

# Rachel's Environment & Health News

## #435 - House Passes Costly Risk Assessment Bill

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On March 3 the U.S. House of Representatives passed the "Risk Assessment and Cost-Benefit Act of 1995," also known as "Division D" of HR 9. (HR 9 is the Job Creation and Wage Enhancement Act of 1995; Division D incorporates the text of a bill originally known as HR 1022).[1] Division D of HR 9 requires all government agencies to conduct risk assessment and cost-benefit analyses for every major rule or regulation. If the Senate approves this bill, it will effectively end government regulation of health, safety and environment. This is not an exaggeration.

HR 9 applies to any regulation that will cost society more than \$25 million, regardless of what the benefits may be. If the combined costs to all governments (federal, state, local, tribal) AND to the private sector (including wage earners, consumers, and the general economy) total \$25 million or more, HR 9 kicks in. It is hard to imagine any meaningful regulation that would not "cost" the economy \$25 million, even if it will "benefit" the economy far more than \$25 million. Banning a chemical, so that industry must substitute another, or preventing the Forest Service from selling timber from public land at give-away prices --such rules as these will "cost" the economy \$25 million, even as they create benefits far exceeding \$25 million. (After all, any "benefit" can be viewed as a "cost" by someone. If we reduce the rates of death and disease, undertakers and physicians will suffer "costs." If we reduce crime, police may get laid off.) Therefore, nearly all regulations worth passing will be covered by this law. Furthermore, every Superfund cleanup costing more than \$5 million is explicitly covered by HR 9. Because the average Superfund cleanup has cost \$10 million so far, HR 9 will cover most cleanups.

For every decision covered by HR 9, here is what is required: (These are quotations from HR 9; items inside square brackets [ ] are our comments.)

(1) When discussing human health risks, a significant risk assessment document shall contain a discussion of both relevant laboratory and relevant epidemiological data of sufficient quality which finds, or fails to find, a correlation between health risks and a potential toxin or activity. [In other words, all scientific literature will have to be discussed.] Where conflicts among such data appear to exist, or where animal data is used as a basis to assess human health, the significant risk assessment document shall, to the extent feasible and appropriate, include discussion of possible reconciliation of conflicting information, and as relevant, differences in study designs, comparative physiology, routes of exposure, bioavailability, pharmacokinetics, and any other relevant factor, including the sufficiency of basic data for review. [All subtle differences between all scientific studies will have to be discussed.] The discussion of possible reconciliation should indicate whether there is a biological basis to assume a resulting harm in humans. Animal data shall be reviewed with regard to its relevancy to humans.

(2) Where a significant risk assessment document involves selection of any significant assumption, inference, or model, the document shall, to the extent feasible--(A) present a representative list and explanation of plausible and alternative assumptions, inferences, or models; (B) explain the basis for any choices; (C) identify any policy or value judgments; (D) fully describe any model used in the risk assessment and make explicit the assumptions incorporated in the model; and (E) indicate the extent to which any significant model has been validated by, or conflicts with, empirical data. [Whew!]

Each significant risk characterization document shall meet each of the following requirements:

(1) Estimates of risk: The risk characterization shall describe the populations or natural resources which are the subject of the risk characterization. If a numerical estimate of risk is provided, the agency shall, to the extent feasible, provide--(A) the best estimate or estimates for the specific populations or natural resources which are

the subject of the characterization (based on the information available to the Federal agency); and (B) a statement of the reasonable range of scientific uncertainties.

In addition to such best estimate or estimates, the risk characterization document may present plausible upper-bound or conservative estimates in conjunction with plausible lower bounds [sic] estimates. Where appropriate, the risk characterization document may present, in lieu of a single best estimate, multiple best estimates based on assumptions, inferences, or models which are equally plausible, given current scientific understanding. To the extent practical and appropriate, the document shall provide descriptions of the distribution and probability of risk estimates to reflect differences in exposure variability or sensitivity in populations and attendant uncertainties. Sensitive subpopulations or highly exposed subpopulations include, where relevant and appropriate, children, the elderly, pregnant women, and disabled persons.

(2) Exposure scenarios: The risk characterization document shall explain the exposure scenarios used in any risk assessment, and, to the extent feasible, provide a statement of the size of the corresponding population at risk and the likelihood of such exposure scenarios.

(3) Comparisons: The document shall contain a statement that places the nature and magnitude of risks to human health, safety, or the environment in context. Such statement shall, to the extent feasible, provide comparisons with estimates of greater, lesser, and substantially equivalent risks that are familiar to and routinely encountered by the general public as well as other risks, and, where appropriate and meaningful, comparisons of those risks with other similar risks regulated by the Federal agency resulting from comparable activities and exposure pathways. Such comparisons should consider relevant distinctions among risks, such as the voluntary or involuntary nature of risks and the preventability or nonpreventability of risks.

