

## REGULATION OF THE BIOTECH INDUSTRY Comparison of Several Jurisdictional Approaches

*(Underlined terms are defined in the glossary.)*

<b>Jurisdiction Contact Phone</b>	<b>Regulations specific to Biotech?</b>	<b>Any regulations stricter than state law?</b>	<b>New ways of monitoring?</b>	<b>Other regulations?</b>
<b>San Diego</b> Environmental Health John Misleh (619) 338-2395	No	Annual hazardous materials disclosure for any carcinogen, reproductive toxin, toxic gas local ordinance ( <u>Proposition 65 chemicals</u> )	Annual disclosures	Hazardous Materials Hazardous Waste Medical Waste
<b>Cambridge, MA</b> DPH/Environmental Health Sam Lipson (617) 665-3838	Yes Recombinant DNA (R-DNA) Regulation	Yes. Local ordinance in effect since 1977.	Initial presentations from business to committee (Citizens +Env Health Director) Submittal of Biosafety Committee's minutes & annual report	Hazardous Materials Hazardous Waste Medical Waste
<b>Seattle, WA</b> King Cty/Seattle Health Jill Trohimovich (206) 296 3988 State Health Wayne Turnberg (206) 522-0132	No	No. In fact, there is no state wide medical waste law. All is left up to the locals. Hazardous Waste is regulated by State Dept of Ecology and Radiation by State Health. Regulation here seems very low key and extremely fractured.	NO	Hazardous Waste

<b>San Mateo</b> Bill Lent Environmental Health (650) 363-4366	No	No. They biotech industries very responsive to regulatory needs since they are accustomed to dealing with other regulatory agencies such as FDA.	No. However, due to specialized nature of these industries they do have a specialist who is responsible for them. (other than regular district staff) Some specific businesses do increased stack monitoring due to proximity to residences. Stack emissions is regulated by AQMD.	Hazardous Materials Hazardous Waste Medical Waste
<b>Alameda</b> Aria Levi (510) 567-6862 Environmental Health	No	No. Biotech only regulated within the specific context of existing laws for Hazardous waste, Hazardous materials, etc.	No	Hazardous Materials Hazardous Waste Medical Waste
<b>Contra Costa</b> Steve Morioka (925) 646-2286 Environmental Health	CA Department of Health Services is the main regulatory agency for radioactive materials handling.	No	No	Hazardous Materials Hazardous Waste Medical Waste
<b>San Francisco</b>	No	No. Refer to Table 1.	No	Hazardous Materials Hazardous Waste Medical Waste Possibly regulated under the following: <ul style="list-style-type: none"> <li>• Regulated Substances</li> <li>• Underground Storage Tanks</li> <li>• Back Up Diesel Generators*</li> </ul> <i>* Unique to SF</i>

## GLOSSARY

**Aggregate Quantities** – State law requires reporting of hazardous materials if a *single* hazardous material is stored in quantities equal to or greater than the threshold quantities. (55 gallons for liquids, 500 pounds for solids and 200 cubic feet for compressed gases) Businesses in San Francisco are required to report if the total quantity of *all* hazardous materials equals or exceeds the thresholds. For example, a business storing eleven 5-gallon containers of different hazardous materials would not be required to report under state law but because the aggregate amount is 55 gallons, would be required to report in San Francisco.

**Business Plan** – Is a regulatory document that includes a facility map, emergency response plan, employee training plan, chemical inventory, and business owner/ operator information. Information that is collected as part of the business plan is available for review by the public. It is also provided to the Fire Department for use during fires and other emergencies involving hazardous materials.

**Hazard and Operability Study** – Is an engineering report that is part of the Risk Management Plan. It results from an exercise by individuals knowledgeable in a specific operation. During the exercise, the team evaluates, in extreme detail, each part of the operation and asks questions such as “What can go wrong here?” and “What if ....?” Once the answers to these questions are established, specific hazard minimization measures are developed for each part of the operation.

**Hazardous Materials** – Defined very broadly in environmental regulation. Generally, if a mixture contains more than 10% of a hazardous material (1% for carcinogens) it is considered a hazardous material. Examples of hazardous materials include relatively low hazard substances such as latex paint and detergents well as more hazardous substances like ammonia and chlorine gas.

**Hazardous Waste** – Includes those hazardous materials which are no longer useable for any reason. They may be a by product of some industrial process, or have exceeded their shelf life or are simply excess. Hazardous waste is defined in 2 ways: Listed wastes are those that are specifically included in a list of hazardous wastes prepared by the CA Environmental Protection Agency such as latex paint. Characteristic wastes demonstrate hazardous characteristics such as physical hazards or adverse health effects. An example of a characteristic waste is spilled gasoline because it exhibits the characteristic of flammability.

**Medical Waste** – Is waste that is produced as a result of certain activities such as diagnosis, treatment or immunization of human beings or animals or research pertaining to such activities. Medical waste is either biohazardous like fluid blood, or animal parts or “sharps waste” like needles scalpels, or other devices capable of cutting or piercing.

**Off site consequence analysis** -- Is an engineering report that is part of the Risk Management Plan. The study uses established scientific computer programs to “model” the extent of contamination should a release of a regulated substance occur. The study aids the regulated substance operator as well as community response agencies to plan for such releases and determine best evacuation routes, potentially affected communities and “sensitive receptors” like schools and nursing homes.

**Proposition 65 Chemicals** – Proposition 65 was a 1986 California voter initiative that regulated toxic chemicals. Specifically it placed restrictions on two categories of hazardous materials: those “known by the state” to cause cancer or reproductive toxicity. The primary compliance activities mandated by Proposition 65 related to these listed chemicals. It also requires public notification of any unauthorized discharges of hazardous waste.

**Regulated Substances** – A specific subset of hazardous materials that has been defined by the State of California as well as the Federal government which could cause extreme adverse health effects in the surrounding community should they be accidentally released into the atmosphere. The legal definition included minimum threshold planning quantities which trigger compliance with Regulated Substance laws. The only regulated substance currently being used in San Francisco in quantities that exceed the threshold planning quantity is ammonia gas. There are 5 such facilities in the City.

**Risk Management Plan** – Is a type of complex compliance document that includes a number of engineering studies. The main purpose of this document is to evaluate and minimize the risk associated with the release of a regulated substance and establish a plan for the mitigation of such a release should one occur.

**Stack Monitoring** – A specialized type of chemical air monitoring that is performed at the release point just prior to being emitted into the atmosphere. Allowable amounts and types of air pollutants are strictly regulated so as to maintain air quality in specific geographic area.