Date of Hearing: March 8, 2022

ASSEMBLY COMMITTEE ON ENVIRONMENTAL SAFETY AND TOXIC MATERIALS
Bill Quirk, Chair
AB 1787 (Quirk) – As Amended February 24, 2022

SUBJECT: Pesticide testing

SUMMARY: Extends the sunset on the data reporting and medical supervisor registration requirements of the agricultural pesticide worker protection program known as the California Medical Supervision Program (Program), and requires laboratories to submit additional information to the State to help identify workers, and medical supervisors of workers, in the Program. Specifically, **this bill**:

1) Adds the following information to that which a testing laboratory must report, as part of the Program, to the Department of Pesticide Regulation (DPR):

   a) The unique identifier of the person tested, including both of the following:

      i) The health care facility-assigned patient identification number; and,

      ii) The member identification, group number, and medical group name, or the provider group to which the tested person belongs.

   b) The National Provider Identifier (NPI).

   c) The accession number of the specimen.

2) Extends the sunset on the data reporting and medical supervisor registration requirements of the Program from January 1, 2023, to January 1, 2027.

3) Makes other technical and clarifying changes to statute related to the data reporting and medical supervisor registration requirements of the Program.

EXISTING LAW:

1) Requires each employer who has an employee who regularly handles Toxicity Category 1 or 2 organophosphate or carbamate pesticides (OP/CB pesticides) to contract with a physician to provide medical supervision of the employee. (California Code of Regulations (CCR), Title 3, § 6728 (b))

2) Delineates the employer's responsibilities for medical supervision for employees who regularly handle OP/CB pesticides, including requiring baseline cholinesterase tests and follow-up tests after the employee has handled OP/CB pesticides, as specified. Requires the employer to follow the recommendations of the medical supervisor concerning matters of occupational health. (CCR, Title 3, § 6728 (c))

3) Requires an employer to investigate the work practices and remove an employee from exposure to OP/CB pesticides if the employee's cholinesterase level falls below specified baseline values. (CCR, Title 3, § 6728 (d - e))

4) Requires any physician and surgeon who knows, or has reasonable cause to believe, that a patient is suffering from pesticide poisoning or any disease or condition caused by a pesticide to promptly report that fact to the local health officer. (Health and Safety Code (HSC) § 105200)

5) Requires an employer, in order to satisfy his or her responsibilities for medical supervision of his or her employees who regularly handle OP/CB pesticides, to contract with a medical supervisor registered with the Office of Environmental Health Hazard Assessment (OEHHA). (HSC § 105206 (a))

6) Requires a laboratory that performs tests ordered by a medical supervisor to report specified information, including cholinesterase test results, to DPR, which then shares this information with OEHHA and the State Department of Public Health (DPH). (HSC § 105206 (b))

7) Requires OEHHA to establish a procedure for registering and deregistering medical supervisors for the purposes of outreach and training and authorizes OEHHA to establish reasonable requirements for performance. (HSC § 105206 (f))

8) Requires OEHHA to review the cholinesterase test results submitted as part of the Program. Authorizes OEHHA to provide an appropriate medical or toxicological consultation to the medical supervisor, and, in consultation with DPR and the local health officer, to provide medical and toxicological consultation, as appropriate, to the county agricultural commissioner to address medical issues related to the investigation of cholinesterase inhibitor-related illness. (HSC § 105206 (f))

9) Requires DPR and OEHHA to prepare and publicly post an update on the effectiveness of the Program and the utility of laboratory-based reporting of cholinesterase testing for illness surveillance and prevention by January 1, 2021. (HSC § 105206 (g))

10) Sunsets the data reporting and medical supervisor registration provisions of the Program on January 1, 2023. (HSC § 105206 (h))

FISCAL EFFECT: Unknown.

COMMENTS:

Need for the bill: The California Medical Supervision Program (Program) is designed to protect workers who regularly mix, load, or apply Toxicity Category I and 2 organophosphate and carbamate pesticides (OPs/CBs), which are highly toxic pesticides that inhibit the nerve enzyme, cholinesterase. Under the Program, employers must contract with a medical supervisor to monitor their workers for overexposure to OP/CB pesticides by testing workers' blood cholinesterase activity levels. In order for the State to ensure that the Program is effectively protecting workers, agricultural worker cholinesterase test results are transmitted to DPR, and OEHHA registers and provides outreach and consultation to the medical supervisors overseeing the workers' cases. These reporting and registration requirements sunset on January 1, 2023.

AB 1787 extends the sunset on the reporting and registration requirements to January 1, 2027, so that the State can continue to effectively evaluate and manage the Program. Additionally, the bill requires reporting laboratories to submit specific identifying information to DPR on the patient and medical supervisor so the State can better identify, track, and protect the health of workers in the Program.

