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The Kid Safe Chemicals Act:
A Significant Potential Change to the Toxic Substances Control Act

Senator Jeffords, when introducing The Child, Worker, and Consumer-Safe Chemicals Act of 2005, or the “Kid Safe Chemicals Act” (“KSCA”)¹ to the Senate floor on July 13, 2005, stated that the bill would “fundamentally overhaul the nation’s chemical management framework.”² Even a cursory review of the KSCA validates this assertion. The KSCA proposes significant changes to the current TSCA framework, including new reporting requirements tied to a threshold safety standard for each chemical, biomonitoring testing and reporting, and changes to the procedures for classifying confidential business information. Notably, it also ties the Environmental Protection Agency’s (“EPA”) performance on a range of new tasks to specific timeframes that are not realistic and would be impossible for EPA to meet given current capacity. EPA’s failure to meet these timeframes would have significant repercussions for industry, including a ban on the marketing and/or use of a particular chemical if EPA fails to make a safety determination or take action on a particular chemical within the allotted time.

This article examines the key provisions of the KSCA and highlights the major proposed changes and their impact on chemical manufacturers. First, the article looks at the background surrounding the development of the KSCA, including two Government Accountability Office (“GAO”) reports requested by Senators Frank Lautenberg, James Jeffords and Patrick Leahy. A more detailed, bullet point analysis of both GAO Reports has been annexed to this report. Following this brief examination of the background, the article examines the KSCA proposed amendments in detail. It concludes with a critical analysis of the proposed amendments.

I. Background

Senators Lautenberg and Jeffords, who have been the leading proponents of the KSCA, approached the Government Accountability Office (“GAO”) in early 2004 with Senator Leahy and asked the GAO to report on options to improve EPA’s implementation of the Toxic Substances Control Act (“TSCA”). A year later, in June of 2005, the GAO issued its report entitled “Chemical Regulation: Options Exist to Improve EPA’s Ability to Assess Health Risks and Manage Its Chemical Review Program” (“Report”).³ The Report, summarized in detail in Annex I, was critical of EPA’s implementation of TSCA, targeting three main implementation issues and providing specific recommendations for EPA’s management of the TSCA program.

Specifically, the Report criticized the pre-manufacture notification (“PMN”) process for new chemical review, claiming that it fails to provide EPA with enough test data to make a

¹ Child, Worker, and Consumer-Safe Chemicals Act of 2005, S. 1391, 109th Cong. (2005); Child, Worker, and Consumer-Safe Chemicals Act of 2005, H.R. 4308, 109th Cong. (2005) (“KSCA”).

² 151 Cong. Rec. S177, 8236 (daily ed. July 13, 2005) (“Senator Jefford’s Remarks”).

³ Government Accountability Office, GAO No. 05-458, *Chemical Regulation: Options Exist to Improve EPA’s Ability to Assess Health Risks and Manage Its Chemical Review Program* (June 2005) (“GAO Report”).

determination whether regulatory restrictions on new chemicals are needed.⁴ The GAO also found that EPA does not periodically assess existing chemicals, maintains very limited information on their health and environmental risks, and rarely regulates their use.⁵ Finally, the GAO concluded that TSCA limits EPA's ability to collect and share data because of confidentiality claims.⁶

The conclusions from the Report proved to be what Senator Jeffords described as a "call to action."⁷ Shortly after receiving the Report, Senators Frank Lautenberg and Jim Jeffords introduced the KSCA with Senators Boxer, Kerry, Corzine, Clinton and Kennedy.⁸ Congressman Henry Waxman followed suit on November 10, 2005 and introduced the same bill in the House of Representatives with Representatives Solis, Slaughter and Pallone.⁹ Currently both bills are before their respective committees, the Senate Committee on Environment and Public Works and the House Committee on Energy and Commerce.

Perhaps in an effort to build the case for KSCA, Senators Lautenberg, Jeffords and Leahy approached the GAO again in July 2005 and asked for a follow-up study comparing the United States, Canada, and the European Union's approach to chemicals regulation (including the EU's proposed "REACH" regulation). Specifically, the Senators requested information on the following four subjects: (i) controlling chemical risks; (ii) reviewing existing chemicals used in commerce; (iii) assessing new chemicals; and (iv) handling confidential business information.¹⁰ The GAO returned with a final report on November 10, 2005, summarized in Annex II. The Report acknowledges that nuances in the legal frameworks make comparisons somewhat difficult in these four areas.¹¹ However, the GAO concluded that there existed enough commonality to provide what it deemed "useful" comparisons.¹² Not surprisingly, many of the comparisons highlighted areas where the European Union and Canada had implemented more restrictive regulations.

