

The Core Legal Test In A Chemicals Law

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The world is searching for better legal systems for controlling the chemicals we place into commerce. Diverse chemicals laws already exist, including California's Proposition 65, the federal Toxic Substances Control Act (TSCA) and the European regulation called the Restriction, Evaluation and Authorization of Chemicals (REACH), which the European Union is working to implement later in 2007. But more are coming. Senator Lautenberg and six other U.S. Senators introduced the Kids Safe Chemicals Act of 2005 (S.1391), and non-governmental organizations around the country are developing still other approaches.

While all these laws can seem complex and even impenetrable, they are all built around something simple and yet profoundly important, something that can be called the law's "core legal test."

All laws start with a central policy objective, and then have a structure designed to further that objective. In any chemicals law, the central policy objective is to keep undesirable chemicals off the market or otherwise control them. To do this, the law must specify how desirable chemicals are to be distinguished from undesirable chemicals. This test, the test specified by the law for determining whether a chemical is undesirable and therefore to be regulated, is what we call the "core legal test."

As with all laws, such a core legal test can only be effectively implemented and enforced if it is clear and unambiguous. The result of ambiguity or vagueness in what a law requires is to grant corresponding discretion to the executive (president or governor) and the courts as to how the law should be implemented. Therefore, we believe it is of central importance for advocates of chemicals policy reform, especially those seeking a precautionary approach, to develop a clearly articulated chemicals policy goal and to craft a clear, unambiguous core legal test that will implement that goal.

Most if not all chemicals laws have the policy goal of regulating chemicals that are deemed by the law to be "too unsafe/hazardous," though there are of course widely varying views on what that means. Could other options for a central policy goal be considered? One might be to eliminate all chemicals from commerce, regardless of whether they are unsafe/hazardous. Another might be to dramatically shrink the consumer economy. There may be still others. But for now, we assume the broad goal of a chemicals law is to regulate chemicals that are too unsafe/hazardous.

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Our core legal test, then, must be one that identifies chemicals that are too unsafe/hazardous. In this paper, we examine the connection between the varying policy views reflected in the laws about what makes a chemical too unsafe/hazardous and the core legal tests they employ to implement those views. We first describe and define the three key structural elements that must be present in any core legal test in a chemicals policy (Section I). Then we examine the core tests of TSCA, REACH, S.1391 (the Kids Safe Chemicals Act of 2005) and California's Proposition 65 (Section II). We believe it will become apparent how the structure of the core legal test, especially in the case of TSCA, can make it very difficult for government to regulate chemicals.

While we do not specify here precisely what core legal test we think would be best, any test we could support must reflect the policy objectives of acting with precaution, responding to early warnings and placing a high value on protection of the environment and human health, including children, workers and fence-line communities. Perhaps the most important element of any legal test for implementing a precautionary approach to chemicals policy is to place the burden of proof on industry to show that a chemical is safe/not hazardous before introducing it into commerce. Hence, we have paid particular attention to this issue.

I. THE STRUCTURE OF A CORE LEGAL TEST

The core legal test in a chemicals policy must specify three essential elements:

- a. Who bears the "burden of proof?"
- b. What is the "standard of proof?"
- c. What does the person with the burden of proof have to prove?

Let's define and examine the options for each element in turn.

A. Who Bears The Burden of Proof?

Who bears the burden of proof is the key element of a legal test. What this means is: who has to show the test is met? There are only two options: (1) the government seeking to regulate a chemical or (2) the industry seeking to market the chemical.

- (1) If the burden of proof is on government, then government must prove that a chemical fails the chosen safety/hazard test in order to regulate it. If insufficient information is available for government to meet the core test, then the government cannot regulate it. Placing the burden of proof on government represents a policy decision that in the absence of any information at all, a chemical will be allowed on the market. Placing the burden of proof on government motivates industry not to produce information for fear it could lead to government regulation.

- (2) If the burden of proof is on industry, then industry must prove that the chemical passes the safety/hazard test before it can be put on the market. If insufficient information is available to prove the chemical passes the test, then industry cannot market the chemical. Placing the burden of proof on industry represents a policy decision that in the absence of any information at all, a chemical cannot be marketed. Placing the burden of proof on industry motivates industry to produce information necessary to prove the chemical passes the safety/hazard test.