Organophosphate and carbamate (OP/CB) pesticide exposure: According to DPR, OPs and CBs work as pesticides by inhibiting the nerve enzyme cholinesterase, which breaks down the neurotransmitter acetylcholine, leading to the death of an insect. OPs and CBs can also affect humans by inhibiting cholinesterase. High exposure to OPs/CBs can cause a variety of acute symptoms of neurological poisoning in exposed people, including blurred vision, diarrhea, increased respiratory secretions, tremors, seizures, loss of consciousness, and death. The acute symptoms of OP/CB overexposure can sometimes mimic other illnesses, and people can be sub-clinically affected without showing major acute symptoms. Due to the potential for sub-clinical effects or misdiagnosis of the acute effects, tests for cholinesterase depression are essential for identifying potential overexposure.

Toxicity Category 1 and 2 OP/ CB pesticides: The United States Environmental Protection Agency (U.S. EPA) determines pesticide toxicity categories based on the effects of consumption of, inhalation of, or dermal contact with a pesticide. The degree of toxicity determines which precautions and signal word must appear on the pesticide label. Toxicity Category 1 pesticides are highly toxic and are required to prominently display the signal word "DANGER" on product labels. Toxicity Category 2 pesticides are moderately toxic and are required to prominently display the signal word "WARNING" on product labels.

While the use of Toxicity Category 1 and 2 OP/ CB pesticides in California has declined 89% since 1995, growers still applied an average of 2 million pounds per year of these cholinesterase-inhibiting pesticides from 2011 to 2019. Employers of handlers of Toxicity Category 1 and 2 OP/ CB pesticides are required to monitor their employees' cholinesterase under the Program.

California Medical Supervision Program (Program): Established in 1974, the Program is intended to protect pesticide handlers from excessive exposure to Toxicity Category I and 2 OPs and CBs. Under the Program, employers must contract with a licensed physician as a "medical supervisor" to test the blood cholinesterase level of workers who regularly handle these pesticides. To monitor each employee, the medical supervisor establishes baseline values of cholinesterase during non-exposure periods, and then periodically measures cholinesterase activity levels while the worker handles OPs/CBs. If the employee's cholinesterase is depressed below certain levels, the employer must take immediate specified actions, such as promptly retesting the employee, evaluating the employee's work practices, or immediately removing the employee from further exposure, in order to prevent excessive pesticide exposure and pesticide-related illness.

Reporting requirements: While the Program had been in existence for more than 30 years, prior to 2010 the State had received very little information from the field to determine whether the Program was effective. Assembly Bill (AB) 1963 (Nava, Chapter 369, Statutes of 2010) added HSC § 105206, which requires laboratories that conduct cholinesterase tests as a part of the Program to report test results to DPR. The results are then analyzed by DPR and OEHHA, in consultation with DPH. These provisions were meant to give the State a better idea of whether workers are actually being protected in the field and whether the Program is working as intended.

2015 Program analysis: AB 1963 also required, by December 31, 2015, DPR and OEHHA, in consultation with DPH, to prepare a report on the effectiveness of the medical supervision program and on the utility of laboratory-based reporting of cholinesterase testing for pesticide illness surveillance and prevention. AB 1963 stated that the report may include recommendations to the Legislature that DPR and OEHHA deem necessary.

DPR and OEHHA submitted the resultant report, *"The Report to the California Legislature: California's Cholinesterase Test Results,"* in December 2015, which found that overall the Program appears effective in protecting agricultural workers who handle cholinesterase-inhibiting pesticides. The report did find, however, that based on the data submitted from 2011-2013, the utility of the data analysis is hampered by the inclusion of thousands of records from individuals who are not in the Program, and by missing data on the purpose (i.e. baseline, follow-up, or recovery) of the cholinesterase test. DPR and OEHHA laid out specific "future directions," or actions that the two entities will take to improve the Program and to improve the utility of the data collected. DPR and OEHHA also made two recommendations that required legislation for Program improvement: 1) Cholinesterase reporting should continue at least through December 31, 2018, so that DPR and OEHHA can obtain additional data with clearer information on the purpose of the test and to allow further evaluation of the Program; and, 2) Transferring some cholinesterase reporting responsibilities from the laboratories to the medical supervisors as a more efficient way to implement the Program. The report also recommended enhanced outreach to and training activities for medical supervisors to increase their understanding of the Program.

