



Common Sense Initiative

Mike DeWine, Governor
Jon Husted, Lt. Governor

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Business Impact Analysis

Agency, Board, or Commission Name: Ohio Environmental Protection Agency

Rule Contact Name and Contact Information:

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Regulation/Package Title (a general description of the rules' substantive content):

Set Gen (Generator Improvements, Export/Import, CCR, Hazardous Waste Pharmaceuticals, and Hazardous Airbag Wastes)

Rule Number(s): 130 rules in OAC Chapters 3745-50 to 3745-55, 3745-65, 3745-66, 3745-69, 3745-205, 3745-256, 3745-266, 3745-270, 3745-273 and 3745-279

Date of Submission for CSI Review: December 4, 2019

Public Comment Period End Date: January 20, 2020

Rule Type/Number of Rules:

New/ 52 rules

No Change/ 0 rules (FYR? 0)

Amended/ 63 rules (FYR? 63)

Rescinded/ 15 rules (FYR? 15)

The Common Sense Initiative is established in R.C. 107.61 to eliminate excessive and duplicative rules and regulations that stand in the way of job creation. Under the Common Sense Initiative, agencies must balance the critical objectives of regulations that have an adverse impact on business with the costs of compliance by the regulated parties. Agencies should promote transparency, responsiveness, predictability, and flexibility while developing regulations that are fair and easy to follow. Agencies should prioritize compliance over punishment, and to that end, should utilize plain language in the development of regulations.

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Reason for Submission

1. **R.C. 106.03 and 106.031 require agencies, when reviewing a rule, to determine whether the rule has an adverse impact on businesses as defined by R.C. 107.52. If the agency determines that it does, it must complete a business impact analysis and submit the rule for CSI review.**

Which adverse impact(s) to businesses has the agency determined the rule(s) create?

The rule(s):

- a. ☐ **Requires a license, permit, or any other prior authorization to engage in or operate a line of business.**
- b. ☐ **Imposes a criminal penalty, a civil penalty, or another sanction, or creates a cause of action for failure to comply with its terms.**
- c. ☒ **Requires specific expenditures or the report of information as a condition of compliance.**
- d. ☐ **Is likely to directly reduce the revenue or increase the expenses of the lines of business to which it will apply or applies.**

Regulatory Intent

2. **Please briefly describe the draft regulation in plain language.**

Please include the key provisions of the regulation as well as any proposed amendments.

This rule package includes a number of hazardous waste management rules regarding generator standards; treatment, storage, and disposal standards; land disposal restrictions; management standards for hazardous waste pharmaceuticals and airbag waste. It updates the hazardous waste generator regulations to make the rules easier to understand, facilitate better compliance, provide greater flexibility in how hazardous waste is managed and close important gaps in the regulations without increasing burden. These will be considered and bundled together as the “Set Gen” rules. These rules are Federally driven changes. Ohio’s hazardous waste rules must match their federal Resource Conservation and Recovery Act (RCRA) counterpart rules. This package includes the following rules:

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Rule Number	Rule Title	Proposed Action
3745-50-02	Availability of information; confidentiality of information.	New
3745-50-04	Manifest copy submission requirements for certain interstate waste shipments.	New
3745-50-05	Applicability of electronic manifest system and user fee requirements to facilities receiving state-only regulated waste shipments.	New
3745-50-10	Definitions and computation of time.	Amended
3745-50-11	Incorporated by reference.	Amended
3745-50-28	Procedures for case-by-case regulation of hazardous waste recycling activities.	Amended
3745-50-45	Special inclusions and exclusions for hazardous waste permits.	Amended
3745-51-01	Purpose and scope of Chapter 3745-51 of the Administrative Code.	Amended
3745-51-04	Exclusions.	Amended
3745-51-05	Special requirements for hazardous waste generated by conditionally exempt small quantity generators.	Rescinded
3745-51-06	Requirements for recyclable materials.	Amended
3745-51-07	Residues of hazardous waste in empty containers.	Amended
3745-51-11	Criteria for listing hazardous waste.	Amended
3745-51-30	Lists of hazardous wastes - general.	Amended
3745-51-33	Discarded commercial chemical products, off-specification species, container residues, and spill residues thereof.	Amended
3745-51-39	Conditional exclusion for used, broken CRTs and processed CRT glass undergoing recycling.	Amended
3745-52-01	Terms used in Chapter 3745-52.	New
3745-52-10	Applicability- generator standards.	Amended
3745-52-11	Hazardous waste determination.	Rescinded
3745-52-11	Hazardous waste determination and recordkeeping.	New
3745-52-12	Generator identification numbers.	Rescinded
3745-52-13	Generator category determination.	New
3745-52-14	Conditions for exemption for a very small quantity generator.	New
3745-52-15	Satellite accumulation area regulations for small and large quantity generators.	New
3745-52-16	Conditions for exemption for a small quantity generator that accumulates hazardous waste.	New
3745-52-17	Conditions for exemption for a large quantity generator that accumulates hazardous waste.	New