⁴ *Id.* at pgs. 10-18.

⁵ *Id.* at pgs. 18-31.

⁶ *Id.* at pgs. 31-34.

⁷ Senator Jefford's Remarks, *supra* note 2.

⁸ Child, Worker, and Consumer-Safe Chemicals Act of 2005, S. 1391, 109th Cong. (2005).

⁹ Child, Worker, and Consumer-Safe Chemicals Act of 2005, H.R. 4308, 109th Cong. (2005) ("KSCA").

¹⁰ Government Accountability Office, GAO No. 06-217R, *Chemical Regulation: Approaches in the United States, Canada, and the European Union*, pgs. 3-4 (November 4, 2005) ("GAO Comparative Report").

¹¹ *Id.* at pg. 17.

¹² *See id.*

II. Key Changes in the KSCA

The KSCA would amend TSCA by adding a new chapter entitled “Title V - Child Safe Chemicals.”¹³ Its overarching goal, as stated in section 2(c), is “to eliminate the exposure of all children, workers, consumers, and sensitive subgroups to harmful chemicals distributed in commerce by 2020.”¹⁴ To reach this goal, EPA would have to accomplish three main tasks required by KSCA. First, EPA would have to identify the highest priority chemicals for review by 2007.¹⁵ Second, EPA would have to make safety determinations on 300 or more chemicals drawn from a priority list and take action against these chemicals if found to not meet a safety standard set forth in section 503(a) by 2010.¹⁶ Finally, EPA would have to make a safety determination and take action on all remaining chemicals by 2020.¹⁷

A. New Policies

The KSCA bill includes several policies drawn from the June 2005 GAO Report.¹⁸ The KSCA encourages the promotion of safer chemical substitutes through market-based incentives.¹⁹ The bill also calls for holding chemical manufacturers accountable for providing “complete health and safety data for each chemical they produce prior to distribution.”²⁰ EPA is granted the authority to permit chemicals to enter the marketplace only after reviewing the data and determining with a “reasonable certainty” that the substance poses “no harm to human health or the environment.”²¹ Finally, the policy supports the public and workers’ “full right to know” about health effects from exposure to certain chemicals.²²

B. The Priority List and New Safety Standard

The KSCA would require EPA to create and maintain a priority list of chemical substances that meet certain criteria.²³ The criteria include whether a substance: (i) is found in

¹³ KSCA, *supra* note 1, §3(a).

¹⁴ *See id.* at §2(c).

¹⁵ *Id.* at §2(c)(1).

¹⁶ *Id.* at §2(c)(2).

¹⁷ *Id.* at §2(c)(3).

¹⁸ *Id.* at §2.

¹⁹ *Id.* at §2(b)(2)(A).

²⁰ *See id.* at §2(b)(2)(B).

²¹ *See id.* at §2(b)(2)(C).

²² *See id.* at §2(b)(3).

²³ *Id.* at §502.

human blood, fluids, or tissue and is not synthetic or naturally present in the human body; (ii) is found in food or drinking water and is not synthetic or naturally present in the human body; (iii) has a production volume of over 1,000,000 pounds per year; (iv) is a known or suspected “reproductive, neurological, or immunological toxicant, carcinogen, mutagen, or endocrine disruptor, or causes developmental defects;” or (v) is persistent or bioaccumulative.²⁴ EPA must develop the initial list of 300 or more priority chemicals within 18 months of the enactment of the KSCA.²⁵ Each year, EPA would have to update the list annually,²⁶ and a failure to do so would be considered a failure to perform a non-discretionary duty, thus permitting judicial review of the failure to update.²⁷

Notably, the KSCA would require EPA to undertake a safety determination and take appropriate action if necessary for the first 300 chemicals within five years of the enactment of the KSCA. If EPA failed to act within this timeframe, the chemical could no longer be distributed in commerce.²⁸ The KSCA gives EPA 15 years to review and approve every chemical distributed in commerce, and these determinations would have to be reviewed every 15 years.²⁹