Program updated: In response to DPR and OEHHA's report, the legislature passed, and the governor signed, AB 2892 (ESTM Committee, Chapter 475, Statutes of 2016), which extended the sunset on the data reporting requirements from January 1, 2017, to January 1, 2021; updated the information that was required to be reported; transferred some of the responsibility of reporting the cholinesterase test results and related information from laboratories to medical supervisors; required OEHHA to establish a procedure for registering and deregistering medical supervisors and to establish requirements for their performance; codified the requirement that an employer of employees who regularly handle pesticides must contract with a medical supervisor registered with OEHHA; and, required DPR and OEHHA to prepare and publicly post an "update" on the effectiveness of the medical supervision program and the utility of laboratory-based reporting of cholinesterase testing for illness surveillance and prevention by January 1, 2021.

The sunset on the data reporting requirements and the medical supervisor registration provisions of the Program were subsequently extended from January 1, 2021, to January 1, 2023, by AB 3220 (ESTM Committee, Chapter 296, Statutes of 2020).

This bill: AB 1787 extends the sunset on the data reporting and medical supervisor registration requirements of the Program from January 1, 2023, to January 1, 2027.

2022 Program analysis: As required by AB 2892, DPR and OEHHA prepared an "update," which was an analysis of the effectiveness of the medical supervision program and the utility of laboratory-based reporting of cholinesterase testing for illness surveillance and prevention, following the programmatic changes required by AB 2892 and recommended in the 2015 report. DPR and OEHHA released that report on January 26, 2022, and subsequently posted it on their websites.

DPR and OEHHA reported in the 2022 update that the Program still appears effective in protecting agricultural workers handling cholinesterase-inhibiting pesticides; however, while data quality improved since 2014, the utility of the data analysis continues to be hampered by the inclusion of tens of thousands of cholinesterase test records from individuals who are not in the Program (e.g. those who are tested for other medical reasons, such as pre-operative tests, liver disease, etc.). Additionally, an analysis of cholinesterase data received by DPR from 2011 to

2019 showed that a large proportion of the cholinesterase test reports still did not include the purpose of the test, and usually did not include the ordering physician's information or the patient's correct name. Consequently, it is resource intensive for DPR and OEHHA to not only identify workers under the Program, but to subsequently follow up with the reporting laboratory or ordering physician to reconcile data discrepancies. To address these data quality concerns, the report recommended amending HSC § 105206 to request additional data elements from reporting laboratories to better identify workers and ordering physicians. According to DPR and OEHHA, while laboratories already submit other personal information, such as the patient's name, date of birth, and test results, the data submitted is currently not adequate to identify all workers and medical supervisors under the Program, thus rendering DPR unable to fully evaluate whether the program is truly effective at protecting agricultural workers.

This bill: AB 1787, as recommended in the 2022 update, requires reporting laboratories to submit additional identifying information for the patient and medical supervisor so the State can better identify, track, and protect the health of workers in the Program. The bill requires laboratories to also submit the health care facility-assigned patient identification number and the member identification, group number, and medical group name, or the provider group to which the person tested belongs, to help identify the employee tested and to connect the employee to their employer. The bill also requires laboratories to submit the accession number of the specimen, which will help DPR determine the number of tests ordered by the provider. Finally, the bill's requirement for laboratories to submit the National Provider Identifier (NPI), along with the medical group name or the provider group, will help DPR and OEHHA identify the medical supervisor.

DPR and OEHHA report that some laboratories already report all of the information required by the bill, and they argue that requiring this data in statute will lead to more consistent reporting across all laboratories. Further, the NPI, patient identification, and accession number can be verified against national databases, making it easier to determine the actual count of employees under the Program, the count of medical supervisors responsible for monitoring workers' cholinesterase levels in a given period, and the number of tests ordered by a medical supervisor.

Related legislation:

1) AB 3220 (ESTM Committee, Chapter 296, Statutes of 2020). Extended the sunset, from January 1, 2021, to January 1, 2023, on the data reporting and medical supervisor registration provisions of the Program.

2) AB 2892 (ESTM Committee, Chapter 475, Statutes of 2016). Updated and enhanced the Program by extending the sunset on the requirement for laboratories to transmit cholinesterase test results to the State; requiring OEHHA to register medical supervisors; requiring medical supervisors to report depressions in cholinesterase levels as a pesticide illness; and, requiring DPR and OEHHA to prepare and publicly post an update on the effectiveness of the medical supervision program and the utility of laboratory-based reporting of cholinesterase testing for illness surveillance and prevention.

3) AB 1963 (Nava, Chapter 369, Statutes of 2010). Required clinical laboratories that perform cholinesterase testing for the purpose of determining workers' pesticide exposure to electronically report test results to DPR.

4) AB 1530 (Lieber, 2007). Would have required clinical laboratories that perform cholinesterase testing for the purpose of determining workers' pesticide exposure to electronically report test results to DPR. This bill was held in the Senate Appropriations Committee.

