中国环境与发展国际合作委员会
China Council for International Cooperation on Environment and Development

# 国合会专题政策研究报告

## SPECIAL POLICY STUDY REPORT

# 中国化学品环境管理问题与战略对策初步研究

# Major Issues and Policy Framework for Environmentally Sound and Strategic Management of Chemicals in China

gtz

中国环境与发展国际合作委员会 2007 年年会

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这项专题政策的研究工作由德国技术合作公司（GTZ）“环境政策咨询”项目提供支持。

德国技术合作公司(GTZ)是一个在全世界范围内致力可持续发展的国际合作企业。她为全球的政策、经济、生态和社会发展提供前瞻性的解决方案。

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| 缩写 | 中文描述 |
|---|---|
| **ACS** | 美国化学学会 |
| **CAIR** | 综合评价信息报告规则 |
| **CCPA** | 加拿大化学生产者协会 |
| **CEC** | 欧盟委员会 |
| **ChemRTK** | 化学品知情权 |
| **CMA** | 美国化学品制造商协会 |
| **CMR** | 致癌性、致突变性和生殖毒性 |
| **COD** | 化学需氧量 |
| **EC50** | 半数效应浓度 |
| **ECB** | 欧洲化学品局 |
| **EDCs** | 内分泌干扰物 |
| **EIA** | 环境影响评价 |
| **EPA** | 美国环保局 |
| **EPA/OPPT** | EPA 污染预防和有毒物质办公室 |
| **EPCRA** | 应急计划与公众知情法案 |
| **GHS** | 化学品统一分类和标签制度 |
| **GLP** | 合格实验室规范 |
| **GTZ** | 德国技术合作公司 |
| **HCB** | 六氯苯 |
| **HPV** | 高产量化学品 |
| **HPVCP** | HPV 化学品挑战计划 |
| **HSDB** | 危险物质数据库 |
| **ICCA** | 国际化学品协会理事会 |
| **IFCS** | 政府间化学品安全论坛 |
| **ILO** | 国际劳工组织 |
| **IOMC** | 组织间化学品安全管理计划 |
| **IPCS** | 国际化学品安全规划机构 |
| **IPCS INCHEM** | 国际化学品安全规划机构化学品安全与环境管理数据库 |
| **ITC** | 部门间测试委员会 |
| **IUCLID** | 国际统一化学品信息数据库 |
| **LC50** | 半数致死浓度 |
| **LD50** | 半数致死剂量 |
| **MPD** | 上市前最低限度数据 |
| **MSDS** | 化学品安全技术说明书 |
| **NCG** | 国家协调小组 |
| **NIOSH** | 美国职业安全与卫生研究所 |

| 缩写 | 中文描述 |
| --- | --- |
| **NIP** | 国家实施计划 |
| **ODS** | 耗损臭氧层物质 |
| **OECD** | 经济合作与发展组织 |
| **PAIR** | 初步评价信息报告规则 |
| **PBT** | 持久性、生物蓄积性和毒性 |
| **PCBs** | 多氯联苯 |
| **PFOA** | 全氟辛酸 |
| **PFOS** | 全氟辛烷磺酰基化合物 |
| **PIC** | 事先知情同意 |
| **POPs** | 持久性有机污染物 |
| **PRTR** | 污染物排放和转移登记 |
| **RC** | 责任关怀 |
| **RCLG** | RC 领导小组 |
| **REACH** | 化学品登记、评估、审批法规 |
| **RTECS** | 化学物质毒性效应登记数据库 |
| **SAICM** | 国际化学品管理战略方针 |
| **SBIR** | 小型产业创新研发项目 |
| **TRI** | 有毒物质排放清单 |
| **TSCA** | 有毒物质控制法 |
| **VAs** | 自愿协议 |
| **VCCEP** | 自愿性儿童化学品评价计划 |
| **vPvB** | 高持久性、高生物蓄积性 |
| **WHO** | 世界卫生组织 |
| **WSSD** | 世界可持续发展首脑会议 |
| **WTO** | 世界贸易组织 |

# 执行摘要

1. 目前世界上大约有 700 万种化学物质，其中常用化学物质超过 7 万种，并且每年还有 1,000 多种新的化学物质问世。中国已生产和上市销售的现有化学物质大约有 45,000 种，每年申报新化学物质约 100 种。许多化学品对人类和环境有不同程度的危害，会对人类健康和生态环境产生不利影响。世界卫生组织（WHO）研究报告表明，全世界癌症发生率在近一个世纪以来猛增，每年因癌症死亡的人数达 400～500 万，占死亡总人数的 12～25%，而在造成癌症的各种因素中化学因素约占 80%。化学品环境管理已经成为世界各国关注的焦点问题。

2. 我国现有化学品环境管理基础比较薄弱。涉及化学品环境管理相关的法律法规包括《固体废物污染环境防治法》、《危险化学品安全管理条例》（以下简称《危化条例》）和《农药管理条例》；涉及的管理内容对建设项目立项、生产、储运、经营、使用、进出口、处置的整个生命周期的各环节都有规定。管理手段有强制性法律制度，也有激励企业自愿执行的政策指导。介入的部门包括环保、经贸、安全生产、海关等。尽管如此，我国对化学品的环境管理体系尚不能满足环境保护和公众健康安全要求。主要体现在（1）国家化学品环境管理方针与战略尚不够明确；（2）管理法规不完善；（3）管理机构能力不足，执法监督能力不足；（4）公众参与不足；（5）管理技术支持体系不完善，综合管理措施不足。

3. 当今的化学品管理概念综合涵盖“安全（狭义）、环境和健康”的这三个方面，可以分为：（1）化学品环境管理，（2）化学品消费者人群的健康保护管理；（3）作业场所工人职业安全和健康管理。化学品环境无害管理（Environmentally sound management of Chemicals）一词语来自 1992 年联合国环发大会通过的纲领性文件——《21 世纪议程》第 19 章，该文件提出了六大国际化学品管理战略规划，包括：（1）扩展和加快化学品风险评价；（2）统一化学品分类和标识；（3）加强有毒化学品和化学品风险的信息交流；（4）建立风险减低计划；（5）加强国家化学品管理能力；和（6）防止有毒和危险化学品的非法国际贸易。随后，国际社会建立了 IFCS 和 IMOC 这两个基础国际化学品管理组织协调机制，从安全和环境的角度管理化学品，保护生态环境与人类健康。

4. 中国环境与发展国际合作委员会具备多边国际咨询机制，能够为中国化学品污染防治政策、预警机制和治理技术提供国际化学品污染防治与管理经验的平台。曾培炎副总理在对国际合作委员会政策研究工作的要求中专门提出：“尤其在防治化学品污染方面，如何建立健全化工企业环保设施、切实加强化学品储存和运输管理、及时防范和处理化学气体液体泄漏事故等，有不少紧迫的问题需要解决。希望组织力量开展一些专题研究，提供有效的智力支持”。

5. 为全面有效的推进化学品管理制度和能力建设，把政策研究、管理和预防、预警、处理技术结合起来，在分析评估中国化学品管理制度现状、借鉴国际先进经验的基础上，为化学品管理提供重大政策建议是紧迫和必要的。

6. 本研究报告得到了德国 GTZ 和环保总局的支持，报告主要由 4 位国内专家胡建信、李政禹、刘建国、毛岩以及 3 位国际专家 Ulrike Kowalski, Silke Schmidt 和 David van Hoogstraten 编写完成。报告编写过程多次征求了相关利益方的意见，通过召开交流讨论会、咨询等，听取了来自国内有关部门、相关行业、企业、非政府组织、公众以及国内外有关专家的意见，并做出相应修改。

7. 本报告有关中国化学品环境管理政策和制度的框架建议如下：

## 1 制定国家化学品环境管理战略方针

8. 所有未来的化学品环境管理措施应当成为国家政策方针的一部分。 **建议:** （1）中国的化学品环境管理战略首先应明确国家化学品环境管理的基本方针、原则、政策及总体战略目标，其中应综合考虑“预先防范”原则与中国化学工业生产和使用情况的基本国情，制定合理的战略目标。（2）战略需要和科学发展观相一致。推行循环和回收使用，保护环境，营造一个资源节约型和环境友好型社会，清洁和安全发展应该纳入在这个战略中。（3）化学品的生产和管理需要遵循清洁生产和绿色化学的理念。（4）如果经济可行性是可行的，对人体健康和环境具有高风险的化学品应该首先被替代。（5）中国的化学品管理战略应建立一项国家化学品环境管理能力建设规划，包括立法体系、机构职能、管理技术支持体系、信息交流和公共参与等机制建设等。（6）中国的化学品管理战略应包含一项长期但有时限的对国内现有化学物质风险评价与风险管理行动计划，遵循特定的优先原则和行动步骤，逐步收集现有化学物质固有危险性信息，开展风险评价和风险管理，并逐步减少和淘汰那些具有对环境和人类健康具有无非接受风险的化学品的生产和消费的化学品，最后但并非最不重要的一点是实现中国的环境友好型环境。所选择的战略必须顺应 WTO 的要求。（7）为了化学品环境管理战略的顺利制定，应该基于环境和人类健康保护的部门建立一个国家协调机构来确保战略能够体现利益相关方的利益。

## 2 制定专门的化学品环境管理法律或行政条例

9. 根据当前国情，建议制定一部化学品环境管理专项法律或行政条例，填补国家现行化学品环境管理立法体系在化学品环境管理方面存在的空白。**建议:**化学品环境管理法律或行政条例应与风险管理的理念相一致，制定建立危害测试要求，采取全球化学品统一分类和标签制度对化学品进行分类和标识，从而有助于化学品的有效的风险评价和风险管理，包括针对新的毒性和生态毒性测试的合格实验室规范的要求，建立一整套化学品危害性测试、评价与分类等科学标准为管理工具，建立和完善以新化学物质申报登记、现有化学物质风险评价与风险管理、有毒化学品排放与转移登记、公共知情与参与、重大环境事故防范与应急等为基本制度的化学品环境管理制度体系，并与现行的危险化学品安全管理和公共卫生管理相关立法相协调。

## 3 需优先进行的化学品环境管理基本制度建设

10. 需优先进行的化学品环境管理基本制度包括：（1）全面推行 GHS 化学品分类和标签制度；（2）提升和完善新化学物质申报登记制度；（3）建立现有化学品风险评价与风险管理制度；（4）建立高度关注的优先化学品的国家标准；（5）建立有毒化学品排放登记及公众知情制度；（6）建立优先有毒化学污染物质排放监测制度；（7）完善重大危险源登记与报告制度；（8）引进和优化化学品审查机制，关注高风险化学品的健康和环境影响。

## 4 能力建设

11. 化学品环境管理现有国家行政职能和机构建设 （1）通过建立各级国家化学品管理部门间的协调机制，建立起国家化学品环境管理行政执法和监督管理体系；（2）通过增加相关各级部门的职能提高国家环保总局在中国化学品管理体系中的地位；（3）建立健全国家和地方环保机构中化学品环境管理的机构及其职能，包括增设相关管理部门和管理人员；（4）加强相应管理设施建设和人员培训。

12. 国家化学品信息系统建设 （1）以新化学物质申报登记制度、现有化学物质风险评价与风险管理制度、优先有毒化学品环境监测、有毒化学污染物排放统计和重大危险源登记和报告等化学品环境管理制度为基础，集中收集、整理和发布国家化学品环境和健康风险的各种相关信息，并且注意商业机密的保护。（2）整合与现有化学物质和新化学物质以及职业健康与安全相关的国家现有化学物质信息资源和管理系统。（3）进一步增强化学品的国际间信息交流。

13. 国家化学品测试和评价科研与监测能力建设（1）建立符合OECD/GLP准则的化学品测试与评价实验室，引进GLP监测和其他制度，例如数据互认，增加化学品环境和健康危害性测试的能力。（2）推动环境与健康监测及风险评价方面的基础科研与监测能力建设，尤其是针对某些优先性高风险有毒化学品。（3）积极开展化学品危害测试及风险评价相关的国际合作，学习和采纳国际化学品风险评价方法，不断提高自身相关能力。

## 5 推动构建国家化学品环境公共治理体制

14. 建立自愿性化学品风险控制保障制度和鼓励政策 （1）鼓励与化工协会交流，在中国实施VA，RC以及产品管理制度，并建议在《清洁生产促进法》现有规定的基础上，研究和制定一系列相关配套政策和管理措施，从而推动化学品环境管理的VA及RC实践在中国的逐步开展。（2）通过立法、过程控制和绩效审核来提高VAs的执行效果。

15. 加强化学品环境管理的信息公开及公共参与机制建设 （1）通过发布有

毒化学品污染排放及环境监测报告等方式，增进国家化学品环境和健康风险信息的公开与交流。开展有毒化学品环境和健康风险公众宣传与教育。建立公共参与机制，使社会各利益相关方能够参与政府化学品环境管理决策，符合当今化学品环境管理的国际发展潮流。

# 1 导言

## 1.1 化学品应用及其危害

1. 目前世界上大约有 700 万种化学物质，其中常用化学物质超过 7 万种，并且每年还有 1,000 多种新的化学物质问世。中国已生产和上市销售的现有化学物质[1]大约有 45,000 种，每年申报新化学物质约 100 种。化学品是现代社会不可缺少的生产资料和消费品，并作为医药、农药、化学肥料、塑料、纺织纤维、电子化学品、家庭装饰材料、肥皂和洗衣粉、化妆品、食品添加剂等广泛应用。但是，许多化学品对人类和环境有不同程度的危害，在其生产、存储、销售、运输、使用以及作为废物处置的整个生命周期过程中，由于误用、滥用、化学事故或处理处置不当，会对人类健康和生态环境产生不利影响。

2. 对化学品环境和健康危害的认识经历了一个漫长的过程。随着人类文明的发展，化学品的大量生产和广泛应用产生了区域和全球性的环境和健康危害，如持久性生物累积性有毒化学品问题、内分泌干扰物质问题、危险化学品泄漏事故问题、危险废弃物的跨国转移和处置问题、臭氧层消耗物质问题等。此外，生产生活过程中无意产生的有毒有害化学污染物的危害也有显现，如二恶英的污染问题。自 1960 年代开始的研究逐渐发现并证实，为数众多的人工合成的有机化学品在流入环境后，对鱼类、鸟类、爬行类和哺乳类野生动物的内分泌功能产生干扰作用，导致野生动物种群雌性化和生殖繁衍衰竭等现象。世界卫生组织（WHO）研究报告表明，全世界癌症发生率在近一个世纪以来猛增，每年因癌症死亡的人数达 400～500 万，占死亡总人数的 12～25%，而在造成癌症的各种因素中化学因素约占 80%。化学品环境管理已经成为世界各国关注的焦点问题。

## 1.2 中国对化学品环境管理的需求

3. 随着传统环境污染问题的逐步解决，中国对化学品环境问题的管理需求正在逐步提高。

### 1.2.1 政府执政观念改变

4. 中国政府在 2006 年已经明确提出要努力实现三个转变：一是从重经济增长轻环境保护转变为保护环境与经济增长并重，把加强环境保护作为调整经济结构、转变经济增长方式的重要手段，在保护环境中求发展；二是从环境保护滞

[1] 现有化学物质指列入《中国现有化学物质名录》的化学物质。新化学物质指未列入《中国现有化学物质名录》的化学物质。

后于经济发展转变为环境保护和经济发展同步，做到不欠新账，多还旧账，改变先污染后治理、边治理边破坏的状况；三是从主要用行政办法保护环境转变为综合运用法律、经济、技术和必要的行政办法解决环境问题，自觉遵循经济规律和自然规律，提高环境保护工作水平。在《国务院关于落实科学发展观加强环境保护的决定》中第五部分关于建立和完善环境保护的长效机制明确指出，要健全有关化学物质污染控制的环境法规和标准体系。

### 1.2.2 调整产业结构适应经济发展、可持续发展的需要

5. 根据《国民经济和社会发展第十一个五年规划纲要》（以下称《规划纲要》），中国将加快转变经济增长方式。要把节约资源作为基本国策，发展循环经济，保护生态环境，加快建设资源节约型、环境友好型社会，促进经济发展与人口、资源、环境相协调。要求推进国民经济和社会信息化，切实走新型工业化道路，坚持节约发展、清洁发展、安全发展，实现可持续发展。《规划纲要》中关于“调整化学工业布局”等章节明确了实施上述战略目标有关化学品产业结构调整的具体要求，强调基地化、大型化、一体化方向，强调优化发展基础化工原料，积极发展精细化工，淘汰高污染化工企业等。

### 1.2.3 国际环境保护形势的要求

6. 随着科学技术的进步和传统环境问题的逐步解决，化学品生命周期过程中产生的环境和健康问题成为国际社会关注的焦点，化学品管理已经成为世界各国环境和健康领域管理的重点内容。发达国家不仅从 1970 年代就制定了化学品管理相关法律，逐步完善化学品管理体系；并促使联合国相关机构在全球范围逐步建立和实施了《关于作业场所安全使用化学品的公约》、《关于防止重大工业事故公约》、《关于控制危险废物越境转移及其处置巴塞尔公约》、《关于在国际贸易中对某些危险化学品和农药采用事先知情同意程序的鹿特丹公约》、《关于持久性有机污染物的斯德哥尔摩公约》、采用《全球化学品统一分类和标签制度》以及制定《国际化学品管理战略方针》等[2]。目前，包括中国在内的广大发展中国家，化学品管理与发达国家存在很大的差距。而作为实现可持续发展的必要条件，化学品的环境管理已经成为发展中国家，尤其是世界化学品生产和消费大国的中国，经济发展和社会进步的必然要求和紧迫任务。

[2] 《关于防止重大工业事故公约》、《关于控制危险废物越境转移及其处置巴塞尔公约》、《关于在国际贸易中对某些危险化学品和农药采用事先知情同意程序的鹿特丹公约》、《关于持久性有机污染物的斯德哥尔摩公约》、《全球化学品统一分类和标签制度》和《国际化学品管理战略方针》分别简称：174 公约、巴塞尔公约、鹿特丹公约、斯德哥尔摩公约、GHS，和SAICM。

### 1.2.4 国际贸易的要求

7. 中国目前已经成为世界上最大的出口国之一，对外贸易已经成为国内 GDP 增长的重要推动力。然而，近年来发达国家实施日益严格的“技术性贸易壁垒（TBT）”阻止或限制我国产品出口问题越来越突出，尤其是关于化学品残留所引发的“绿色壁垒”。据商务部调查，仅在我国加入 WTO 的第一年 2002 年，我国农产品等六大行业的出口因技术壁垒的限制严重受挫，当年中国有 71%的出口企业、39%的出口产品遭到国外技术壁垒的限制，造成损失约 170 亿美元，相当于当年出口额的 5.2%，其中，近 90％的食品土畜类出口企业受限，造成损失约 90 亿美元。此外，中国关于食品、饲料等商品中化学物质污染的相关法规和标准不完善，不利于人类健康和动植物保护。

### 1.2.5 化学品环境管理存在问题

8. 我国现有化学品环境管理基础比较薄弱。涉及化学品环境管理相关的法律法规包括《固体废物污染环境防治法》、《危险化学品安全管理条例》（以下简称《危化条例》）和《农药管理条例》；涉及的管理内容对建设项目立项、生产、储运、经营、使用、进出口、处置的整个生命周期的各环节都有规定。管理手段有强制性法律制度，也有激励企业自愿执行的政策指导。介入的部门包括环保、经贸、安全生产、海关等。尽管如此，我国对化学品的环境管理体系尚不能满足环境保护和公众健康安全要求。主要体现在（1）国家化学品环境管理方针与战略尚不够明确；（2）管理法规不完善；（3）管理机构能力不足，执法监督能力不足；（4）公众参与不足；（5）管理技术支持体系不完善，综合管理措施不足。

## 1.3 化学品的环境管理范畴

9. 当今的化学品管理概念综合涵盖“安全（狭义）、环境和健康”的这三个方面，可以分为：（1）化学品环境管理，（2）化学品消费者人群的健康保护管理；（3）作业场所工人职业安全和健康管理。化学品环境无害管理（Environmentally sound management of Chemicals）一词语来自 1992 年联合国环发大会通过的纲领性文件——《21 世纪议程》第 19 章，该文件提出了六大国际化学品管理战略规划，包括：（1）扩展和加快化学品风险评价；（2）统一化学品分类和标识；（3）加强有毒化学品和化学品风险的信息交流；（4）建立风险减低计划；（5）加强国家化学品管理能力；和（6）防止有毒和危险化学品的非法国际贸易。随后，国际社会建立了IFCS和IMOC[3]这两个重要的国际化学品管理组织与协调机制，从安全和环境的角度管理化学品，保护生态环境与人类健康。

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[3] 政府间化学品安全论坛（Intergovernmental Forum on Chemical Safety） 和the Inter-Organization Programme for the Sound Management of Chemicals组织间化学品安全管理计划

### 1.4 本研究任务来源与目标

10. 中国环境与发展国际合作委员会具备多边国际咨询机制，能够为中国化学品污染防治政策、预警机制和治理技术提供国际化学品污染防治与管理经验的平台。曾培炎副总理在对国际合作委员会政策研究工作的要求中专门提出：“尤其在防治化学品污染方面，如何建立健全化工企业环保设施、切实加强化学品储存和运输管理、及时防范和处理化学气体液体泄漏事故等，有不少紧迫的问题需要解决。希望组织力量开展一些专题研究，提供有效的智力支持”。为全面有效的推进化学品管理制度和能力建设，把政策研究、管理和预防、预警、处理技术结合起来，在分析评估中国化学品管理制度现状、借鉴国际先进经验的基础上，为化学品管理提供重大政策建议是紧迫和必要的。