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Rule Number	Rule Title	Proposed Action
3745-52-18	EPA identification numbers and re-notification for small quantity generators and large quantity generators.	New
3745-52-20	Manifest - general requirements.	Amended
3745-52-24	Use of the electronic manifest.	New
3745-52-25	Electronic manifest signatures.	New
3745-52-32	Marking.	Amended
3745-52-34	Accumulation time of hazardous waste.	Rescinded
3745-52-35	Liquids in landfills prohibition.	New
3745-52-40	Recordkeeping - generator standards.	Amended
3745-52-41	Biennial report- generator standards.	Rescinded
3745-52-41	Biennial report for large quantity generators.	New
3745-52-44	Recordkeeping and reporting requirements for generators of between one hundred and one thousand kilograms per month.	Rescinded
3745-52-44	Recordkeeping for small quantity generators.	New
3745-52-50	Applicability- exports of hazardous waste to a foreign country.	Rescinded
3745-52-60	Imports of hazardous waste from a foreign country.	Rescinded
3745-52-80	Applicability - transboundary movement of hazardous waste for recovery or disposal.	New
3745-52-200	Definitions - laboratories owned by eligible academic entities.	Amended
3745-52-201	Applicability - laboratories owned by eligible academic entities.	Amended
3745-52-202	Use of the rules for laboratories owned by eligible academic entities is an option.	Amended
3745-52-203	Notification requirement - eligible academic entity.	Amended
3745-52-204	Withdrawal notification - eligible academic entity.	Amended
3745-52-207	Training - eligible academic entity.	Amended
3745-52-208	Removing containers of unwanted material from the laboratory.	Amended
3745-52-209	Where and when to make the hazardous waste determination and where to send containers of unwanted material upon removal from the laboratory.	Amended
3745-52-210	Making the hazardous waste determination in the laboratory before the unwanted material is removed from the laboratory.	Amended
3745-52-211	Making the hazardous waste determination at an on-site central accumulation area.	Amended
3745-52-212	Making the hazardous waste determination at an on-site interim or permitted treatment, storage, or disposal facility.	Amended
3745-52-213	Laboratory clean-outs.	Amended

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Rule Number	Rule Title	Proposed Action
3745-52-214	Laboratory management plan.	Amended
3745-52-216	Non-laboratory hazardous waste generated at an eligible academic entity.	Amended
3745-52-230	Applicability - alternative standards for episodic generation.	New
3745-52-231	Definitions - alternative standards for episodic generation.	New
3745-52-232	Conditions for a generator managing hazardous waste from an episodic event.	New
3745-52-233	Petition to manage one additional episodic event per calendar year.	New
3745-52-250	Applicability - preparedness, prevention, and emergency procedures for large quantity generators.	New
3745-52-251	Maintenance and operation of facility.	New
3745-52-252	Required equipment - preparedness, prevention, and emergency procedures for large quantity generators.	New
3745-52-253	Testing and maintenance of equipment.	New
3745-52-254	Access to communications or alarm system.	New
3745-52-255	Required aisle space.	New
3745-52-256	Arrangements with local authorities.	New
3745-52-260	Purpose and implementation of contingency plan.	New
3745-52-261	Content of contingency plan.	New
3745-52-262	Copies of contingency plan.	New
3745-52-263	Amendment of contingency plan.	New
3745-52-264	Emergency coordinator.	New
3745-52-265	Emergency procedures.	New
3745-53-10	Applicability- transporter standards.	Amended
3745-53-11	U.S. EPA identification number- transporters.	Amended
3745-53-12	Transfer facility requirements.	Rescinded
3745-53-12	Transfer facility requirements.	New
3745-53-20	Acceptance and handling of hazardous waste and the manifest system.	Rescinded
3745-53-20	The manifest system.	New
3745-53-21	Compliance with the manifest.	Amended
3745-53-25	Electronic manifest signatures.	New
3745-54-01	Purpose, scope, and applicability of Chapters 3745-54 to 3745-57 and 3745-205 of the Administrative Code.	Amended
3745-54-12	Required notices.	Rescinded
3745-54-12	Required notices.	New
3745-54-15	General inspection requirements.	Amended
3745-54-71	Use of manifest system.	Amended