REGISTERED SUPPORT / OPPOSITION:

Support

Department of Pesticide Regulations (DPR) (Sponsor)
California Rural Legal Assistance Foundation (CRLA Foundation)
Californians for Pesticide Reform (CPR)
Environmental Working Group (EWG)
Natural Resources Defense Council (NRDC)
Pesticide Action Network (PAN)
Sierra Club California
Sustainable Agriculture Education (SAGE)

Opposition

None on file.

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Date of Hearing: March 8, 2022

ASSEMBLY COMMITTEE ON ENVIRONMENTAL SAFETY AND TOXIC MATERIALS
Bill Quirk, Chair
AB 1793 (Quirk) – As Amended March 2, 2022

SUBJECT: Hazardous waste: identification: testing

SUMMARY: Requires the Department of Toxic Substances Control (DTSC) to evaluate the existence of alternate test methods or calculation-based method that avoid the use of live vertebrate fish for hazardous and extremely hazardous waste identification, and, if such an alternate method or calculation-based method exists, requires DTSC to include it as an optional test method. Specifically, **this bill**:

1) Requires DTSC, upon an appropriation by the Legislature, to review its acute toxicity criteria and guidelines for the identification of hazardous wastes and extremely hazardous wastes.

2) Requires DTSC to evaluate the existence of alternate test methods or calculation-based methods that avoid the use of live vertebrate fish for the identification of hazardous wastes and extremely hazardous wastes.

3) Requires DTSC to update regulations, provided it finds an adequate alternate test method or calculation-based method, to include the alternate test method or calculation-based method as an optional method for the identification of hazardous wastes and extremely hazardous wastes.

EXISTING LAW:

1) Establishes the Resource Conservation and Recovery Act (RCRA) to authorize the United States Environmental Protection Agency (US EPA) to manage hazardous and non-hazardous wastes throughout its life cycle. (42 United States Code (U.S.C.) § 6901 et seq.)

2) Establishes the Hazardous Waste Control Law (HWCL) to authorize DTSC to regulate the management of hazardous wastes in California. (Health and Safety Code (HSC) § 25100 et seq.)

3) Defines "waste" as any solid, liquid, semisolid, or contained gaseous discarded material. (HSC § 25124)

4) Requires DTSC to develop and adopt regulatory criteria and guidelines for the identification of hazardous wastes and extremely hazardous wastes. (HSC § 25141(a))

5) Defines a "hazardous waste" as waste, because of its quantity, concentration, or physical, chemical, or infectious characteristics, that:

   a) Causes, or significantly contributes to an increase in mortality or an increase in serious irreversible, or incapacitating reversible, illness; or,

b) Poses a substantial present or potential hazard to human health or the environment, due to factors including, but not limited to, carcinogenicity, acute toxicity, chronic toxicity, bio-accumulative properties, or persistence in the environment, when improperly treated, stored, transported, or disposed of, or otherwise managed. (HSC § 25141(b))

6) Defines a "toxic hazardous waste" as waste that is identified as toxic by any one (or more) of the following: Toxicity Characteristic Leaching Procedure, Totals and Waste Extraction Test, Acute Oral Toxicity, Acute Dermal Toxicity, Acute Inhalation Toxicity, Acute Aquatic Toxicity, Carcinogenicity, or Experience or Testing. (California Code of Regulation (CCR) Title 22 § 66261.24)

FISCAL EFFECT: Unknown.

COMMENTS:

Need for the bill: According to the author,

> "California has over 100,000 generators of hazardous waste, including many businesses and retailers. The state requires these waste generators to separate hazardous from nonhazardous waste and dispose of it in a manner that protects public health and the environment. In determining whether a waste is hazardous, its toxicity in various contexts is measured, including acute toxicity to aquatic life. This test, commonly referred to as the "fish test", was developed in the 1980s and has not been refined since, despite the US EPA, the European Union (EU), and the Organization for Economic Co-operation and Development (OECD) approving alternative methods that do not conduct tests on live vertebrate fish. When waste generators decide not to perform animal testing for their products, including the "fish test", they must treat their waste as hazardous by default. This leads to over-classification of waste as hazardous despite potentially being harmless to aquatic life. Retailers at times also choose not to undergo toxicity testing due to its complexities, over-classifying more waste as hazardous. AB 1793 tackles this problem by requiring DTSC to evaluate alternative test methods or calculation-based methods and to allow such an alternative, if identified, to be used by waste generators."

Hazardous waste management: In California, DTSC is authorized by the US EPA to implement the RCRA requirements and its associated regulations. In addition to implementing RCRA, California implements additional state law hazardous waste requirements that are more stringent than those established under RCRA.