11. 本研究的主要目标是识别我国化学品环境管理的基本状况及存在的主要问题、分析未来管理需求，评述国外管理状况和经验，提出我国化学品环境管理的制度安排和政策框架建议。

### 1.5 本报告起草

12. 本研究得到了德国 GTZ 和环保总局的支持，报告主要由胡建信、李政禹、刘建国、毛岩以及 3 位国际专家 Ulrike Kowalski, Silke Schmidt 和 David van Hoogstraten 编写完成。报告编写过程多次征求了相关利益方的意见，通过召开交流讨论会、咨询等，听取了来自国内有关部门、相关行业、企业、非政府组织、公众以及国内外有关专家的意见，并做出相应修改。

## 2 中国化学工业和化学品环境问题

### 2.1 中国化学工业概况

13. 随着经济的快速增长，中国化学工业蓬勃发展，中国现已成为世界化学品生产和消费大国。2000 以来，中国化学工业总产值年平均增长率在 30%左右。中国现已经形成了门类比较齐全、品种大体配套、基本可以满足国内需要、部分行业自给和有余产品出口的化学工业体系，根据国民经济分类国家标准（GB/T4754-2002）划分，中国化学工业由化学矿、基础化学原料、肥料、农药、涂料，油墨和颜料、合成材料、专用化学产品、橡胶制品以及化工专用设备制造业十个化工行业组成。其中，基础化学原料和合成材料分别占中国化工总产值的 20%，专用化学产品、橡胶制品和肥料则各约占 10～15%，上述五类化学品生产行业合计占中国主要化工行业总产值的 85%[4]。2005 年中国化学工业总

[4] 中国化学工业年鉴，2005/2006。

产值达到 21164.8 亿元（2576.6 亿美元），占全国工业总产值的 8.4%；2005 年全国化工进出口总额达到 1335.61 亿美元。其中，化工出口额为 480.63 亿美元，进口额为 854.98 亿美元。职工人数约 410 万，共有相当规模各类化工企业 21,000 多家（年销售收入在 500 万RMB以上者），其中小型企业占 90％以上[5]。

14. 目前，中国有 20 余种化学品的产量和消费量居世界前列，其中：硫酸、化肥和染料的产量及合成纤维生产能力居世界第一，农药和涂料的产量分别居世界第二和第三，主类合成树脂和合成橡胶的生产能力居世界第四，农药和合成橡胶等多种化学品消费量位居世界第一[6,7]。据OECD组织估计，全球化学工业的年增长幅度将在 2.6~3.5%之间，预计到 2020 年全球化学工业产值将比 1996 增长 85%，其增长量将主要来自发展中国国家。按照中国经济发展态势，中国未来化学品的生产和消费仍将保持快速增长趋势，并对世界化学品生产和消费产生显著影响。

15. 全国化工企业主要分布在华东地区（上海市，江苏省，浙江省，安徽省，福建省，江西省，山东省）、华中地区（河南省，湖北省，湖南省，广东省，广西壮族自治区，海南省），两者合计占化工企业总数的 71%以上。近年来面对环境保护和产业结构调整的双重压力，中国化工企业开始向集团化、大型化转化、改组,形成了许多化工企业集中生产的化学工业园区。目前中国经省级以上政府批准设立的化学工业园区已超过 60 个。各化工园区主要集中生产精细化工、化工制药、新材料等产品。

16. 化学品生产和使用涉及的行业和部门十分广泛，包括医药、农药、化学肥料、塑料、纺织纤维、电子化学品、家庭装饰材料、肥皂和洗衣粉、化妆品、食品添加剂等行业，涉及到国民经济各产业部门以及人民群众日常生活领域。

## 2.2 中国化学品环境问题概况

17. 中国作为一个发展中国家，某些化工行业和企业的生产工艺技术及化学品风险管理水平明显落后于发达国家，特别是对大量中小企业来说更是如此。这也预示着中国面临十分严峻的化学品环境污染及其生态和健康风险形势。截至 2005 年，中国生产或者进口的现有化学物质已达 45,000 多种，有些国际上和发达国家已禁止或严格限制的危险化学品目前国内仍在生产和使用。

18. 现有科研监测显示，由于滴滴涕等有机氯杀虫剂的持续生产和应用，在国

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[5] 同上。

[6] 屠豫钦，加入世界贸易组织前夕的中国农药行业，世界农药，2001。

[7]冯世良（中国石化协会），2005 年中国石油和化工行业经济形势和展望，中国石油和化学工业经济分析，2005。

际普遍禁用此类POPs[8]杀虫剂近 30 年后，中国珠江三角洲地区沉积物中滴滴涕等有机氯污染物的浓度仍然高于国外风险评价标准，可列为高风险生态区；中国一些地区的茶叶和鱼类、贝类等水产中滴滴涕、六六六等POPs的污染浓度依然较高，母乳中滴滴涕、六六六等POPs的含量仍然显著高于发达国家以及国际组织相关标准。由于有机锡在船舶油漆中的广泛应用，这类重要的EDCs（内分泌干扰物）类物质在中国内陆水域和海滨港口存在着较为严重的污染；因含有壬基酚聚氧乙烯醚等表面活性剂的合成洗涤剂的广泛使用，京杭大运河及江南江湖水中均存在一种典型的EDCs类污染物——壬基酚污染，浓度高于国外报道，并且在上海市自来水中也检测出壬基酚。近年来，在长江下游监测显出大量的有毒有机污染物,其中PCBs、六氯苯、林丹等POPs类物质的检出率达到或接近 100％；在三峡库区重庆段水域中检测出难降解有机污染物 178 种[9]，其中有 18 种属于美国国家环保局（EPA）优先控制污染物黑名单所列物质，某些具有EDCs作用的有机化合物的检出率较高。

19. 中国近年来有毒化学品环境污染事故日益频发。全国环境统计公报显示，2005 年全国共发生环境污染与破坏事故 1,406 起，其中：水污染事故 693 起；大气污染事故 538 起；海洋污染事故 19 起；固体废物污染故 48 起；其他污染事故 108 起。污染与破坏事故直接经济损失 10,515 万元（未包括松花江事件）。环境污染受害面积达到 4,691 万㎡，其中，农作物受害面积 4,318.91 万㎡；鱼塘 345.53 万㎡；自然保护区 26.68 万㎡。2005 年 11 月 13 日，中石油吉林石化分公司双苯厂发生爆炸事故，共造成 6 人死亡、60 多人受伤，紧急疏散群众 10,000 多人。爆炸造成约 100t 苯类物质流入松花江，造成了松花江及其下游水体严重污染，沿岸数百万居民的生活受到影响。

20. 另据统计，2002 - 2004 年北京、成都、重庆、广州、哈尔滨、南京、青岛、上海、沈阳、武汉、西安和郑州等 12 个城市共计发生非爆炸品类危险化学品事故 435 起。事故共计造成 189 人死亡、390 人受伤和 962 人中毒。在 435 起危险化学品事故中,有 70 起发生在临近城市居民区的生产企业内部,造成大量人员伤亡和中毒和人员疏散。例如，2004 年 4 月 16 日重庆天原化工总厂发生氯气罐爆炸事故,导致重庆市江北区事故附近居住的 15 万居民被迫紧急转移,给城市正常的秩序和城市居民生活造成严重影响。

21. 现有信息表明，中国的化学品环境问题已日趋严重，全社会正面临着日益加剧的化学品环境和健康风险。

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[8] Persistent Organic Pollutants, 持久性有机污染物

[9] 难降解有机污染物包括

# 3 中国化学品安全和环境管理现状和存在问题分析

## 3.1 中国化学品安全和环境管理立法现状

22. 中国相继颁布了一系列涉及环境保护、危险化学品、农药、医药品、兽药等安全管理的法律、行政法规。在此基础上,国务院相关部委分别制定了相应的法规及部门规章，对法律的具体实施做出了详细的规定，如附件 1 中表格 1 和表格 2 所示.中国还颁布了一系列危险化学品分类、储存、运输、包装与标志等安全标准、控制化学污染物排放、危险废物处理等环境标准以及职业卫生标准。

23. 中国已经建立了国家与地方各级危险化学品安全和环境无害管理的监督管理机构。中央政府涉及化学品安全和环境管理的国务院主要部委有：环保总局、安监总局、卫生部、药监局、农业部、质检总局、交通部、铁道部、民航总局、公安部。详见附件 2.

24. 根据国家相关法律、法规和国务院授权，国家发展和改革委负责制定有利于环境保护的产业政策，包括资源节约和综合利用政策、清洁生产和循环经济政策、限制或淘汰落后的工艺技术、装备和产品的政策，推进可持续发展战略以及部分农药产品生产许可批准文件的审核发放工作；外交部负责化学品的国际谈判及组织履约事项等工作；海关总署负责受控制危险化学品进出口审核验放工作；商务部、科技部等部委负责化学品进出口贸易以及化学品及其污染防治技术研究开发等。

25. 环保总局设有固体废物与有毒化学品管理部门专门负责制定与执行固体废物（尤其是危险废物）、化学品的环境管理政策、法规、标准，负责实施危险废物经营许可、有毒化学品进出口环境管理登记、新化学物质生产前和进口前申报登记等审批工作。环境监察局负责指导和协调解决各地方、各部门以及跨地区、跨流域的重大环境问题；组织建立重大环境污染事故和生态破坏事件的应急预案，以及突发性事件的环境应急处理等工作。国际合作司负责环境公约的对外谈判和与外交部联系，对口管理有关化学品环境公约的履约工作。

26. 此外，国务院相关部委均下设专门的管理和技术支持机构，如环保总局化学品登记中心和固体废物管理中心。在各自主管部门的直接指导下，这些机构负责新化学物质申报登记、有毒化学品进出口环境管理登记；危险化学品安全登记、农药登记等。

27. 中国地方各级也设有危险化学品安全和环境管理的监督管理机构。各省（自治区、直辖市）、设区的市级和县人民政府的环境保护局（厅）、安全生产局、卫生厅局、农业厅局、质量技术监督局等地方主管部门分别负责本辖区地方危

险化学品和农药等化学品的安全与环境保护监督管理工作。

28. 地方政府工作部门与上级政府对口部门之间的关系绝大多数属于业务指导关系。例如，县级以上人民政府设有地方环境保护局，他们接受同级政府的领导，并接受上级环境保护主管部门的业务指导。地方政府环境保护局下也有直属的环境监测站和环境科学研究所。

29. 在危险化学品安全管理方面，中国通过《危化条例》的授权，确立了一个由多部门分工负责的国家危险化学品管理体制框架，覆盖危险化学品的生产、经营、储存、运输、使用和废物处置全过程。为了协调国务院相关部委对危险化学品安全的监督管理，经国务院批准，2007 年 6 月中国建立了危险化学品安全生产监管部际联席会议制度。该机构成员单位包括：安监总局、发展改革委、公安部、监察部、建设部、铁道部、交通部、工商总局、质检总局、环保总局、民航总局、全国总工会、劳动保障部、卫生部、国资委、国务院法制办等 16 个与危险化学品安全监管相关的国务院部委。各成员单位按照职责分工，主动研究涉及危险化学品安全管理的有关问题；通过联席会议制度，建立危险化学品安全监管部门联合执法机制以及情况通报、信息共享机制。

30. 此外，中国政府还组建了由环保总局、外交部、发展改革委、科技部、财政部、建设部、商务部、农业部、卫生部、安监总局、质检总局等 13 个部委为成员单位的“国家履行斯德哥尔摩公约工作协调组”，负责审议和执行国家 POPs 管理和控制的方针和政策，协调国家 POPs 管理及履约方面的重大事项。

### 3.2　中国主要环境和安全管理制度及其实施情况

31. 全国人大常委会和国务院颁布了对药品、化妆品、食品和食品添加剂、饲料和饲料添加剂、农药等专用化学品管理法律法规，针对专用化学品的安全审查和生产许可制度如附件 1 表格 3 所列。其他用作为工业原材料和日用化学品生产原料的工业化学品目前主要根据国务院颁布的《危化条例》进行监管。

32. 自 1994 年 5 月起，中国开始实施有毒化学品进出口环境管理登记制度。环保总局将列入《鹿特丹公约》管制名单上的有毒化学品列入了《中国禁止或严格限制的有毒化学品目录（第一批）》，实施进出口环境管理登记，并对相关进出口国家履行了 PIC 程序。2005 年 6 月，为履行《鹿特丹公约》、《斯德哥尔摩公约》，环保总局与海关总署联合发布了《中国禁止或严格限制的有毒化学品目录（第二批）》，将公约新增有毒化学品（7 种）增补进管理目录，纳入进出口环境管理的范围，自同年 7 月 10 日起实施。2005 年 12 月，环保总局和海关总署联合发布的 2005 年第 65 号公告《中国严格限制进出口有毒化学品目录》，将限制管理的有毒化学品品种由 34 种增加到 188 种，自 2006 年 1 月 1 日起实施。

33. 为了从源头上预防和控制工业化学物质对人类健康和生态环境造成的危害和环境风险，2003 年 10 月 15 日环保总局颁发并实施了《新化学物质环境管理办法（第 17 号令）》，开始对新化学物质实施生产或进口前申报登记。在对新物质的健康和环境危险性鉴别和审查评价的基础上，对符合危害性评估标准的新物质，批准登记并许可其生产和进口，而对具有高健康和环境风险的化学物质采取禁止或限制其生产和使用等措施。

34. 新化学物质登记制度实施的三年多来，环保总局组织编制和更新了《中国现有化学物质名录》[10]。该名录经过 5 次增补和更新，目前已经收录 45,000 多种化学物质的标识信息。

35. 为了鉴别和评价新化学物质的危险性和环境风险，环保总局组建了由国内化学、毒理学与生态毒理学、环境科学和安全科学领域的技术和管理专家组成的新化学物质评审专家委员会，依据《新化学物质危害评估导则（HJ/T154-2004）》对申报的新物质的物理、健康和环境危害性和环境风险进行鉴别评价，提出科学管理的决策建议。

36. 在化学品生产建设项目的环境管理中，中国在严格工业建设项目环境影响评价管理以及加强突发环境事件应急能力方面也取得较大进展。多年来，全国大中型化工建设项目环境影响评价报告书（表）执行率保持在 98%以上。2005 年以来，环保总局在审批石化建设项目环境影响评价中，要求项目选址应当满足国家产业政策、规划和环保要求，并选择环境友好型生产技术路线和产品方案。同时为确保项目所在地区环境质量满足功能区规划，要求新建项目实施污染物区域削减，改扩建项目实行“以新带老”，总体上达到“增产不增污”或“增产减污”。

37. 鉴于 2005 年 11 月中国吉林石化双苯厂爆炸导致松花江发生严重环境污染事件的经验教训，环保总局下发了《关于加强环境影响评价管理，防范环境风险的通知[环发（2005）152 号]》,要求加强化工、石化行业的规划环评，从决策源头防范环境风险，严格项目审批，加强建设项目环境风险评价管理，同时全面排查、补充完善环境风险防范措施。

38. 根据 2005 年国务院颁发《国家突发性环境事件应急预案》，环保总局环境监察局组织制定了相关应急工作程序，并指导省级环保部门制定完善地方环境应急预案和应急体系。

39. 此外，2002 年以来国家安全生产监管总局依据国务院《危化条例》的规定，

[10] 现有化学物质是指被中国生产或进口并且已经被《中国现有化学品名录》收录的化学物质。

在对危险化学品生产、储存建设项目进行安全评价基础上，对危险化学品的生产、储存、经营企业实行安全生产许可证、经营许可证制度和安全登记制度。对列为重大危险源的危险化学品设施建立了事故应急预案和报告制度，并组建了全国危险化学品安全生产应急救援指挥中心和地方应急救援中心。

3.3　化学品管理名单和管理重点

40. 据环保总局颁布《新化学物质环境管理办法》规定，1992-2005 年期间中国国内已经生产或进口并列入《中国现有化学物质名录》的化学物质有 45,000 多种。根据国务院《危化条例》规定，目前列入安监总局编制的《危险化学品名录（2002 年版）》的危险化学品大约 3,700 种。

41. 此外，截至 2006 年 9 月统计，国务院相关部委依法颁布的各类安全和环境监管化学品名单中受控化学品数量大约 1,000 多种（见附件 1 表 4）。

42. 根据国务院《危化条例》的规定，中国危险化学品安全管理对象是列入《危险货物品名表》的危险化学品；剧毒化学品以及构成重大危险源的危险化学品生产和储存设施等。关注的重点对象是具有爆炸性、易燃性、氧化性、腐蚀性以及急性毒性的危险化学品。

43. 环保总局对化学品的环境管理侧重于化学品生命周期过程中化学污染物排放和泄漏污染环境后的末端污染治理和处理处置，以及有毒化学品的进出口和新化学物质的环境管理。

3.4　化学品管理技术支持体系情况

44. 在国家和地方环保、卫生、农业、质检、工业、科技和教育等部门隶属下，全国建有数以千计从事化学污染物环境监测、农药残留监测和农药替代品的研究开发、标准制订、污染防治、疾病和中毒预防、信息管理等领域研究的国家和地方的研究机构，他们为政府主管部门化学品安全和环境管理决策提供技术支持。

45. 中国的环境监测已经形成了总站、省站、市站和县级站的四级的监测管理体系。其中，国家和省级环境监测中心（站）配备有先进大型分析仪器，拥有较强专业技术人员和化学污染物分析检测能力。

46. 目前中国已经建立了一批从事化学品理化、毒理学和生态毒理学数据测试的实验室。这些实验室大都隶属于国务院相关主管部门的科研机构或者大型企业。

47. 环保总局系统建有中国环境科学研究院国家环境保护化学品生态效应与风险评估重点实验室等 8 个生态毒理学测试实验室，可从事水生毒性、生物降解性和生物蓄积性等环境危险性测试评价工作。

48. 卫生部和国家食品药品监督管理局系统建有中国疾病预防控制中心职业卫生与中毒控制所等 25 个健康毒理学测试实验室，可从事药品、化妆品和其他化学品的急性毒性、慢性毒性、致癌性、致突变性、生殖毒性、安全性药理试验和毒代动力学试验等测试项目。

49. 农业部系统建有农业部农药检定所生物技术研究测试中心等几百家实验室组成的农药测试实验室体系，可从事农药残留、农药毒理学、环境毒性、农药药效和生物学测试等测试评价项目。

50. 质检总局系统也建有中国检验检疫科学研究院工业品检验研究所等一批从事工业品、化妆品、电子电器产品和食品等中有毒有害物质检测评价实验室，并正在组建 10 个化学品燃烧、爆炸和氧化性等理化危险性检测实验室。

51. 在化学品测试实验室(GLP)认证和监管方面，中国各主管部门各自对本系统的化学实验室进行管理。例如，2004 年国家环境保护总局参照《OECD 化学品测试准则》和《合格实验室规范原则（GLP)》，颁布了《化学品测试导则——化学品测试方法(HJ/T153-2004）》和《化学品测试合格实验室导则（HJ/T155-2004)》行业标准，并着手开展本系统内生态毒理学实验室管理和合格实验室 GLP 检查工作。

52. 2006 年 11 月国家食品药品监督管理局发布《关于推进实施药物非临床研究质量管理规范的通知》，要求自 2007 年 1 月 1 日起，对未在国内上市销售的化学原料药及其制剂、生物制品、中药注射剂的新药的非临床安全性评价研究必须在通过 GLP 认证的实验室进行。否则，其药品注册申请将不予受理。同时发布了 22 家已经通过医药品 GLP 检查认证的实验室名单。

53. 农业部于 2003 年颁布了《农药毒理学安全性评价良好实验室规范》，并于 2006 年 11 月发布实施了《农药良好实验室考核管理办法（试行)》，开始对农药测试实验室推行 GLP 检查和考核。

54. 卫生部于 2001 年颁布了《化学品毒性鉴定管理规范》，对从事化学品毒性鉴定机构和鉴定工作提出了规范性要求，但是对其监管的化妆品的安全评价实验室和毒理学测试实验室未进行 GLP 认证管理。

55. 2006 年国家认证认可监督管理委员会颁布实施了《实验室能力验证实施办

法》和《实验室资质认定评审准则》。参照国际标准《检测和校准实验室能力的通用要求(ISO/IEC17025：2005)》和国家标准《检测和校准实验室能力的通用要求（GB/T15481：2000）》等，开始对从事向社会出具具有证明作用的数据和结果的实验室的能力资质的计量认证等的评审认定。认定内容包括：组织机构、管理体系、文件控制、管理要求以及技术要求等。

56. 中国的化学品测试和合格实验室评定、审查认证与监管未完全采用国际通用的《OECD 化学品测试准则》和《合格实验室规范（GLP）原则》等管理规范，大部分化学品测试实验室的测试方法、管理程序和管理要求是否符合国际管理规范要求尚有待调查评定。中国化学品测试实验室能力的评审认定管理尚处于起步阶段，实验室测试能力和管理工作不能满足国内化学品安全和环境管理的需要。因此，化学品测试结果尚不能被其他国家相互认可和接受。