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Rule Number	Rule Title	Proposed Action
3745-54-75	Biennial report.	Rescinded
3745-54-75	Biennial report.	New
3745-55-70	Applicability - use and management of containers.	Amended
3745-55-74	Inspections- containers.	Amended
3745-55-91	Assessment of existing tank systems integrity.	Amended
3745-65-01	Purpose, scope, and applicability of Chapters 3745-65 to 3745-69 and 3745-256 of the Administrative Code.	Amended
3745-65-12	Required notices.	Rescinded
3745-65-12	Required notices.	New
3745-65-15	General inspection requirements.	Amended
3745-65-71	Use of manifest system.	Amended
3745-65-75	Biennial report.	Rescinded
3745-65-75	Biennial report.	New
3745-66-74	Inspections- containers.	Amended
3745-66-90	Applicability- tanks.	Amended
3745-66-93	Containment and detection of releases- tanks.	Amended
3745-66-101	Special requirements for generators of between one hundred and one thousand kilograms per month that accumulate hazardous waste in tanks.	Rescinded
3745-69-01	General operating requirements and applicability- chemical, physical, and biological treatment.	Amended
3745-256-200	Applicability- military munitions.	Amended
3745-266-70	Applicability and requirements- recyclable materials utilized for precious metal recovery.	Amended
3745-266-80	Applicability and requirements- spent lead-acid batteries being reclaimed.	Amended
3745-266-108	Small quantity on-site burner exemption.	Amended
3745-266-111	Standards for direct transfer.	Amended
3745-266-255	Re-entry of LLMW into regulation as a hazardous waste.	Amended
3745-266-500	Definitions - hazardous waste pharmaceuticals.	New
3745-266-501	Applicability - hazardous waste pharmaceuticals.	New
3745-266-502	Standards for healthcare facilities managing non-creditable hazardous waste pharmaceuticals.	New
3745-266-503	Standards for healthcare facilities managing potentially creditable hazardous waste pharmaceuticals.	New
3745-266-504	Healthcare facilities that are very small quantity generators for both hazardous waste pharmaceuticals and non-pharmaceutical hazardous waste.	New
3745-266-505	Prohibition of sewerage hazardous waste pharmaceuticals.	New

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3745-266-506	Conditional exemptions for hazardous waste pharmaceuticals that are also controlled substances and household waste pharmaceuticals collected in a take-back event or program.	New
3745-266-507	Residues of hazardous waste pharmaceuticals in empty containers.	New
3745-266-508	Shipping non-creditable hazardous waste pharmaceuticals from a healthcare facility or evaluated hazardous waste pharmaceuticals from a reverse distributor.	New
3745-266-509	Shipping potentially creditable hazardous waste pharmaceuticals from a healthcare facility or a reverse distributor to a reverse distributor.	New
3745-266-510	Standards for the management of potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals at reverse distributors.	New
3745-270-01	Purpose, scope, and applicability - land disposal restrictions.	Amended
3745-270-07	Testing, tracking, and recordkeeping requirements for generators, reverse distributors, treaters, and disposal facilities.	Amended
3745-270-50	Prohibitions on storage of restricted wastes.	Amended
3745-273-08	Applicability- household and very small quantity generator waste.	Amended
3745-273-13	Waste management - standards for small quantity handlers of universal waste.	Amended
3745-273-33	Waste management - standards for large quantity handlers of universal waste.	Amended
3745-273-39	Tracking universal waste shipments- standards for large quantity handlers of universal waste.	Amended
3745-273-62	Tracking universal waste shipments- standards for destination facilities.	Amended
3745-273-80	General requirements for petitions to include other wastes under Chapter 3745-273 of the Administrative Code.	Amended
3745-273-81	Factors that the director may evaluate regarding petitions to include other wastes under Chapter 3745-273 of the Administrative Code.	Amended
3745-279-10	Applicability - recycled used oil management standards.	Amended

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3. Please list the Ohio statute(s) that authorize the agency, board or commission to adopt the rule(s) and the statute(s) that amplify that authority.

Ohio Revised Code (ORC) 3734.02, 3734.05, 3734.12, and 3734.18 provide the authority for these rules. Additionally, ORC 3734.02, 3734.05, 3734.12, 3734.13, 3734.18 and 3745.01 are amplified by these rules.

4. Does the regulation implement a federal requirement? Is the proposed regulation being adopted or amended to enable the state to obtain or maintain approval to administer and enforce a federal law or to participate in a federal program?

If yes, please briefly explain the source and substance of the federal requirement.