Thus, when little or no safety/hazard data is available about a chemical, who bears the burden of proof in and of itself determines whether a chemical may be placed or remain on the market. Who bears the burden also has enormous impact on whether industry voluntarily produces safety/hazard information.

Note that who bears burden of proof need not be the same for all chemicals in a chemicals law. For example, under REACH, the government bears the burden of proof for most chemicals (Restriction), but industry bears the burden once a chemical is classified as "highly dangerous" (i.e., a carcinogen, mutagen, reproductive toxicant, persistent bioaccumulative toxicant, etc.) under the Authorization provisions.

For a chemicals statute to provide the greatest protection for human health and the environment, the burden of proof should be placed on industry for as many chemicals as possible, preferably all chemicals.

B. What is the Standard of Proof?

In many cases, both parties have some evidence on their side. The "standard of proof" refers to the degree to which the evidence must favor a party in order for that party to prevail. The question is: with what certainty must the party with the burden of proof show that he or she is correct in order to pass the legal test? Must the person have to show only some possibility that he or she might be right, or must the person be extremely likely to be correct? There is a continuum of possibilities for defining the standard of proof, subject only to one's imagination.

Three standards of proof are common in the law, and these can be seen in the chemicals policies discussed below.

In the most frequently used burden of proof, applying to almost all civil [non-criminal] cases, the plaintiff must typically prevail by a "preponderance" of the evidence. This can also be articulated as: the plaintiff must be "more likely than not" to be correct, or the plaintiff must have more than a 50% probability of being correct, or the plaintiff must have more than 50% of the evidence on her side.

Higher standards of proof are also used. In a criminal case, the government must show the accused is guilty "beyond a reasonable doubt," which is much, much harder to prove,

and might be thought of as over 95% probability of being correct. An intermediate standard is "a reasonable certainty," which is generally taken to be in between the "preponderance" and "no reasonable doubt" standards, perhaps something like a 75-85% probability of being correct. This is similar to the "clear and convincing evidence" standard also used in some cases.

Lower standards of proof are also known and can be appropriate. For example, a law could require that a person show only that he or she "may" be correct. This might be satisfied by evidence establishing only a 10-20% probability of being correct.

The higher the standard of proof, the harder it is for the party bearing the burden of proof to prove its case. Thus, the choice of a standard of proof reflects a policy determination of what kinds of mistakes by decision-makers we can most tolerate. For example, we place a very high burden on government in criminal cases, because we say that "it is better that 10 guilty people go free than that one innocent person be convicted." If we wanted most guilty people to be convicted and were not so concerned about wrongly convicting innocent people, we could require the government to show only that a person "may" be guilty. Exactly the same principles apply to what kinds of errors we prefer for hazardous/unsafe chemicals, and the standard of proof we therefore should adopt. Also, the standard of proof could conceivably be different for different classes of chemicals.

For a chemicals statute to provide the greatest protection for human health and the environment, whenever the burden of proof is placed on industry, the standard of proof should be as high as possible (making the test harder to meet). Whenever the burden of proof is placed on government, the standard of proof should be as low as possible (making the test easier to meet so that government can best act on early warnings).

C. What Has to be Proved to Meet the Test?

The last of the three elements is what the person with the burden of proof has to prove.

As we will see in the next section, various chemicals laws require proof most commonly of some or all of the following four factors in different degrees and combinations:

- (1) whether a chemical is a hazard to human health and/or the environment;
- (2) whether a chemical presents a risk to human health and/or the environment;
- (3) social/economic factors, such as cost-benefit criteria; and
- (4) whether safer alternatives are available.

Other requirements are sometimes incorporated as well, as we will see.

There are many possibilities for what a person with the burden of proof can be required to show, subject only to one's imagination. Also, what has to be proved can be different for

different classes of chemicals. For example, under REACH once a chemical is classified as "highly dangerous," industry must prove various elements under the Authorization process.