# 4 发达国家化学品环境管理制度和国际化学品环境管理行动

57. 在滴滴涕和 PCBs 等化学品造成严重环境和健康问题的影响下，上世纪 70～80 年代，世界发达国家普遍建立了具有显著环境管理特征的专门性化学品管理法；并在此基础上逐步建立了以化学品的风险评价与风险管理为基本框架的化学品环境管理制度体系，其核心内容是对新生产、进口或入市的所谓新化学物质进行申报、评估与审查，对市场现有化学物质按照特定的优先原则和顺序进行危害测试、风险评价和风险管理。同时，发达国家还在化学品生命周期的各主要环节建立起有害化学品的环境污染控制、污染事故防范和污染事故应急预案等多项基本化学品环境管理制度，控制有害化学品的环境和健康风险。鉴于现有化学物质危害和风险信息收集、评价与风险管理进程的缓慢，进入 21 世纪初以来，为了加速现有化学物质危害和风险信息的收集、评估和风险管理的进程，发达国家进一步改革现有化学品的风险评价与风险管理制度，推行以“预先防范原则”和扩大化学品生产厂商的风险责任为主要内容的化学品测试、评价和优先性化学品风险管理制度，如欧盟 REACH 法规。此外，还探索和实施了许多新的化学品环境管理的有效手段，以加快现有化学物质的危害、风险评价进程，不断识别、筛选和淘汰 PBT 类化学品和其他具有高环境风险的危险化学品。

## 4.1 发达国家化学品环境管理的基本制度体系

### 4.1.1 新化学物质申报登记制度

58. 新化学物质申报制度是化学品环境管理的一项基本制度。新化学物质生产厂商或进口商在生产、进口或上市销售一种新化学物质以前，向国家行政主管

部门申报新化学物质的基本性质和危害性信息，主管部门据此对该化学品的危害性及环境和健康风险进行评估和审查，并酌情给予许可登记、禁止或限制等管理措施。上个世纪 70～80 年代，发达国家普遍通过制定化学品专项立法建立了新化学物质申报制度，如日本于 1973 年颁布的“化学物质控制法”，美国于 1976 年发布的《有毒物质控制法》（TSCA）和欧盟于 1979 年颁布的“关于危险物质分类、包装和标志指令（79/831/EEC）”（该法令是对欧盟 67/548/EEC 的第六次修订）。

59. 在欧盟，根据新化学物质的上市销售或进口数量，新物质的申报被分为三个级别。新化学物质的上市量/进口量越高，所要求提供的数据越详细。欧盟要求申报者提供的各种健康和环境危害性数据必须符合《OECD 合格实验室规范（GLP）》以及《化学品测试准则》的要求。OECD 制定了欧盟和其他 OECD 国家普遍遵循的关于新化学物质申报的统一最低限度数据要求，即所谓“上市前最低限度数据（MPD）”，其内容基本上与附件 3 中的“基础数据（Base set）”一致。

60. 美国有毒物质控制法（TSCA）规定的新化学物质申报数据内容可分为四部分：1）一般信息，主要包括新化学物质的种类、分子式、组成成分、纯度以及制备工艺、生产/进口量、用途和职业安全说明等；2）人体暴露和环境释放信息，主要包括操作规程、职业暴露估计和防护措施，环境释放估量和控制技术信息；3）附录安全和测试信息，主要包括安全技术说明书（MSDS）、现有健康和环境毒性研究数据、理化性质等任何测试数据（可选）；4）可选择提供信息，包括污染防治相关信息。附件 4 显示了根据美国新化学物质申报制度评估和审查的广泛化学品健康和环境危害信息。但与欧盟不同，美国 TSCA 对于新化学物质申报的上述数据是以现有数据为基础，通常不强制要求进行测试。

61. 对于经过风险评价判定具有健康和环境风险的新化学物质，新化学物质申报登记制度规定将对其采取生产、使用和进出口的禁止或限制等风险管理措施。

### 4.1.2 现有化学物质风险评价与风险管理制度

62. “现有化学物质”是指在过去某一段时期内（如欧盟）或者从某一时间到目前（如美国）一个国家或地区已经生产、进口或上市销售和使用的化学物质。1993 年，欧盟颁布了“关于现有化学物质风险评价和控制条例（EEC793/93）”，要求生产和进口量超过 10 吨/年的化学品生产厂家或进口商在 1998 年前按产量分阶段申报要求的信息，规定生产和进口量超过 1,000 吨/年的高产量（HPV）化学品的生产厂家或进口商必须提交包括进入环境途径与转归、生态毒性、急

性毒性、亚急性毒性等多项化学品风险评价数据[11]。欧盟建立了一个称为 “欧洲现有商业物质名录（EINECS）”的现有化学品名录[12]，并启动了一项由欧盟各成员国分工合作的现有化学物质优先风险评价与风险管理计划，旨在逐步评估和控制现有化学物质的环境和健康风险[13]。

63. 美国 TSCA 规定：当 EPA 认定一种现有化学物质可能对人类健康或环境产生“不合理风险”（unreasonable risk）或因该化学品的大量生产造成人体或环境显著的暴露、但缺乏风险评价数据或需要进行必要的毒性测试时，则可要求该化学品生产者或进口者提供该化学品危害测试信息，并可采取强制性管理措施，包括禁止该物质的生产，或者严格管制其使用或者两者；同时，TSCA 还授权设立了一个测试咨询委员会，负责向 EPA 推荐需优先开展毒性测试、评价和风险管理的现有化学物质的名单。

64. 鉴于现有化学物质数目庞大以及化学品风险评价的复杂性，优先风险管理已成为各国现有化学物质风险评价与风险管理的一项基本政策，即：对通常意义上意味着具有高暴露概率的高产量化学品（High Production Volume chemicals，简称HPV，产量>1000 吨/年）开展制度化或组织化的危害性质测试，并根据对某些高风险或优先类化学品的特定标准，采取风险管理措施，禁止或限制使用某些高风险的“优先有毒化学品”，如PBT、CMRs或vPvB类化学品。优先性风险管理也反映在欧盟新的REACH法规制度中，其要求年生产量和进口量在 10t以上的化学品生产厂家或进口商必须对它们化学品“已确定”的用途进行风险评价[14]。

65. 由此可见，发达国家以上所建立的现有化学物质的风险评价与风险管理制度、优先化学品的风险信息报告、必要的测试、风险评价及风险管理可以使政府主管人员获得现有化学品危害性和风险的基本信息。根据这些信息，主管当局可以对具有高环境和健康风险的某些优先化学品合理地采取风险管理行动，包括禁止或限制其生产和使用措施，可以逐步降低现有化学品的环境和健康风险。因此，现有化学品的风险评价和风险管理制度成为是化学品环境管理的另一项基本制度。欧盟 REACH 法规可以认为是对这一基本制度加强。欧盟 REACH 法规的目的是让企业来承担风险评价的责任。此外，通过采取限制措施和批准授权制度在整个欧洲范围内为主管部门对具有不合理风险的化学品提供风险管理手段。

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[11] EEC793/93 建立的现有化学物质风险评价与风险管理程序

[12] “EINECS”是指欧洲现有商业化学物质名录。此名录包括 1981 年 9 月 18 日时被认为已经上市销售的所有化学物质，见欧盟指令 92/32/EEC第二条第一款。（颁布于 1992 年 7 月 5 日）

[13] C. J. Van Leeuwen, et al., Risk assessment and management of new and existing chemicals, Environmental Toxicology and Pharmacology, 1996.

[14] EU-REACH作为欧盟最新实施的化学品管理体系，将在稍后章节中专门阐述。

### 4.1.3 欧盟-REACH管理体系（2006/2007）

66. 2006 年 12 月，欧盟委员会通过了“化学品登记、评估、审批法规（Registration, Evaluation and Authorization of Chemicals, 简称 REACH）”，并于 2007 年 6 月 1 日起实施。该法规替代了从上世纪 70 年代以来建立的多项主要化学品环境管理法规。欧盟-REACH 法规的目标是：“在保证欧盟统一市场和化学工业竞争力的同时，确保给予人类健康和环境高水平的保护”。因此，REACH 法规对经济发展和人类健康和环境保护进行了综合的考虑，并且在发展和满足需求的同时贯彻了预先防范原则。

67. REACH 法规特别针对解决现有化学物质的危害和风险信息的缺乏问题，并加快现有化学物质风险管理进程。REACH 保留了对现有化学物质“提供证据的负担”要求，并将提供证据的责任由主管部门移交给企业，要求生产厂家和进口商对其超过规定数量生产或进口化学物质，针对“已确定的”用途开展风险评价，并将评价结果报告主管部门和告知下游用户和消费者。欧盟 REACH 法规的主要内容见附件 5.

### 4.1.4 排放控制与公众知情监督制度——TRI及PRTR制度

68. 污染物排放和转移登记制度（Pollutant Release and Transfer Register，简称 PRTR），是指建立一个从各类排放源向环境排放和通过废弃物转移的各种指定极危险化学物质的报告和登记制度，并将收集的数据向社会公众散发和用于化学品环境管理。

69. PRTR 制度是在重大有害化学品紧急事故频发的背景下产生的。在 1984 年印度博帕尔事件的影响下，美国国会于 1986 年通过了《应急计划与公众知情法案》（EPCRA），其中提出建立了有毒物质排放清单（TRI）制度，规定所有超过一定数量排放列入排放清单中有毒物质的企业，每年必须上报向环境排放和转移的有毒化学品数量。目前规定申报的有毒化学品达 600 多种。同时，EPCRA 要求 EPA 每年将上述数据汇总，形成 TRI 报告，向社会公众公开。实践证明，TRI 制度对有害化学污染物排放控制以及重大化学事故防范方面成效显著。例如收集的有毒化学品环境污染排放和处置信息对风险的鉴别、污染控制措施的有效性评估以及环境管理决策提供了基础支持。

70. PRTR 制度在各发达国家的名称和具体实施形式有所不同，但是，其通常具备如下基本要素：各种化学品污染物分别报告（遵照一个 PRTR 有毒化学品清单）；各个工业企业或实施分别报告；报告所有排放和转移数量；报告所有环境介质去向(空气, 水, 土壤)；定期报告（一年）；统一的数据报告格式和数据库

系统；信息向公众开放（仅保留有限的商业秘密）；促进环境质量改善和清洁生产技术。目前，PRTR 制度已经在大多数 OECD 国家中建立。在“政府间化学品安全论坛（IFCS）”第 III 次会议上，建立 PRTR 制度被列为国际社会 2000 年以后化学品安全管理的行动重点目标之一。2003 年 5 月，欧洲 36 个国家共同签署了一项《PRTR 议定书》，力求在国际社会建立起统一的 PRTR 制度。

### 4.1.5 有毒化学品污染物环境标准与监测制度

71. 1972 年美国的颁布的《清洁水法》提出“禁止大量排放有毒物质”的政策，要求 EPA 公布一份有毒污染物的清单，并建立一个“充分的安全限度”标准。1977 年，《清洁水法》修正案正式提出了一个包括 129 种优先有毒污染物的标准控制清单，要求 EPA 针对当时的 21 类工业污染源类型制定相应的有毒污染物排放标准。目前，美国、欧洲和 WHO 制定的生活水质标准中一般都有 50 多项指标，其中有相当大的一部分指标都是有毒污染物，尤其是美国当前的饮用水水质标准中有多达 50 多种有毒有机污染物和 10 多种重金属等无机有毒污染物。同时，有毒污染物通常是饮用水水源环境标准和生活饮用水水质卫生标准中的重要指标。1990 年，美国在《清洁空气法》中提出了包括 189 种有毒污染物清单，要求 EPA 对 41 类污染源制定和颁布排放标准控制。截止到 1996 年，美国 EPA 共制定了 52 个行业的水污染排放标准和 47 类污染源的有毒大气污染物排放标准。

72. 在欧盟有关水管理框架指令中，优先管理物质名单将被建立[15]，欧盟的饮用水[16]和空气质量标准[17]在指令中均有规定。

73. 虽然有毒化学污染物种类众多，通常难以保证进行日常的常规环境监测，但是，在发达国家，有毒污染物作为年度环境质量评价报告的一项基本内容。例如，美国的年度环境质量报告中就专门有“有毒化学物质”一章，报告全国各地有毒污染物环境监测的实际结果。监测和报告某些优先有害化学品的环境污染状况，是化学品环境风险识别、评价与风险管理的一项基础工作。

### 4.1.6 重大危险源管理与应急预案制度

74. 重大危险源管理与应急预案制度是专门针对重大危险化学品泄漏事故的预防和应急处置而建立的一项化学品管理制度。1993 年，国际劳工组织（ILO）组织世界各国共同签订《关于防治重大工业事故公约》(简称 174 公约)，使重

[15] http://ec.europa.eu/environment/water/water-framework/priority_substances.htm

[16] http://ec.europa.eu/environment/water/water-drink/index_en.html

[17] http://ec.europa.eu/environment/air/index.htm

大危险源管理制度得以在世界各国普遍建立。根据 174 公约的定义，“重大危险源”是指永久性或临时生产、加工、搬运、使用、处置或储存一种或多种数量超过规定的阈值的有害化学品的设施。174 公约规定，各成员国应当根据本国的立法、条件和规范，制定、执行和定期审查一项关于保护工人、公众和环境，防止重大事故风险的国家政策。

75. 重大危险源鉴定标准、安全通报书和安全报告制度是重大危险源管理制度的基本内容。欧盟 1996 年颁布的“关于防止危险物质重大事故危害的指令（96/82/ EC）”（简称塞维索指令Ⅱ） 提出的重大危险源鉴定标准（见附件 6），按照危害性质和危害程度对重大危险源进行了比较详细的划分，包括具有“环境危害性”物质指标；同时，欧盟的这一重大危险源鉴定标准中分为两个级别阈值，根据不同量级以及相应的危险程度而采取不同程度的管理措施。欧盟的重大危险源分类性鉴定标准具有广泛的指导意义。国际劳工组织已参照塞维索指令制订了 180 种（类）化学品的重大危险源鉴定阈值，供世界各国参考采用。安全报告制度是指重大危险源企业首先必须向政府主管部门报告其重大危险源相关的各种信息和资料，由政府主管部门进行动态信息管理。塞维索指令Ⅱ则根据不同量级及相应的不同危险程度分别采取所谓“安全通报书”制度和“安全报告“制度。

76. 应急预案又称应急计划，是针对可能的重大事故(件)或灾害，为保证迅速、有序、有效地开展应急与救援行动、降低事故损失而预先制定的有关计划或方案。它是在辨识和评估潜在的重大危险、事故类型、发生的可能性、发生过程、事故后果及影响严重程度的基础上，对应急机构的职责、人员、技术、装备、设施（备）、物资、救援行动及其指挥与协调等方面预先做出的具体安排，明确了在突发事故发生之前、发生过程中以及刚刚结束之后，谁负责做什么，何时做，以及相应的策略和资源准备等。总体而言，应急计划将是一个包括企业、政府、社区和公众，涉及公安、消防、环保、医疗、卫生和媒体等各政府机构的系统计划。

77. 美国在 1986 年出台的《应急计划与公众知情法案》将有毒化学品事故的应急反应计划作为一项法律制度。在欧盟，应急预案也被做为塞维索指令 II 的一部分。

78. 1993 年，国际劳工组织（ILO）大会通过的《关于预防重大工业事故公约》也将应急预案作为预防重大事故的必要措施而列入其中。

## 4.2 发达国家化学品环境管理的非强制性措施与行动

### 4.2.1 自愿协议（VAs）

79. 上世纪 90 年代以来，政府与化学品产业界之间旨在实施化学品风险评价与风险管理的自愿协议（Voluntary Agreement, 简称VAs）在发达国家广泛开展，成为各国实施化学品环境管理政策的一项重要手段。根据欧盟委员会（CEC）的一项研究统计，在欧洲各国政府与企业间签订的总共 300 多个环境保护VAs中，政府与化工行业之间VAs占总数量近 30%，而其余几个行业大概各占 10%左右。美国在化学品环境管理中更加广泛地使用VAs手段，VAs成为美国化学品环境管理政策和战略的主要实施手段之一。“33/50 计划”是EPA早期开展的旨在削减 17 种有毒化学品污染排放的一项著名的VAs计划，该计划的主要目的之一是示范VAs手段的运用是否会比单纯利用传统的“命令-控制”管理方式能显著增进环境污染控制的效果，而实践证明这一新管理方式取得了巨大的成功。1998年，美国提出旨在加速化学品环境和健康危害的测试和风险信息公布的“化学品知情权”（Chemical Right-to-Know，简称ChemRTK) 一项政府动议，并启动了“HPV化学品挑战计划（HPVCP）”和“自愿性儿童化学品评价计划”（VCCEP），这两项计划成功建立了政府与社会上化学品产业和公共利益集团之间的广泛的伙伴关系，数百家社会利益相关方自愿承担了 2800 多种HPV化学品中绝大多数现有化学物质和某些优先性高风险有毒化学品的危害测试和风险评价。2006 年 1 月，EPA与杜邦等 8 家公司在达成的PFOA削减和淘汰的VAs计划——“2010/15PFOA责任管理计划”中，各家PFOA生产和加工企业承诺，到 2015 年前逐步消除PFOA及其相关前体物质的排放和在产品中的残留，这是化学品环境管理VAs手段的一个典型案例。

### 4.2.2 工商界责任关怀行动（Responsible Care）

80. “责任关怀”（Responsible Care，简称 RC） 行动是化学工业界的自发性行为规范，致力于持续提高化学品整个生命周期中的技术、工艺和产品的环境、安全和健康知识与绩效，开放信息并进行与社会各利益相关方的交流与合作，推进化学品工商业者在化学品产业和消费链中的化学品管理责任，保护环境和人类健康。

81. RC 理念和运动产生由加拿大化学生产者协会(CCPA) 于 1985 年首次发起，相继被美国化学品制造商协会(CMA)以及欧盟和日本等国家化学工业协会所采纳，后在国际化学品协会理事会（ICCA）的正式推动下，至今已在全世界 52 个国家推广，参加企业的化学品产量接近全球化学品总产量的 90%，成为一项全球领先的产业界自发环境管理行动。ICCA 专门设立 RC 领导小组（RCLG），

负责与世界各国的国家级化学品产业组织开展合作，共同制定和完善 RC 规则并提高 RC 绩效，持续推动 RC 规范的广泛采用。RC 行动主要通过各个国家的化学品产业协会来实施，ICCA/RCLG 制定了 8 项 RC 各国需一致遵循的 RC 核心准则，并且化学品公司必须签署一份正式的承诺协议，承诺履行一系列 RC 规范；

82. RC 运动 2002 年 8 月在南非约翰内斯堡召开的可持续发展大会上受到了 UNEP 的高度评价。

### 4.2.3 绿色化学(Green Chemistry)

83. “绿色化学”项目旨在主要通过政府与科技界及产业研发团体建立广泛的伙伴关系进行环境友好的化学产品和工艺的创新设计，减少化学品的环境和健康风险。1991 年，EPA 污染预防和有毒物质办公室（EPA/OPPT）发起的“预防污染的替代合成路线”计划，其主要包括四个主要领域：（1）绿色化学研究计划：1992 年和 1994 年，EPA/OPPT 与美国国家科学基金会签署谅解备忘录，建立伙伴关系，联合建立“可持续环境技术”资助计划，共同资助绿色化学研究。总统绿色化学挑战计划：这是一项年度奖励计划，目标是对在绿色化学方面取得突出业绩的化学工商业者给予高层认可和奖励，以推动绿色化学的推广.（2）绿色化学教育计划：EPA 与美国化学学会(ACS)建立伙伴关系，推动绿色化学教育在化学工程师、大学或科研机构的学生和研究人员中的普及。（3）绿色化学的科学传播计划：“绿色化学”项目资助各种面向各行业、决策者和科学团体的绿色化学科学和技术宣传和普及活动。

## 4.3 发达国家化学品环境管理的基本政策与原则

84. 综合以上对发达国家化学品环境管理体系与实践做法的分析，可以看出国际化学品环境管理普遍遵循的一些基本政策与指导原则。

### 4.3.1 预先防范原则

85. 许多曾大量生产和使用的化学品后来经测试被发现具有重大健康和环境危害或风险，如上个世纪 70 年代的滴滴涕、PCBs 和近来的 PFOS。这促使发达国家引入这样的制度，即在新化学物质生产或者上市销售之前要求产生相关信息（预防）。此外，“为保护环境，各国应当采取适当的预先防范措施，当存在严重的或不可逆转的损害威胁时，不应以缺乏充足的科学确定性为理由，贻误采取防止环境退化的有效措施”，目前，这一基本原则不仅在发达国家化学品环境管理的基本政策和制度中得到充分体现，也反映在美国有毒化学品管理制度

上，如新化学物质的申报登记制度和现有化学物质的风险评价与风险管理制度中，而且构成了欧盟新 REACH 法规的基础。该新法规在企业要面对的提供数据负担和采取风险管理措施所依赖的关于化学品危害与风险的数据产生数量之间找到了平衡点。

