer-term) scientific studies; (4) are not discarded annually in a quantity which could reasonably be considered to pose a "substantial present or potential hazard to human health or the environment" when improperly treated, stored, transported, or disposed of, or otherwise managed; and (5) are not considered hazardous by other government agencies and regulatory programs. Therefore, there is no basis for retaining the listing for saccharin and its salts as a hazardous waste under 40 CFR 261.33(f).

EPA's listing of saccharin and its salts as hazardous substances under CERCLA (40 CFR 302.4) was based solely upon these substances being listed as U202 hazardous wastes under RCRA (40 CFR 261.33(f)). Therefore, since the Agency is removing saccharin and its salts as U202 listed hazardous wastes and saccharin and its salts are not designated or listed as hazardous substances on any of the other environmental statutes identified in section 101(14) of CERCLA that defines the term "hazardous substance," there exists no independent basis for retaining saccharin and its salts on CERCLA's list of hazardous substances (40 CFR 302.4). Based on the above conclusions, EPA has decided to finalize the proposed rule granting CCC's petition without any substantive changes.

## VII. Status of Land Disposal Restrictions for U202 Listed Wastes

As discussed in the previous section, the Agency is removing saccharin and its salts from the list of unused commercial chemical products, manufacturing chemical intermediates,

off-specification material, container residues, and spill residues which are hazardous wastes when discarded or intended to be discarded (40 CFR 261.33(f)). These chemicals are specifically listed as RCRA Hazardous Waste No. U202 under 40 CFR 261.33(f). The regulations under 40 CFR part 268, prohibit the land disposal of RCRA hazardous waste unless they meet a certain level or have been treated by a technology specified by EPA prior to land disposal. See the table "Treatment Standards for Hazardous Wastes" in § 268.40. The land disposal restrictions (LDRs) only apply to solid wastes that are RCRA hazardous wastes. Because saccharin and its salts are being removed from the list of hazardous wastes based on this final rule, they would not be subject to the LDRs. Therefore, EPA is also removing saccharin and its salts from the table "Treatment Standards for Hazardous Wastes" in § 268.40.

## VIII. State Authorization

### A. Applicability of the Rule in Authorized States

Under section 3006 of RCRA, EPA may authorize a qualified State to administer and enforce a hazardous waste program within the State in lieu of the Federal program, and to issue and enforce permits in the State. Following authorization, EPA retains enforcement authority under sections 3008, 3013, and 7003 of RCRA, although authorized States have primary enforcement responsibility. The standards and requirements for State authorization are found at 40 CFR part 271.

Prior to enactment of the Hazardous and Solid Waste Amendments of 1984 (HSWA), a State with final RCRA authorization administered its hazardous waste program entirely in lieu of EPA administering the Federal program in that State. The Federal requirements no longer applied in the authorized State, and EPA could not issue permits for any facilities in that State, since only the State was authorized to issue RCRA permits. When new, more stringent Federal requirements were promulgated, the State is obligated to enact equivalent authorities within specified timeframes. However, the new Federal requirements do not take effect in an authorized State until the State adopted the Federal requirements as State law.

In contrast, under RCRA section 3006(g), (42 U.S.C. 6926(g)), new Federal requirements and prohibitions imposed pursuant to HSWA authority take effect in authorized States at the same time that they take effect in

unauthorized States. Although authorized States still are required to update their hazardous waste programs to remain equivalent to the Federal program, EPA is directed by the statute to implement the requirements and prohibitions in authorized States, including the issuance of new permits implementing those requirements, until EPA authorizes the State to do so.

Authorized States are required to modify their programs only when EPA promulgates Federal requirements that are more stringent or broader in scope than existing Federal requirements. RCRA section 3009 allows the States to impose standards more stringent than those in the Federal program. See also 40 CFR 271.1(i). Therefore, authorized States may, but are not required to adopt Federal regulations, both HSWA or non-HSWA, that are considered less stringent than previous Federal requirements.

