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Regulatory Studies Program Public Interest Comment on the European Union's 2003 Draft Legislation on its Proposed Chemicals Policy

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The Regulatory Studies Program (RSP) of the Mercatus Center at George Mason University is dedicated to advancing knowledge of the impact of regulation on society. As part of its mission, RSP conducts careful and independent analyses employing contemporary economic and legal scholarship to assess rulemaking proposals from the perspective of the public interest. Thus, this comment on the European Union's draft legislation of its proposed chemicals policy does not represent the views of any particular affected party or special interest group, but is designed to evaluate the effect of the European Union's proposal on overall consumer welfare.[1]

I. Overview of Chemicals Policy

In February 2001, the European Commission released a white paper on Strategy for a future Chemicals Policy.[2] The strategy seeks to protect human health and the environment from the toxic effects of chemicals by creating a new system to test and regulate chemicals called REACH (Registration, Evaluation and Authorization of Chemicals). In November 2001, the European Parliament passed a resolution to expand the scope of the strategy to include all chemicals and consumer products that use chemicals.[3] Draft legislation to implement REACH was published in May 2003.[4] The European Commission is seeking public comment on the legislation until July 10, 2003.

The White Paper

The stated objective of the EU's chemicals policy is to ensure a high level of protection of human health and the environment, while maintaining market competitiveness. The paper states that the precautionary principle is fundamental to achieving these objectives. The paper defines the precautionary principle as follows:

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[1] Prepared by Eileen C. Norcross, Research Fellow at the Mercatus Center. This comment is one in a series of Public Interest Comments from the Mercatus Center's Regulatory Studies Program and does not represent an official position of George Mason University.

[2] European Commission, *White Paper: Strategy for a future Chemicals Policy*, (European Commission, February 27, 2001)

[3] European Parliament, *Resolution on the Commission White Paper on Strategy for a future chemicals Policy*, p. 12, (European Parliament, November 15, 2001)

[4] European Commission, *The New Chemicals Legislation – REACH*, (European Commission, May 7, 2003) http://www.europa.eu.int/comm/enterprise/chemicals/chempol/whitepaper/reach.htm

> "Wherever reliable scientific evidence is available that a substance may have an adverse impact on human health and the environment but there is still scientific uncertainty about the precise nature or the magnitude of the potential damage, decision-making must be based on precaution in order to prevent damage to human health and the environment."[5]

Another stated objective of the chemicals policy is to encourage the "substitution principle," or the substitution of dangerous by less dangerous substances where suitable alternatives are available.[6]

The REACH system

The EU's present system for testing chemicals currently distinguishes between "existing substances" or those chemicals placed on the market before September 1981, which represent 30,000 substances, or 99 percent of the total volume of all substances on the market[7], and "new substances," or those placed on the market since that date. The new system would require that all existing and new substances be subjected to the testing and registration criteria.

Under the proposed legislation, manufacturers and importers of chemicals must comply with a three-step process before being permitted to sell their products on the EU market. The REACH system consists of:

1) **Registration** – Manufacturers and importers must submit information to a central database on hazard, exposure, and risk on 30,000 new and existing substances that are produced or imported in yearly quantities exceeding 1 metric ton.

2) **Evaluation** – Authorities will assess risks for 5000 substances that are produced or imported in yearly quantities exceeding 100 tons, and also for substances in lower quantities if they are 'of concern.' The newly established European Chemicals Agency will then determine if further testing is needed.

3) **Authorization** – Substances of "very high concern"—those that are carcinogenic, mutagens, bioaccumulative, persistent, reproductive toxins, or endocrine disruptors—will require specific permission for certain uses. An estimated 1400, or 5 percent, of registered substances will be subject to authorization. In addition to running tests, manufacturers must also provide risk characterizations and exposure information. If the company is unable to demonstrate the safety of a substance, the precautionary principle may be invoked implementing a ban of the substance.

This is a departure from the present system that places the burden on the government to show a given substance poses a risk. The REACH system places the burden on manufacturers and importers to prove that their substances are safe.

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[5] White paper, p. 5
[6] Ibid.
[7] White paper, p. 6

The precautionary principle may also be invoked if data are not provided in a timely manner. Products may be denied entry into the EU if their data are incomplete or late: "no data, no market."

Another change from the present system is that REACH requires that every manufacturer or importer of a substance greater than one ton, submit a registration. That is, the registration is manufacturer-based, not substance-based. This includes all new and existing substances regardless of whether another manufacturer has already submitted a registration for a particular substance, thus creating duplication of registrations for the same substance. Cooperation between companies to register the same substance is encouraged.

REACH gives particular attention to chemicals that can be classified as carcinogens, mutagens, or reproductive toxins (CMRs); persistent, bioaccumulative, and toxic (PBTs); very persistent and very bioaccumulative (vPvBs); and endocrine disrupting. These substances of "very high concern" will require specific permission for certain uses.