EPA’s review of each chemical would be based on a new threshold safety standard provided in section 503(a) of the KSCA. The safety standard is defined as “a standard that provides a reasonable certainty that no harm will be caused by aggregate exposure of a fetus, infant, child, worker, or member of other sensitive group.”³⁰ In the case of a fetus, infant, or child, EPA should implement a standard that takes into account their “special vulnerability” by applying an additional 10-fold safety factor to the level established for adults.³¹

C. New Reporting Requirements

The KSCA safety standard also serves as the threshold measure for reporting required by chemical manufacturers. For existing chemicals, all manufacturers would have to submit to EPA within one year of enactment of the KSCA statements signed by their CEOs certifying that chemicals meet the safety standard and that this conclusion is supported by all “reasonably

²⁴ *See id.* at §502(b).

²⁵ *Id.* at §502(a)(1).

²⁶ *Id.* at §502(a)(2).

²⁷ *Id.* at §502(a)(3).

²⁸ *Id.* at §503(c)(1).

²⁹ *Id.* at §503(c)(2).

³⁰ *See id.* at §503(a)(1).

³¹ *See id.* at §503(a)(2).

available” information in their possession or control.³² EPA would provide manufacturers with a set of requirements outlining the required data to support certification.³³ Relevant information would include, at a minimum, toxicological properties, annual production volume, and exposure and disposal data.³⁴

Chemical manufacturers would also have to update any information necessary to meet the safety standard on existing chemicals every three years.³⁵ Manufacturers must also provide EPA any significant new information that becomes available regarding a “physical, chemical, or toxicological property of, or exposure to, the chemical substance.”³⁶ Toxicological property is defined broadly under section 501(d).³⁷

Ninety days after the enactment of the KSCA, the CEO of each chemical manufacturer would also have to certify in pre-manufacture notices that each new chemical meets the safety standard. After this date, no new chemicals could be distributed in commerce until they have met the safety standard.³⁸

Notably, chemical manufacturers would also be required to provide EPA with biomonitoring data within five years of the enactment of the KSCA for certain chemicals. Manufacturers would have to undertake studies to determine the presence of any chemical substance found in blood, tissue, or fluids if it is either manufactured annually in quantities greater than 1,000,000 pounds or there exists a concern regarding human exposure and the chemical is distributed in commerce.³⁹ The KSCA requires EPA to issue a regulatory standard for biomonitoring studies that would address the type of representative sample to be used and the appropriate detection levels. In particular, the representative sample should cover likely exposed populations of children.⁴⁰

³² *Id.* at §501(a).

³³ *Id.* at §502(b)(3). EPA may also provide a tiering process for the submission of data. *Id.* at §502(b)(4).

³⁴ *Id.* at §501(a)(2).

³⁵ *Id.* at §501(b)(1).

³⁶ *See Id.* at §501(b)(2).

³⁷ *Id.* at §501(a).

³⁸ *Id.* at §503(c).

³⁹ *Id.* at §503(d)(1).

⁴⁰ *Id.* at §503(d)(2).

D. Enforcement

Under section 504(a) of the KSCA, chemical manufacturers would not be allowed to manufacture any chemical if EPA determines that it has not met the safety standard or if they have not followed the procedures provided on reporting requirements or safety standard determinations. Market restrictions would also apply if EPA failed to make a safety determination by the deadlines provided in section 503.⁴¹ Only the President of the United States, in a non-delegable duty, could exempt a chemical if it is in the paramount interest of national security or if the lack of the chemical would disrupt the economy.⁴² The President would also have to determine that no feasible alternative exists for the specific use.⁴³

After a period of notice and comment, exemptions could last up to five years, and would be renewable for an additional five.⁴⁴ Any chemical manufacturer that receives an exemption from the President would have to notify all “known” customers. The President would also have to provide notice of the exemption to the public.⁴⁵

E. Access to Information and Confidentiality

Federal agencies and institutions, under section 509(a) of the KSCA, would be required to provide EPA with all information in their possession on exposure risk or toxicity of chemical substances. EPA would be responsible for developing and maintaining an electronic database to facilitate the exchange of this information within 180 days of the enactment of the KSCA.⁴⁶ All information on the properties or risks associated with a chemical substance would be available to the public.⁴⁷

Notably, EPA could also release any information related to exposure risks not protected as confidential under section 510. Section 510 would amend TSCA section 14 by requiring a CEO to justify in writing why information related to a chemical substance must remain confidential.⁴⁸ As part of the justification, the CEO would be required to demonstrate that the information is not otherwise available to the public.⁴⁹ The name of a chemical and all

⁴¹ *Id.* at §504(a)(3).

