

AMENDED IN SENATE AUGUST 15, 2006

AMENDED IN SENATE AUGUST 7, 2006

AMENDED IN SENATE JUNE 13, 2006

AMENDED IN ASSEMBLY APRIL 18, 2006

CALIFORNIA LEGISLATURE—2005—06 REGULAR SESSION

ASSEMBLY BILL

No. 2155

**Introduced by Assembly Member Wolk
(Coauthor: Assembly Member Mullin)**

February 21, 2006

An act to add Section 25201.17 to the Health and Safety Code, relating to hazardous waste.

LEGISLATIVE COUNSEL'S DIGEST

AB 2155, as amended, Wolk. Hazardous waste: treatment: pharmaceutical activities.

(1) Existing law requires hazardous waste facilities, including, but not limited to, treatment facilities, to operate under hazardous waste facilities permits or other grants of authorization issued by the Department of Toxic Substances Control. Existing law exempts from the requirements relating to generators, tanks, and tank systems imposed pursuant to the hazardous waste control laws, and from the requirement to obtain a hazardous waste facilities permit, biotechnology elementary neutralization activities, as defined. A violation of the hazardous waste control laws is a crime.

This bill would additionally exempt pharmaceutical neutralization activities from those requirements, if specified conditions are met with regard to the pharmaceutical manufacturing or process development

activities that generate or use the hazardous waste subject to the neutralization treatment and if the owner or operator of the pharmaceutical neutralization unit complies with specified requirements. The bill would require the owner or operator to establish and maintain documentation substantiating its compliance and would require the documentation to be available for inspection upon the request of the department or the Certified Unified Program Agency.

Since a violation of the requirements imposed by the bill upon the owner or operator of a pharmaceutical neutralization unit would be a crime, the bill would impose a state-mandated local program by creating new crimes.

(2) The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: yes.

The people of the State of California do enact as follows:

1 SECTION 1. Section 25201.17 is added to the Health and
2 Safety Code, to read:
3 25201.17. (a) For purposes of this section, the following
4 terms have the following meanings:
5 (1) "Pharmaceutical manufacturing or pharmaceutical process
6 development activities" means activities conducted in North
7 American Industry Classification System Code subgroups
8 325411 and 325412, to the extent they meet either of the
9 following:
10 (A) Research, development, and production activities
11 conducted in relation to an investigational new drug application
12 or new drug application as set forth in Part 312 (commencing
13 with Section 312.1) of, and Part 314 (commencing with Section
14 314.1) of, Subchapter D of Chapter 1 of Title 21 of the Code of
15 Federal Regulations, that is filed with the United States Food and
16 Drug Administration, or research and development activities
17 conducted to support the future filing of an investigational new

1 drug application or new drug application, or research,
2 development, and production activities that are conducted in
3 relation to a filing with a corresponding governmental authority
4 in the European Union, Japan, or Canada that imposes similar
5 requirements.

6 (B) The production of a pharmaceutical product, including
7 starting materials, intermediates, and active pharmaceutical
8 intermediates.

9 (2) “Pharmaceutical neutralization activities” means the
10 ~~neutralization~~ *deactivation* of a material generated by, or used in,
11 pharmaceutical manufacturing or pharmaceutical process
12 development activities through the addition of a ~~neutralizing~~
13 reagent, including, but not limited to, a caustic, before
14 management of the material as a hazardous waste subject to this
15 chapter.

16 (b) Pharmaceutical neutralization activities are exempt from
17 any requirement imposed pursuant to this chapter, including any
18 regulation adopted pursuant to this chapter, that relates to
19 generators, tanks, and tank systems, and the requirement to
20 obtain a hazardous waste facilities permit or other grant of
21 authorization from the department, except as otherwise provided
22 in subdivision (c), if all of the following conditions are met:

23 (1) A permit is not required to conduct neutralization under the
24 federal act pursuant to Section 264.1(g)(5) of Title 40 of the
25 Code of Federal Regulations.

26 (2) The pharmaceutical manufacturing or pharmaceutical
27 process development activities are conducted in accordance with
28 the United States Food and Drug Administration’s current good
29 manufacturing practices, as set forth in Part 210 (commencing
30 with Section 210.1) of, and Part 211 (commencing with Section
31 211.1) of, Subchapter C of Chapter 1 of Title 21 of the Code of
32 Federal Regulations.

