

EU Environmental Law Bulletin

A Regular Update on Legal Developments Affecting the Regulation of Pesticides, Biocides and Chemicals in the European Union

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McKenna Long & Aldridge has developed the *EU Environmental Law Bulletin* to inform and, as significant developments warrant, periodically update our clients on the most significant aspects of environmental laws in the European Union. This inaugural Bulletin is devoted to one of the most significant environmental law initiatives now undergoing development in the EU -- the so-called White Paper on a future chemicals policy.

Proposed New EU Chemicals Legislation: The White Paper

The European Union is moving forward with its **White Paper** on a *Strategy for a future Chemicals Policy*. Issued in February 2001, the White Paper sets forth the elements of a chemicals registration and testing program that, in scope and substance, will dwarf even the Toxic Substances Control Act. It presents further evidence that, in setting standards on health, safety and environmental matters that affect the interests of global businesses, the EU has surpassed the United States.

The potential impacts of EU-wide legislation patterned on the White Paper are numerous and significant. It would impose substantial testing requirements on virtually every chemical manufactured in or imported into the EU, irrespective of its current listing and status. Some estimates put the price of such testing in excess of \$9 billion. It would create a major new data generation/protection program which, among many impacts, would negatively affect both the ability of manufacturers to safeguard their R&D investments and the relationship between such manufacturers and their customers. It could, in a very real sense, drive corporate business strategies, including in R&D and global marketing decision making.

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New EU Chemicals Legislation Topical Summaries Links

This Bulletin includes links to *New EU Chemicals Legislation Topical Summaries* -- short summaries and analyses of the specific White Paper issues and requirements that present the most significant challenges to industry, which will be updated and supplemented when there are significant new developments.

1. [Scope/Exemptions](#)
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Topical Summaries can be found at www.mckennalong.com/news-advisory.html under the "European Union" heading.

Estimated Timetable of New EU Chemicals Legislation Adoption

January-February 2003: Orientation Debate in the College of Commissioners within the European Commission

February-March 2003: Publication of the Commission's **draft proposal** and **brief internet consultation**

March-April 2003: Adoption of the **final Commission Proposal**

April-May 2003: First Reading in the European Parliament and the Council

End 2003 / April 2005: Formal Adoption of the Legislation / Publication in the OJ / Direct applicability into Member States' legislation

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Summary of the EU White Paper

On 27th February 2001, the European Commission issued a White Paper on the *European Strategy for the future Chemicals Policy* (COM (2001) 88 final),* with the objective to revise and consolidate the current European Union (EU) legislation on chemicals.

The White Paper is a non-binding Community instrument designed to make public the intention of the European Commission to present new or amended requirements and to obtain the reactions of interested parties, regulatory authorities, and industry and other stakeholders. The proposed legislation will be adopted through a complicated and burdensome procedure, the so-called "co-decision" procedure, which may take up to two years until final legislation is adopted. It is expected that the legislation will be proposed in the form of Regulations, which are directly applicable in the EU Member States and do not need formal implementation.

The major change that the White Paper announces will be the introduction of the so-called **REACH** (**R**egistration, **E**valuation and **A**uthorization of **C**hemicals) system.

Registration

The Registration process will require submission of data (including test data and a preliminary risk assessment) for all substances produced or imported in the EU in yearly quantities of over 1 ton, by each producer or importer. The Registration will apply to all substances, irrespective of their marketing history or current status. The information submitted will be included in an electronic database. Under the new system, substances will be phased in gradually, starting with substances produced or imported in highest quantities.

Evaluation

All substances produced or marketed in quantities above 100 tons per year per manufacturer, and all substances presenting persistent or bioaccumulative properties, will be subject to evaluation by Member States Competent Authorities. The review may result in further testing requirements or proposed marketing restrictions.

Accelerated Risk Management

Following evaluation, Member State Competent Authorities may determine that specific substances require marketing or labeling restrictions. These will be addressed by decisions adopted through a centralized procedure at Community level.

Authorization

The production and marketing of substances classified as category 1 and 2 CMRs (Carcinogenic, Mutagenic & Reprotoxic) and as POPs (Persistent Organic Pollutants) will be prohibited unless specific uses are authorized because they are found to be of "negligible or acceptable risk". Authorization of uses may be made on a general EU-wide basis, or at the national level (for local uses).

Endocrine disruptors, PBT (Persistent, Bioaccumulative & Toxic) and vPvB (very Persistent & very Bioaccumulative) substances, and targeted respiratory sensitizers may also be subject to the same prohibitions.

Other Issues Addressed by the White Paper

Data Protection

Currently REACH proposes to create a broad database on chemicals, but does not provide for a specific and coherent data protection system. It furthermore remains unclear how the expenses linked to a specific substance or use are to be shared between the various producers and downstream users. (See [Topical Summary: Data Protection.](#))

Interplay with Existing Legislation

Existing EU legislation (such as that concerning plant protection products and biocides, or the Water Framework Directive) sets forth authorization procedures for specific regulated chemicals. The relationship between those ongoing procedures and REACH remains unclear. (See [Topical Summary: Scope/Exemptions.](#))

Downstream Users

Downstream users are not directly regulated by existing chemicals legislation, but rather by legislation of a horizontal nature that applies to specific applications. The new legislation would require downstream users to conduct risk assessments on specific uses not covered by the risk assessment submitted by the manufacturers during the registration phase. (See [Topical Summary: Manufacturers v. Downstream Users.](#))

Finished Articles

There is no definition of “article” under any of the existing chemicals legislation. Under existing guidelines established by the Member States’ Competent Authorities, however, substances included in finished articles are subject to the chemicals legislation only if they are released during the use of these articles, and there is no barrier to prevent human or environmental exposure. The new chemicals legislation is expected to clarify this issue.

The Substitution Principle

The White Paper cites as an important objective the substitution of less dangerous substances for dangerous substances where suitable alternatives are available. The potential arbitrary nature of such decisions will remain a significant concern to industry pending the establishment of specific criteria affecting the substitution principle.

Footnote

* Full text accessible on the following link: http://www.europa.eu.int/comm/environment/chemicals/0188_en.pdf

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What You Can Do Now

McKenna Long & Aldridge is currently advising several of its clients on the potential impact of the White Paper on the manufacturing and marketing of their specific products in the EU. We are assisting clients in providing greater inputs into the ongoing legislative development process, and on how the final legislation might affect their data protection and data compensation rights. For consultation on specific issues of concern to your company, please see the contact information below.

Contact Information

If you have any questions or would like more information about the above topics, please contact the McKenna Long & Aldridge attorney with whom you regularly work or any member of our [European Union Practice Group](#):

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