⁴² *Id.* at §504(d)(1)(A).

⁴³ *Id.* at §504(d)(1)(B).

⁴⁴ *Id.* at §504(d)(2).

⁴⁵ *Id.* at §504(d)(3).

⁴⁶ *Id.* at §509(b).

⁴⁷ *Id.* at §509(c).

⁴⁸ *Id.* at §510(a).

⁴⁹ *Id.* at §510(a)(2).

information concerning its effects on human health or the environment would never be considered confidential information.⁵⁰

Finally, EPA would be responsible for developing procedures to measure the reliability of data.⁵¹ EPA would have to randomly inspect 3 percent or more of the commercial or private laboratories that test chemicals to meet the new safety standards.⁵² EPA would also be required to audit a statistically significant number of data submissions to check veracity.⁵³

F. Additional Provisions

The KSCA includes additional provisions on the minimization of animal testing⁵⁴ and the creation of an Interagency Advisory Board on Children's Health and Toxic Substances, an entity of volunteers that would provide technical advice to EPA and Congress on review standards, rules, and other science-based EPA determinations.⁵⁵ The KSCA also calls for EPA to create a program, within one year of enactment of the KSCA, on market incentives for the development or use of safer chemicals.⁵⁶ EPA would develop programs, such as good practice awards, to encourage the development and use of safer alternatives.⁵⁷ Additionally, manufacturers could expedite the review of PMNs by including an alternatives analysis that shows the new chemical to provide a safer alternative to an existing substance.⁵⁸ A Green Chemistry Research and Clearinghouse Network, created by EPA, would help to research and support the development of safer alternatives.⁵⁹

III. Conclusions

The KSCA raises several issues that call into question whether it is a viable alternative to the current TSCA framework. First, EPA does not currently have the capacity or the funding to implement all of its new tasks within the timetables set by the KSCA. For example, EPA is given three years after the enactment of the KSCA to determine whether the initial 300

⁵⁰ *Id.* at §510(c).

⁵¹ *Id.* at §509(d).

⁵² *Id.* at §509(d)(1).

⁵³ *Id.* at §509(d)(2).

⁵⁴ *Id.* at §505.

⁵⁵ *Id.* at §507.

⁵⁶ *Id.* at §506(a).

⁵⁷ *Id.* at §506(a)(2).

⁵⁸ *Id.* at §506(a)(3).

⁵⁹ *Id.* at §506(b).

chemicals on the priority list meet the safety standard and five years to take action.⁶⁰ As the GAO found in its report, it takes EPA on average from two to ten years to issue a testing rule under TSCA section 4 for one chemical.⁶¹ Clearly EPA would not have the resources to review and make more comprehensive risk determinations on 300 chemicals in 3-5 years.

Secondly, industry would bear the brunt of EPA's failure to meet the unrealistic deadlines. In particular, if EPA failed to act on a certain chemical within five years of the enactment of the KSCA, that chemical could no longer be distributed in commerce.⁶² If the EPA failed to make a safety standard determination on a particular chemical within three years of enactment, that chemical could not be manufactured, and marketing restrictions would apply until EPA completed its review.⁶³ These are harsh penalties with broader implications for the U.S. economy which could be avoided with a more realistic regulatory scope and timeframe.

The safety standard may also prove problematic in implementation, as its exact definition is not clear. Additionally, the decision to use a hazard based approach for the standard could have serious repercussions for chemical manufacturers and users of regulated chemicals. A more appropriate standard would be one, like TSCA's current risk-benefit approach, that considers exposure levels and uses in addition to toxicity. As the KSCA standard now reads, should EPA determine that a chemical did not meet the safety standard, industries that rely on chemicals to, for example, produce consumer goods would lose their ability to continue production even if they used only de minimis amounts of the chemical or the chemical was used in a way that did not result in meaningful exposure.