There are more than 100,000 entities that generate hazardous waste in California. Waste generators are responsible for determining whether a waste is hazardous or non-hazardous and disposing of the waste accordingly. In California, a hazardous waste is any waste on a federally maintained RCRA list of hazardous wastes, that is derived from these wastes, or that is ignitable, corrosive, reactive, or toxic. In order to list a waste, as hazardous, US EPA assesses whether the waste:

1) Exhibits any of the characteristics, i.e., ignitability, corrosivity, reactivity, or toxicity;

2) Is fatal to humans or animals at low doses i.e. is acutely toxic; or,

3) Is capable of posing a substantial present or potential hazard to human health or the environment when improperly treated, stored, transported, or disposed of, or otherwise managed.

The listed wastes are categorized into:

1) F-list: Wastes common to many manufacturing and industrial processes, such as solvents used for cleaning.

2) K-list: Wastes generated by specific industries, including petroleum refining and pesticide manufacturing.

3) P-list and U-list: Commercial products, such as industrial chemicals or pharmaceuticals that have not been used and will be discarded.

4) M-list: Wastes known to contain mercury, such as fluorescent lamps.

Identification of hazardous waste in California: In California, a waste is classified as hazardous due to toxic properties if it is identified as having one or more of eight types of toxicity, which includes acute oral toxicity, acute dermal toxicity, acute inhalation toxicity, acute aquatic toxicity, or carcinogenicity (CCR Title 22 § 66261.24). All of these types of toxicity can be determined using knowledge about the toxicity of constituent components of the waste, except for acute aquatic toxicity.

A waste is defined as having "acute aquatic toxicity" when less than 500 milligrams (mg) per liter (L) kill 50% of the population (LC_{50}) of fathead minnows (*Pimephales promelas*), rainbow trout (*Salmo gairdneri*) or golden shiners (*Notemigonus crysoleucas*) in 96 hours (CCR Title 22 § 66261.24). This test is most commonly performed on fathead minnows and is colloquially referred to as the "fish test" or "minnow test". Other than Washington State, this committee is not aware of any other states that use acute aquatic toxicity testing as part of hazardous waste determination.

Over-classification of hazardous waste: SB 423 (Bates, Chapter 771, Statutes of 2016) required DTSC to convene a Retail Waste Workgroup (Workgroup) tasked with identifying regulatory and policy directives that need clarification for managing consumer products. Over an eight-month period (October 2016 through May 2017), the Workgroup identified problems faced by the retail industry in applying the hazardous waste management standards in California and worked to identify possible solutions. In the Workgroup's final report to the legislature, the regulated community estimated that, "About 30% of the total hazardous waste generated in California is "California-only" hazardous waste [i.e., waste that is only classified as hazardous because of California's requirements, including the fish test]. The percentages for retail waste can be much higher, with some retailers managing up to 67% of their hazardous waste as "California-only" hazardous waste."

While there is no legal definition of "Cruelty Free" and "Not Tested on Animals," many companies only use these labels if their products' toxicity has not been evaluated using the fish test. Companies that do not test products using the fish test treat their waste as hazardous by default, or risk liability. Violations of the HWCL can lead to penalties up to $70,000 per day for each violation (HSC §25188). This adds to the over-classification of waste as hazardous in the state.

Fish test protocol: The fish test protocol for hazardous waste identification was developed as a special protocol for "materials that do not readily lend themselves to standard toxicity testing," such as oily samples and samples containing sediment, and draws from previously developed wastewater protocols.

In concept, a waste fails the acute aquatic toxicity test if, in a tank containing the test organism and 500 mg of waste/L, half of the fish in the tank are dead within 96-hours. In order to produce reliable results, this procedure must be performed multiple times at the 500 mg/L concentration, and at concentrations above and below 500 mg/L, each time using a minimum of twenty fish. Along with wastes containing intuitively toxic substances, such as arsenic, based on data from the Draft Retail Waste Aquatic Toxicity Project available on DTSC's website, many household products fail this test as well, including gingko, ginger, zinc, and most, if not all, soaps and shampoos tested.

DTSC selection of the fish test: According to DTSC's final statement of reasons justifying its criteria for hazardous waste identification, issued in 1984, the US EPA established the toxicity criteria to define commercial substances which may pose a hazard if spilled or discharged into an aquatic environment (40 Code of Federal Regulations (CFR) 116). As part of those criteria, aquatically toxic substances were defined as those that demonstrate a 96-hour LC_{50} of less than 500 mg/L. As a result, DTSC used the same standard to define aquatic toxicity of a waste or material as "numerous accidental and intentional discharges of toxic wastes into an aquatic environment have occurred, and the impacts are similar to that caused by commercial substances."