4.3.2　优先性管理

86. 目前，在市场上销售流通的工业和商业化学品达 10 万余种。因此，许多国家化学品环境管理普遍采取“优先性管理”的基本政策和原则，首先管理那些具有较高健康和环境风险的化学品，如 HPVCs、PBT、vPvB 和 CMR 类化学品。“优先性管理”不仅贯彻在有毒化学品环境监测、PRTR、重大危险源控制等化学品环境管理的各项基本制度中，还体现在 POPs 和 PIC 等化学品国际公约当中。

4.3.3　污染者付费、举证责任和责任分担

87. 近年来欧盟国家化学品环境管理战略和制度改革中，普遍将化学品环境管理的责任转移给生产厂家及进口商。在欧盟 REACH 法规中，虽然下游用户也被牵扯进来，但是产生化学品危害和风险信息的主要责任由其生产者和进口者承担。欧盟 REACH 法规采取了与美国现行的主要由政府开展危害性测试和风险评价的不同做法，要求化学品危害性测试及风险评价的责任应当由化学品生产者或进口者承担。

4.3.4　公共参与

88. PRTR 制度以及发达国家化学品环境管理中普遍推行的 VAs 和 RC 行动突出体现了公共参与的政策与原则。

4.4国际化学品环境管理政策和行动

89. 1992 年在巴西召开的全球环境与发展大会上，将化学品环境无害化管理写入了人类社会可持续发展的纲领性文件《21 世纪议程》。在进入 21 世纪以来，国际化学品环境管理活动深入发展，这主要体现在三个方面： 全球化学品统一分类和标签制度（Globally Harmonized System of Classification and Labelling of Chemicals, 简称 GHS）的逐步推广； 化学品环境管理公约的广泛签署； 以及国际化学品管理战略方针（Strategic Approach to International Chemicals Management, 简称 SAICM）的制定实施。

4.4.1全球化学品统一分类和标签制度（GHS）

90. 人类社会对于化学品危害性（Hazards）的认识是渐进性的。世界各国早期应用的化学品危害性分类制度是由联合国危险货物专家委员会于上世纪 50 年代推出的危险货物分类体系，由此产生了危险化学品的概念，并将其分为爆炸品、压缩气体/液化气体、易燃液体、易燃固体、自燃物品/遇湿易燃物品、氧化剂/有机过氧化物、有毒品、放射性物品和腐蚀品等 8 类。随着人们对化学品危害性认识的扩展，尤其是对化学品的慢性、潜在的健康危害和生态环境危害性方面认识，欧盟通过 Directive 92/32/EEC（67/548/EEC 的第 7 次修订）指令对其原有分类制度进行修订，将化学品危害性分类由原来的 8 种扩大到 15 种，主要新增了“敏感性（sensitizing）”、“致癌性（carcinogenic）”、“致突变性（mutagenic）”、“生殖毒性（toxic for reproduction）”和“环境危害性（dangerous for the environment）”等健康和环境危害性类别。1992 年，建立“全球化学品统一分类和标签制度”成为《21 世纪议程》提出的国际化学品环境管理战略中的一项重要内容。2003 年，GHS 终于得以完成并发布，其基本分类体系如附件 7 所示。国际社会已将 2008 年在全世界推广 GHS 列为国际化学品管理行动的一项基本战略目标，GHS 必将成为世界各国未来普遍遵循的统一的化学品危害性分类制度，并极大地推动国际化学品环境管理进程。

4.4.2化学品环境管理国际公约（POPs与PIC）

91. 1998 年，国际社会共同达成了《关于国际贸易中特定危险化学品和农药事先知情同意程序的鹿特丹公约》； 2001 年通过了《关于持久性有机污染的斯德哥尔摩公约》；此外，UNEP 等国际机构目前正积极开展全球范围内汞和内分泌干扰物质的评估活动。

4.4.3　国际化学品管理战略方针——SAICM

92. 这一全球自愿积极性机制建立在这样的观念的基础上，“通过基于科学的风险评价以及考虑费用和获利以及安全替代品的可行性及其绩效，对于对人体健康和生态环境造成不可接受的和难以管理的风险的化学品或者化学品的使用应该不再生产或者不再用于这样的用途。”2002 年的世界可持续发展首脑会议（WSSD）通过了为实现《21 世纪议程》可持续发展目标而敦促世界各国进行统一和实际行动的《执行计划》。《执行计划》设定了实现化学品环境无害化管理的一项具有时限性的战略目标 “为了实现化学品整个生命周期内的无害化管理，到 2020 年，实现化学品生产、使用对人类健康和环境不利影响的最小化。”。

93. 2006 年 2 月 4-6 日，经过国际社会共同努力，“国际化学品安全战略方针”

于阿联酋迪拜召开的国际化学品管理大会暨 UNEP 理事会第 9 次特别会议和全球环境部长会议获得一致通过。

94. SAICM 和 WSSD 都在努力实现化学品环境和健康风险最小化目标，提出了包括风险减少、知识与资讯、公共治理、能力建设与技术合作等方面的总体政策战略和一系列具有明确的行动步骤和时间表、综合和协调现有国际化学品安全管理行动的统一战略和行动方案。

# 5 中国化学品环境无害管理与法发达国家的差距分析

## 5.1 在环境管理指导方针上的差异

### 5.1.1 化学品环境管理指导方针

95. 中国目前危险化学品安全生产的理念主要指保障人民生命和财产安全，防止事故发生及其对环境的污染危害，促进经济发展。根据《危险化学品安全管理条例》，危险化学品安全生产监管的范围虽然涉及到危险化学品的生产、经营、储存、运输、使用和废弃危险化学品处置活动，但是侧重于劳动生产过程安全和化学事故防范，较少考虑人类健康安全和生态环境安全。环境管理更侧重于化学污染物排放的“末端治理”。

96. 中国化学品安全和环境管理决策基本上是依据一种化学品固有的危险性及其潜在危害程度大小进行管理，较少考虑其暴露场景和风险大小。例如，中国对危险化学品中的剧毒化学品实行了购买凭证、准购证、记录保存以及使用单位登记备案制度等非常严格的许可证管理制度。而列入中国《剧毒化学品管理目录》中的 335 种剧毒化学品完全是根据化学品对哺乳动物的急性毒性大小确定的。剧毒化学品的判定指标不仅没有考虑化学品长期和反复接触可能造成的慢性毒性，特别是致癌性、致突变性和生殖毒性等特殊毒性，也没有考虑化学品的生物毒性、持久性和生物蓄积性等环境危险性以及使用量、使用方式等与化学品暴露直接相关的健康危害因素。中国化学品环境管理尚缺乏一套综合性科学管理政策和指导原则。

### 5.1.2 化学品环境管理的重点对象

97. 化学品环境管理应当确立清晰的目标和设定管理重点，以便将有限的人力物力资源花费在需优先改进的领域上。

98. 各国重点管理的危险化学品一般具有以下特性：(i)对人类具有严重致癌性、

致突变性、致畸性的化学品（CMR 化学品）；（ii）具有持久性、生物蓄积性和毒性的 PBT 类化学品；（iii）具有毒性、易燃性、爆炸性和环境危险性等危险特性，且当其生产或储存数量超过一定临界量时，可能构成重大危险源的化学品。

99. 中国危险化学品安全管理也没有明确区分管理的重点对象和一般对象。只要是危险化学品，不考虑其危险性大小以及使用量和可能的暴露程度，一律需要进行管理登记，对相关生产、经营单位审查核发安全生产许可证或经营许可证。目前，对于已经生产和上市销售的数量众多的现有化学物质，没有优先机制，既没有要求生产企业进行危险性鉴别测试，以确定其固有的危险性及评估其风险，也没有采取措施来识别和管理其中引起高度关注的具有 CMR 特性和 PBT 特性的化学品。

### 5.1.3 生产企业应当承担的社会责任

100. 一种化学物质固有的危险性和风险的信息不论对适当控制化学品风险，还是对保护环境和人类健康、事故预防和应急都是十分重要的。在发达国家，化学品的生产厂家和进口商在向政府、企业职工、消费者提供化学品安全信息方面负有不可推卸的责任。产生化学品污染风险的企业应当负责对其生产的危险化学品进行适当分类、包装和标签，提供其生产和销售化学品的安全评价数据，评估风险并确定适当的控制风险的措施，并且为了监督风险管理，政府主管部门应该采取化学品污染预防合控制措施。。

101. 中国化学品主管部门对通过法律、法规施行鉴别化学品固有危险性，要求生产企业产生和报告化学品安全数据的重要性认识不足。虽然中国在污染物排放和污染治理上遵循了“污染者付费”原则和实行排污收费等制度，但是在化学品管理上没有将产生和报告化学品安全信息作为生产企业不可推卸的社会责任。现行《危险化学品安全管理条例》等法规没有要求工业化学品的生产厂家对其生产的化学品进行安全性测试和提交测试数据和风险评价报告。加上完成化学品监控管理所需测试实验室分析能力不足，中国生产和使用的绝大部分工业化学品，即使是高产量化学品也没有要求进行危险性测试和评价，不能进行适当分类和标志，它们的风险也就得不到充分地管理。

## 5.2 法规和管理制度上的差异

102. 中国缺少一部针对工业化学品污染环境防治问题进行规范的综合性环境管理基本法律或国务院行政条例。

103. 中国在工业化学品环境管理法规及其相应管理制度方面与发达国家的

主要差异表现在：

5.2.1　新化学物质管理上的差距

104.　中国从 2003 年 10 月才开始施行新化学物质申报登记制度。在对新物质的健康和环境危险性鉴别和审查评价的基础上，对符合危害性评估标准的新物质，在生产和进口前批准登记，而对具有高健康和环境风险的化学物质采取禁止或限制其生产和使用等措施。

105.　中国新化学物质申报登记制度的实施尚处于起步阶段。新化学物质的评审方法基本上是基于危害评估，对新物质的暴露评估和环境风险评价还有许多需要改进完善之处。由于环保总局颁布的《新化学物质环境管理办法》属于部门规章，其法律地位低，执行力度也不尽人意。新化学物质申报审查制度实施情况与发达国家存在不小差距。

5.2.2　现有化学物质管理上的差距

106.　鉴于化学品安全立法颁布以前已经生产和上市销售的现有化学物质品种众多，而绝大部分现有化学物质固有危险性没有进行过测试评价，难于准确地进行危险性分类和安全管理。从预防和控制现有化学物质中引起高度关注化学品的风险并实施重点安全管理的理念出发，发达国家普遍建立了优先化学品的测试评价制度。所谓优先化学品（priority chemical substances）是指由于它们对人类健康或环境造成或可能造成严重有害影响，已被主管当局列入优先名单进行测试评价，以确定是否需要采取的管制行动的化学品。

107.　中国没有建立优先化学品测试评价制度。现行《危险化学品安全管理条例》等法规中对具有潜在健康和环境风险的化学品的筛选、风险评价缺少明确的立法规定。中国目前只是列入斯德哥尔摩公约和鹿特丹公约等监控名单上的化学品建立了禁止或限制生产和使用的淘汰制度。因而，国家主管部门难于对引起高度关注的危险化学品适时采取禁止生产和使用或严格限制使用对策。

108.　那些国际上引起高度关注的危险化学品可能由国外向国内转移，将导致中国化学品安全和环境风险显著增大。

5.2.3　重大环境危险源报告和预案制度－控制重大危险源的差距

109.　中国危险化学品种类只包括爆炸品、易燃物质、活性化学物质和有毒物质四类危险物质，未包括致癌物质和环境危险物质；除了标准的控制名单上列

出的 142 种物质之外，缺少其他危险源的类别标准，无法识别特定名单之外的其他重大危险源物质。由于许多引起国际关注的致癌物质和危害环境化学物质未列入国家重大危险源辨识标准，也没有建立重大环境危险源报告和应急预案制度，不能保证危害环境化学品事故预防和应急管理的有效实施。

5.2.4 污染物释放和转移登记制度－控制极危险物质排放上的差距

110. 中国自 20 世纪 90 年代初起，根据《水污染防治法》和《大气污染防治法》等环境法律法规授权，颁布并实施了《排放污染物申报登记管理规定》。中国的排污申报登记制度是申报国家确定实行排放总量控制的 12 种污染物(COD、石油类、氰化物、苯酚类、砷、汞、镉、六价铬；烟尘、粉尘、二氧化硫和工业固体废物排放量)的排放情况，对其他化学污染物质未列入申报登记范围。排污申报登记制度的实施，使政府环保部门可以获得全国企业排放主要污染物的信息，用作为排污收费的核定依据以及环境统计、污染源分析、环境规划等环境管理用途。排污申报登记获得的信息主要通过环保总局定期发布的《中国环境统计年报》形式公布，供社会公众查询使用。

111. 中国化学品环境管理没有建立 PRTR 制度，现行的排污申报登记制度与国际通行的 PRTR 制度有较大差异。由于不能掌握和公布引起高度健康和环境关注的危害环境化学物质的生产、使用、排放和污染防治信息，化学品环境管理在国家污染防治法规和管理政策上得不到充分体现。

5.2.5 化学品危险性分类和标签制度－分类管理的差距

112. 化学品分类和标签制度是化学品危险性公示的重要手段。发达国家普遍建立并完善了化学品危险性分类、标签和安全数据说明书（MSDS）等公示制度。中国已经建立了危险化学品分类、标签和 MSDS 制度。中国化学品危险性分类主要依据联合国《关于危险货物运输建议书》中危险货物分类确定。目前联合国《全球化学品统一分类和标签制度》分类标准提出的具有其他健康危险性以及环境危险性的化学品在中国没有被列入危险化学品范畴。对于国际上引起高度关注的具有致癌、致突变和生殖毒性以及具有持久性、生物蓄积性和毒性的危害环境化学品没有或很少作为安全管理的对象。

113. 中国现行《危险化学品名录》也是依据联合国《关于危险货物运输建议书》中危险货物一览表确定的，其涵盖的危险化学物质只有大约 3,000 多种。未列入危险化学品名录的其他上市销售的危险化学物质和配制品没有要求生产企业进行危险性评估和做出分类、标签。迫切需要根据联合国 GHS 分类标准，修改完善现行危险化学品的分类和管理范围。

5.3　监督管理方法上的差异

114.　为预防和控制化学品的风险，发达国家采取各种管理措施和对策，包括（i）通过对化学品进行测试，鉴别其固有危险性；(ii)对危险化学品进行分类和标签，做出危险性警示标志；(iii)建立暴露情景已经评估风险；(iv)通过编制MSDS，传递公示化学品危险性和风险信息；(v)在没有适当方法控制化学品风险时，采取禁止或限制使用等措施等。

115.　在中国，主管部门青睐于采用“命令-服从”的许可管理制度以及登记管理的方式，很少考虑采用其他方式鼓励和推动企业自愿参与化学品安全管理。许多国内企业的领导都把化学品安全和环境保护看成是国家有要求，自己不得不做的事情，而不是企业对社会应尽的责任和职业道德。中国公众在化学品安全和环境保护决策上的知情权和参与上也与发达国家存在很大差距。

116.　考虑上述差距，中国化学品环境管理需优先改进的领域包括如下方面：

5.4　健全的化学品环境管理法规、标准体系

117.　中国对农药、医药品、兽药、食品添加剂等专用化学品的管理已经建立与国外同类化学品相适应的管理法规和标准，但是缺少一部针对工业化学品环境安全实施污染控制的环境法律或行政法规。在工业化学品危险性鉴别评价、审查管理制度和污染控制标准等方面存在许多空白点和不完善地方。中国在化学品健康与环境风险评价和风险管理以及危险化学品分类和标签制度等方面与国际化学品安全管理体系存在较大差异。

118.　中国现行《大气污染防治法》、《水污染防治法》和《固体废物污染环境防治法》等环境保护法律均侧重于控制化学品的生产和使用过程中排放的化学污染物的末端治理与控制。

119.　因此，需要通过制定一部对工业化学品环境安全实施污染控制的环境法律或国务院行政条例，采取风险预防和风险管理措施，来解决对危害环境化学品的污染防治问题。

120.　为了鉴别和评价化学品对人类健康和环境的风险，还需要制订和完善化学品风险评价的导则、标准、化学品的环境标准（如大气环境和水环境质量标准和污染物排放标准）和管理技术规范等。

5.5　明确化学品环境无害管理指导方针和原则

121.　中国化学品环境无害管理尚未制定一套综合性科学管理政策和指导原

则。在以下涉及国家化学品环境无害管理的一系列问题上，需要研究提出明确清晰的政策导向：（1）化学品环境无害管理在国家环境污染防治总体战略中所处的地位及其重要性是什么？（2）化学品环境无害管理的目标和指导原则是什么？（3）化学品环境无害管理与化学品安全管理的相同点和差别是什么？（4）在化学品环境无害管理中，哪些类化学品应当引起高度关注？（5）如何从众多的现有化学物质中筛选和评价确定需优先（重点）管理的化学品？（6）如何加强化学品环境无害管理能力建设等？

122. 中国迫切需要加强国际合作，借鉴发达国家行之有效的成功管理经验和做法，制定出一套符合国情的化学品环境无害管理技术政策。

5.6 加强各级环境保护主管部门执法监督能力

123. 虽然中国已经制定了一系列环境法律法规管理化学品环境污染，但是由于危险化学品生产、使用、进出口和污染防治等管理环节多，主管执法部门人手少，缺少必要的监控手段和经验以及对危险化学品潜在危害认识不足等原因，致使化学品环境无害管理和污染防治执法能力不足，特别是在省级以下的设区的市级和县级，国家许多环境保护法规和环境标准没能得到有效贯彻执行。

124. 第一，作为一个发展中国家，中国许多地区人民生活水平还较低，需要发展经济解决社会温饱问题。某些地方部门的管理人员可能出于经济或其他方面的考虑，放宽对国家环境法律、法规规定的执行力度，使得化学品污染环境的监督管理达不到要求。提高各级环境保护主管部门管理人员对化学品环境无害管理重要性的认识，加强执法能力建设以及建立有效的监督执法机制成为迫切需要解决的问题。

125. 其次，中国化学品环境无害管理体系建设尚处于起步阶段。对于环境污染防护，国家尚未制定清晰明确的化学品环境无害管理方针、政策并建立与国际相接轨的化学品环境风险评价和风险管理制度和技术导则。缺少化学品风险管理专家支持系统和必要的评价和监控管理手段。

126. 当前国家环境污染防治的重点仍然是预防和控制工业生产中排放“三废”造成的污染问题，化学品环境无害管理问题尚未提高到环境保护的重要议事日程之上。国家尚未根据国际社会的实践制订明确的化学品环境无害化管理的原则政策从而建立化学品环境风险评价和风险管理制度已经技术导则。国家还缺少支持化学品风险管理和评估及监督管理的能力。

127. 第三，环境保护执法管理人员缺少必要的培训。缺少有经验、训练有素的危险化学品环境管理人员和专业技术人员也是实施有效监督管理的制约因素。

128. 由于国务院机构以及地方政府机构的改革，各级政府环境保护主管部门的管理人员精简，造成新老人员更迭，管理岗位变动较大。目前全国省级和设区的市级环境保护局的污染管理处一般只有 1-2 名官员兼职管理有毒化学品污染环境防治工作。管理人员水平参差不齐，对化学品环境管理相关法律法规不熟悉，也制约着管理能力的发挥。

129. 因此，迫切需要加强各级环境保护主管部门管理人员的技术管理培训，提高他们对化学品环境无害管理重要性的认识并提高他们的监督管理执法能力。

5.7 健全的化学品环境无害管理技术支持体系

130. 建立化学品环境管理技术支持体系是实现化学品环境安全管理的重要技术支撑与保障。技术支持体系包括化学品测试分析的合格实验室系统、化学品测试、评价使用的测试准则、合格实验室规范原则、风险评价准则等标准规范以及化学品安全信息管理系统。

131. 目前中国尚未建立统一的化学品测试合格试验室规范标准。各主管部门下属的从事化学品测试评价的试验室大多未执行国际公认的《OECD 合格试验室规范原则》，并通过国家认证，无法保证化学品安全数据测试结果的可靠性和满足国内化学品安全和环境管理登记对测试数据的要求。中国环境保护、卫生、农业、安全生产等行政主管部门及其技术支持单位都建立和拥有自己的化学品登记管理数据库系统，并利用国外权威机构建立的化学品安全数据库系统进行化学品管理相关信息查询。例如，美国 NIOSH 的 RTECS 数据库、美国医学图书馆的危险物质数据库（HSDB）、联合国 IPCS-INCHEM 数据库和国际化学品安全卡查询系统等。但是，关于中国国内化学品的生产、使用情况、生产装置所在地点以及化学品储存、运输和处置情况；有关人群和环境暴露于危险化学品的场景和污染危害情况；有关化学品及化工产品的危险特性、毒性、环境转归以及潜在健康和环境影响等基础信息还难于准确查询获得。社会公众也难于通过政府部门的网站查询到国外权威机构和自己关注的危险化学品的分类标志、消防、泄漏处置、安全防护、污染防治等信息数据。建立和完善化学品安全信息管理和公示系统也是加强中国化学品环境无害管理能力建设面临的重要问题。