Several other provisions, such as the exemption of chemicals by the President,⁶⁴ simply do not appear to be realistic and should be tabled for a more viable process that would work for all stakeholders. Others, like the publication of all information concerning the effects on human health and the environment,⁶⁵ may be harder to counter. Ultimately, the question becomes whether the KSCA, which proposes several programs similar to those already available under the current TSCA, would truly represent an improvement. Additionally, Congress should consider whether TSCA requires a complete overhaul given that resource limitations rather than existing statutory language are primary reasons for the "deficiencies" identified in the GAO reports. Given the above noted problems, the answer to both of these questions appears to be no.

Significantly, EPA and industry over time have developed voluntary mechanisms for chemicals management that supplant difficult to implement regulations. This has proven to be a

⁶⁰ *Id.* at §503(c)(1).

⁶¹ GAO Report, *supra* note 3 at pg. 26.

⁶² *Id.* at §503(c)(1)(B)(ii).

⁶³ *Id.* at §503(c)(1)(B)(i).

⁶⁴ *Id.* at §504(d).

⁶⁵ *Id.* at §510(c).

fruitful partnership, leading to successful programs like the High Production Volume Challenge Program and the extended HPV Program. Furthermore, EPA has developed pilot programs like the Voluntary Children's Chemical Evaluation Program that work because they integrate hazard and exposure data to make a more integrated assessment of risks to children's health. Programs like these would in the future provide a more effective and appropriate chemicals regulatory approach than those proposed under the KSCA.

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ANNEX I: THE GAO REPORT (JUNE 2005)

“CHEMICAL REGULATION: OPTIONS EXIST TO IMPROVE EPA’S ABILITY TO ASSESS HEALTH RISKS AND MANAGE ITS CHEMICAL REVIEW PROGRAM”

The Government Accountability Office (“GAO”) published a report in June 2005 entitled “Chemical Regulation: Options Exist to Improve EPA’s Ability to Assess Health Risks and Manage Its Chemical Review Program,”⁶⁶ (“GAO Report”) that is critical of EPA’s implementation of TSCA. The GAO Report, requested by Senators Frank Lautenberg, James Jeffords and Patrick Leahy, discusses three main implementation issues and provides specific recommendations for EPA’s management of the TSCA program.

Issue I: “The EPA lacks sufficient data to ensure that potential health and environmental risks of new chemicals are identified.”

- The Report criticizes the pre-manufacture notification (“PMN”) process for new chemical review (TSCA § 5), claiming it fails to provide the EPA with enough test data to determine whether regulatory restrictions or new chemicals are needed.
 - The lack of data, the Report claims, has led EPA to rely on structure activity relationship (“SAR”) analysis to screen for chemical toxicity. SAR analysis uses models of molecular structures to compare new chemicals to existing chemicals that already have test data available on health and environmental effects. This methodology has not been validated, and EPA officials noted in the Report that there should be a formal review process for SAR analysis in place.
 - Industry representatives interviewed for the Report were generally willing to work with EPA on addressing data shortcomings in the PMNs.
- The Report raises concern that information (e.g. production volume, pollution controls, anticipated uses) in PMNs may change after manufacturing begins. Absent the PMN submitter’s agreement to be bound by the PMN information, there is nothing short of a “significant new use rule” to require manufacturers to keep production and use in line with PMN (The GAO report seems to overlook other regulatory options such as § 5(e) and (f) Consent Orders and regulation under § 6.)

Issue II: “The EPA does not routinely assess existing chemicals, has limited information on their health and environmental risks, and has issued few regulations controlling such chemicals.”

- The Report finds that EPA maintains very limited toxicity and exposure data on existing chemicals. According to the authors, this is due to:
 - the lack of a “specific requirement, time frame or methodology for reviewing existing chemicals” in TSCA; and

⁶⁶ Government Accountability Office, GAO No. 05-458, *Chemical Regulation: Options Exist to Improve EPA’s Ability to Assess Health Risks and Manage Its Chemical Review Program* (June 2005) (“GAO Report”).