According to the statement of reasons, performing the test on readily available and commonly used fish is preferable because "it is not considered feasible, or necessary, to try to devise a bioassay method, or methods, which will anticipate waste pollution scenarios involving different conditions of water temperature and hardness of the exposure of any of the numerous species of common native fishes." The fathead minnow is not native to California, but is a common test organism that has been used historically in regulatory ecotoxicology for its sensitivity to a wide variety of chemicals and amenability to laboratory environments (The fathead minnow in aquatic toxicology: Past, present and future, Ankley 2006). All three fish species were chosen for their common use in tests and readily available 96-hour LC_{50} data.

DTSC reasoned that testing on live organisms detects toxic characteristics of wastes that may not be captured in lists either because toxicity of constituent substances is unknown or because of synergistic toxicity of multiple constituent substances. In one example, a printing company dumped waste ink sludge at a municipal landfill not authorized to receive hazardous wastes. Analysis of the waste did not establish the presence of toxic materials; however, the acute aquatic fish toxicity test showed the sludge was highly toxic to fish. It was speculated that the ink contained a fungicide to prevent mildew. In several cases, DTSC noted that accidental or illegal discharge of hazardous waste resulted in fish kills. The statement of reasons also noted that the fish test may serve as an indicator of general toxicity of a waste, including to humans, in the view that fish are generally more sensitive to toxic substances than mammals.

Excessive fish use and animal welfare concerns: Fish have pain receptors (nociceptors), which are a prerequisite for pain sensation. It is unclear if apparent pain responses are unexperienced and reflexive, or a more conscious experience. Notably, at the conclusion of the aquatic toxicity

test, all fish must be euthanized. According to the National Toxicology Program (NTP), administered by the US Department of Health and Human Services, testing of a single chemical can require up to 260 fish, depending on the specific test design. To address the need to reduce or replace animal use for ecotoxicity testing, the NTP's Scientific Advisory Committee on Alternative Toxicological Methods has scheduled a meeting for September 2022.

Shift toward alternative test methods: Alternative test methods are methods that replace, reduce, or refine animal use in research and testing, a concept first described by William Russell and Rex Burch (The Principles of Humane Experimental Technique, 1959). California state law prohibits manufacturers and contract testing facilities from using traditional animal testing methods when an appropriate alternative test method has been scientifically validated and recommended by the Interagency Coordinating Center for the Validation of Alternative Methods (ICCVAM) (Civil Code Section 1834.9 (a)). Although this law exempts testing at regulatory agencies, there have been federal efforts to replace, reduce, or refine animal testing at federal agencies. The National Institutes of Health Revitalization Act of 1993, the ICCVAM Authorization Act of 2000, and the Frank R. Lautenberg Chemical Safety for the 21st Century Act require federal agencies to support the development of alternative test methods.

In 1997, US government agencies formed ICCVAM with several objectives, which includes ensuring that new and revised test methods are validated to meet the needs of US federal agencies, and reducing, refining, or replacing the use of animals in testing where feasible. ICCVAM consists of 15 research and regulatory agencies, among which include the US EPA, the Food and Drug Administration (FDA), and the Agency for Toxic Substances and Disease Registry (ATSDR). These organizations provide or use toxicological information for risk assessment processes.

Alternative test methods: Alternative test methods to the fish test have been studied by various entities. The Organization for Economic Cooperation and Development (OECD) maintains the *Guidelines for the Testing of Chemicals*, a collection of about 150 of the most relevant internationally agreed testing methods used by governments, industry, and independent laboratories to identify and characterize potential hazards of chemicals. While the guide does have a fish test similar to the one used in California (OECD TG 203: Fish, Acute Toxicity Test), a fish embryo test is also outlined (OECD TG 236: Fish Embryo Acute Toxicity (FET) Test).

The FET test is performed on embryos of the globally used model organism zebrafish (*Danio rerio*). In this test, newly fertilized zebrafish eggs are exposed to the test chemical for a period of 96 hours and increasing concentrations. Every 24 hours, various indicators of lethality are assessed and an LC_{50} calculated based on embryo survival. The EU Reference Laboratory for Alternatives to Animal Testing independently validated the FET test and concluded that it should be used for generating information on acute fish toxicity, where appropriate. Notably, the European Chemicals Agency (ECHA) has so far declined to accept the FET test as a stand-alone alternative to OECD TG 203 for regulatory purposes, citing "knowledge gaps that arose during validation of OECD TG 236 and within the current ECHA report "Analysis of the relevance and adequateness of using Fish Embryo Acute Toxicity test (FET) Test Guidelines (OECD TG 236) to fulfil the information requirements and addressing concerns under REACH" (Joint Report ECHA and UBA on 'Expert Workshop on the potential regulatory application of the Fish Embryo Acute Toxicity (FET) Test under REACH, CLP and the BPR', 2017).

