



**Matthew Rodriguez**  
Secretary for  
Environmental Protection



## Department of Toxic Substances Control

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Barbara A. Lee, Director  
1001 "I" Street  
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Sacramento, California 95812-0806



**Edmund G. Brown Jr.**  
Governor

December 18, 2015

Mr. Mickey Pierce  
County of Santa Clara  
Department of Environmental Health  
1555 Berger Drive, Suite 300  
San Jose, California 95112-2716

Dear Mr. Pierce:

Thank you for your letter dated July 08, 2015, in which you asked the Department of Toxic Substances Control (DTSC) for clarification regarding the proper management of Resource Conservation and Recovery Act (RCRA) regulated pharmaceutical (pharma) hazardous wastes in California. In your letter, you specifically wanted to know if a facility that generates no more than 100 kilogram (kg) of RCRA-regulated waste and no more than 1 kg of acutely hazardous waste per month is subject to full "California" requirements. DTSC has considered the views expressed in your letter and provides the following response based on the DTSC's understanding of the hazardous waste laws and regulations.

In the example outlined in your letter, you stated that the definition of "medical waste" as codified in the California's Medical Waste Management Act (MWMA), Health and Safety Code section 117690, subdivision (a), does not include any pharma waste that is "regulated by the federal RCRA." However, the MWMA does not specify the extent to which a waste must be regulated under RCRA to be excluded from the definition "medical waste." Thus, there is some ambiguity as to whether or not RCRA-Conditionally Exempt Small Quantity Generators (CESQGs)-pharma wastes are included under the MWMA. You further pointed out that DTSC's website could be misconstrued as being less stringent than the literal read of MWMA for RCRA hazardous wastes generated by CESQGs under RCRA.

In response to your questions, DTSC referred to the Medical Waste Management Act of the Health and Safety Code as chaptered September 25, 2014 through Assembly Bill 333, Medical Waste (AB 333, Wieckowski: 564, 2014). In sections 117747 and 117690, the definition of a pharma does not include a pharma regulated by RCRA. Therefore, a RCRA regulated pharma that meets the definition of hazardous waste shall be managed according to hazardous waste regulations.

According to California Code of Regulations, title 22, subsection 66260.200(c), it is the generator's responsibility to determine if the waste is classified as a hazardous waste pursuant to the hazardous waste determination process set forth in California Code of Regulations, section 66262.11. When determining generator status, the generator must include all hazardous waste that is generated within that month. The monthly quantity is achieved by totaling up all of the RCRA hazardous wastes and non-RCRA hazardous wastes.

### Federal Regulations

Under the federal program, EPA established three categories of generators in 40 California Federal Regulations (C.F.R.):

- Conditionally Exempt Small Quantity Generators (CESQGs),
- Small Quantity Generators (SQGs), and
- Large Quantity Generators (LQGs).

In brief, CESQGs generate less than 100 kg of hazardous waste per month and no more than 1 kg of acutely hazardous waste per month. SQGs generate more than 100 kg of hazardous waste per month but less than 1000 kg of hazardous waste per month and no more than 1 kg of acutely hazardous waste per month. LQGs generate 1000 kg per month or more of hazardous waste per month and/or more than 1 kg per month of acutely hazardous waste per month.

According to 40 C.F.R., part 261.5, a CESQG is defined as a generator that generates no more than 100 kg of hazardous waste in that month. Qualifying generators may be exempt from many of the requirements that apply to generators of less than 1000 kg of hazardous waste per month provided they comply with special requirements in 40 C.F.R., part 261.5 for this exemption.

### California Regulations

In California, generators of hazardous waste fall into two categories:

- Generators of less than 1000 kg per month of hazardous waste that do not hold more than one kg of acutely hazardous waste or extremely hazardous waste for more than 90 days and,
- Generators of equal to or more than 1000 kg of hazardous waste or more than 1 kg of acutely or extremely hazardous waste per month.

Mr. Mickey Pierce  
December 20, 2015  
Page 3

California did not adopt the federal CESQG exemption, nor the corresponding generator category for generators. Qualifying generators that generate less than 1000 kg and also no more than 100 kg of hazardous waste per month must comply with generator standards set forth in section 66262.34(d) of Title 22, California Code of Regulations. Additional exemptions and requirements for qualifying generators of less than 1000 kg and no more than 100 kg of hazardous waste per month are found in the Health and Safety Code; section 25218, "Household Hazardous Waste and Small Quantity Generator Waste."

In conclusion, the extent of regulation to which hazardous waste generators are subject depends on the volumes and types of hazardous waste that each generator produces each month. Waste pharma that meet the definition of a RCRA hazardous waste shall be managed according to hazardous waste regulations. For clarity, wastes that would be federally exempt CESQG hazardous wastes are "RCRA hazardous wastes" in California and are regulated as such.

A generator of no more than 100 kg of RCRA regulated and non-RCRA regulated hazardous wastes per month (total) and of no more than 1 kg of acutely and extremely hazardous wastes (total) per month is subject to the standards in California Code of Regulations, title 22, subsection 66262.34(d) and Health and Safety Code section 25123.3(b). Such generators in California are not eligible to manage their hazardous wastes under the federal exemption in 40 C.F.R., part 261.5. However, if they qualify, a business may utilize the exemption in Health and Safety Code, section 25218 et seq.

DTSC has removed the misleading information at the following DTSC website:  
[http://www.dtsc.ca.gov/AssessingRisk/PPCP/Pharmaceutical\\_Regulatory.cfm](http://www.dtsc.ca.gov/AssessingRisk/PPCP/Pharmaceutical_Regulatory.cfm). We thank you for pointing out such occurrences.

If you have any additional questions, please contact Ms. Julie Cooper at (916) 445-5658 or via [Julie.Cooper@dtsc.ca.gov](mailto:Julie.Cooper@dtsc.ca.gov).

Sincerely,



Charles Corcoran, Chief  
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Policy Implementation and Support Branch  
Policy Program and Support Division  
Hazardous Waste Management Program  
Department of Toxic Substances Control

Mr. Mickey Pierce  
December 20, 2015  
Page 4

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