- the time consuming and difficult procedures in place under section 8 for procuring additional data from chemical manufacturers (estimate several months to a year to issue a section 8 rule).
- the significant findings required to issue a rule under section 4 for additional testing (estimate 2-10 years to move through rulemaking process).
- The Report praises EPA’s enforceable consent agreements (“ECAs”) (promulgated in a 1986 EPA rule), which impose testing requirements by agreement between EPA and manufacturers of the affected chemicals, avoiding the need for rulemaking and addressing data and testing shortages for existing chemicals.
 - However, the Report cautions that ECAs are at risk should they be challenged in court. Therefore, the Report suggests that Congress should amend TSCA to provide for the ECA procedure in law.
- The Report also commends EPA’s High Production Volume Challenge Program (“HPV”), which is a program where chemical companies agree to provide existing data on one or more of the approximately 2,800 chemicals reported in 1990. Acknowledging that HPV has been successful, the Report finds it lacks a methodology for prioritizing chemicals to determine which need further testing.
 - A federal advisory group has been set up to address the issue.
 - The Report questions whether company sponsors of chemicals under HPV provide enough information to evaluate health and environment risks.
- The Report is particularly critical of EPA’s failure to regulate existing chemicals under section 6, which provides for the ban or limitation of the production, importation or use of a chemical substance if EPA finds it presents an unreasonable risk of injury to human health or the environment.
 - The Report found that not only does EPA have great difficulty meeting rulemaking requirements under section 6, but EPA must offer significant evidence to survive judicial scrutiny.
 - For example, in *Corrosion Proof Fittings v. EPA*, 947 F.2d 1201 (5th Cir. 1991), the Fifth Circuit ruled for chemical companies who claimed that the EPA had failed to provide enough evidence to justify its ban on asbestos. The Court held that EPA should have given more consideration to every available regulatory option, including the least burdensome, and their costs and benefits.
 - Since this 1989 decision, the EPA has undertaken a Section 6 proceeding to ban or limit a chemical only once.
- The Report highlights the work in Canada and the EU on chemicals regulation.

Issue III: “EPA’s ability to share data collected under TSCA is limited.”

- The Report estimates that 95% of PMNs prepared and submitted by manufacturers claim some of their information as confidential under TSCA section 14, preventing EPA from sharing information with state regulatory and international government officials.
 - EPA has not studied the validity of confidentiality claims, and several officials interviewed for the Report feel a review is warranted.

- According to the Report, EPA challenges only those claims it feels are inappropriate and the “most potentially important” (an estimated 14 a year).
- The Report noted some chemical manufacturers do voluntarily inform EPA when confidentiality is no longer necessary.
- Several companies suggested that they might be receptive to a requirement that confidentiality claims expire after five years if not reasserted and resubstantiated.

Recommendations

GAO recommended that Congress consider amending TSCA to:

- grant EPA formal regulatory authority to enter into enforceable consent agreements requiring testing;
- authorize EPA to require chemical manufacturers and processors to develop test data based on “substantial production volume” and the “necessity for testing;” and
- permit EPA to share chemical companies’ confidential business information with states and foreign governments, subject to regulations to be established by EPA in consultation with the chemical industry and other interested parties. Regulations would set forth the requirements to protect against unauthorized disclosures by recipients of the information.

GAO recommended that EPA:

- build into the HPV Challenge Program a methodology that uses collected data to prioritize chemicals for further review and to identify and obtain additional information required for risk assessment;
- promulgate a rule under section 8 of TSCA requiring chemical companies to submit to EPA the following: (i) health and safety studies; and (ii) information submitted to foreign governments concerning environmental and health effects of chemicals that companies manufacture, process, or import to the United States;
- elaborate a strategy to improve and authenticate models used to assess risk so that they can more effectively guide regulatory decisions on production, use, and disposal of chemicals; and
- require by regulation that chemical manufacturers “reassert” confidentiality claims within a certain time period after the initial claim.

1994 GAO Report Recommendations

The 2005 GAO Report included in Appendix III the recommendations from a 1994 GAO Report on TSCA.

- Reduce EPA’s evidentiary burden
 - Amend the unreasonable risk standard under TSCA section 6 for regulating existing chemicals to a “significant risk” standard.
 - Reduce the judicial review standard to review a TSCA rule from “presents or will present” to “may present.”