Another promising alternative is OECD TG 249 which uses a rainbow trout (*Oncorhynchus mykiss*) gill cell line, RTgill-W1, to test acute toxicity. After 24 hours of exposure to a test chemical, cell viability is assessed using fluorescent indicator dyes. The data are expressed as the percent cell viability of unexposed cells (control) values versus the test chemical concentration. The resulting concentration-response curves serve to determine the effective concentrations causing 50% loss in cell viability (EC_{50}).

It is noteworthy that US EPA has approved invertebrate aquatic organisms for acute toxicity testing of whole effluent and receiving waters; these are also used in California. These methods are approved under the federal Clean Water Act (section 304(h)) and specified in 40 Code of Federal Regulations 136.3 Table I A. Besides several vertebrate fish species, water fleas (species: *Ceriodaphnia dubia; Daphnia pulex, and Daphnia magna*) are approved for acute fresh water toxicity. To study acute estuarine and marine toxicity, mysids (*Mysidopsis bahia*), a shrimp-like crustacean, is an approved alternative to fish. Water fleas (*Daphnia* spp.) comprise small planktonic crustaceans, about 0.2 to 6 millimeters in length, and could lend themselves as alternative test organisms in hazardous waste identification.

If used for hazardous waste identification, both the zebrafish embryo test and the daphnid test may need to be adapted to work with the wide range of types of waste, some of which cannot undergo standard toxicity testing. Adopting a daphnid test as an optional alternative would have the advantage of avoiding testing on vertebrate species altogether and building off of methods already widely used in the state. Over-classification of hazardous waste, unnecessary use of animals, and burdens on businesses committed to avoiding animal testing could be avoided with the adoption of the FET or daphnid tests as an optional alternative, if found to be adequate by DTSC.

Lastly, the National Toxicology Program Interagency Center for the Evaluation of Alternative Toxicological Methods (NICEATM) and US EPA are conducting a retrospective evaluation of existing data to explore the potential for relying on fewer fish species tests. The goal is to support a protective ecological risk assessment. Results from the study will be used to determine whether all three fish species currently in use are necessary to assess acute lethal risks to fish, and explore if reduced species testing could be combined with an adjustment factor to meet risk protection goals. This project was presented in March 2021 at the 11th World Congress on Alternatives and Animal Use in the Life Sciences (Ceger et al., *Retrospective Evaluation of the Acute Fish Toxicity Test for Pesticide Regulation*). A peer-reviewed study had not been published as of March 2, 2022.

Calculation-based methods: Computational toxicology is an actively developing area of research that leverages existing toxicity data, applies machine learning models, and attempts to build mathematical models of biological systems *in silico*. The field is progressing rapidly due to an increasing availability of curated public and commercial databases and development of new computational tools (Kleinstreuer et al, 2020). However, the technology has not matured to the point where it can entirely replace toxicity testing of new chemicals or chemical mixtures. However, computational toxicology builds on established calculation-based methods that leverage existing toxicity data for individual chemicals to estimate acute toxicity of mixtures of chemicals.

The European Chemicals Agency (ECHA), in its guidance on classification, labelling and packaging of substances and mixtures, outlines that when data are available for all ingredients,

an estimation calculation can be performed and the acute toxicity estimate (ATE) of ingredients shall be considered as follows:

1) Include ingredients with a known acute toxicity, which fall into any of the acute toxicity categories, as specified;

2) Ignore ingredients that are presumed not acutely toxic (e.g., water, sugar); and,

3) Ignore components if the data available are from a limit dose test and do not show acute toxicity.

The ATE of a mixture is determined by calculation from the ATE values for all relevant ingredients according to a given formula for oral, dermal, or inhalation toxicity.

Indeed, California already allows calculation-based estimates in its classification of dermal and oral toxicity. CCR Title 22 § 66261.24(c) states that, "A waste containing one or more materials which exhibit the characteristic of toxicity [...] may be classified as nonhazardous pursuant to section 66260.200 if the waste does not exhibit any other characteristic of this article [...] and the calculated oral LD_{50} of the waste mixture is greater than 2,500 milligrams per kilogram and the calculated dermal LD_{50} is greater than 4,300 milligrams per kilogram by the following equation [...]". Such calculation-based methods have not been expanded to acute aquatic toxicity evaluations.

Washington State also permits toxicity to be determine from available data, in addition to testing on live fish. Under Washington Administrative Code (WAC) 173-303-100 (5)(b)(i): "A person must determine the toxic category for each known constituent. The toxic category for each constituent may be determined from available data, for example, Registry for Toxic Effects of Chemical Substances (RTECS), Hazardous Substances Data Bank (HSDB), and Ecotoxicology database (ECOTOX). The toxic category should then be identified, using the table below. If data are available for more than one test endpoint (that is, fish, oral rat, inhalation rat, or dermal rabbit), the value with the highest toxicity must be used."