REACH also sets requirements for downstream users who make products that use chemicals. This would extend to manufacturers of toys, textiles and other consumer products.

Timeframe and Cost

Testing 30,000 substances over the suggested timeframe of 11 years will amount to 2.1 billion euros ($2.37 billion US) by the EU's own estimates.[8] Independent analysis has estimated the cost to be much higher. The UK-based Institute for Environment and Health estimates REACH will cost 8.68 billion euros ($9.83 billion US).[9]

Exceptions

After taking into consideration the concerns of stakeholders, the European Commission agreed to meet some demands of European chemicals industry manufacturers and associations. As a result, the draft legislation has made a few exceptions for certain chemicals. Certain polymers and intermediaries are exempted from registration, under the REACH system, or are subject to less stringent registration requirements. Exempted products include: food additives, natural gas, crude oil, coal, and pharmaceuticals. The draft legislation does not fully exempt all polymers but subjects polymers to less stringent requirements. Polymers imported in quantities greater than one ton, or those that are classified as dangerous, are not exempt from registration.

II. Analysis

[8] White paper, p. 15

[9] Institute for Environment and Health, "*Testing Requirements for Proposals Under the EC White Paper 'Strategy for a Future Chemicals Policy"*", IEH Web Report W6 (July 2001), p.2 http://www.le.ac.uk/ieh/pdf/w6.pdf

The driving force behind the EU's chemicals policy is the precautionary principle. Though the precautionary principle is not yet recognized as part of customary law, variations of it can be found in at least 14 international environmental declarations, agreements, and conventions.[10] The EU's legislation is a further enshrinement of an unsound and potentially harmful approach.

The most widely circulated definition of the precautionary principle is the Wingspread Declaration:

> "When an activity raises threats of harm to human health or the environment, precautionary measures should be taken even if some cause and effect relationships are not established scientifically. In this context, the proponent of the activity, rather than the public, should bear the burden of proof."[11]

This approach asserts the existence of a hazard in the absence of proof. In this framework, the burden of proof does not rest with the party asserting the existence of a hazard or danger, but rather with the party undertaking the activity.

The EU's definition of the precautionary principle differs slightly,

> "Wherever reliable scientific evidence is available that a substance may have an adverse impact on human health and the environment but there is still scientific uncertainty about the precise nature or the magnitude of the potential damage, decision-making must be based on precaution in order to prevent damage to human health and the environment."[12]

Thus, when a party undertaking an activity or producing a substance cannot prove with absolute certainty that a risk is acceptable or that no risk exists, decision-making rests with the party making the claim to curtail, limit, or ban the activity, technology, or substance.

There are several objections to the precautionary approach. Each of these objections is explored below.

- ***Rejection of Scientific Risk Assessment***

The precautionary principle is a rejection of the established principles of scientific risk assessment, and thus cannot be used to manage risks effectively. Risk assessment is the process that is used to quantitatively or qualitatively estimate and characterize risk, including the probabilities of various outcomes. The precautionary principle does not *assess* risk but rather *assumes* hazard where scientific evidence is lacking. Further it does

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[10] Goklany, Indur M. The Precautionary Principle: A Critical Appraisal of Environmental Risk Assessment, (The CATO Institute, 2001), p. 3.
[11] Raffensperger, Carolyn and Joel Tickner, Eds. Protecting Human Health and the Environment: Implementing the Precautionary Principle (Washington: Island Press, 1999)
[12] White paper, p. 5

not set any criteria for what constitutes an acceptable level of risk, nor for comparing the relative risks associated with alternative policies.

Risk management is a distinct process that takes risk assessment information and combines it with other information, such as cost and the feasibility of reducing risks, to determine what action to take in order to provide the greatest benefit to the public.[13]

The precautionary principle focuses on risks that are speculative. In order to test risk, a risk must first be hypothesized. If a risk cannot be hypothesized, it cannot be tested, it cannot be assessed, and therefore, it cannot be managed. Thus the precautionary principle cannot maximize benefits because it seeks to eliminate unspecified risks.[14] And when it causes a new technology or substance to be banned, the precautionary principle forces the public to forgo all of the associated benefits, as well.

The white paper states that the current risk assessment process is not adequate:

> "The risk assessment process is slow and resource-intensive and does not allow the system to work efficiently and effectively. The allocation of responsibilities is inappropriate because authorities are responsible for the assessment instead of enterprises that produce, import or use the substances."[15]

It is certainly possible to remedy these inadequacies without invoking the precautionary principle. Responsibility for the actual conduct of chemical testing and risk assessment can be assigned to the appropriate enterprises, rather than government authorities. Responsibility for paying the associated costs can be allocated appropriately to the private sector as well. None of this, however, requires that the principles of scientific risk assessment be rejected.