# 6 中国化学品环境管理政策和制度的框架建议

132. 在全球化的背景下，发达国家逐步出现、分阶段解决的各种环境问题在发展中国家集中产生，使中国环境问题呈现出“复合型”和“压缩型”特征。

中国正同时面临着传统或第一代环境问题，比如城市大气污染或湖泊富营养化和所谓“新型或第二代环境问题”的化学品污染问题。对于化学品的环境及环境管理的关注和理解不够充分。并且，基于现行化学品管理体系仍然是传统化学品危险分类体系，在管理的范围和目标上都具有极大的局限性。中国目前的化学品环境管理主要局限在对于具有易燃、易爆和急性毒性等显性和急性危害性的化学品的职业安全管理上，对于大量具有潜在性、长期性的人体健康和环境危害的化学品并未进行系统化和制度化的环境管理。由于缺乏基本的立法和行政基础，中国化学品环境管理制度急需完善。此外，现行化学品环境管理实际上主要局限在有毒化学污染物的末端污染控制以及有毒化学品进出口登记管理上，预先防范及风险管理等化学品环境管理的基本原则和方法未能得到充分体现。

133. 在化学品环境管理相对落后的情况下，中国当前正面临着日益严重的化学品环境污染，许多国际禁止或严格限制的化学品仍在中国生产和使用，危险化学品事故频发，国内化学品的生态和健康风险正在与日俱增。与此同时，进入 21 世纪以来，发达国家不断加强化学品环境管理，主要表现在不断采取立法及多种管理措施，加快化学品的测试、评估和淘汰有害化学品；国际社会大力推动全球化学品环境管理进程，将其作为全球可持续发展战略的一个重要组成部分，并提出了具有时限性的战略目标以及相应的战略行动方针—SAICM。应该看到，化学品的环境管理直接关系到我国未来生态环境和人类健康安全。国家正致力于调整产业机构，构建环境友好型社会。在科学发展的背景下，化学品环境管理必然需要提上政府环境保护的重要议程。

134. 综合本报告关于中国化学品环境管理问题的分析，结合国际化学品环境管理形势、发达国家化学品环境管理成功经验和中国国情及发展形势，提出如下关于中国化学品环境管理政策和制度的框架建议。

## 6.1 制定国家化学品环境管理战略方针

135. 所有未来的化学品环境管理措施应当成为国家政策方针的一部分。

***建议:***

A. 中国的化学品环境管理战略首先应明确国家化学品环境管理的基本方针、原则、政策及总体战略目标，其中应综合考虑“预先防范”原则与中国化学工业生产和使用情况的基本国情，制定合理的战略目标。
B. 战略需要和科学发展观相一致。推行循环和回收使用，保护环境，营造一个资源节约型和环境友好型社会，清洁和安全发展应该纳入在这个战略中。
C. 化学品的生产和管理需要遵循清洁生产和绿色化学的理念。

D. 如果经济可行性是可行的，对人体健康和环境具有高风险的化学品应该首先被替代。
E. 中国的化学品管理战略应建立一项国家化学品环境管理能力建设规划，包括立法体系、机构职能、管理技术支持体系、信息交流和公共参与等机制建设等。
F. 中国的化学品管理战略应包含一项长期但有时限的对国内现有化学物质风险评价与风险管理行动计划，遵循特定的优先原则和行动步骤，逐步收集现有化学物质固有危险性信息，开展风险评价和风险管理，并逐步减少和淘汰那些具有对环境和人类健康具有无非接受风险的化学品的生产和消费的化学品，最终实现中国的“无毒环境”；此外，战略所涉化学品管理的法规和技术规范体系需顺应 WTO 的要求。
G. 为了化学品环境管理战略的顺利制定，应该以环境和人类健康保护的部门为主体，建立一个化学品环境管理国家协调机构，确保战略能够体现国家生态环境和人体健康保护需求以及各利益相关方的利益。

### 6.2 制定专门的化学品环境管理法律或行政条例

136. 根据当前国情，建议制定一部化学品环境管理专项法律或行政条例，填补国家现行化学品环境管理立法体系在化学品环境管理方面存在的空白。

**建议：**

A. 化学品环境管理法律或行政条例应与风险管理的理念相一致，制定全面、科学、规范的危害测试要求，采取全球化学品统一分类和标签制度对化学品进行分类和标识，从而有助于化学品的有效的风险评价和风险管理，包括建立和完善以新化学物质申报登记、现有化学物质风险评价与风险管理、有毒化学品排放与转移登记、公共知情与参与、重大环境事故防范与应急等为基本制度的化学品环境管理制度体系，并与现行的危险化学品安全管理和公共卫生管理相关立法相协调。

### 6.3 需优先进行的化学品环境管理基本制度建设

#### 6.3.1 全面推行 GHS 化学品分类和标签制度

137. 科学、全面的化学品分类和标识系统是化学品危害性识别的基础条件，从而有助于有效的风险评价和信息交流与传递并实施化学品风险管理。中国现行的危险化学品分类系统无法全面反映当今化学品各种潜在的环境和健康危害及风险，并严重制约了中国化学品环境管理的发展。

***建议：***

A. 中国应全面实施 GHS 化学品分类和标签制度，作为新化学物质申报、现有化学物质风险评价与风险管理以及重大环境危险源管理以及 MSDS 等管理制度的依据。这要求化学品生产厂商和下游用户按照 GHS 要求，对危险化学产品进行危害性分类、标签和风险信息传递等，从而有效控制化学品的环境和健康风险。

6.3.2 提升和完善新化学物质申报登记制度

138. 新化学物质申报登记制度是化学品环境管理的基础性制度，发达国家在上世纪 70 年代开始普遍采取专项化学品立法的形式建立了该项制度，并逐步建立了一套较为完备的规范、程序及相关技术和机构支持体系。相比之下，中国的新化学物质申报登记制度三年前才以一部部门规章的形式建立起来。

***建议:***

A. 通过上述提出的化学品环境管理专项立法的形式，提升新化学物质申报登记制度的法律地位和执行效力。
B. 充分吸取发达国家先进经验，进一步完善执行程序和各相关政府管理部门之间的合作与协调机制。
C. 在横向和纵向上创立有利于促进国内各相关政府部门和机构合作和信息交流的职责。
D. 完善相关规程及相应技术和机构支持体系（如 GLP 准则、危害测试数据的国际互认等），从而建立一套与国际接轨的新化学物质申报体系。
E. 简化程序并且引进机制来精简那些负责很少关注的诸如极小量的化学品的机构。特别关注那些对人体健康和环境具有高风险的化学品。

6.3.3 建立现有化学品风险评价与风险管理制度

139. 现有化学物质风险评价与风险管理制度是收集国家现有化学物质风险信息并开展风险管理行动的基础，也是目前世界各国化学品环境管理的重点。正是由于该制度的欠缺，中国对当前国内化学品的环境和健康风险缺乏认识，未对现有高风险化学品构成管理约束，并经常面临国际化学品环境管理行动的种种“制约”。

***建议:***

A. 尽快研究建立与新化学物质申报登记相关测试和数据要求相同或相近的现有化学物质风险评价与风险管理制度，其中主要包括：建立现有化学物质危害性测试及风险信息收集制度和优先性风险管理制度。
B. 对于化学物质的生产进口超过特定数量的生产和进口商，规定其有义务提交该化学物质的危害测试申报信息和收集市场中现行化学品的风险信息。

C. 建议提出优先性风险管理基本原则、政策和法律规定，如规定对PBT、CMRs 和 vPvB 等优先化学品采取生产、使用和进出口的禁止和严格限制等优先管理政策和法律制度。
D. 规定按照 GHS 对现有化学物质进行分类和标识。
E. 为实行现有化学品风险评价与风险管理制定包含上述所提及的制度的特定的立法，确定现有化学品风险评价与管理体系中的执行机制。

6.3.4 建立高度关注的优先化学品的国家标准

140. 根据本国化学品产业的情况，参考国际标准，拟定本国的高度关注的优先化学品的国家标准。

***建议:***

A. 参考国际优先有毒化学品标准，种类（化学品的数量），制订高度关注的优先化学品标准。国家的优先化学品的类别可能包括 PBT、vPvB、CMRs 和 EDCs 等。
B. 对优先化学品的风险管理应当基于其不同特性及不同程度的环境和健康风险，并根据其生产使用和流通时的暴露情况，采取不同的风险管理措施。建议国家建立优先化学品鉴定和风险管理标准，在此基础上构成对于 PBT 等引起高度关注的化学品的风险管理政策和制度。
C. 拟定相应的风险管理战略和行动计划，逐步减低，限制和消除国内引起高度关注的化学品的生产和消费，并能促进国家对于斯德哥尔摩公约等重要化学品环境管理国际公约的顺利履约。

6.3.5 建立有毒化学品排放登记及公众知情制度

141. PRTR 制度是有毒化学污物排放统计及公众知情制度的代表。这一制度已经成为世界各国有效控制有毒化学品环境污染控制、事故预防以及信息公开与公众参与的通行做法。

***建议:***

A. 建议吸取国外成功经验，采取特定的优先管理原则，合理确定申报有毒化学品清单和相关行业企业范围，建立相应的数据收集和发布的管理信息系统，逐步建立中国的有毒化学污物排放统计及公众知情制度。

6.3.6 建立优先有毒化学污染物质排放监测制度

***建议:***

A. 建立对 PBT 等优先化学污染物质的环境监测制度，依据中国现有环境和卫生监测体系现状和能力，对环境介质中的某些高生态和健康风险的有毒化学污染物质进行制度化和系统化的环境监测，并编写和发布年度国家优先有毒化学品的监测报告，使政府和社会了解本国化学品环境污染状况及其生态和健康风险，为有效开展化学品环境管理提供决策基础。

6.3.7 完善重大危险源登记与报告制度

***建议:***

A. 修订和完善重大危险源辨识标准，尤其是需要补充其中环境有害物质的相关类别和标准；完善现行的重大危险源登记与报告制度的执行和监督机制，增加环保部门在重大危险源登记与报告制度中的数据共享以及监督和执行职责和权利；加强有关机构的执法能力，充分防范重大有害化学品泄漏事故及其引发的公共环境事件的发生；参考 ILO，欧盟塞维索指令及 EPCRA 等重大危险源管理的有关国际标准与实践，促进现有重大危险源管理制度的相关立法。

6.4 能力建设

6.4.1 化学品环境管理现有国家行政职能和机构建设

***建议:***

A. 通过建立各级国家化学品管理部门间的协调机制，建立起国家化学品环境管理行政执法和监督管理体系；
B. 通过增加相关各级部门的职能提高国家环保总局在中国化学品管理体系中的地位。建立健全国家和地方环保机构中化学品环境管理的机构及其职能，包括增设相关管理部门和管理人员。
C. 加强相应管理设施建设和人员培训。

6.4.2 国家化学品信息系统建设

142. 化学品危害性和风险信息是化学品环境管理的基础条件。

***建议:***

A. 以新化学物质申报登记制度、现有化学物质风险评价与风险管理制度、优先有毒化学品环境监测、有毒化学污染物排放统计和重大危险源登记和报告等化学品环境管理制度为基础，集中收集、整理和发布国家化学品环境和健康风险的各种相关信息，并且注意商业机

密的保护。

B. 评估、整合与现有化学物质和新化学物质以及职业健康与安全相关的国家现有化学物质信息资源和管理系统。

C. 进一步增强现有化学品危害性和风险信息的的国际信息交流。

6.4.3 国家化学品测试和评价科研与监测能力建设

143. 促进国家环保管理机构与公共卫生管理部门、科学技术管理部门以及下述领域各部门间的合作。

***建议:***

A. 建立符合 OECD/GLP 准则的化学品测试与评价实验室，引进 GLP 监测和其他制度，例如数据互认，增加化学品环境和健康危害性测试的能力。

B. 推动环境与健康监测及风险评价方面的基础科研与监测能力建设，尤其是针对某些优先性高风险有毒化学品。

C. 积极开展化学品危害测试及风险评价相关的国际合作，学习和采纳国际化学品风险评价方法，不断提高自身相关能力。

6.5 推动构建国家化学品环境公共治理体制

6.5.1 建立自愿性化学品风险控制保障制度和鼓励政策

144. 在逐步构建完善的政府管理制度的前提下，社会各化学品利益相关方共同参与，尤其是化学品产业界的广泛参与，是顺利推行国家各项化学品环境政策和实现无害化管理的重要基础。政府和企业间化学品环境管理 VA 及化学品企业 RC 行动是发达国家化学品环境管理中推行多年的良好实践，值得中国化学品环境管理借鉴。实际上，中国的《清洁生产促进法》已经确立了 VA 的法律地位，并提出了一些鼓励政策。

***建议:***

A. 建议在《清洁生产促进法》现有规定的基础上，研究和制定一系列相关配套政策和管理措施，从而推动化学品环境管理的 VA 及 RC 实践在中国的逐步开展。

B. 鼓励与化学品产业协会及其他相关商业协会进行交流，并在中国实施 VA、RC 以及产品环境安全保障制度。

C. 通过立法、过程控制和绩效审核来提高 VA 的执行效果。

6.5.2 加强化学品环境管理的信息公开及公共参与机制建设

***建议:***

A. 通过发布有毒化学品污染排放及环境监测报告等方式，增进国家化

学品环境和健康风险信息的公开与交流。

B. 开展有毒化学品环境和健康风险公众宣传与教育。

C. 建立公共参与机制，使社会各利益相关方能够参与政府化学品环境管理决策，符合当今化学品环境管理的国际发展潮流。

## 附件 1 中国化学品环境和安全管理相关的主要法律、法规和规章

**附表 1 中国与化学品管理相关主要环境保护法律、法规和规章**

| 法律、法规和规章 | 施行日期 | 适用范围 |
|---|---|---|
| **环境保护法** | 1989 年 12 月修订 | 环境保护基本法 |
| **水污染防治法** | 1996 年修订 | 江河、湖泊、运河、渠道、水库等地表水体以及地下水体的污染防治 |
| **大气污染防治法** | 2000 年 9 月修订 | 防治大气污染，保护和改善生活环境和生态环境 |
| **固体废物污染环境防治法** | 2005 年 4 月修订 | 固体废物和危险废物污染环境的防治。 |
| **海洋环境保护法** | 1999 年修订 | 保护海洋环境及资源，防止污染损害 |
| **环境影响评价法** | 2003 年 9 月 | 预防化工及其他建设项目实施后对环境造成不良影响，促进经济、社会和环境协调发展 |
| **清洁生产促进法** | 2003 年 1 月 | 实行清洁生产，淘汰浪费资源和严重污染环境的落后生产技术、工艺、设备和产品 |
| **关于落实科学发展观加强环境保护的决定** | 2005 年 12 月 | 落实科学发展观，加强环境保护和有毒有害物质污染控制 |
| **国家突发环境事件应急预案** | 2006 年 1 月 | 建立突发环境事件应急机制，提高应急能力，保护公众生命健康和环境 |
| **新化学物质环境管理办法** | 2003 年 10 月 | 新工业化学物质生产和进口前申报登记管理 |
| **化学品首次进口及有毒化学品进出口环境管理规定** | 1994 年 5 月 | 中国禁止或严格限制的有毒化学品的进出口 |
| **废物进口环境保护管理暂行规定** | 1996 年 | 废物进口的环境监督管理 |
| **废弃危险化学品污染环境防治办法** | 2005 年 10 月 | 废弃危险化学品处理处置、污染防治 |
| **电子信息产品污染控制管理办法** | 2007 年 3 月 | 控制废弃电子信息产品的环境污染，减少和消除电子信息产品中有毒、有害物质的使用 |

**附表 2 中国危险化学品安全管理相关专项法规**

| 法律/法规名称 | 施行日期 | 适用范围 |
|---|---|---|
| 安全生产法 | 2002 年 11 月 | 安全生产监督管理、事故应急处理 |
| 食品卫生法 | 1995 年 10 月 | 食品卫生与生产经营 |
| 职业病防治法 | 2002 年 5 月 | 职业病防治和职业卫生监督管理 |
| 药品管理法 | 2001 年 12 月 | 药品的研制、生产、经营、使用和安全监督管理 |
| 危险化学品安全管理条例 | 2002 年 3 月 | 危险化学品生产、经营、使用、进出口及重大危险源监控管理 |
| 农药管理条例 | 2001 年 11 月修订 | 农药登记、生产许可证、安全使用、进口农药管理 |
| 安全生产许可证条例 | 2004 年 1 月 | 对危险化学品、烟花爆竹、民用爆破器材等生 |

| 法律/法规名称 | 施行日期 | 适用范围 |
| --- | --- | --- |
| | | 产企业实行安全生产许可制度 |
| 使用有毒物品作业场所劳动保护条例 | 2002 年 4 月 | 作业场所有毒物品职业中毒危害的劳动保护 |
| 化妆品卫生监督条例 | 1990 年 1 月 | 化妆品的生产、经营管理 |
| 工业产品生产许可证管理条例 | 2005 年 9 月 | 对危险化学品等影响生产安全、公共安全、人身财产和金融安全的 6 类重要工业产品实行生产许可证管理 |
| 麻醉药品和精神药品管理条例 | 2005 年 11 月 | 麻醉药品和精神药品种植、实验研究、生产、经营、使用、储存和运输监督管理 |
| 饲料和饲料添加剂管理条例 | 2001 年 11 月 | 饲料和饲料添加剂的生产、进口、使用和销售的质量和安全管理 |
| 民用爆炸物品管理条例 | 1984 年 1 月 | 爆破器材，包括各类炸药、雷管、黑火药、烟火剂、民用信号弹和烟花爆竹等民用爆炸品的安全管理 |
| 监控化学品管理条例 | 1995 年 12 月 | 可作为化学武器及其前体等监控化学品的生产、经营和使用管理 |
| 易制毒化学品管理条例 | 2005 年 11 月 | 易制毒化学品生产、经营、运输和进出口管理和许可制度 |
| 危险化学品经营许可证管理办法（原国家经贸委） | 2002 年 11 月 | 危险化学品经营销售许可证管理 |
| 危险化学品登记管理办法（原国家经贸委） | 2002 年 11 月 | 危险化学品登记管理 |
| 危险化学品生产储存建设项目安全审查办法（安监总局） | 2005 年 1 月 | 危险化学品生产、储存企业新建、改建、扩建项目安全审查与评价 |
| 危险化学品生产企业安全生产许可证实施办法（安监总局） | 2004 年 5 月 | 危险化学品生产企业安全生产许可证的颁发与管理 |
| 铁路危险货物运输管理规则（铁道部） | 1996 年 1 月修订 | 危险化学品的铁路运输 |
| 水路危险货物运输规则（交通部） | 1996 年 | 危险货物水路运输管理 |
| 道路危险货物管理规定 | 1993 年 | 危险货物的公路运输管理 |

**附表 3 中国现行危险化学品安全和环境管理制度**

| 项目 | 安全生产管理 | 化学品环境管理 |
|---|---|---|
| 管理法规名称 | 《危化条例》、《危险化学品建设项目安全许可实施办法》、《危险化学品经营许可证管理办法》等 | 《环境影响评价法》、《新化学物质环境管理办法》、《化学品首次进口及有毒化学品进出口环境管理规定》等 |
| 适用范围 | 危险化学品生产、储存、经营、运输、使用、事故应急、进出口、废弃处置 | 新化学物质生产或进口、有毒化学品进出口、突发环境事件应急和废弃危险化学品处置 |
| 管理对象物质 | 爆炸品、压缩气体和液化气体、易燃液体、易燃固体、自燃物品和遇湿易燃物品、氧化剂和有机过氧化物、有毒品和腐蚀品 | 新工业化学物质；列入鹿特丹公约、斯德哥尔摩公约、巴塞尔公约受控名单的危险化学品和危险废物；中国禁止和严格限制的有毒化学品等； |
| 管理目录 | 危险化学品名录<br>剧毒化学品目录<br>重大危险源辨识标准 | 中国现有化学物质名录<br>中国禁止或严格限制有毒化学品目录；<br>中国严格限制进出口有毒化学品目录；<br>中国进出口受控制消耗臭氧层物质名录；<br>中国危险废物名录； |
| 生产/进口前 | 无 | 新化学物质生产和进口前登记制度； |
| 生产、储存建设项目 | 建设项目安全评价制度；<br>安全生产许可证制度；<br>生产、储存企业登记备案制度； | 环境影响评价报告书和审批制度 |
| 经营销售 | 经营许可证制度；<br>剧毒化学品实行购买凭证、准购证制度； | 无 |
| 使用 | 剧毒化学品实行记录保存制度、使用单位登记备案制度；<br>危险化学品分类、标签和 MSDS 制度 | 禁止类、限制类有毒化学品按管理目录实行分类管理 |
| 运输 | 危险货物运输许可证；<br>承运单位资质认定制度；<br>包装、容器、运输车辆检验制度；<br>剧毒化学品公路运输通行证制度，禁止利用内河封闭水域运输剧毒化学品规定 | 依照危险货物运输管理 |
| 事故应急救援 | 事故应急救援预案备案制度；<br>重大危险源企业登记备案制度；<br>危险化学品事故报告制度 | 突发环境事件应急预案备案制度；<br>环境污染和破坏事故报告制度； |
| 废弃处置 | 只有职责授权，无明确具体规定 | 废弃危险化学品按照危险废物进行监管，实行废物经营许可证、危险废物转移联单制度等；<br>废弃污染场地环境风险评估制度 |
| 进出口 | 只有职责授权，无明确具体规定 | 列入鹿特丹公约、斯德哥尔摩公约和禁、限类名单的有毒化学品进出口登记制度 |