Obviously, the more a person has to prove, the harder it is to meet the legal test. To be protective of human health and the environment, a statute should require industry to bear the burden to prove as much as possible about whether a chemical presents a safety/hazard threat to human health or the environment. However, we must consider one consequence of placing the burden of proof on industry to prove generally that a chemical is safe/not hazardous. Taken literally, this could require generating information about all possible effects on human health and the environment, which may be impractical or even impossible. This probably means that the burden of proof on industry is unlikely to be imposed as an open-ended requirement, but ultimately would have to be imposed with respect to some initial baseline data set, plus any additional information that becomes known or is required by the government.

Let us clarify what is meant by some of the terms commonly used in chemicals policies, and discuss a few implications.

- (1) "Hazard" refers to whether a chemical inherently has a hazardous property. Thus, asking whether a chemical is a carcinogen, a reproductive toxin, an allergen, etc., is asking whether it is hazardous. "Hazard" also refers to the potency of the chemical, i.e., the strength of its intrinsic ability to cause the hazard. These are essentially scientific questions, although data gaps and uncertainty can and do lead to differences in the scientific community as to whether a body of evidence shows that a chemical is a hazard, as well as to conflicts between environmental health advocates, industry and government.

Thus, for the purposes of a law, whether a chemical will be designated as a "hazard" is essentially definitional. That is, the law will have to provide the criteria that will be used to determine, for purposes of the law, whether a chemical is classified as a hazard. This can be spelled out in the statute itself, or this determination can be delegated to an administrative agency such as EPA.

Various "authoritative bodies," such as the WHO, have created sets of criteria that they use in making such determinations for their own purposes. These authoritative bodies could be relied on in a chemicals statute. For example, the Proposition 65 list is essentially a list of carcinogens and reproductive toxins that have been classified as hazards by such authoritative bodies.

- (2) "Risk," or safety, refers to the degree of danger a chemical presents, taking into account how it is used. This takes exposure into account, so that: hazard x exposure = risk. Thus, lower exposures to a chemical often causes less risk (i.e., is safer) than higher exposures, even though the intrinsic hazard of the chemical does not change. Quantifying risk is "risk assessment," which not only involves all the uncertainties involved in hazard assessment, but also the uncertainties

involved in evaluating exposure, thresholds, cumulative impacts, etc.

A chemicals law relying on a risk determination also has to spell out the degree of risk that will be permitted. Terms such as "no harm," "unreasonable risk," "no significant risk," and "unacceptable risk" are found in the laws. These terms must be defined in the law itself, or by an administrative agency specified by the law.

- (3) "Social/economic factors" refers to the social/economic value of the product. These can be evaluated in a wide variety of ways, and can be monetized or evaluated qualitatively. When these elements of proof are present in a chemicals law, they are part of a cost-benefit test in which economic factors are balanced against health and safety impacts.
- (4) "Safer alternatives" is the subject of an enormous amount of thought and work that we don't attempt to summarize here. Generally, a "safer alternative" refers to a substitute for a chemical that is safer/less hazardous for human health and the environment. "Alternatives" should include non-chemical substitutes such as process or design changes.

II. EXAMPLES OF CORE LEGAL TESTS

Let's look at the core legal tests of TSCA, Proposition 65, S.1391 (the Kids Safe Chemicals Act) and REACH. As you look at them, note how they differ dramatically in who bears the burden of proof, the standard of proof, whether the test is solely a safety/hazard test, a risk test or a cost-benefit test (i.e., balancing social/economic factors with health/safety), and whether the test deals with human health and/or the environment.

A. TSCA

1. TSCA test for government to regulate a chemical in commerce (TSCA Section 6)

To regulate a chemical, EPA must (by a preponderance) show, on a chemical by chemical basis, that:

- (a) the chemical presents or will present an "unreasonable" risk to health or the environment; and
- (b) the regulatory action is the least burdensome way to protect adequately against the unreasonable risk.
- (c) EPA may not regulate a chemical under TSCA unless it determines that the unreasonable risk cannot be protected against using other statutes (such as the Clean Air Act, Clean Water Act, etc.)