In the course of shifting the responsibility, and the burden of cost, from the public sector to the private sector, the proposed legislation goes too far in that it seeks to shift the burden of proof. But proof should not be required from either party. It would be unreasonable to require regulatory authorities to support every action with absolute proof that a serious hazard will be thereby prevented; it would be impossible to require that private enterprises prove that every substance is completely safe. Regardless of who conducts the risk assessment, the objective should be to elicit an accurate and unbiased estimate of risk. Neither an "innocent until proven guilty" rule, nor a "guilty until proven innocent" rule will advance that objective.

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[13] Mercatus Center Public Interest Comment on OMB's 2003 Benefit Cost Report, RSP 2003-11 (www.mercatus.org)

[14] Andrew Apel, "*Are Risk Assessment and the Precautionary Principle Equivalent?*", June 20, 2002 (remarks presented at the International Society of Regulatory Toxicology and Pharmacology, Arlington Virginia)

[15] White paper, p. 6

Under the Toxic Substances Control Act (TSCA), the United States keeps an inventory of chemicals used in commerce. It requires pre-manufacturer notification of new chemicals being introduced. The U.S. Environmental Protection Agency (EPA) has an opportunity to require testing, and where appropriate, to take regulatory action, up to and including a ban, when warranted. There is one fundamental difference with the EU's proposal. TSCA requires the EPA to justify its regulatory interventions using traditional risk assessment and benefit-cost balancing.

Why the precautionary principle may cause harm

The stated intent of the EU's chemicals policy is to protect human health and the environment while preserving market competitiveness and encouraging innovation.

"The potential benefits of this policy would stem from improved risk management, in all likelihood leading to safer handling of substances, and to less exposure of consumers and environment to dangerous substances."[16]

The assertion that such improved risk management will lead to less exposure of chemicals and thus improve human health and the environment is far from clear. Reliance on the precautionary principle is likely to have the opposite effect because overlooks the benefits forgone by its application.[17]

Indeed, the banning of certain substances in recent decades based on assumed hazards led to a loss of human life far exceeding any supposed benefit from ban.

- *Chlorine in Drinking Water*
  In the 1980s there was a growing fear among environmentalists that chlorine in drinking water might act as a carcinogen. The Peruvian government, in response to a budget crisis, used the allegations about the harmful effects of chlorine to cut chlorination from their drinking water. This led to a cholera epidemic in Peru between 1991-1996, which killed 11,000 of 1.3 million sufferers.[18]

- *Ban on DDT*
  Among pesticides, DDT has a relatively low toxicity. Though it has been shown to pose a threat to some bird and fish species, it has not been proven to have an adverse impact on human health. Based on assertions of DDT's extreme toxicity to humans and the environment in Rachel Carson's influential 1962 book, *Silent Spring*, the U.S. Environmental Protection Agency banned the pesticide in 1972. Farmers turned instead to far more toxic organophosphate pesticides, which may have lead to some farmers suffering injuries by handling a substance far more dangerous than DDT.[19]

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[16] Ibid
[17] Goklany, p. 7
[18] Gregory Conko and Henry I. Miller, "*Precaution (Of A Sort) Without Principle,*" Priorities for Health, Vol 13, No. 3 (American Council on Science and Health, November 1, 2001)
[19] Ottoboni, M. Alice, 1991. *The Dose Makes the Poison: A Plain Language Guide to Toxicology*, 2nd ed. New York: Van Nostrand Reinhold

> The US ban on DDT led environmental activists to lobby for a worldwide ban of the pesticide. Though activists failed to implement a worldwide ban, many countries were pressured to limit or ban the use of DDT. For example, South Africa nearly eradicated malaria-carrying mosquitoes when it used DDT. When DDT use ended, malaria cases rose from 4,117 in 1995 to 27,238 by 1999.[20]

What impact will the EU's chemicals policy have on human health?
The white paper begins by stating that the use of chemicals in the 20th century may have lead to an increase in cancer rates. In fact, the first chemical the white paper cites as a dangerous carcinogen to humans is asbestos. Yet asbestos is a naturally occurring mineral.