- Change the court standard under section 6 from a “substantial evidence” standard to more of a rational basis test.
- Amend or repeal the requirement that EPA choose the “least burdensome” regulatory requirement when regulating existing chemicals.
- Improve new chemicals review
 - Amend section 4 to require certain testing to support PMNs.
 - Grant EPA the authority to establish a minimal set of tests for new chemicals submitted with PMNs, with further tests possible on the basis of initial test results.
 - Require testing only for new chemicals before they are sold in commerce and not before they are manufactured (Report found only 1/2 of chemicals submitted for review ever make it to the marketplace).
- Implement systematic testing of existing chemicals
 - Amend TSCA to establish methodology and timeframe for testing existing chemicals similar to the one in place for new chemicals.
 - Allow for some prioritization of chemicals to be scheduled for testing.
 - The HPV program could serve as a model.
- Additional recommendations
 - Use market-based incentives, such as a pollution tax or market for emission credits.
 - Amend TSCA to allow EPA to set overall goals for reducing use of toxic chemicals.
 - Initiate mechanisms to encourage industry to use safer chemical substitutes in manufacturing process or final product.

ANNEX II: THE GAO REPORT (NOVEMBER 2005)
“CHEMICAL REGULATION: APPROACHES
IN THE UNITED STATES, CANADA, AND THE EUROPEAN UNION”

The GAO Report entitled “Chemical Regulation: Approaches in the United States, Canada, and the European Union” compares three countries’ chemical control laws: the U.S. TSCA; the Canadian Environmental Protection Act; and EU current legislation and the proposed Registration, Evaluation, Authorization and Restriction of Chemicals (“REACH”).⁶⁷ Specifically, Senators Lautenberg, Jeffords and Leahy requested information on the approaches taken by each country’s laws on: (i) controlling chemical risks; (ii) reviewing existing chemicals; (iii) assessing new chemicals; and (iv) handling confidential business information. The Report made the following observations regarding these four areas.

I. Controlling Chemical Risks

A. EPA

- The report cites sections 5(e), 5(f) and 6(a) of TSCA as examples of control actions available to EPA for new chemicals or uses of chemicals.
- With respect to section 6(a), the Report refers to *Corrosion Proof Fittings v. EPA*, 947 F.2d 1201 (5th Cir. 1991) and outlines the additional evidentiary requirements provided in the case.

B. CEPA

- Regulators can control chemicals that they determine to be toxic through a screening assessment. They may also control chemicals if the Ministers of Health and the Environment require it.
- CEPA includes a savings clause for chemicals regulated by other laws, provided the other laws require sufficient protection for the environment and human health.
- The costs and benefits of control actions are not factors considered to determine chemical risk. They are only considered as factors in determining what control action to take.
- Regulators do not have to choose the least burdensome regulatory requirement.

C. Current EU Law

- Member states draft risk assessments and submit them to a chemicals regulatory committee made up of representatives of all member states.
 - From 1993-2003, 140 chemicals were singled out for risk assessment and only a few made it through the entire process.

D. REACH

- Would require chemical companies to register all chemicals produced or imported in specified quantities per manufacturer or importer per year.
- Certain uses of registered chemicals of concern require authorization.

⁶⁷ Government Accountability Office, GAO No. 06-217R, *Chemical Regulation: Approaches in the United States, Canada, and the European Union* (November 4, 2005) (“GAO Comparative Report”).

- Chemicals of concern include: those that are carcinogenic, mutagenic, or toxic for reproduction; persistent, bioaccumulative and toxic or very persistent and very bioaccumulative; and those that cause serious irreversible effects to humans or the environment (endocrine disruptors)
- Companies using chemicals of concern or marketing them must apply for an authorization, which may be granted only if the risks to health and environment are properly controlled.
- Time limited authorization may be granted even if risks can not be adequately controlled, provided that the risks do not outweigh the social benefits.
- Downstream users of the substance may be required to notify authorities about use and must obtain any substance of concern from an authorized source.

II. Reviewing Existing Chemicals

A. TSCA

- The Report notes that TSCA does not require EPA to systematically prioritize or review existing chemicals.
 - Existing chemicals are defined as those chemicals on the TSCA Inventory.
 - Study does not mention SNURs.