"Unreasonable risk" is defined in the statute as a risk-benefit standard, so that the benefits of regulation must outweigh both the costs to industry and the lost economic and social value of the product. The agency must consider the effects of the chemical on public health and the environment, the benefits of the substance and the availability of substitutes, and the economic consequences (after considering the national economy, small business, technological innovation, the environment and public health).

Quick Summary

Burden of proof: on government
Standard of proof: preponderance
What is proved: chemical-by-chemical unreasonable risk exists or will exist (cost-benefit balancing), least burdensome regulation, no other statute possible

2. TSCA test for government to require more information about a chemical on the market (TSCA Section 4)

To require new testing for a chemical, EPA must show (by a preponderance) that:

- (a) The chemical either
 - (1) may present an unreasonable risk to human health or the environment, or
 - (2) the chemical is or will be produced in substantial quantities and (i) enters or is reasonably likely to enter the environment in substantial quantities or (ii) there is or may be significant or substantial human exposure to the chemical.
- (b) EPA must also demonstrate that the available environmental health information is insufficient to make a reasonable determination of whether there is a risk, and that testing is necessary to provide the needed data.

Quick Summary

Burden of proof: on government
Standard of proof: preponderance
What is proved: chemical-by-chemical (i) unreasonable risk may exist (cost-benefit balancing) or substantial production/exposure and (ii) available information is insufficient and testing is necessary

B. CALIFORNIA'S PROPOSITION 65

Under Proposition 65, once the State of California determines that a chemical is a carcinogen or reproductive toxin and puts it on the Proposition 65 list, the warning requirement applies unless the person causing exposure meets their burden of proof to show the exposure causes no significant risk. Thus, the State must do the initial listing, but then the burden of proof switches to the person causing an exposure to prove that there is no significant risk.

1. Warning Requirement (Cal. H&SC Section 25249.6): No person may knowingly and intentionally expose an individual to a chemical on the Proposition 65 list without first giving the individual a clear and reasonable warning, except as provided in Cal. H&SC Section 25249.10.
2. Exemption from Warning Requirement (Cal. H&SC Section 25249.10): The warning requirement of Section 25249.6 shall not apply to an exposure for which the person responsible can show the exposure poses no significant risk assuming lifetime exposure at the level in question.

"Significant risk" has been defined by the State as a specified level of cancer risk and as below the "no observed effect" level by specified amounts for reproductive toxins. The burden is on the defendant to make this showing (by a preponderance of the evidence). This is essentially a risk assessment, except the burden is on the defendant to prove the risk is not "significant". The defendant can challenge the listing of the chemical as a hazard and can develop evidence on all issues relevant to risk (hazard x exposure), including what lifetime exposure is, absorption and metabolism by humans, relevance of animal studies, etc. There are no economic elements to this test.

Quick Summary

Burden of proof: on person causing exposure
Standard of proof: preponderance
What is proved: product-by-product, no significant risk of cancer or reproductive toxicity from lifetime exposure ("significant" defined in regulations)

C. S.1391 (THE KID SAFE CHEMICALS ACT OF 2005)

Under this proposed legislation, to keep or place any chemical on the market, EPA must determine that a manufacturer has proved that there is a "reasonable certainty that no harm" will be caused by aggregate exposure of a worker, sensitive subgroup or (with 10x safety factor) a child, fetus or infant. Sections 503 (c), (a). There are no economic elements in this test.

The "reasonable certainty of no harm" test is also present in the Food Quality Protection Act (FQPA), which amended FIFRA, the federal pesticides law. In the FQPA, that test is interpreted to mean a one per million risk for cancer or 1000-fold less than a reference dose (often referred to as a "safe" dose) for other effects. If this definition is also intended in S.1391, then the definition specifies in a single phrase both the standard of proof and what is to be proved.

In determining whether this standard is met, EPA shall consider (i) environmental fate and transport, (ii) biological fate and transport, (iii) acute, chronic and subchronic human health effects, (iv) additive or synergistic effects, (v) ecotoxicity, (vi) presence of the chemical in humans, food or drinking water and (vii) releases of the chemical. Section 503(b)(2).