**附表 4 中国各类安全和环境监管的化学品数量一览表**

| 序号 | 管理目录 | 颁布机关 | 受控化学品数量 | 说　明 |
|---|---|---|---|---|
| **1** | 剧毒化学品目录（2002 年） | 国家安监总局等 | 335 种 | 作为判定剧毒化学品的依据 |
| **2** | 重大危险源辨识标准（GB18218-2000） | 国家质检总局 | 爆炸、易燃、反应活性和有毒四类重大危险源物质 142 种 | 作为重大危险源判别依据，并规定了临界量。 |
| **3** | 高毒物品目录（2003 年） | 卫生部 | 54 种 | 职业病防护和作业场所健康防护 |
| **4** | 中国禁止或严格限制的有毒化学品目录 | 环保总局等 | 第一批 27 种<br>第二批 7 种 | 有毒化学品进出口环境管理登记 |
| **5** | 中国严格限制进出口有毒化学品目录 | 环保总局 | 30 类 183 种 | 有毒化学品进出口环境管理登记 |
| **6** | 中国进出口受控制消耗臭氧层物质名录（2000-2006 年） | 环保总局，海关总署等 | 第一至四批共 56 种 | 履行保护臭氧层蒙特利尔议定书，进出口环境管理 |
| **7** | 禁止和限制使用的农药名单（农业部公告第 199 号） | 农业部 | 禁止使用农药 18 种；限制使用农药 21 种 | 农药安全管理 |
| **8** | 易制毒化学品分类和品种目录（2005 年 8 月） | 安监总局 | 各类易制毒化学品 23 种 | 易制毒化学品安全管理 |
| **9** | 各类监控化学品名录（1995 年） | 国家化学武器控制办公室 | 各类监控化学品共 53 种（类） | 化学武器及其前体化学品的安全控制 |
| **10** | 化妆品卫生标准（GB7916-87） | 卫生部/质检总局 | 化妆品中禁用化学品 359 种（类）；限用化学品 57 种（类） | 化妆品安全和健康保护 |
| **11** | 国家职业卫生标准（GBZ2-2002） | 卫生部/质检总局 | 颁布了空气中容许浓度的有害物质 329 种 | 工作场所空气中有害物质职业接触限值 |
| **12** | 淘汰落后生产能力、工艺和产品目录（1999 年 1 月） | 原国家经贸委 | 第一、二、三批淘汰落后产品共 29 种 | 淘汰技术落后、污染严重产品和生产工艺 |
| **13** | 产业结构调整指导目录(2005 年第 40 号令) | 国家发展改革委 | 淘汰化工产品 29 种（类），限制化工产品 41 种（类）。 | 淘汰技术落后，资源消耗高、污染严重的化工产品和工艺 |

## 附件 2 中国化学品主管部门的分工

**环保总局**：根据《大气污染防治法》、《水污染防治法》、《固体废物污染环境防治法》、《环境影响评价法》以及《危化条例》等法律、法规的授权，环保总局对排放到大气、水体和陆地环境的化学污染物实施统一监督管理。负责化学品和化学污染物的环境污染防治、新工业化学物质申报登记、废弃危险化学品处置、重大危险化学品污染事故调查、应急监测以及危险化学品进出口登记等监督管理工作。环保总局还是《鹿特丹公约》、《斯德哥尔摩公约》和《巴塞尔公约》国内履约牵头单位和国家联络点，代表国家参与环境保护的国际活动，组织协调和监督管理国内的环境履约活动。

**安监总局**：根据《安全生产法》、《危化条例》等法律法规的授权，安监总局负责危险化学品安全监督管理综合工作。负责审批核发安全生产许可证、经营许可证、危险化学品事故应急救援的组织和协调等工作。

**卫生部**：根据《职业病防治法》、《危化条例》、《化妆品卫生监督条例》等法律、法规的授权，卫生部负责危险化学品毒性鉴定及其对人类健康危害评价、化妆品安全评价、公共卫生以及职业病防治等工作；

**药监局**：根据《药品管理法》、《食品卫生法》等法律、法规的授权，国家食品药品监督管理局负责对药品、麻醉药品、卫生材料等的研究、生产、流通、使用进行行政和技术监督；负责食品、保健品、化妆品安全管理的综合监督并负责保健品的审批工作。

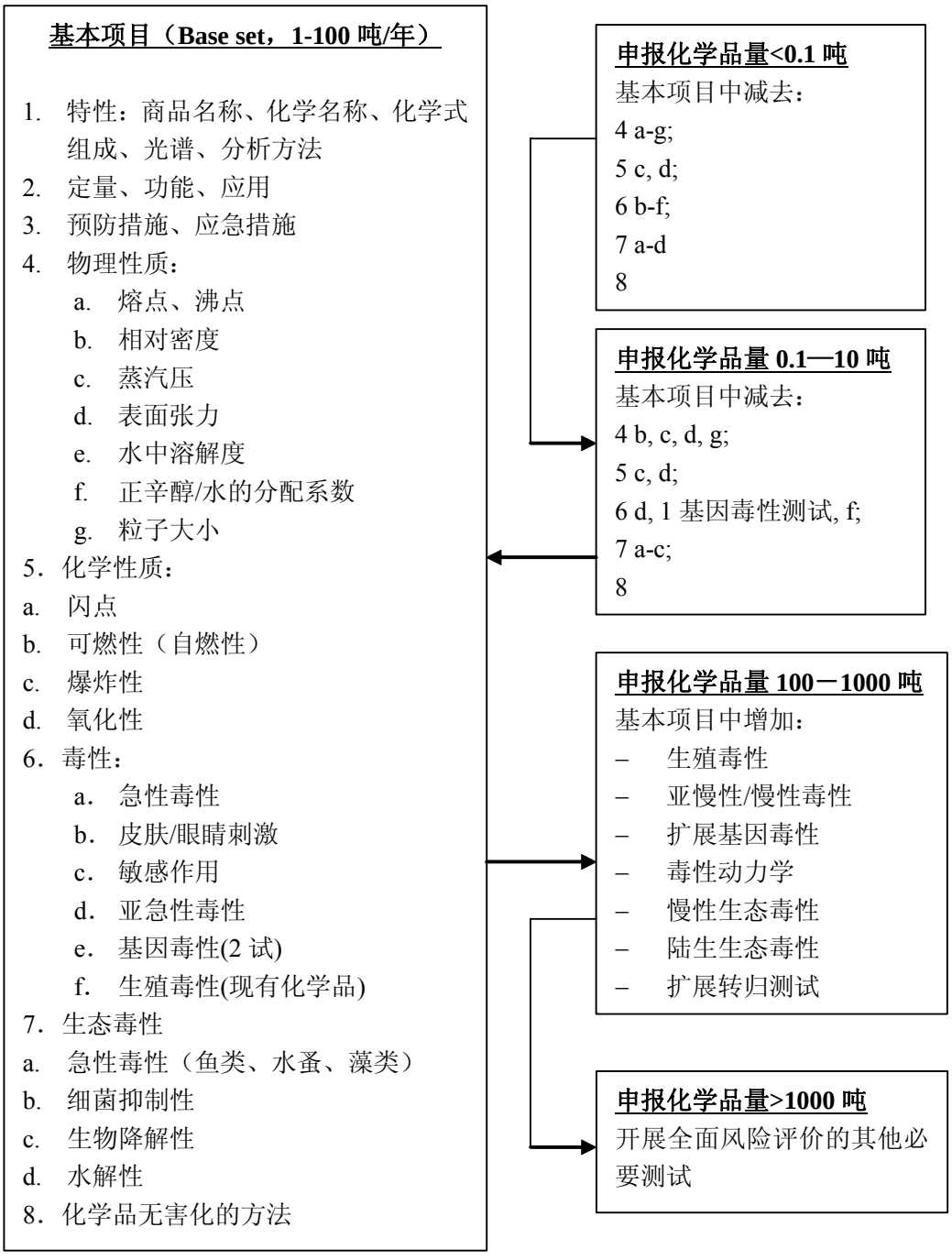
农业部：根据国务院《农药管理条例》、《兽药管理条例》等法规的授权，农业部负责农药生产的登记、使用和鹿特丹公约控制的农药进出口以及兽药安全的监督管理工作。

**质监总局**：根据《产品质量法》、《工业产品生产许可证管理条例》、《危化条例》等法律、法规的授权，质量监督检验检疫总局负责工业产品质量、进出境商品卫生检疫、危险化学品包装物和容器生产许可证发放、监督检查以及认证认可和标准化等工作。质检总局隶属下设国家认证认可监督管理委员会以及国家标准化管理委员会两个职能机关，分别负责依照有关国家标准、国际准则制定有关分析实验室能力验证工作的基本规范和实施规则，统一监管和综合协调能力验证活动以及负责起草国家标准化法律、法规、政策，并组织实施；负责组织协调国家标准的制定、修订，审查批准和发布等工作。

**交通部、铁道部和民航总局**：根据《危化条例》等行政法规的授权，交通部、铁道部和民航总局分别负责危险化学品的公路、水路运输，铁路运输和航空运输单位及其运输工具的安全监督管理等工作。

**公安部**：根据《危化条例》等行政法规的授权，公安部负责危险化学品的公共安全管理，负责发放剧毒化学品购买凭证和准购证，审查核发剧毒化学品公路运输通行证以及危险化学品道路运输安全的监督管理工作。

## 附件 3 欧盟新化学物质申报数据要求



## 附件 4 美国环保局对于新物质测试数据的要求

数据举例

以下是数据类型的列表，所有拥有的数据都必须附到通知文件中。这个列表并不完备。

| 理化性质和环境归趋数据 | 健康影响数据 | 环境影响数据 |
|---|---|---|
| 色谱 | 基因突变 | 微生物鉴定 |
| 光谱（紫外，可见，红外） | 致癌作用 | 海藻生物鉴定 |
| 密度/相对密度 | 致畸作用 | 大型水生植物生物鉴定 |
| 水中溶解度 | 神经毒性/行为影响 | 种子萌芽及根的蔓延 |
| 熔点 | 哺乳动物吸收 | 秧苗生长 |
| 沸点/升华温度 | 扩散行为 | 植物吸收 |
| 软化点 | 新陈代谢和排泄 | 对无脊椎动物的剧毒性 |
| 蒸汽压 | 累积效应、成瘾效应和协同效应 | 对无脊椎动物的生命周期实验 |
| 解离常数 | 急性效应、亚急性效应和慢性效应 | 对鱼类的剧毒性 |
| 粒径分布 | 结构和活动性的关系 | 鱼的早期生命阶段 |
| 辛醇/水分配系数 | 流行病学 | 鸟类的食物和繁殖 |
| 亨利常数 | 生殖影响 | 生物累积性/生物浓缩性 |
| 土壤挥发性 | 临床研究 | 模拟生态系统研究 |
| 可燃性 | 皮肤腐蚀性 | 自然环境损害效应 |
| 爆炸性 | 光学毒性 | 水生生物体着色性 |
| 吸附/解吸特性 | 刺激性 | |
| 粘度 | 过敏性 | |
| 气味 | 敏感性 | |
| 水解性 | *皮肤着色* | |
| 热力分析 | | |
| 化学分析 | | |
| 化学氧化 | | |
| 化学还原 | | |
| 生物降解性 | | |
| 持久性有毒产物的转化 | | |

*来源于 2004 年美国环保局有毒污染控制法第 5 章新化学物质申报程序的报告手册*

- **登记**：要求化学品产量或进口量大于 1 吨/年的生产或进口商在规定的期限内向欧盟主管机构申报一份其所生产或进口的化学品的风险信息档案，其中须包括：规定的各项理化、健康和环境危害测试数据，用途和预计的人体和环境暴露，产量或进口量，建议的化学品分类和标识，安全数据清单，化学品用途的初级风险评价，风险管理措施建议。

  现有化学物质（～30000 种）需要在约 10 年的期限内分批完成危害测试和风险评价等工作并进行登记，其中：在 2010 年 12 月 1 日前完成产量>1000 吨/年的化学品和 CMRs 和 PBT（未来包括 EDCs）等优先化学品的申报登记；在 2013 年 6 月 1 日前完成产量>100 吨/年的化学品的申报登记；在 2018 年 6 月 1 日前完成产量>1 吨/年的化学品的申报登记。

  生产和使用商还需以安全数据表格的形式在整个供应链中提供并交流这些风险管理信息。

- **评估**：位于赫尔辛基的欧盟化学品中心将对产量>100 吨/年的化学品（～5,000 种）或可疑具有vPvB或CMR性质的（未来包括EDCs）化学品申报登记信息或测试计划进行评估审查，以最终评价确定这些优先化学品的环境和健康风险。
- 下游用户责任：为确保物质的风险在整个供应链中的控制，欧盟将物质的下游用户也包括到系统当中。
- **审批**：在欧盟体系下，其主要理念是引入了企业责任进而确保对于物质风险的充分控制。因此，这个限制体系对于在欧洲水平下的不可接受风险形成一个安全网络。对此类物质的生产进口和投入市场可以被社会所禁止或限制。特别审批程序将被应用于“高度关注”的化学品。CMRs、PBT、vPvB等优先化学品或具有EDCs性质的特定化学品的使用将需要特别审批。首先，这些化学品在REACH法规附件中被鉴定 并确定其优先性，然后这些附件包含物质的生产商将对于这类物质的使用提交申报。只有在其在使用过程中的环境和健康风险得到足够控制，或该化学品的社会经济价值超过其环境和健康风险、且尚无合适替代品的情况下，才可以欧盟委员会的批准下限制使用。

## 附件 6 欧盟重大危险源分类性鉴定标准

特定的危险物质及其临界量

如果该类物质也符合《其他危险物质类别和临界量》的要求，则按照本表要求进行管理

| 危险物质名称 | 临界量（t） | | 危险物质名称 | 临界量(t) | |
|---|---|---|---|---|---|
| | 需要通报书 | 需安全报告和应急计划 | | 需要通报书 | 需安全报告和应急计划 |
| 硝酸铵[1] | 350 | 2500 | 环氧丙烷 | 5 | 50 |
| 硝酸铵[2] | 1250 | 5000 | 甲醇 | 500 | 5000 |
| 五氧化二砷，砷酸盐 | 1 | 2 | 4,4-亚甲基双（α-氯苯胺）及其盐类 | | 0.1 |
| 三氧化二砷，亚砷酸盐 | - | 0.1 | 甲基异氰酸酯 | -- | 0.15 |
| 溴 | 20 | 100 | 氧 | 200 | 2000 |
| 氯 | 10 | 25 | 甲苯二异氰酸酯 | 10 | 100 |
| 吖丙啶 | 10 | 20 | 砷化三氢（胂） | 0.2 | 1 |
| 氟 | 10 | 20 | 磷化三氢（膦） | 0.2 | 1 |
| 甲醛（≥90%） | 5 | 50 | 二氯化硫 | 1 | 1 |
| 氢 | 5 | 50 | 二氧化硫 | 15 | 75 |
| 氯化氢（液化气体） | 25 | 250 | 汽油及其他石油溶剂油 | 5000 | 50000 |
| 烷基铅 | 5 | 50 | 光气 | 0.3 | 0.75 |
| 乙炔 | 5 | 50 | 环氧乙烷 | 5 | 50 |
| 镍化合物粉末（一氧化镍、二氧化镍、硫化镍、二硫化三镍、三氧化二镍） | -- | 1 | 多氯二苯并呋喃和多氯二苯并二恶英（以TCDD当量计） | -- | 0.001 |
| 极易燃液化气体（包括液化石油气和天然气） | 50 | 200 | 下列致癌物质：<br>4-氨基联苯及其盐<br>联苯胺及其盐<br>双（氯甲基）醚<br>氯甲基甲醚<br>二甲氨基甲酰氯<br>二甲基亚硝胺<br>六甲基三酰胺<br>二萘胺及其盐<br>1,3-丙磺酸内酯<br>4-硝基联苯 | 0.001 | 0.001 |

注解:

[1] 指氮含量大于 28%（重量）的硝酸铵和硝酸铵化合物（不包括注解[2]）以及硝酸铵浓度大于 90%（重量）的硝酸铵水溶液。

[2] 指符合指令 80/876/EEC 规定的单一硝酸铵肥料以及氮含量大于 28%（重量）复合肥料（复合肥料中含有硝酸铵和磷酸铵和/或钾肥）。

其他危险物质类别和临界量

（如果未包括在上表中）

| 危险性类别 | 临界量（t） | | 危险性类别 | 临界量(t) | |
|---|---|---|---|---|---|
| | 需要通报书 | 需安全报告和应急计划 | | 需要通报书 | 需安全报告和应急计划 |
| 1、极高毒性物质[1] | 5 | 20 | 7a、高度易燃液体[3b1] | 50 | 200 |
| 2、有毒物质[1] | 50 | 200 | 7b、高度易燃液体[3b2] | 5000 | 50000 |
| 3、氧化性物质 | 50 | 200 | 8、极易燃气体和液体[3c] | 10 | 50 |
| 4、爆炸性物品[2a] | 50 | 200 | 9、环境危险物质[4]<br>i. 对水生生物极高毒性物质<br>ii. 对水生生物有毒和对水生环境有长期影响的物质 | <br>200<br><br>500 | <br>500<br><br>2000 |
| 5、爆炸性物品[2b] | 10 | 50 | 10、其他物质<br>i. 与水发生剧烈反应的物质<br>ii. 与水接触释放出有毒气体的物质 | <br>100<br><br>50 | <br>500<br><br>200 |
| 6、易燃液体[3a] | 5000 | 50000 | | | |

注解：

[1]“极高毒性物质”是指具有下列急性毒性值的化学物质：

$LD_{50}$（大鼠经口）≤25 mg/kg；$LD_{50}$（大鼠经皮）≤50 mg/kg；$LC_{50}$(大鼠吸入) ≤0.5mg/l

“有毒物质”是指具有下列急性毒性值的化学物质：

$LD_{50}$（大鼠经口）>25 ～200 mg/kg；$LD_{50}$（大鼠经皮）>50～400 mg/kg；$LC_{50}$(大鼠吸入) >0.5～2 mg/l

[2] “爆炸性物品”是指：

（a）（i） 受冲击、摩擦、遇火焰或其他引燃源会引起爆炸危险的物质和制剂（风险术语为 R2）；

（ii）设计用来产生热量、光、声响、气体或烟雾或者通过非起爆自持的放热化学反应产生这些效应的

结合的烟火物质；

（iii）物体中含有的爆炸或烟火物质或制剂（风险术语为 R3）。

（b）受冲击、摩擦、遇火焰或其他引燃源会产生极大爆炸危险的物质和制剂。

[3]第 6、第 7 和第 8 类中，“易燃的”、“高度易燃的”和“极易燃的”分别指：

(a)**易燃液体**是指 21℃≦闪点≦55℃（风险术语为 R10），支持燃烧的物质和制剂。

(b)**高度易燃液体**是指：

（i）在室温下没有投入任何能量，与空气接触时可能变热，最终着火的物质和制剂（风险术语为 R17）；或者闪点低于 55℃，在加压下保持液态，在特定加工条件下，如高温或高压下可能产生重大事故危险的物质；

(ii)闪点低于 21℃，且非极易燃的物质和制剂（风险术语为 R11）。

(c)**极易燃气体和液体：**

(i)闪点低于 0℃和在常压下沸点（或初始沸点）≦35℃的液体物质和制剂（风险术语为 R12）；

(ii)在常温常压下与空气接触是易燃的气体物质和制剂（风险术语为 R12），不论其在加压下是保持气态还是液态。但不包括极易燃的液化气体（含液化石油气）和天然气；

(iii)保持在高于沸点温度下的液体物质和制剂。

[4] 环境危险物质

(i) 对水生生物极高毒性物质是指具有下列生态毒性的物质：

$LC_{50}$(鱼类) ≤ 1mg/l； $EC_{50}$(水蚤) ≤ 1mg/l

(ii) 对水生生物有毒物质是指具有下列生态毒性的物质：

$LC_{50}$(鱼类) 1～10mg/l；$EC_{50}$(水蚤) 1～10mg/l

## 附件 7 GHS 系统中的化学品危害性基本类别

| 危害性类别 | 分类 |
| --- | --- |
| 固有理化危害（Physical hazards） | 爆炸性（Explosive）；可燃性（flammable）；氧化性（oxidizing）；压缩气体（Gases under pressure）；自反应性（Self-reactive）；自燃性（Pyrophoric）；自加热性（Self-heating）；触水释放可燃气体（contact with water emit flammable gases）；有机过氧化物 (Organic peroxides)；金属腐蚀性（corrosive to metals） |
| 健康和环境危害（Health and Environmental hazards） | 急性毒性（Acute toxicity）；皮肤腐蚀/刺激性(Skin corrosion/irritation)；严重刺激和伤害眼睛(Serious eye damage/irritation)；呼吸或皮肤敏感性（Respiratory or skin senzitisation）；生殖细胞突变性（Germ cell mutagenicity）；致癌性（Carcinogenicity）；生殖毒性（Reproductive toxicity）；特定靶器官系统毒性（Specific target organ systemic toxicity）；水生环境危害性（Hazardous to the aquatic environment） |

# Annex 8 Chemicals Management in Europe, Germany and in the United States of America

By: Ulrike Kowalski[18], Silke Schmidt[19], David J. van Hoogstraten[20]

## A8-1 Introduction

The China Council for International Cooperation on Environment and Development (CCICED) is a high-level international advisory body, established in 1992 with the approval of the Chinese Government. CCICED has conducted in-depth research on a number of key environmental and development issues and has submitted its policy recommendations to the Chinese government. CCICED is now entering its fourth phase of activity from 2007 to 2011. During this phase, several Special Policy Studies Projects will be carried out. The first is on "Environmentally-Sound Management of Chemicals in China" and consists of a study on major issues and policy framework for Chemicals Management. In this project, a multilateral team of experts will analyze and evaluate the environmental management system on chemicals in China and will learn from advanced international experiences.