Yes, the proposed changes are being made to address changes in the federal RCRA program. Ohio hazardous waste management rules are required to be consistent with and equivalent to their federal counterpart provisions, with exceptions provided in the Ohio Revised Code.

5. If the regulation includes provisions not specifically required by the federal government, please explain the rationale for exceeding the federal requirement.

The proposed changes are specifically required by U.S. EPA. None of the changes proposed exceed the federal requirements.

6. What is the public purpose for this regulation (i.e., why does the Agency feel that there needs to be any regulation in this area at all)?

In order for Ohio EPA to maintain its authorization to regulate hazardous waste in Ohio, the Agency must adopt rules that meet the federal requirements. The proposed rules are being adopted to maintain Ohio's authorization. Further, these changes are important because they protect human health and the environment and enhance the safety of facilities, employees, and the general public by improving hazardous waste risk communication and ensuring that emergency management requirements meet today's needs.

7. How will the Agency measure the success of this regulation in terms of outputs and/or outcomes?

The Agency will measure the success of these regulations through the degree of compliance with these regulations by the regulated community, the minimal occurrences of hazards to public health, safety and the environment, and continuation of the Agency's federal authorization to regulate hazardous waste in Ohio.

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- 8. Are any of the proposed rules contained in this rule package being submitted pursuant to R.C. 101.352, 101.353, 106.032, 121.93, or 121.931?**

If yes, please specify the rule number(s), the specific R.C. section requiring this submission, and a detailed explanation.

None of the proposed rules are being submitted pursuant to R.C. 101.352, 101.353, 106.032, 121.93, or 121.931.

Development of the Regulation

- 9. Please list the stakeholders included by the Agency in the development or initial review of the draft regulation.**

If applicable, please include the date and medium by which the stakeholders were initially contacted.

These rules were sent out for Early Stakeholder Outreach on three different occasions via the Agencies website and listserv. The hazardous waste rule listserv is an email list comprised of various interested stakeholders representing regulated entities, professional associations, environmental groups, consultants, and attorneys. The agency is combining the following three topics into one rulemaking for interested party review:

May 2017 – Generator Improvements, Export/Import and Coal Combustion Residuals (CCR)

May 2018 – eManifest

May 2019 – Pharmaceutical and Airbags

- 10. What input was provided by the stakeholders, and how did that input affect the draft regulation being proposed by the Agency?**

For Generator Improvements, Export/Import and CCR, Ohio EPA received two comments describing support for the adoption of the new rules.

For the pharmaceutical and airbag rules, one comment was received as a result of Ohio EPA's ESO request for input, and it was generally supportive of all aspects of the new pharmaceutical rules.

Ohio EPA now intends to release an interested party draft of the Set Gen rule amendments for stakeholder review and comment.

- 11. What scientific data was used to develop the rule or the measurable outcomes of the rule? How does this data support the regulation being proposed?**

The Ohio hazardous waste rules are required by state and federal law to be equivalent to the federal rules.

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12. What alternative regulations (or specific provisions within the regulation) did the Agency consider, and why did it determine that these alternatives were not appropriate? If none, why didn't the Agency consider regulatory alternatives?

Alternative provisions would not be appropriate for these rules. The Ohio hazardous waste rules are required by state and federal law to be equivalent to the federal rules.

13. Did the Agency specifically consider a performance-based regulation? Please explain.
Performance-based regulations define the required outcome, but don't dictate the process the regulated stakeholders must use to achieve compliance.

No. The Ohio hazardous waste rules are required by state and federal law to be equivalent to their federal counterpart rules.

14. What measures did the Agency take to ensure that this regulation does not duplicate an existing Ohio regulation?

When they were originally promulgated, Ohio EPA worked with LSC and the regulated community to ensure that these rules did not duplicate any other Ohio rules. These rules and/or other Ohio EPA rules have been amended in the past to eliminate duplicative requirements. Also, Ohio EPA is the only agency that has jurisdiction to adopt regulations governing the management of hazardous wastes. Furthermore, many of these rules are new and allow for greater flexibility and reduce the burden on the regulated community.

15. Please describe the Agency's plan for implementation of the regulation, including any measures to ensure that the regulation is applied consistently and predictably for the regulated community.

Ohio EPA implementation of this rule package will include notifying the regulated community of the rule requirements, providing guidance to the regulated community, and offering presentations on rule updates. Ohio EPA is developing guidance and presentations for inspectors and field staff as well, so they will be well equipped to offer assistance as they interact with the regulated community.