#### B. Effect on State Authorization

This rule is promulgated pursuant to non-HSWA authority. The changes included in this rule are less stringent than the current Federal requirements. Therefore, States will not be required to adopt and seek authorization for these changes. EPA will implement the changes in this rule only in those States which are not authorized for the RCRA program. Nevertheless, EPA believes that this rule has considerable merit, and the Agency thus strongly encourages States to amend their programs and become Federally-authorized to implement this rule.

### IX. CERCLA Designation and List of Hazardous Substances and Reportable Quantities

Section 101(14) of CERCLA defines the term "hazardous substance" as those substances designated or listed under several other environmental statutes and those substances designated by EPA as hazardous under CERCLA section 102(a). In particular, CERCLA section 101(14)(C) incorporates by reference any hazardous waste having the characteristics identified under or listed pursuant to section 3001 of the Solid Waste Disposal Act. CERCLA section 102(a) authorizes EPA to designate as hazardous those substances that, when released into the environment, may present substantial danger to the public health, welfare or the environment, and to establish the reportable quantity (RQ) for all CERCLA hazardous substances. CERCLA section 102(b) sets a RQ of one pound (statutory RQ) for hazardous substances, except those for which RQs have been established pursuant to section 311(b)(4) of the Clean Water Act

(CWA). A list of CERCLA hazardous substances with their corresponding RQs is provided in Table 302.4 at 40 CFR part 302. CERCLA section 103 requires any person who releases a CERCLA hazardous substance in an amount equal to or greater than its RQ to report the release immediately to the National Response Center.

On April 4, 1985, EPA issued a final rule, "Notification Requirements, Reportable Quantity Adjustments; Final Rule and Proposed Rule" (see 50 FR 13456). The final rule retained the statutory RQ of one pound for saccharin and its salts with a note that the final RQ is subject to change when the assessment of potential carcinogenicity and/or chronic toxicity is completed.

On March 16, 1987, EPA proposed to adjust the statutory RQ for saccharin and its salts to 100 pounds (45.5 kg) (see 52 FR 8140), which EPA finalized on August 14, 1989 (see 54 FR 33418). Saccharin and its salts, at the time of RQ adjustment, were classified as weight of evidence Group C,<sup>9</sup> potency Group 3<sup>10</sup> substances and received a "low" hazard ranking.

In this rule, the Agency is removing saccharin and its salts<sup>11</sup> from the list of CERCLA hazardous substances in conjunction with the removal of saccharin and its salts from the list of hazardous constituents (40 CFR part 261, Appendix VIII) and the list of commercial chemical products deemed hazardous waste (40 CFR 261.33(f)). With removal of the RCRA hazardous waste listing, the Agency does not have an independent basis upon which to retain saccharin and its salts as CERCLA hazardous substances. That is, the Agency's designation of saccharin and its salts under section 102(a) was based solely upon its inclusion as a hazardous substance under section 101(14)(C) of CERCLA.

### X. Relationship to Other Rules

This action is not intended, and should not be inferred, to affect the status of saccharin and its salts under any statute or program other than RCRA and CERCLA. The granting of CCC's petition does not remove saccharin from

the EPCRA section 313 list, which requires annual reporting of environmental releases of toxic chemicals.

### XI. Statutory and Executive Order Reviews

#### A. Executive Order 12866: Regulatory Planning and Review

This action is not a "significant regulatory action" under the terms of Executive Order (EO) 12866 (58 FR 51735, October 4, 1993) and is therefore not subject to review under the EO.

#### B. Paperwork Reduction Act

This action does not impose an information collection burden under the provisions of the *Paperwork Reduction Act*, 44 U.S.C. 3501 *et seq.* Burden is defined at 5 CFR 1320.3(b). In fact, EPA expects that the total annual respondent burden from this final rule would result in a net reduction in national annual paperwork burden to the affected facilities because of elimination of hazardous waste, and CERCLA hazardous substance reporting requirements. EPA also expects this rule to result in net annual cost savings to these same facilities from reduced waste management costs, by the expected shift of waste management from RCRA Subtitle C hazardous waste management, to RCRA Subtitle D nonhazardous waste management.