This report is a contribution of the International Team that provides an overview on German and European as well as American experiences and trends on Chemical Management.

## A8-2 European and National Chemicals Legislation in Germany

### A8-2.1 Introduction

"Sustainable development" is the overarching long-term goal of the European Union (EU) set out in the Treaty. The European Sustainable Development Strategy aims, in tandem with the "Lisbon Strategy for Growth and Jobs", for a more prosperous, cleaner and fairer Europe. As an overarching concept, the EU Treaty requires the integration of sustainable development into all European policies, so that they contribute in an integrated way to meeting environmental, economic and social objectives. Art. 6 of the EC-Treaty provides that "*Environmental protection requirements must be integrated into the definition and implementation of the Community policies and activities […], in particular with a view to promoting sustainable development.*"

Recognising these linkages, the EU is exploiting the mutually reinforcing elements of environmental, social and economic policy. The Commission now undertakes impact assessments for all major policy proposals to assess whether these are consistent with better regulation and sustainability principles.

As chemicals legislation sets rules for products on the EU market, it is based on Art. 95 of the EC-Treaty, which allows the Community to set rules for establishment and functioning of the

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internal market. However, chemicals legislation strongly affects areas such as health, consumer and environmental protection in the European Union and therefore the EU institutions need to consider them and find a good balance when developing of any new piece of chemicals legislation.

The first EEC-Directive on chemicals was adopted in 1967. Thereafter, EU Chemicals legislation consisted of a mixture of EC Directives - which must be transposed into national law by national regulations - and EC Regulations, which apply directly. The main pieces of the future general EU Chemicals legislation will be two Regulations: The REACH Regulation[21] and the GHS Regulation[22]. *General* EU chemicals legislation thus means legislation focussing on substances and preparations rather than addressing specific products at a later stage in the life cycle like e.g. rules on toys or batteries or addressing specific environmental compartments like air, water or soil. The waste stage is also excluded from chemicals legislation as there is specific legislation for it.

The Federal Republic of Germany is a member of the European Union and is therefore subject to "primary" EU legislation like the "Treaty for the Foundation of the European Community (EC)" as well as to "secondary" EC-legislation in form of Regulations and Directives. Regulations are directly applicable in Germany, whereas Directives need to be transposed into German law.

Germany is a Federal State. The Powers between the Federal level and the 16 Länder are distributed in the German Constitution. The legislative competencies are divided between the federal level and the Länder level. In contrast, the Länder are generally solely responsible for the enforcement of laws. In the area of chemicals legislation, federal authorities also perform some tasks. Some of these tasks will be shifted to the European Chemicals Agency (ECHA) in future.

The concept of environmental protection is also set out in Article 20a of the German Constitution which provides a basis for the development and interpretation of environmental legislation in Germany. In most areas, laws are adopted on the federal level, however the Länder contribute to the legislative process in the "Bundesrat", which is the "Federal Council of Germany", the "Chamber of the Länder".

## **A8-2.2** The "Old" European System of Industrial Chemicals Legislation

### A8-2.2.1 Introduction

The German Chemicals Act is the central part of German chemicals legislation. It entered into force on 1st January 1982 to implement the 6th amendment of Directive 67/548/EEC. It was amended 1994 to implement Directive 92/32/EC, which was the 7th amendment of Directive 67/548/EEC. With the latest change in 2002 the Biocides Directive 98/8/EC had been included.

There are different European directives implemented in the German Chemicals Act and its ordinances (Hazardous Substance Ordinance and the Chemicals Prohibition Ordinance):

[21] Regulation on the Registration, Evaluation and Authorisation and Restrictions of chemicals
[22] Regulation on the classification, labeling and packaging of substances and mixtures (based on the Globally Harmonized System)

Directive 67/548/EEC on notification, information exchange, risk assessment, classification, packaging and labeling of chemicals, Directive 1999/45/EC on Classification, packaging and labeling of preparations and Directive 76/769/EEC on Limitations of Marketing and Use.

The European Regulation (EEC) No 793/93 on the Evaluation and Control of Risks of Existing Substances, those chemicals which have been produced and marketed before 1981, is directly applicable in Germany. This Regulation however will be repealed on 1st June 2008. Most parts of the German chemicals Act will become obsolete at the same time, as then REACH will become operational and most parts of the REACH Regulation apply.

The purpose of the German Chemicals Legislation is the protection of human health (both workers and consumers) and the environment from harmful effects of hazardous chemical substances. This purpose is achieved by the identification of the hazard through testing of chemicals, by the warning of hazards through classification and labeling of the chemicals, the communication of basic information about hazards and risks in safety data sheets and by bans or other restrictions, if no other means of protections is possible.

To perform the tasks of gathering, exchange of information and assessment on chemicals for the performing the risk assessment and for proposing risk management measures and restriction the **BAuA, Division 5,** as the appointed Competent Authority (***therafter: CA***) co-operates with the following German authorities, the **UBA**, the Federal Environmental Agency, the **BfR**, the Federal Institute for Risk Assessment, the **BAuA**, **Division 4**. In certain cases the **Federal Biological Research Centre for Agriculture and Forestry** (BBA) and the **Federal Institute for Materials Research and Testing** (BAM) are included in the process.

The Chemicals Act regulates the duties to test, notify, classify, label and package new substances properly. New substances are all substances not listed in EINECS, the European Inventory of Existing Commercial Chemical Substances. Substances, preparations or products which are regulated by special laws are exempted or only subject to the scope of the law to a limited extent.

The Chemicals Act follows the following main principles: The Producer or importer is responsible for the chemical, not the user or the consumer. The producer or importer of a new chemical has to submit a notification before marketing of the substance by testing the chemical and providing the Competent Authority with a defined set of information. Dangerous (= classified) chemicals must be properly packed and labelled. The Government (under the conditions of art. 95 (4) und (5) EC-Treaty) and the Länder authorities in individual cases are empowered to restrict or ban a chemical if no other means is present to ensure the protection of health and the environment. The Länder authorities are also responsible to pursue regulatory offences and where violations of chemicals legislation result in criminal offences, they will be prosecuted.

### A8-2.2.2. Procedure for Notification of New Chemical Substances

Pre-Marketing Notification of a New Chemical Substance in Germany thus means that the producer or importer submits notification documents to **BAuA, Division 5**, **Chemicals,**

**Notification and Authorization**. This procedure will be replaced by the registration procedure under REACH from 1st June 2008.

#### A8-2.2.2.1 Tonnage-Related Procedure

The Chemicals Act provides for the tonnage-related notification of each new substance placed on the market in quantities of ≥ 10 kg per year. Once the next tonnage threshold, 10, 100 or 1000 tonnes per year has been reached, further documents must be submitted. The decisive factor with regard to import notifications is the total quantity of the substance which is imported into the EU and the EEA states per producer/importer.

#### A8-2.2.2.2 Prior Inquiry Duty / Utilization of Existing Test Reports

Each notifier has the duty to make a prior inquiry before performing animal tests for the purpose of preparing a notification or a reduced notification. Within the framework of this procedure the potential notifier must inquire about the need to perform animal tests. If the Competent Authority already possesses sufficient knowledge about the relevant substance from a third party's test reports, a procedure for the utilization of the third party's test reports is initiated whereby the third party and the subsequent notifier have the opportunity to reach an agreement about joint utilization of the test reports. If no agreement is reached, so-called compulsory referencing is undertaken. According to this procedure, the third party whose test reports are utilized has the right to seek compensation from the subsequent notifier at a level of 50% of the saved expenditure. For his part, the subsequent notifier has a right to be provided with a copy of the utilized test report.

#### A8-2.2.2.3 Good Laboratory Practice (GLP)

Non-clinical experimental tests whose results are to be submitted within the framework of the notification procedure must be performed in accordance with the principles of Good Laboratory Practice (GLP). Proof that the test results satisfy these demands must be furnished in the form of a certificate from the competent authority (GLP certificate) that the test institute and the tests it performs comply with the principles of good laboratory practice and a written declaration from the test institute that the particular test has been performed according to the principles of good laboratory practice.

Test results are regarded as not having been submitted if one of the above-mentioned reports has not been provided.

#### A8-2.2.2.4 Submission of Notification Documents

The notification procedure requires the completion of a form in the German language. The use of the SNIF format (Structured Notification Interchange Format) on disk is the preferred option here. This format is a development for the information exchange within the EU. The documents consist of a notification form with test results, spectral and analytical data confirming/proving the chemicals identity and the test reports (physical-chemical properties, toxicology, and eco-toxicology).The submitted documents are checked for completeness and forwarded to the assessment authorities.

The assessment units and the CA examine, within their area of competence, the plausibility and validity of the notification documents. In total a period of **30 days** for reduced notifications and **60 days** for a complete notification at base-set level is available for this procedure.

If the documents are in compliance with the legislative provisions the CA confirms this fact by issuing a notice of acceptance. If the submitted notification documents and test reports do not permit adequate assessment of whether the notified substance has adverse effects on man or the environment and if this inability to perform an assessment is due to incomplete or incorrect notification documents, the CA requests the notifier to supplement or correct his documents within the 30/60-day period.

A consequence of this request is that the notifier is not allowed to place the substance on the market until 30 or 60 days respectively after receipt of all the required corrections or supplementary data to the CA. If adequate assessment is not possible even after the subsequent submission of further documents, the procedure is repeated. On conclusion of the procedure the notifier is sent a notice of the relevant costs.

The CA can issue further requests due to incomplete or incorrect test reports even after expiry of the notification period if, for example, new aspects have come to light after expiry of the specified period. However, where an assessment of the notified substance would not otherwise be possible, supplementary information can also be demanded in the case of complete and correct documents, too. Furthermore, the CA can request the submission of test reports at an earlier stage if there are grounds for suspecting a particular substance of being dangerous. Such grounds may, for example, result from structure-activity-relationships and exposure to the substance or exist in cases where the test reports are required for performance of the risk assessment. In addition, the CA can order that substances may only be placed on the market if certain conditions are fulfilled or after a future event has occurred. If documents are not submitted within the specified period or if obligations or conditions are not met, the CA can prohibit the marketing of the substance concerned.

A Summary with the relevant information on the substance, the test results, the proposals on classification and labeling and the assessment of the risks is sent to the European Chemicals Bureau (ECB) of the EU Commission, which is located in Ispra in Italy. The ECB circulates the summary to all other member states of the Community. This procedure ensures that the Member States CAs are informed about the notified substances in the Community with the effect, that a producer or importer has to notify only once before marketing. After a notification has been undertaken, producers or importers may freely market the substance throughout the entire EU area as well as in states within the European Economic Area which have transposed the 7th Amendment into national law.

However, the producer or importer has to submit his notification to that CA where his headquarter or the importer’s office is located. A choice of the CA is therefore not possible.

In addition the CA forwards information about notified substances to the German Länder. They need it for reasons of monitoring and controlling and to inform e.g. fire workers.

## A8-2.2.3 EC Regulation No 793/93 on Existing Substances

Substances produced and marketed before 1981 are the so called „Existing Substances“, they are listed in the EINECS (European Inventory of Existing Commercial Chemical Substances).

Council Regulation No. 793/93 of 23 March 1993 on the Evaluation and Control of the Risks of Existing Substances came into force on the 04.06.1993. It takes direct effect in the Member States. It will be repealed on 1st June 2008 and replaced by the REACH Regulation.

About 100,000 substances, which in principle can be freely traded and used, are listed in the EINECS. As there was a lower level of information, it was therefore necessary for existing substances to be regulated on their own - in accordance of Annex VII of Directive 67/548/EEC, the procedure for new substances - in order to be able to perform, at EU level, systematic assessments of the risks posed by chemicals from which, if necessary, specific protection measures for workers, consumers and the environment can be derived. Work on existing substances took place in four steps:

### A8-2.2.3.1 Information Gathering

Producers or importers of high volume or dangerous chemicals submitted data to the EC-Commission. It was a collection of available information, at first for substances produced or imported in quantities of more than 1,000 tonnes per year, and at a later date for substances in quantities between 10 and 1,000 tonnes per year. The **European Chemicals Bureau** in Ispra/Italy therefore possesses an extensive pool of data on substances produced in large volumes. In particular, data on producers, quantities and intended uses are available.

### A8-2.2.3.2 Priority Setting

Based on this information the EC-Commission drew up a priority list and divided the substances among the Member States. If there was an information gap in the data or due to problems related to handling, substances were included in a priority list after joint discussion between the European Commission and the Member States. Four priority lists, containing a total of 140 substances, currently exist. A Member State was assigned to each substance as rapporteur. Germany was designated as the rapporteur for 37 of the 140 substances.

### A8-2.2.3.3 Completion of Data

Each Member State responsible for a substance checked whether the information submitted by the manufacturer or importer was at least equivalent to the data necessary for marketing a new substance. It included test protocols, data relating to use, exposure data and other available knowledge concerning the priority substances. The minimum amount of data required in connection with the properties of the substance depends on the extent of testing at base-set level within the framework of the procedure for new substances. If certain data were missing, tests had to be conducted within 1 year to close the data gap.

#### A8-2.2.3.4 Risk Assessment (and Risk Management)

The Member States produce comprehensive risk assessments for the substances for which they are rapporteur, using the documents conveyed to them as well as available knowledge.
A Risk Assessment includes an assessment of the risks to workers, consumers and the environment which are posed by the substance, a report includes a proposal for protective measures and, if necessary, the indication of substitute substances and their risks and availability.

In Germany, the responsibility for performing this work is regulated by the Administrative Provision for Existing Commercial Chemical Substances (ChemVwV-Altstoffe) of the 11.09.1997. Accordingly, the national rapporteur is the **BAuA Division 5, Notification Unit within the Chemicals Act** and the assessment units are the **Federal Environmental Agency** (UBA), the **Federal Institute for Risk Assessment** (BfR) and the **Federal Institute for Occupational Safety and Health, Division 4** (BAuA), each having responsibility for the specific areas targeted by them for protection. The **Advisory Committee on Existing Chemicals of Environmental Relevance** (BUA), which comprises experts from the scientific field, industry and the authorities, can be called upon if the above-mentioned state bodies consider external support with selected risk assessments to be appropriate.

The draft risk assessments produced by the individual Member States were distributed to the **European Commission** and all the other Member States. In several different phases of work, the risk assessments were discussed and, if necessary, altered before being accepted by all of those participating in the procedure. The results obtained were subsequently published in the Official Journal of the European Communities, while protecting confidential business information.

Necessary measures such as, inter alia, classification, labeling, establishment of limit values for the workplace, restrictions, and prohibitions must then be derived from the generally accepted risk assessments and pushed through politically.

### A8-2.2.4 Directive 76/769/EEC and its Implementation in Germany

The German Chemicals Act empowers the ministries to issue ordinances e.g. for the restrictions of chemicals as adopted in Directive 76/769/EEC. These restrictions will be replaced by Annex XVII of the REACH Regulation on 1st June 2009.

#### A8-2.2.4.1 Chemicals Prohibition Ordinance

The Chemicals Prohibition Ordinance implements Directive 76/769/EEC, which also is a source for the PIC procedure. It restricts and bans the marketing of certain dangerous chemicals. The central part is the annex with the 3-column table, the first column includes the substance, the second one the kind of restriction and the third one the exemptions of the regulation. REACH will combine the restriction and the exemptions in one column.

#### A8-2.2.4.2 Hazardous Substance Ordinance

The Hazardous Substance Ordinance is another ordinance based on the Chemicals Act and implements Directive 76/769/EEC by restricting the use of certain dangerous chemicals.

### A8-2.2.5 Classification and Labeling Rules and Work-Place Related Rules: Hazardous Substance Ordinance

The Hazardous Substance Ordinance implements Directive 1999/45/EEC on preparations as well as other EC-Directives on classification, packaging, labeling, and handling of chemicals. It also regulates and restricts chemicals at workplaces. However, it does not apply to private households. The classification, labeling and packaging provisions will be replaced by the GHS Regulation in future.

## A8-2.3 The "New" European System of Industrial Chemicals Legislation: The REACH Regulation and the Future GHS Regulation

### A8-2.3.1 Introduction

Chemicals Policy in the EU has been revised in the past decade and will soon mainly consist of two Regulations (i.e. directly applicable European laws), the REACH Regulation EC no 1907/2006[23] and the proposal for the GHS Regulation[24]. REACH stands for the "Registration, Evaluation, Authorisation and Restrictions of chemicals"; GHS Regulation stands for the Regulation on the classification, labeling and packaging of substances and mixtures (based on the Globally Harmonised System). The REACH-Regulation was adopted on 13.12. 2006 and entered into force on 1st June 2007. As the new European Chemicals Agency has to be established, most provisions will only have to applied after the Agency will have been set up and the IT-System will be ready which shall be the 1st June 2008.

The REACH Regulation and the GHS Regulation follow the same main principle as the new substance regime: The manufacturer or importer is responsible for the chemical, not the user or the consumer. The REACH regulations contains rules on the following subjects:

1. Information to be generated, including by testing, on substances in quantities of 1 tonne or more per year by enterprises manufacturing or importing such substances
2. Chemical Safety Assessment for substances in quantities of 10 tonnes or more per year
3. Submission of the defined dataset in a registration dossier to the European Chemicals Agency (ECHA) before manufacturing or importing the substance
4. Communication via safety data sheets or other means and application of identified measures by enterprises in the supply chain, i.e. manufacturers, importers and downstream users
5. Review of the quality of the information submitted to the ECHA and clarifying suspicion of risks
6. Procedures and requirements for European wide chemicals management

The GHS Regulation contains rules on determining the hazards of substances and preparations i.e. classify and properly package and label classified substances and preparations.

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[23] OJ L 396 30.12.2006, p. 1

[24] Document COM(2007) 355 final, Proposal for a Regulation of the European Parliament and of the Council on classification, labeling and packaging of substances and mixtures, and amending Directive 67/548/EEC and Regulation (EC) No 1907/2006, 27.06.2007

In Germany the Länder authorities will remain responsible to take administrative decisions needed to ensure the application of the two Regulations and to pursue regulatory offences and prosecute companies in case of criminal offences. The information necessary will be submitted by the BAuA, Division 5, who will be appointed as the Federal Agency for Chemicals in Germany. The BAuA is establishing an IT-system that is linked with the European ECHA-IT-system.

These regulations will also be the – legal or factual - basis for numerous other European provisions dealing with the protection of the environment and human health as well as emergency management. Sound knowledge about hazards and risks of chemical substances is not only essential for the adequate control of chemicals, but also for the protection of the environment and human health as well as for accident and emergency prevention. Therefore, the table below shows the different areas of law and how they can benefit from the REACH and the GHS Regulation:

<table>
<tr><th rowspan="2">Subject of protection/rules</th><th colspan="2" rowspan="2">Intended production process</th><th colspan="2">Unintended production process</th></tr>
<tr><th>Disturbed working processes</th><th>Disturbed plant processes</th></tr>
<tr><td>Product</td><td rowspan="3">GHS and REACH:<br><br>information about hazard of substances and exposure (risks) of the use of substances covering life cycle and workers and environment and people via the environment</td><td></td><td></td><td>Quality assurance: Measures against disturbance of intended processes</td></tr>
<tr><td>Workers (within plant)</td><td>protection of health measures against long term exposure due to<br>- surroundings and<br>- work/process</td><td>worker protection measures against risks due to surroundings and work-related, spontaneous risks, accidents</td><td>plant safety measures against<br>- fire<br>- explosions<br>- release of substances</td></tr>
<tr><td>Environment and neighbourhood (outside plant)</td><td>environmental protection: measures<br>- against emissions into air<br>- against emissions into water<br>- waste disposal saving of resources</td><td></td><td>Measures to reduces the consequences of accidents<br><br>emergency management</td></tr>
</table>

## A8-2.3.2 Procedure for Registration of Chemical Substances under REACH

Registration under REACH requires manufacturers and importers to collect and/or generate information on the hazards and risks of substances in quantities of 1 tonne or more per year before they manufacture or import such substances (this includes the import of substances in preparations). The complete registration dossier will have to be sent to the European Chemicals Agency in Helsinki. Enterprises also apply the identified risk management measures and communicate them along the supply chain. Thus, the aim of registration is to screen, collect and gather information about substances in order to ensure the application, communication and documentation of responsible risk management measures on the basis of sound information.