Minnesota also allows calculation estimates of LD_{50} values of a waste. To calculate an estimated LD_{50} the state requires that appropriate LD_{50} data are available for all components of the waste that may reasonably produce a toxic effect.

DTSC to review its hazardous waste criteria: As part of the Governor's proposed 2022-2023 budget, DTSC has a submitted a Budget Change Proposal (BCP) requesting 8 positions and $1.5 million annually to evaluate the existing California hazardous waste criteria, recommend modifications to those criteria, assist in the adoption of any approved recommendations, and provide waste classification determination and recycling exclusion interpretations and technical support. As part of the stated need for a review of hazardous waste criteria, in the BCP DTSC states:

> "When the hazardous waste control laws were enacted in 1972, the Department of Health Services (the predecessor of DTSC) was mandated to develop criteria and guidelines for the identification of hazardous wastes and extremely hazardous wastes. This mandate continues to exist in DTSC's authorizing statutes. DTSC's hazardous waste identification criteria and test methods were originally proposed in 1978 and formally

adopted into regulation in 1985 and readopted to be renumbered and reorganized in 1991. Except for minor modifications, the current hazardous waste identification criteria are nearly identical to those adopted in 1985.

California's hazardous waste identification criteria were considered advanced and groundbreaking at the time they were adopted and continue to be protective and are the most stringent hazardous waste identification criteria in the nation. The criteria application results in more wastes being identified as hazardous waste than the federal hazardous waste identification criteria. The criteria, however, have not been modified or expanded to keep pace with advances in the science of toxicology, in analytical testing methodology or in environmental monitoring efforts. [...]

In addition, newer and more advanced equipment is able to detect the presence of contaminants at lower levels than before. Analytical test methods, once able to reliably measure environmental contaminants in water and soil at parts per million, are now able to measure at concentrations in parts per billion or lower."

Proper identification of hazardous waste: The goal of AB 1793 is to ensure that DTSC uses an acute aquatic toxicity test that accurately captures toxicity, while reducing the burden associated with this testing on waste-generating entities. Any acute toxicity test must ensure that wastes that are harmful to human health and the environment are managed correctly, but also prevent over-classification of waste that is not harmful as hazardous waste. As noted by DTSC's BCP, current hazardous waste identification testing methods are over 30 years old and have not been reviewed or updated. Given that DTSC is undertaking a review of its hazardous waste classification, AB 1793 is consistent with that effort and directs the department to review newer physical test and calculation-based alternatives.

Arguments in Support: The sponsor of the bill, the National Stewardship Action Council, writes, "Regulated state waste identification remains a persistent and costly problem. Retailers must understand both federal and state toxicity regulations to sell and manage consumer products compliantly or are subject to hefty fines and brand risk. When faced with onerous or complicated state hazardous criteria, many retailers will skip the hazardous evaluation process altogether. [...] Brands that do not test their products on animals are automatically deemed hazardous and specific and expensive waste handling procedures are required, mainly hazardous waste incineration. AB 1793 would update California processes to eliminate unnecessary and costly hazardous waste management of non-toxic products."

The Personal Care Products Council writes, "California's use of the aquatic toxicity test is grossly out of alignment with more modernized testing methods, and over classifies as "hazardous waste" products that would not otherwise be captured under more modern tests. [...] The cosmetic and personal care products industry hast taken a strong stand against animal testing; consequently, our members do not conduct this test on finished products and we do not believe that a California State Agency should either."

Related legislation:

1) AB 733 (Quirk, 2019). Would have required DTSC to evaluate the existence of an alternative test method to the acute toxicity test that avoids the use of live vertebrate fish and, if such a method were identified, to adopt it as an option for hazardous waste identification. Vetoed.

2) AB 2474 (Quirk, 2018). Would have required DTSC to evaluate, and adopt as optional tests if suitable, the fish embryo test and daphnid test as alternatives to the fish test used in hazardous waste identification. Vetoed.

3) SB 1249 (Galgiani, Chapter 899, Statutes of 2018). Prohibits a manufacturer of cosmetic products to import for profit, sell, or offer for sale in this state, any cosmetic, if the cosmetic was developed or manufactured using an animal test that was conducted or contracted by the manufacturer, or any supplier of the manufacturer, on or after January 1, 2020, as specified. Specifically excludes from the prohibition an animal test of any cosmetic that is required by a federal or state regulatory authority, as specified.

REGISTERED SUPPORT / OPPOSITION:

Support

National Stewardship Action Council (Sponsor)
Personal Care Products Council

Opposition

None on file.

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