#### C. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) generally requires an agency to prepare a regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements under the Administrative Procedure Act or any other statute, unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. Small entities include small businesses, small organizations, and small governmental jurisdictions.

For purposes of assessing the impacts of today's rule on small entities, small entity is defined as: (1) A small business as defined by the Small Business Administration's (SBA) regulations at 13 CFR 121.201; (2) a small governmental jurisdiction that is a government of a city, county, town, school district or special district with a population of less than 50,000; and (3) a small organization that is any not-for-profit enterprise which is independently owned and operated and is not dominant in its field.

After considering the economic impacts of today's final rule on small entities, I certify that this action will not

<sup>9</sup> Group C (possible human carcinogen) includes hazardous substances with "limited" evidence of carcinogenicity in animals and "inadequate evidence," "no data," or "no evidence" from human epidemiologic studies.

<sup>10</sup> Group 3—"low" hazard category. RQ levels are assigned to the hazard rankings as follows: high (one pound RQ), medium (10 pound RQ), and low (100 pound RQ).

<sup>11</sup> The Agency is also removing the chemical name for saccharin and its salts, 1,2-Benzisothiazol-3(2H)-one, 1,1-dioxide, & salts which appears as a separate entry on the list of CERCLA hazardous substances.



have a significant economic impact on a substantial number of small entities. In determining whether a rule has a significant economic impact on a substantial number of small entities, the impact of concern is any significant adverse economic impact on small entities, since the primary purpose of the regulatory flexibility analyses is to identify and address regulatory alternatives "which minimize any significant economic impact of the final rule on small entities" (5 U.S.C. 603 and 604). Thus, an agency may certify that a rule will not have a significant economic impact on a substantial number of small entities if the rule relieves regulatory burden, or otherwise has a positive economic effect on small entities subject to the rule.

This action is designed to lower the cost of waste management for affected entities, by removing saccharin and its salts from the lists of hazardous constituents and commercial chemical products which are hazardous wastes when discarded or intended to be discarded under RCRA and from the list of hazardous substances under CERCLA. We have therefore concluded that today's final rule will relieve regulatory burden for all affected small entities.

#### *D. Unfunded Mandates Reform Act*

This action contains no Federal mandates under the provisions of Title II of the Unfunded Mandates Reform Act of 1995 (UMRA), 2 U.S.C. 1531–1538 for State, local, or tribal governments or the private sector. This is because this final rule imposes no enforceable duty on any State, local, or tribal governments or the private sector. Therefore, this action is not subject to the requirements of sections 202 or 205 of the UMRA.

This action is also not subject to the requirements of section 203 of UMRA because it contains no regulatory requirements that might significantly or uniquely affect small governments.

#### *E. Executive Order 13132: Federalism*

This action does not have federalism implications. It will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132. This final rule primarily affects generators of certain hazardous wastes from the discard of unused commercial products that contain saccharin and its salts. There are no State and local government bodies that incur direct compliance costs by this rulemaking. Thus,

Executive Order 13132 does not apply to this action.

#### *F. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments*

This action does not have tribal implications, as specified in Executive Order 13175 (65 FR 67249, November 9, 2000). This final rule does not significantly or uniquely affect the communities of Indian tribal governments, nor would it impose substantial direct compliance costs on them. Thus, Executive Order 13175 does not apply to this rule.

#### *G. Executive Order 13045: Protection of Children From Environmental Health and Safety Risks*

This action is not subject to EO 13045 (62 FR 19885, April 23, 1997) because it is not economically significant as defined in EO 12866, and because the Agency does not believe the environmental health or safety risks addressed by this action present a disproportionate risk to children.

#### *H. Executive Order 13211: Actions That Significantly Affect Energy Supply, Distribution, or Use*

This action is not subject to Executive Order 13211 (66 FR 28355, May 22, 2001), because it is not a significant regulatory action under Executive Order 12866.