Adverse Impact to Business

16. Provide a summary of the estimated cost of compliance with the rule. Specifically, please do the following:

a. Identify the scope of the impacted business community; and

The business community impacted by Ohio's hazardous waste rules consists of the businesses that generate, treat, store, dispose of, or transport hazardous waste.

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b. Identify the nature of all adverse impact (e.g., fees, fines, employer time for compliance,);

It is anticipated that businesses will be impacted by initial training time and costs, however the flexibilities these rules provide for will result in a long-term savings for businesses.

c. Quantify the expected adverse impact from the regulation.

The adverse impact can be quantified in terms of dollars, hours to comply, or other factors; and may be estimated for the entire regulated population or for a “representative business.” Please include the source for your information/estimated impact.

Generally, U.S. EPA found that the rules being adopted by Ohio EPA in this rule package will provide a savings to the regulated community overall. U.S. EPA expects that industry will save from approximately \$14.09 to \$17.36 million annually from the adoption of these rules. Most of these savings will be from the adoption of the Generator Improvements and the Pharmaceutical (including the revision to the definition of nicotine) rules. For further analysis of the savings see below.

For the Generator Improvements Rule, U.S. EPA estimates that while there will be an initial annualized cost to industry to comply with the requirements, entities opting to take advantage of two voluntary programs in the final rule (e.g., consolidation of very small quantity generators' hazardous waste by large quantity generators under the same ownership, and generators who change regulatory status episodically) could result in a net annualized benefit for the rule of 1.1 million to \$2.4 million.

For the pharmaceutical rules, U.S. EPA estimates that while there will be an initial annualized cost to industry to comply with the requirements, the streamlined management standards for healthcare facilities and the regulatory relief in regard to FDA-approved over-the-counter nicotine replacement therapy products (i.e., patches, gums and lozenges) is estimated to result in a net annualized cost savings for the rule of \$12.99 to \$14.96 million.

For the airbags rule, U.S. EPA estimates a nationwide cost of \$130,791 (per year), including \$0 annualized capital or operation & maintenance costs.

During the promulgation of the federal rules, costs and adverse impacts are taken into consideration, and comments regarding those issues are addressed before federal rules are published as final rules. Federal preamble (in the Federal Registers listed in the table in 1.a. and listed at the end of each federal rule in the CFR) includes discussion of costs and adverse impacts that were identified by commenters and addressed during the federal rulemaking.

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17. Why did the Agency determine that the regulatory intent justifies the adverse impact to the regulated business community?

Ohio EPA must promulgate rules for the management of hazardous waste that are protective of human health and the environment. Ohio EPA feels that the initial costs businesses may incur will be outweighed by the regulatory flexibility and long-term cost savings provided by the adoption of these rules.

Regulatory Flexibility

18. Does the regulation provide any exemptions or alternative means of compliance for small businesses? Please explain.

Yes, the Generator Improvements, pharmaceutical rules, the airbag rule and CCR rule provide exemptions and exclusions from the hazardous waste generator regulations as long as, in some cases, certain conditions, described in the rules, are met.

19. How will the agency apply Ohio Revised Code section 119.14 (waiver of fines and penalties for paperwork violations and first-time offenders) into implementation of the regulation?

The director will evaluate the applicability of ORC section 119.14 to entities regulated by these rules when assessing fines and penalties for paperwork violations and first-time offenders.

20. What resources are available to assist small businesses with compliance of the regulation?

The following resources are available:

- Ohio EPA's Office of Compliance Assistance and Pollution Prevention (OCAPP) is a non-regulatory program that provides information and resources to help small businesses comply with environmental regulations. OCAPP also helps customers identify and implement pollution prevention measures that can save money, increase business performance and benefit the environment. Services of the office include a toll-free hotline, on-site compliance and pollution prevention assessments, workshops/training, plain-English publications library and assistance in completing permit application forms. Additional information is available at <http://www.epa.ohio.gov/ocapp>.

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- Ohio EPA also has a permit assistance web page (http://www.epa.ohio.gov/dir/permit_assistance.aspx) that contains links to several items to help businesses navigate the permit process, including the Permit Wizard, Answer Place, Ohio EPA's Guide to Environmental Permitting and eBusiness Center.
- Ohio EPA maintains the Compliance Assistance Hotline 1-800-329-7518, weekdays from 8:00 a.m. to 5:00 p.m.
- U.S. EPA Small Business Gateway also has information on environmental regulations for small businesses available at <http://www.epa.gov/smallbusiness/> and a Small Business Ombudsman Hotline 1-800-368-5883.
- Ohio EPA's Division of Environmental Response and Revitalization (DERR) Hazardous Waste Program offers free technical assistance to the regulated community.

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