EU Commissioner Margot Wallstrom estimates that after implementation of the policy between 18 billion euros ($20.28 billion US) and 54 billion euros ($61.64 billion US) might be saved over 30 years due to a decrease in chemically related diseases, in particular, occupationally induced cancer. That corresponds to a decrease of 2200 to 4300 cancer deaths per year.[21] However, in the main, these are asbestos-related cancer deaths; a mineral that should not even be covered by the policy.[22]

The white paper also suggests that an increased incidence of some diseases over the last decades, such as testicular cancer in young men and allergies, may be related to the use of chemicals, while providing no evidence of a causal link. Indeed, one reason for an increased rate of some types of cancer may be due to better screening and data reporting.[23]

Indeed, the assertion that synthetic chemicals has lead to an increase in cancer rates is not based on chemicals' effects in humans, but in high-dose rodent tests, which are not the same as low-dose human exposures.[24] Regulatory policy focuses on synthetic chemicals, but 99.9 percent of the chemicals human ingest are natural. In high-dose rodent tests many naturally occurring chemicals also have carcinogenic effects[25]

Studies that have looked at cancer rates around the world indicate that the major, avoidable causes of cancer are related to environmental (i.e. not genetic) or lifestyle factors: smoking, diet, hormonal factors (some of which are diet related), and infections.[26] In fact, neither epidemiology nor toxicology supports the idea that exposures

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[20] Angela Logomasini, "*Deploy DDT to Fight Malaria*", June 18, 2002
[21] Speech by Margot Wallstrom, "*Beyond REACH", European Voice Conference*, Brussels, March 31-April 1, 2003
http://europa.eu.int/comm/enterprise/chemicals/chempol/whitepaper/reach.htm
[22] Speech by Eggert Voscherau, "*A Task for Europe – A New Industrial Policy*", CEFIC General Assembly, Hamburg, Germany, June 27, 2003
[23] Doll, R., and Peto, R. (1981), The Causes of Cancer, Oxford University Press, New York
[24] Gold, Lois Swirsky, Sloane, Thomas H., Manley, Neela B and Ames, Bruce N. "*Misconceptions about the Causes of Cancer*", Risk Controversy Series 3, The Fraser Institute (2002) p. 3
[25] Ibid. p.23
[26] Ibid. p.7

to synthetic chemicals at the level they are found in the environment are an important cause of human cancer.[27]

Though REACH will not lead to a ban of all chemical substances, it has the potential to arbitrarily ban substances in the absence of proof. The benefits of banning a given substance on the suspicion that they are carcinogenic in humans are not likely to exceed the costs of removing a chemical from usage. It will promote reliance on potentially more toxic substances, or none at all.

- ***Higher Costs***

The costs of the REACH plan are tremendous. Testing costs range between 85,000 euros ($96,271 US) to 250,000 euros ($238,150 US) per substance.[28] Small and medium-sized manufacturers (SMEs) will be disproportionately affected by the testing costs. For chemicals produced in one ton/year, testing costs will amount to 85,000 euros, ($96,271 US) representing 42.5 percent of the selling price of that substance.[29]

Eighty percent of chemicals SMEs in France will experience a 10 percent or greater drop in production.[30] Further, it is projected that in certain chemicals manufacturing segments, 10 to 40 percent of products will not be able to recoup the cost of registration and will stop production by 2012.[31]

These costs are not only passed on to the consumer through higher prices, but in many cases will not be recouped, cutting into companies ability to innovate and engage in research and development.

US chemical imports totalling $20 billion (17.52 billion euros) annually will also be affected. The US chemicals industry estimates the total cost of REACH to amount to between $5.5 billion (4.85 billion euros) and $9.6 billion (8.48 billion euros).[32] This does not include the impact on downstream users of chemicals.

- ***Barrier to Innovation***

The policy and subsequent draft legislation is structured to have a devastating economic impact on chemical companies worldwide, in particular, small and medium sized manufacturers. As companies try to absorb the testing costs, many will be faced with cutting back on research and development, or simply going out of business. This will have the effect of denying the public access to new chemicals technology. Rather than promote innovation, older chemicals will

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[27] Ibid.
[28] white paper, p. 15
[29] John Morris, KPMG presentation to the Chemical Industry Association
[30] Mercer Management Consulting, *Study of the Impact of the Future Chemicals Policy*, (April 24, 2003), p. 35
[31] Ibid, p. 36
[32] U.S. State Department, "U.S. Government Views on EU Chemicals Policy: Action Request to non-EU States," 2002 (U.S. State Department, March 22, 2002)

remain on the market and thus provide the public with fewer alternatives, and promote reliance on less effective substitutes.

III. Recommendations

It is laudable that the EU wants to protect its citizenry and environment from the ill effects of chemicals; however, a sound policy should be based on scientific risk assessment and a balanced approach to risk management. The effects of the proposed policy and legislation will be to deny the public access to new and improved chemicals technology. The risk-based approach is rooted in the assessment of risks, and the management of those risks to maximize public benefit. The precautionary approach cannot maximize public benefit because it manages unspecified or unproven risk. It fails to take into consideration the negative outcome of its application.

To improve its chemicals policy, the EC should consider the following points:

- Regulation of substances should be based on scientific risk assessment rather than the precautionary principle.

- Risk management should be kept apart from risk assessment, and should take account of the risks and benefits of alternative policy decisions.