#### *I. National Technology Transfer and Advancement Act*

Section 12(d) of the National Technology Transfer and Advancement Act of 1995 ("NTTAA"), Public Law 104–113, section 12(d) (15 U.S.C. 272 note) directs EPA to use voluntary consensus standards in its regulatory activities, unless to do so would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (e.g., materials specifications, test methods, sampling procedures, and business practices) that are developed or adopted by voluntary consensus standards bodies. NTTAA directs EPA to provide Congress, through OMB, explanations when the Agency decides not to use available and applicable voluntary consensus standards.

This action does not involve technical standards. Therefore, EPA is not considering the use of any voluntary consensus standards.

#### *J. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations*

Executive Order (EO) 12898 (59 FR 7629, Feb. 16, 1994) establishes Federal executive policy on environmental justice. Its main provision directs Federal agencies, to the greatest extent practicable and permitted by law, to make environmental justice part of their mission by identifying and addressing, as appropriate, disproportionately high and adverse human health or environmental effects of their programs, policies, and activities on minority populations and low-income populations in the United States.

EPA has determined that this final rule will not have disproportionately high and adverse human health or environmental effects on minority or low-income populations because it does not affect the level of protection provided to human health or the environment. EPA is committed to addressing environmental justice concerns and has assumed a leadership role in environmental justice initiatives to enhance environmental quality for all citizens of the United States. The Agency's goals are to ensure that no segment of the population, regardless of race, color, national origin, income, or net worth bears disproportionately high and adverse human health and environmental impacts as a result of EPA's policies, programs, and activities. Our goal is to ensure that all citizens live in clean and sustainable communities. In response to Executive Order 12898, and to concerns voiced by many groups outside the Agency, EPA's Office of Solid Waste and Emergency Response (OSWER) formed an Environmental Justice Task Force to analyze the array of environmental justice issues specific to waste programs and to develop an overall strategy to identify and address these issues (OSWER Directive No. 9200.3–17).

The Agency's assessment, based on the small quantity of saccharin and its salts that are estimated to be discarded by affected facilities and their relatively low toxicity, is that there is no significant risk to human health or the environment from managing saccharin and its salts in nonhazardous waste landfills (the plausible management scenario). As noted previously in section V.B.2., the facilities that generate these small quantities of waste are distributed across the nation, which makes it unlikely that any one segment of the population would be impacted disproportionately from management of this nonhazardous waste.



*K. Congressional Review Act*

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each house of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a “major rule” as defined by 5 U.S.C. 804(2). This rule will be effective on January 18, 2011.

**List of Subjects***40 CFR Part 261*

Hazardous waste, Recycling, Reporting and recordkeeping requirements.

*40 CFR Part 268*

Hazardous waste, Reporting and recordkeeping requirements.

*40 CFR Part 302*

Air pollution control, Chemicals, Hazardous substances, Hazardous waste, Intergovernmental relations, Natural resources, Reporting and record keeping requirements, Superfund, Water pollution control, Water supply.

Dated: December 13, 2010.

**Lisa P. Jackson**,  
Administrator.

■ For the reasons set out in the preamble, title 40, chapter I of the Code of Federal Regulations is amended as follows:

**PART 261—IDENTIFICATION AND LISTING OF HAZARDOUS WASTE**

■ 1. The authority citation for part 261 continues to read as follows:

**Authority:** 42 U.S.C. 6905, 6912(a), 6921, 6922, 6924(y) and 6938.

**§ 261.33 [Amended]**

■ 2. Section 261.33 is amended by removing the entries for the U202 hazardous waste in the table under paragraph (f).

**Appendix VIII [Amended]**

■ 3. Appendix VIII to part 261 is amended by removing the entries for “Saccharin” and “Saccharin salts” from the table “Hazardous Constituents.”