EPA shall identify a minimum data set for safety standard determinations, and has the authority to create a tiering process for data submissions. Section 503 (b) (3), (4).

EPA may "at its discretion" require any information of the types specified above to be submitted. Section 503 (b) (1). This makes it easy for EPA to require more information than industry has provided, and is subject to court review only if EPA were to "abuse its discretion."

Quick Summary

Burden of proof:	on person causing exposure
Standard of proof:	preponderance
What is proved:	product-by-product, no significant risk of cancer or reproductive toxicity from lifetime exposure ("significant" defined in regulations)

D. REACH

REACH sets up two different safety/hazard tests, one for most chemicals ("Restriction") and one for particularly hazardous chemicals ("Authorization").

1. Restriction

Most chemicals will be regulated under Restriction. To "restrict" a chemical (including any kind of regulation, from requiring labeling to outright bans), the government will carry the burden of proof to show that there exists:

an "unacceptable risk to human health or the environment"

that is not "adequately controlled" and

that needs to be addressed at the "[European] Community level."

While these terms are not well defined, it is clear that these analyses must involve consideration of "socio-economic factors." Articles, 68(1), 69(1), 71.

Quick Summary

Burden of proof: on government
Standard of proof: preponderance (presumably)
What is proved: chemical by chemical, unacceptable risk to human health or environment (cost-benefit balancing), no adequate control, need for Community level action

2. Authorization

- a. The E.U. government authorities will create a list of highly hazardous substances, called Annex XIV substances (Articles 57, 58). These substances are those that meet specific criteria for classification as:

CMRs (carcinogens, mutagens, reproductive toxins);
PBT's (persistent, bioaccumulative and toxic chemicals);
vPvB's (very persistent, very bioaccumulative chemicals); and
Other equivalently hazardous substances.

- b. Annex XIV chemicals are banned from commerce, unless a manufacturer seeks and obtains "authorization" (Article 56).

- c. Annex XIV chemicals may remain on the market only if a manufacturer applies for a time-limited authorization, maintains that application, and then receives authorization to market the chemical. To obtain authorization (Article 60), a manufacturer must prove, for each authorized use, that:

- (a) the chemical is "adequately controlled" (test only allowed for some chemicals), or
(b) that (i) the socioeconomic benefits of the chemical for that use outweigh the risks and (ii) that there are no suitable alternatives.

Quick Summary

Burden of proof: on industry
Standard of proof: preponderance (presumably)
What is proved: chemical by chemical, (i) adequate control or (ii) socioeconomic benefits outweigh risks and no suitable alternatives

III. CONCLUSION

The core legal test of a chemicals law is usually articulated in just a very few words deep inside the law. And yet it has a profound effect on how the law functions, and is worthy of close attention by all concerned with emerging new chemicals laws. For example, our quick review of TSCA reveals why it is so hard to regulate chemicals in the United States: the burden of proof is on government for all chemicals, and the factors that government must prove are numerous.

For a chemicals law to best protect human health and the environment, the most important feature of its core legal test is for the burden of proof to be placed on industry for as many chemicals as possible, so that such chemicals cannot be placed or kept on the market unless industry proves that it meets the core legal test. Examples of laws with a burden of proof on industry are Proposition 65, the proposed S.1391 and REACH (Authorization).

The standard of proof embodied in the test should be as high as possible so that society can be confident that the core legal test is indeed met, and to reduce the frequency with which dangerous chemicals are allowed onto the market despite the law. Finally, industry should be required to prove as much as possible about whether their chemicals are unsafe/hazardous and lack alternatives, and cost-benefit type tests allowing economic factors to outweigh health and safety factors (such as in REACH (Authorization) and TSCA) should be avoided.

Conversely, in cases in which the burden of proof remains on government, so that chemicals are allowed on the market unless government acts to regulate them, then the standard of proof should be low, so that government can act on early warnings of harm. Similarly, what government is required to show in order to regulate should focus on environmental health and safety factors and avoid cost-benefit type tests allowing economic factors to predominate.