33 (3) The pharmaceutical neutralization activity occurs within a
34 unit that meets the standards of a totally enclosed treatment
35 facility, as defined in Section 260.10 of Title 40 of the Code of
36 Federal Regulations and Section 66260.10 of Title 22 of the
37 California Code of Regulations, that is physically connected to
38 the reactor or vessel where the material being neutralized is
39 created.

1 (4) The pharmaceutical neutralization activity is integral to the
2 manufacturing process and occurs within the manufacturing
3 process area and prior to the transfer of the material to a
4 dedicated hazardous waste storage or treatment unit.

5 (5) If the pharmaceutical neutralization activity occurs at
6 greater than 15 pounds per square inch gauge pressure, it shall
7 occur within a unit that meets applicable American Society of
8 Mechanical Engineers (ASME) standards for pressure rated
9 vessels, including the ASME requirements for automatic pressure
10 relief in the event of a system failure, including pressure relief
11 valves, burst discs, or equivalent devices.

12 (6) The pharmaceutical neutralization activities do not raise
13 the temperature of the hazardous wastes to within 10 degrees
14 Celsius of the boiling point or cause the release of hazardous
15 gaseous emissions, using either constituent-specific
16 concentration limits or calculations.

17 (7) The temperature of any unit 100 gallons or larger is
18 automatically monitored, the unit is fitted with a
19 high-temperature alarm system, and, for closed systems, the
20 adding and mixing of in-process and neutralizing solutions are
21 manually controlled.

22 (8) The pharmaceutical neutralization activity occurs within a
23 facility that has design or engineering features, including, but not
24 limited to, trenches, sumps, berming, sloping, or diking, designed
25 to contain all liquid spills from pharmaceutical manufacturing
26 process and neutralization units.

27 (c) An owner or operator of a pharmaceutical neutralization
28 unit exempt under this section shall comply with all of the
29 following requirements:

30 (1) The owner or operator shall successfully complete a
31 program of classroom instruction or on-the-job training that
32 includes, at a minimum, instruction for responding effectively to
33 emergencies by familiarizing personnel with emergency
34 procedures, emergency equipment, and emergency systems,
35 including, where applicable, procedures for using, inspecting,
36 repairing, and replacing facility emergency and monitoring
37 equipment, communications, or alarm systems.

38 (2) Within 10 days of commencing initial operation of the
39 unit, or within any other time period that may be required by the
40 CUPA, the owner or operator shall notify the CUPA of the

1 commencement of the operation of the unit under the exemption
2 made pursuant to this section. A CUPA is authorized to, and is
3 required to, implement the requirements specified in this section.
4 If the owner or operator is not under the jurisdiction of a CUPA,
5 the notice shall be sent to the officer of the agency authorized,
6 pursuant to subdivision (e) of Section 25404.3, to implement and
7 enforce the requirements of this chapter listed in paragraph (2) of
8 subdivision (c) of Section 25404.

9 (3) The owner or operator shall establish and maintain
10 documentation to substantiate its compliance with all of the
11 requirements and conditions of this section, and shall make the
12 documentation available for inspection upon request of the
13 department or the CUPA.

14 (d) Notwithstanding any other provision of law, all air
15 emissions from a pharmaceutical neutralization unit shall be
16 managed in accordance with the requirements of the local air
17 pollution control district or air quality management district.

18 (e) All ~~hazardous~~—wastes generated as a result of
19 pharmaceutical neutralization activities shall be managed *as*
20 *hazardous wastes* in accordance with all applicable ~~hazardous~~
21 ~~waste management~~ requirements *of this chapter*.

22 SEC. 2. No reimbursement is required by this act pursuant to
23 Section 6 of Article XIII B of the California Constitution because
24 the only costs that may be incurred by a local agency or school
25 district will be incurred because this act creates a new crime or
26 infraction, eliminates a crime or infraction, or changes the
27 penalty for a crime or infraction, within the meaning of Section
28 17556 of the Government Code, or changes the definition of a
29 crime within the meaning of Section 6 of Article XIII B of the
30 California Constitution.