**PART 268—LAND DISPOSAL RESTRICTIONS**

■ 4. The authority citation for part 268 continues to read as follows:

**Authority:** 42 U.S.C. 6905, 6912(a), 6921, and 6924.

**§ 268.40 [Amended]**

■ 5. Section 268.40 is amended by removing the entry for waste code U202 from the table “Treatment Standards for Hazardous Wastes.”

**Appendix VII [Amended]**

■ 6. Appendix VII to part 268 is amended by removing the entry for waste code U202 from Table 1, “Effective Dates of Surface Disposed Wastes (Non-Soil and Debris) Regulated in the LDRs—Comprehensive List.”

**PART 302—DESIGNATION, REPORTABLE QUANTITIES, AND NOTIFICATION**

■ 7. The authority citation for part 302 continues to read as follows:

**Authority:** 42 U.S.C. 9602, 9603, and 9604; 33 U.S.C. 1321 and 1361.

**§ 302.4 [Amended]**

■ 8. Section 302.4 is amended as follows:

■ a. By removing the entry for “1,2-Benzisothiazol-3(2H)-one, 1,1-dioxide, & salts” from Table 302.4.

■ b. By removing the entry for “Saccharin, & salts” from Table 302.4.

■ c. By removing the entry for “81072 Saccharin, & salts. 1,2-Benzisothiazol-3(2H)-one, 1,1-dioxide, & salts” from Appendix A to § 302.4.

[FR Doc. 2010–31773 Filed 12–16–10; 8:45 am]

**BILLING CODE 6560–50–P**

**DEPARTMENT OF HOMELAND SECURITY****Federal Emergency Management Agency****44 CFR Part 67**

[Docket ID FEMA–2010–0003]

**Final Flood Elevation Determinations**

**AGENCY:** Federal Emergency Management Agency, DHS.

**ACTION:** Final rule.

**SUMMARY:** Base (1% annual-chance) Flood Elevations (BFEs) and modified BFEs are made final for the communities listed below. The BFEs and modified BFEs are the basis for the floodplain management measures that

each community is required either to adopt or to show evidence of being already in effect in order to qualify or remain qualified for participation in the National Flood Insurance Program (NFIP).

**DATES:** The date of issuance of the Flood Insurance Rate Map (FIRM) showing BFEs and modified BFEs for each community. This date may be obtained by contacting the office where the maps are available for inspection as indicated in the table below.

**ADDRESSES:** The final BFEs for each community are available for inspection at the office of the Chief Executive Officer of each community. The respective addresses are listed in the table below.

**FOR FURTHER INFORMATION CONTACT:** Luis Rodriguez, Chief, Engineering Management Branch, Federal Insurance and Mitigation Administration, Federal Emergency Management Agency, 500 C Street, SW., Washington, DC 20472, (202) 646–4064, or (e-mail) [luis.rodriguez1@dhs.gov](mailto:luis.rodriguez1@dhs.gov).

**SUPPLEMENTARY INFORMATION:** The Federal Emergency Management Agency (FEMA) makes the final determinations listed below for the modified BFEs for each community listed. These modified elevations have been published in newspapers of local circulation and ninety (90) days have elapsed since that publication. The Deputy Federal Insurance and Mitigation Administrator has resolved any appeals resulting from this notification.

This final rule is issued in accordance with section 110 of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4104, and 44 CFR part 67. FEMA has developed criteria for floodplain management in floodprone areas in accordance with 44 CFR part 60.

Interested lessees and owners of real property are encouraged to review the proof Flood Insurance Study and FIRM available at the address cited below for each community. The BFEs and modified BFEs are made final in the communities listed below. Elevations at selected locations in each community are shown.

*National Environmental Policy Act.* This final rule is categorically excluded from the requirements of 44 CFR part 10, Environmental Consideration. An environmental impact assessment has not been prepared.

*Regulatory Flexibility Act.* As flood elevation determinations are not within the scope of the Regulatory Flexibility Act, 5 U.S.C. 601–612, a regulatory flexibility analysis is not required.

*Regulatory Classification.* This final rule is not a significant regulatory action