B. CEPA

- CEPA does provide for the systematic categorization and review of existing chemicals.
 - Existing chemicals are those on the Domestic Substances List.
 - This list is regularly updated to include additional substances assessed under new substance provisions.

C. Current EU Legislation

- Legislation provides for prioritization of existing chemicals for assessment.
- Chemical companies must notify regulatory agencies of new uses of existing chemicals if manufactured or imported at 10,000 kg or more per year.
- Existing chemicals defined as those on the European Inventory of Existing Commercial Chemicals Substances (“EINECS”).

D. REACH

- Also includes prioritization of existing chemicals for assessment and a significant new use rule similar to the current EU version.
- Also would require manufacturers or importers to provide test data on a chemical’s physical properties and ecological and health effects.
- REACH effectively removes the distinction between existing and new chemicals.

III. Reviewing New Chemicals

A. TSCA

- PMN process

- TSCA only requires chemical companies to provide data in their possession.
- The study remarks that data on physical properties and health and ecological effects often are not available at the time of PMN submission, and EPA can not require additional testing unless it undertakes rulemaking procedures.
- Therefore, EPA often bears the responsibility to develop the test data (SAR analysis).
- EPA also considers information provided by manufacturers on anticipated potential uses and estimated exposures of new chemicals.
- New chemicals defined as those not on the TSCA inventory.

B. CEPA

- Chemical manufacturers must notify government only after a new chemical is manufactured or imported at a threshold amount.
- Chemical companies must develop and submit test data on physical chemical properties, toxicology, and exposure risks. Testing varies depending on the use or potential exposure.
- New chemicals defined as those not on the Domestic Substances List.

C. Current EU Legislation

- Same as the first two bullet points for CEPA.
- New chemicals defined as those not listed on the EINECS.

D. REACH

- Would apply the same procedures as those for existing chemicals.

IV. Confidential Business Information

A. TSCA

- EPA can not share confidential business information (“CBI”) with foreign governments (for harmonization purposes).
- EPA required to protect trade secrets and confidential commercial or financial information against unauthorized disclosures.
 - Federal agencies and contractors can obtain access to CBI to carry out government-related responsibilities.
- Health and safety data is not confidential.
- EPA can disclose other information it believes necessary to protect the environment or human health.

B. CEPA

- Sharing information with foreign governments permitted under special agreements or arrangements, provided those governments keep the information confidential.
- CBI can be disclosed if the Canadian Minister of the Environment determines that: (i) it is in the interest of public health and safety or protection of the environment; or (ii) there exists a public interest in the disclosure that either outweighs the potential financial burden or loss of competitiveness or causes damage to an individual’s privacy, reputation or “human dignity.”

- Minister must give 24 hour notice to the company of disclosure.

C. Current EU Legislation

- Companies can make confidentiality claims by indicating that the information is commercially sensitive or that disclosure would be detrimental financially or commercially to the company.
 - Exceptions include: (i) trade names for substances; (ii) certain physicochemical data; (iii) methods to “render the substance harmless;” (iv) name of the testing company and their interpretations regarding toxicological and ecotoxicological tests; (v) recommended precautions; and (vi) emergency procedures.
 - Authority determines what information qualifies for CBI.
 - Chemical companies can appeal authority decisions in court.

D. REACH

- Information not treated as confidential includes: (i) trade name of substance; (ii) physicochemical information and pathways and environmental fate; (iii) results of toxicological and ecotoxicological studies; (iv) classification and labeling requirements; (v) degree of purity of substance; (vi) identity of impurities and/or additives known to be hazardous; (vii) handling instructions; (viii) safety data sheet information (except for the name of the company).
- Confidential information includes: (i) full composition of a preparation; (ii) precise use, function and application of a substance or preparation; (iii) precise tonnage of the substance, preparation or chemical on the market; (iv) relationships between manufacturers or importers and users.
 - In cases where human health or the environment is in immediate risk, the European Chemicals Agency may disclose this CBI.
- Measure proposed that would adopt the current EU legislative provisions on industry justification of confidentiality.
- The European Chemicals Agency must inform a manufacturer of any request for documents relevant to a certain substance.
 - Company would have 30 days to identify the information it wishes to remain confidential.
 - Reason may be because it is commercially sensitive or disclosure would harm the individual or corporation commercially.