

June 12, 2024

Via E-mail (terfani@marincounty.org)

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Re: Substantive Change Proposal - Municipal Waste-to-Energy Incineration for the Treatment of Unwanted Products

Pursuant to the Safe Drug Disposal Ordinance NO. 3635 Section 7.90.090, Inmar seeks to petition the department for approval to use permitted municipal waste-to-energy (WtE) incinerators for the treatment of Unwanted Products. The WtE technology employed in facilities located in Barron County (Wisconsin) and Spokane County (Washington) renders Unwanted Products non-retrievable from abuse and diversion and converts such products into a renewable energy source, satisfying compliance with both the Drug Enforcement Agency (DEA) and the Environmental Protection Agency (EPA).

- Since early 2021, hazardous waste incinerators have been backlogged from processing waste due to a number of factors. This problem persists to this day and has prevented the timely processing of waste at nearly all permitted hazardous waste treatment facilities in the United States.
- Inmar's Reverse Distributor is currently holding collected Unwanted Products due to the inability to transfer them to a hazardous waste incinerator which only heightens the risk of diversion.
- Per 40 CFR part 266 subpart P, hazardous waste pharmaceuticals that are also DEA controlled substances are exempt from Resource Conservation and Recovery Act (RCRA) hazardous waste regulations, and allowed to be destroyed at a municipal waste combustor or industrial solid waste incinerator, provided they are managed in compliance with DEA regulations.
- DEA regulations have clarified in 21 CFR 1300-1317 that controlled substances collected from ultimate users via mail-back programs or collection receptacles fall under RCRA's Household Hazardous Waste Exemption and hence, EPA RCRA regulations would not apply.
- In that same ruling, the DEA declared, simply, that incineration of drugs does achieve the non-retrievable standard.
- Further, California's Medical Waste Management Act (California Health and Safety Code Section 118215), allows medical waste, which includes pharmaceutical wastes, to be treated using incineration at a permitted medical waste treatment facility or other method of incineration approved by the department which provides complete combustion of the waste into carbonized or mineralized ash.

- Finally, both the statute and regulation for the state of California's Pharmaceutical and Sharps Waste Stewardship Programs do not require hazardous waste incineration.

Fortunately, municipal WtE technology is a viable option for the treatment of Unwanted Products.

WtE facilities serve to encourage recycling and waste reduction, along with the recovery of energy. The Spokane facility can generate 22 megawatts of electricity, enough to power 13,000 homes. This process reduces the solid waste by 90 percent by volume and 70 percent by weight, rendering the resulting ash biologically inert. WtE technology reduces greenhouse gas emissions by reducing methane from landfills and replacing fossil fuels with energy from waste. The Spokane facility is regulated by the Spokane Regional Clean Air Agency, the state Department of Ecology, and the Spokane Regional Health District. The Barron County facility is regulated by the Wisconsin Department of Natural Resources.

Use of a permitted municipal waste-to-energy (WtE) incinerators is beneficial to Program operations specifically because:

- There are currently no backlogs at the selected WtE incinerators
- It would automatically resolve the risk of diversion
- It allows that, going forward, Covered Products can be sent for destruction immediately

In summary:

1. The DEA requires controlled substances to be rendered non-retrievable, which is permitted and achieved by non-hazardous incineration.
2. The EPA also allows for non-hazardous incineration of pharmaceutical wastes using municipal combustion or incineration.
3. The state of California also allows for the incineration of pharmaceutical wastes using non-hazardous and non-medical waste incineration.
4. Routing pharmaceutical wastes to hazardous waste incineration is currently problematic due to documented backlogs in the processing of waste at such facilities, with some backlogs dating back years awaiting processing.

Below is the information on the WtE facilities being proposed:

Barron County Waste to Energy and Recycling Facility

585 10 1/2 Ave

Almena, Wisconsin, 54805

Brent Bohn, Waste to Energy/Recycling Plant Director

<https://www.barroncountywi.gov/waste>

(715) 637-6890

wastetoenergy@co.barron.wi.us

Title V EPA PERMIT NO.: 60304904A-P21



INMAR.COM
(866)440-6917
SOLUTIONS@INMAR.COM

City of Spokane WTW & Recycling Disposal Site

2900 S. Geiger Blvd
Spokane, WA, 99224
<https://my.spokanecity.org/solidwaste/waste-to-energy/solidwaste@spokanecity.org>
EPA ID: WAR000000463
Title V Permit #: AOP-3

Thank you. Please let me know if you have any questions or need additional information.

Best Regards,

A handwritten signature in black ink, appearing to read "Nicholas Massaro".

Nicholas Massaro
Sr. Manager, Consumer Drug Take-Back Solutions
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Winston-Salem, NC 27101