(4) Substitution risks: Each significant risk assessment or risk characterization document shall include a statement of any significant substitution risks to human health, where information on such risks has been provided to the agency. [End of quotations.]

That's the gist of HR 9. In other words, a full risk assessment will be required for every significant rule, a full risk assessment like the one EPA (U.S. Environmental Protection Agency) has been conducting since 1991 for dioxin. EPA's dioxin risk assessment is in its 4th year, is still a draft, and still hasn't reached the "policy" stage where the "policy and value judgments" get debated. The dioxin risk assessment has been EPA's best attempt to include everyone in the process, and all available data. And the agency is already being criticized by paid consultants for including dubious scientific studies and opinions, and for reaching wrong conclusions. The real fight on dioxin still lies ahead.

But HR 9 requires much more than EPA is doing on dioxin now. After the risk assessment is complete, then HR 9 requires a full cost-benefit analysis. Furthermore, HR 9 requires that any decision likely to "cost" the economy more than \$100 million must be accompanied by a full peer review panel of outside experts. (Or, the head of the Office of Management Budget (OMB) can require peer review, even if "costs" don't reach \$100 million.) The peer review panel "shall not exclude peer reviewers with substantial and relevant expertise merely because they represent entities that may have a potential interest in the outcome," HR 9 says. In other words, flaks employed by regulated industries will be welcome.

After the risk analysis is done, and the cost-benefit analysis is tallied up, and the peer-panel of industry consultants has taken its bite, then the head of the government agency must "certify" that all of the analyses are "based on objective and unbiased scientific and economic evaluations of all significant and relevant information and

risk assessments provided to the agency by interested parties relating to the costs, risks, and risk reduction and other benefits addressed by the rule." Further, the agency head must "certify" that "the incremental risk reduction or other benefits of any strategy chosen will be likely to justify, and be reasonably related to, the incremental costs incurred by State, local, and tribal governments, the federal Government, and other public and private entities." And the agency head must "certify" that everything that has been "certified" is "supported by substantial evidence of [sic] the rulemaking record." In our opinion, this "certification" requirement will guarantee that only scientific opinions shared throughout industry will be used in risk assessments. If an issue is the least bit controversial or undecided within the scientific community, no agency head is going to "certify" it. Erring on the side of caution to protect public health will become even rarer than it is today.

act of 1995; job creation and wage enhancement act of 1995; risk assessment; dioxin; epa; omb;

After all this, anyone who doesn't like the rule or regulation can demand "judicial review" --in other words, take the agency to court, saying that the HR 9 process has not been followed precisely or that the record of evidence doesn't justify the final regulation.

Under HR 9, we can't imagine any regulations passing in less than a decade; some could take even longer. If anyone ever tried to run a business by the methods required in HR 9, they would soon be bankrupted by delay and indecision. (No doubt, that's the real point of HR 9.)

The irony is that HR 9 says everything about how government must behave and nothing about how the poisoners must behave. Polluters don't even have to formally consider their options for reducing environmental destruction --an alternative decision-making technique that would improve things for everyone.

In truth, passage of HR 9 should come as no surprise. For 15 years, agencies like EPA, and some mainstream environmentalists, have been touting risk assessment as a valuable tool for decision-making. HR 9 is the logical outcome. Environmentalists are now horrified by HR 9, but they brought it on themselves by not promoting alternatives to risk assessment from the start.

In our view, HR 9 should be called the Risk Assessors' Job Creation and Wage Enhancement Act of 1995. It will guarantee employment for an army of cynical consultants, soul-less lawyers, and "realistic" mainstream environmentalists for whom risk assessment is "the only game in town." But it will do nothing to reverse the accelerating deterioration of the planet.

The good news is that HR 9 may finally drive home the truth about risk assessment: that it focuses attention on the tiny details of just exactly how we are going to permit the destruction of our health and environment, meanwhile leaving the poisoners and murders free to strike at will, without even requiring them to explain the choices they make.

In their personal lives, many people try to figure out how they can leave the world a little better than they found it. Shouldn't the nation spend its resources searching for least-damaging alternatives rather than searching for the holy grail of 'acceptable risk'?

--Peter Montague

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[1] The text of HR 9 is available on the internet via world wide web (www) or via anonymous ftp. Via www, go to: <http://thomas.loc.gov>. Via ftp, go to: [ftp://ftp.loc.gov/pub/c\[10\]4](ftp://ftp.loc.gov/pub/c[10]4) and get the file h[9].eh.FT.

Descriptor terms: legislation; congress; hr 9; hr 1022; contract with america; house of representatives; risk assessment and cost-benefit