### A8-2.3.2.1 Scope

For reasons of workability, focussing of resources and considerations of risks, some substances are exempted either from the REACH Regulation as a whole or from the registration part: These are

- radioactive substances
- waste
- non isolated intermediates
- polymers (but monomers have to be registered under certain conditions)
- substances in medicinal products for human or veterinary use
- food or feeding stuff
- substances listed in Annex IV or described in Annex V, e.g. substances occurring in nature unless chemically modified or classified as dangerous
- re-imported substances provided the substance is the same and the information flow is ensured

For scientific research and development, REACH does not need any specific exemption as this form of research takes place in quantities of less than 1 ton per year.
For product and process orientated research and development, REACH requires a simple notification for an exemption from the obligation to register for 5 years. The Agency may extend this exemption for another 5 or 10 years. There is no tonnage limit for this exemption, however, customers must be known.

### A8-2.3.2.2 Information Requirements

The Registration dossier consists of two parts, the **technical dossier** for all substances in quantities of 1 tonne or more per year and for substances in quantities of 10 tonnes or more per year also of the **chemical safety report**. The amount of test data or other information on the properties and hazards of substances mainly depends on the volume manufactured or imported (there are different requirements for substances >= 1000t/year, >=100 t/year, >= 10 t/year and >= 1t/year). There are some general rules for the use of available data and the adaptation of testing requirements, including lack of exposure.

The **Chemical Safety Assessment** includes for classified substances an exposure assessment and risk characterisation. To that end, the registrant has to develop exposure scenarios or exposure categories. Exposure scenarios/categories are recommendations by the manufacturer/importer of

a substance to those carrying out identified uses with the substances on how to control exposure. They describe the conditions (operational conditions and other identified risk management measures) for the use of substances. The objective of the exposure assessment is to derive a quantitative or qualitative estimate of the dose/concentration of the substance to which humans or the environment may be exposed. Quantification of exposure is needed where a DNEL[25] and/or PNEC[26] can be determined (6.4. of Annex I).

**A8-2.3.2.3 GLP Requirement**

New ecotoxicological and toxicological tests and analyses have to be be carried out in compliance with the principles of good laboratory practice provided for in Directive 2004/10/EC or other international standards recognised as being equivalent by the Commission or the Agency and with the provisions of Directive 86/609/EEC, if applicable. Whether available non GLP tests are accepted, depends on whether the conditions set out in Annex XI are fulfilled.

**A8-2.3.2.4 Data Sharing and Consortia Formation**

To avoid the duplication of test data, in particular those involving vertebrate animals, mechanisms have been set up to organise the sharing of data and the preparation of joint dossiers by several enterprises manufacturing or importing the same substance. Two situations have to be distinguished:

For newly created substances, it is presumed that companies will not register those substances at the same time, thus registrants of the same substance will be subsequent registrants in most cases. Therefore a mechanism has been set up that is similar to that of the new substances regime, where the Agency helps to put a later registrant into contact with an earlier one for them to reach an agreement on the sharing of studies.

For substances that have already been on the market, in a first step, the "pre-registration", information is needed on which substances might be registered later in which tonnage band by more than one company. Thus, to bring together companies preparing registrations for the same substance is a prerequisite for their joint work. Possible registrants of the same substance will then form part of a substance information exchange forum (SIEF) where they have to share data involving vertebrate animals, and should also agree on the classification of the substance. They should also prepare most parts of the registration dossier jointly in a consortium.

**A8-2.3.2.5 Submission of Information to the European Chemicals Agency (ECHA)**

REACH requires that a registration, where required, is submitted prior to the manufacture or import of substances (thus according to the principle: no data – no market). While the information requirements are now identical for existing and new substances, a mechanism had to be found to "phase in" the existing substances into the new system. Therefore there are longer periods for enterprises to prepare the registration dossier for those substances that have already been on the market. Substances in quantities of 1000 and more t/a and those with CMR

[25] Derived no effect level
[26] Predicted no effect concentration

properties in quantities of ≥ 1 t/a and those which are dangerous to the environment (R 50/53) in quantities of ≥ 100 t/a have to be registered until the 1st December 2010, substances in quantities of 100 t/a and more until the 1st June 2013 and substances in quantities of 1t/a and more until the 1st June 2018.

The Agency will perform a completeness check within 3 weeks (or another defined period for phase in substances), and if there is no indication to the contrary within this time period, the manufacture or import may be started. A more in-depth quality check of the information will only be done at the evaluation stage.

**A8-2.3.3 Evaluation**

Under Evaluation the quality of information that is submitted to the European Chemicals Agency will be checked. For all missing tests for substances in quantities of 100 tonnes or more per year, only testing proposals have to be submitted in the registration dossier, and the Agency will check the quality to save animals' lives and costs. Also the quality of the other information can be checked by the Agency and in case of insufficient information submitted; enterprises will have to (re-)submit the missing information.

Finally, in case that despite the information already submitted on a substance, there is still a suspicion of risk that needs to be clarified; the Agency will be able to request this information from companies in justified cases.

### A8-2.3.4 Communication in the Supply Chain

The tool for the communication in the supply chain is taken from the globally harmonised system (GHS), i.e. the safety data sheet, which is an internationally widely used instrument and which has already been well known also in the EU since 1991. REACH adds an Annex to the safety data sheet for classified substances in quantities of 10 tonnes or more per year, the exposure scenarios/categories. They sum up the chemical safety assessment and thus contain the conditions for the use of the substance. They explain how to control exposure and how to ensure adequate control of the risks arising from the use of the substance. If customers, i.e. downstream users do not agree for with the conditions for use provided to them, they have to inform their suppliers about this fact.

### A8-2.3.5 Obligations on Downstream Users to Manage their Uses

REACH includes downstream users of substances into the system, however limits their obligations as far as possible. There is no obligation on downstream users to submit a registration dossier for their substances. REACH aims at the generation of information on the top end of the supply chain. The idea is that customers, downstream users, get "ready-made" information on the conditions for their uses of the substances supplied to them. But downstream users have a choice: if they do not want to reveal their uses or any other information with regard to them to their suppliers, they may choose to assess the chemical safety of these uses themselves and report this to the Agency. If they start communicating with their suppliers well in advance, they may not have to do any assessments themselves. Therefore communication between customers and suppliers will be very important. Downstream users and importers in the EU will therefore also

need to communicate with suppliers in non EU Countries.

### A8-2.3.6 Procedures and Requirements for European-wide Chemicals Management: Authorisation and Restrictions System in the REACH Regulation

Under REACH, the main idea is that enterprises take the responsibility to ensure adequate control of risks of the substances that they manufacture, import or use.

Therefore, the restrictions system will be the safety net for cases in which there are risks that – still - need to be addressed on the European level. The procedure in which decisions are taken will start in the Agency on the basis of a dossier prepared either by a Member State or the Agency. The dossier will be discussed in the risk assessment and the socio economic assessment committee in the Agency and the Commission will then take the final decision (comitology) based on the Agency's committees' opinions. Decisions can either prohibit the use of a substance altogether or restrict certain uses, this includes defining conditions for use. The restrictions will be included in Annex XVI. Starting point for this Annex will be the restrictions that are currently included in Directive 76/769/EEC. The Directive will be repealed on 1st June 2009.

For substances of very high concern, which are defined as carcinogenic, mutagenic and toxic to reproduction (CMR) and for substances which are persistent, bioaccumulative or toxic (PBT) or very persistent or very bioaccumulative (vPvB) and substances of equivalent concern like e.g. endocrine disruptors, a specific system is designed, the authorisation procedure to ensure that the risks from these substances are properly controlled and that they are progressively replaced by suitable alternative substances or technologies where these are economically and technically viable.

The authorisation system is a two step procedure:

In a first step substances with the described properties will have to be selected for inclusion into the system in a several stage process (hazard identification, publication on a list of the Agency, inclusion in the Agency's work programme, prioritisation and finally inclusion in Annex XIV of the REACH Regulation by a Commission comitology decision).

Only after the inclusion of the substances in the Annex, thus at the second step, enterprises that want to use or place on the market such substances have to apply for an authorisation for each use of such substances (some uses may be exempt though either in the Articles of the REACH Regulation or in the Annex).

### A8-2.3.7 Classification and Labeling of Substances and Mixtures: The Future GHS Regulation

The REACH regulation does not contain the rules for classification and labeling of substances and preparations. These rules are currently regulated in different European acts which will be replaced by the future GHS regulation. The Commission proposal has been discussed by the Council and Parliament for some months now.

## **A8-2.4** Rules on Specific Substances or Specific Procedures

### A8-2.4.1 Regulation (EC) No 2037/2000 on Substances that Deplete the Ozone Layer

Regulation (EC) No. 2037/2000 of the European Parliament and Council dated 29 June 2000 on substances that deplete the ozone layer regulates the production, import, export, placing on the market, use, recovery, recycling, preparation and destruction of substances that harm the ozone layer. As a regulation it is directly applicable.

The production and placing on the market of the following substances is prohibited within the EU:

- CFCs
- Other fully halogenated CFCs
- Halons
- Carbone tetrachloride
- 1,1,1-trichlorethane
- Partially halogenated halons
- Methyl bromide

Exempted are the use and placing on the market for destruction within the Community, as well as the use as starting and processing auxiliary. Methyl bromide may still be used for quarantine and pre-shipment applications. Halons are used in aviation and military areas (see annex VII of the regulation for further information).

Other uses of regulated substances require the explicit consent of the European Commission. The Commission annually allows companies to produce limited amounts of these substances for critical uses where no acceptable substitute is available. Companies have to apply in advance for these licences. Temporary exemptions can be authorized for pharmaceutical implants, military purposes or in case of sudden pest infestations.

The use of partially halogenated CFCs is not prohibited, but severely restricted. Their use as refrigerant is being reduced step by step until 2015, when it will be generally prohibited. Apart from that they may only be used in a limited amount of areas. These are: the production of foams, carrier of sterilisation substances, solvent in aviation and astronautics, laboratory use, research, halon replacement in fire systems and as starting and processing auxiliary. For further details, see article 5 of the regulation.

The import and placing on the market of products and equipment containing partially halogenated CFCs is prohibited, unless they were produced before the prohibition on use came into force. All imports or exports of regulated substances to or from the EU require a licence by the European Commission.

Going beyond the European Regulation, the national Chemikalien-Ozonschichtverordnung (Substances - Ozone layer Regulation) further regulates the production, the placing on the market and the use of ozone depleting substances in pressurized gas packages and fire extinguishers. It also extends the obligations of producers and owners of products or facilities that contain ozone depleting substances regarding containment and recycling.

## A8-2.4.2 Regulation (EC) No. 304/2003 and ROTTERDAM (PIC) Convention

Council Regulation (EC) No 304/2004 dated 28 January 2003 concerning the export and import of dangerous chemicals (Export-Import Regulation) came into force on 7 March 2003. It implements the Rotterdam Convention and is directly applicable as an EC Regulation.

The exports of dangerous chemicals that are banned or severely restricted within the Community are subject to a common export notification procedure. Accordingly, dangerous chemicals, whether in the form of a substance by itself or in a preparation, which have been banned or severely restricted by the Community as plant protection products, as other forms of pesticides, or as industrial chemicals for use by professional users or by the public, are subject to similar export notification rules to those applicable to such chemicals when they are banned or severely restricted within either or both of the use categories laid down in the Convention, namely as pesticides or chemicals for industrial use. In addition, chemicals subject to the international PIC procedure are subject to the same rules. This export notification procedure applies to Community exports **to all third countries**, whether or not they are Parties to the Convention or participate in its procedures.

Thus the Regulation goes beyond the provisions of the Convention, this is allowed according to Article 15 paragraph 4, and Parties have the right to take an action that is more stringently protective of human health and environment, provided it is consistent with the provisions of the Convention and international law.

The main chemicals legislation, which triggers the listing of chemicals in Regulation (EC) 304/2003 is related to the Directive 91/414/EC, Agricultural Pesticides, and to the Biocide Product Directive 98/8/EC and the Directive 76/769/EEC, industrial pesticides and chemicals.

Under this regulation every exporter must notify certain substances or preparations to the national DNA (Designated National Authorities) responsible, at least 30 days prior to exporting them for the first time in the calendar year in order to make the recipient country aware of the export and, where necessary, obtain permit. If the **European Chemicals Bureau (ECB)** acting as common European authority does not receive an acknowledgement of receipt of the first export notification within 30 days of the dispatch of the notification, a second notification has it be submitted. In Germany, the **Federal Institute for Occupational Safety and Health (BAuA), Division 5** has been appointed as the Designated National Authority (DNA).

The national DNAs work closely together with the Joint Research Centre of the ECB. Each notification has to be inserted in the database, called EDEXIM. The public as well as the DNAs of the Member States, the Customs Service, and the applicants, have access to the database to get information about the export and import of certain dangerous chemicals. DNAs are also in the position to follow the latest development of a notification. An explicit consent status list is also available on EDEXIM. The Export notification procedure applies to exports to any country, irrespective of the intended use. If the statutory EU regulations for placing on the market or for using or labeling the substance concerned have significantly altered or if the composition of the relevant preparation has changed to such an extent that its labeling has also changed it is necessary for the exporter to renew his announcement

The European Union participates in the PIC procedure within the environmental programme of the United Nations (**UNEP**) and the Food and Agricultural Organization (**FAO**). The Rotterdam Convention entered into force on the 24.02.2004. The German Federal Government has designated the **Federal Office of Consumer Protection and Food Safety (BVL)** as the competent national authority vis-à-vis the FAO in connection with plant protection products and the **Federal Institute for Occupational Safety and Health (BAuA),** as the competent national authority vis-à-vis UNEP with regard to all other chemicals.

### A8-2.4.3 Regulation (EC) No. 850/2004, Stockholm (POP) Convention

Regulation (EC) No. 850/2004 dated 29 April 2004 on persistent organic pollutants and to amend Directive 79/117/EEC is aimed at banning or suspending at the earliest opportunity or restricting the production, placing on the market and preventing the use of intentionally produced persistent organic pollutants. Furthermore, it is intended to reduce the release of such substances to a minimum until the earliest possible cessation of such releases.

The focal activities will be to collect information available in Germany in a decreased form and to pass it on to the European Commission within the framework of the reporting duties provided for in the Regulation.

### A8-2.4.4 Directive 98/8/EC Concerning the Placing of Biocides Product on the Market

The German Biocide Act came into force on the 28 June 2002. It essentially integrated into the Chemicals Act (ChemG, in particular section II a) the rules required for transposition of Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market. The authorization procedure for biocidal products which came into force as a result states that biocidal products may only be marketed and used after prior authorization.

The authorization authority is the **Federal Institute for Occupational Safety and Health (BAuA**), **Division 5, Chemicals, Notification and Authorization**.

The national expert authorities included in the procedure as authorities whose consent is sought are **Division 4** of the Federal Institute for Occupational Safety and Health (responsible for the protection of workers), the Federal Environmental Agency, **UBA** (responsible for protection of the environment) and the Federal Institute for Risk Assessment, **BfR** (responsible for the protection of consumers).

The Federal Institute for Materials Research and Testing (**BAM**), the Federal Office of Consumer Protection and Food Safety (**BVL**) and the Robert-Koch Institute (**RKI**) participate in the authorization procedure for certain types of products as consultation authorities.

#### A8-2.4.4.1 Procedure for Active Biocidal Substances

The active substances procedure is an essential process of the statutory rules for biocides. Within the framework of this European procedure it is decided whether an active biocidal substance is

included in one of the Annexes I, IA or IB of Directive 98/8/EC. The inclusion of the active biocidal substance in one of the aforementioned Annexes is a precondition for the authorization of biocidal products.

Within one year after acknowledgement of the documents the participating authorities undertake an assessment and make a recommendation about the inclusion or non-inclusion of the active biocidal substance in the particular annex. If further information is required from the applicant, the one-year deadline is suspended until the documents have been submitted. The recommendation (the report by the competent authority) is passed on to the Commission, the other Member States and the applicant. Subsequently this report will be peer reviewed by other Member States.

At the latest 12 months after receipt of the documents the Commission decides, with the assistance of a Standing Committee containing of all Member States, whether or not the active biocidal substance is included in one of the Annexes I, IA or IB of the Directive.

**A8-2.4.4.1a 10 Year Work Programme for Existing Active Substances**

Existing active substances are active biocidal substances that were already used in biocidal products in an EU Member State prior to the 14th of May 2000. Consequently, in consideration of the already existing statutory rules, they can continue to be marketed for biocidal purposes during the programme for existing active substances as long as they have either been notified or identified.

The notified active biocidal substances which are subjected to examination within the framework of the existing active substances programme are listed in Annex II of Regulation (EC) No 2032/2003. If after examination one of these active substances it is not included in one of the Annexes I, IA or IB of Directive 98/8/EC, all of the biocidal products that include this active substance must be withdrawn from the market. The same applies to the active substance itself. If the active biocidal substance is included in one of the above-mentioned annexes, the corresponding biocidal products require authorization.

Within the framework of the above-mentioned Regulation, which is going to be amended the fifth time, dossiers have to submitted, related to the product types, according to the deadlines laid down in the Review Regulation.

**A8-2.4.4.1b New Active Substances**

New active substances are active biocidal substances which have not been placed on the market in an EU Member State before the 14 May 2000. In contrast to the existing active substances programme, the new active substances may only be marketed in biocidal products after inclusion in one of the annexes of Directive 98/8/EC.

**A8-2.4.4.1c Basic Substances**

A basic substance is a substance which is listed in Annex I B, whose major use is non-pesticidal but which has some minor use as a biocide either directly or in a product consisting of the

substance and a simple diluent which itself is not a substance of concern and which is not directly marketed for this biocidal use. Certain substances could potentially enter Annex IB, in accordance with the procedure laid in this Regulation

#### A8-2.4.4.2 Authorization of a Biocidal Product

The product authorization itself is subject to the rules cited in Article 5 of Directive 98/8/EC. As a rule, the authorization unit decides on fulfilment or otherwise of the preconditions for authorization within one year of receipt of the application. The procedure for the authorization of biocidal products is similar in structure to the active substances procedure.

A precondition for a successful authorization of a biocidal product is that the active biocidal substances contained within it are included in Annex I or IA of Directive 98/8/EC. The authorization procedure therefore builds upon the active substances procedure.

Special facilities during the authorisation procedure are foreseen for the registration of biocidal products with low risk potential, frame formulations and reference products as well as provisional authorization of a biocidal product that may be granted for a limited time period.

#### A8-2.4.4.2a Mutual Recognition of an Authorization or Registration

Initially, authorisations and registrations of biocidal products are only valid in the particular Member State in which it has been authorised. In the mutual recognition procedure a biocidal product that has already been authorized or registered in another Member State this authorisation/registration may be recognized in Germany. The decision is taken within 120 or 60 days respectively after receipt of the application by the authorization unit.

## A8-3 Enforcement of Chemical Control in Germany, Responsible Authorities and Co-operation amongst the Authorities

### A8-3.1 Enforcement Authorities in Germany: The Länder level

The European community is not in charge of enforcement, this is due to the principle of subsidiarity a matter of the Member States. However, regarding the chemicals the Federal Authorities are not empowered to enforce the compliance in the factories and at the production sites. This Task is in the sovereignty of the Federal States (Länder, like Bavaria, Saxony, or North Rhine Westphalia).

The enforcement agencies of the Federal States check that chemicals are properly packed and labelled, new chemicals are notified before marketed or prohibitions or restrictions on chemicals are observed. They are empowered by the chemicals Act to take all the necessary administrative decisions to ensure the application of the chemicals legislation and to prevent possible breaches. If a company is in breach of the regulation, both administrative decisions as well as decisions on regulatory offences may be taken. In case of crimes, there is no discretion – they have to be prosecuted.

An action might be initiated by (yearly) enforcement programmes, by certain European or National projects or if the authorities have become aware of a violation of some provisions.

## A8-3.2 BAuA, Federal Institute for Occupational Safety and Health, www.baua.de

The **Federal Institute for Occupational Safety and Health (BAuA)** is a public law institute without legal capacity. The BAuA is an authority within the portfolio of the Federal Ministry of Labour and Social Affairs.

The **BAuA** has been empowered by the Chemicals Act to become the **Competent Authority (CA)**, also known as **Notification Unit**, for the chemicals notification procedure as well as Authorisation Unit for biocidal products.

The tasks of the **BAuA** are on one side to support the Minister of Labour and Social Affairs, and to generate the knowledge on occupational safety by research done by the **BAuA** itself and by contractors. As a pool of competence and a knowledge service provider in matters of safety and health at work, the **BAuA** offers advice and practical assistance to companies, government, the social partners, the general public and, gives technical assistance to third Countries. The knowledge on occupational safety is transferred by an exhibition, a library, an information centre and a Health Data Archive of German Uranium Mines.

An additional task is the implementation of the notification procedure of chemicals and the authorisation of biocidal products. The **Division 5**, **Chemicals Notification and Authorisation**, which is, inter-alia, responsible for these tasks, supports the Minister of Environment. It has been appointed as REACH-Helpdesk, Competent Authority and DNA for the Rotterdam Convention for Germany, and provides members for relevant committees and fora.

**Division 5**, **Chemicals Notification and Authorisation** is divided into 4 units: The Units are responsible for the Notification of Existing Substances, Chemical Survey, for the time being, for Notification of New Substances, and Information on Chemicals, for the Authorisation of Biocides and for Chemical Law, Legal and Administrational Matters. In Addition to that BAuA has been appointed as DNA for the Rotterdam convention, CA for the Stockholm Convention and CA for the Ozone Depleting Substance Regulation.

The CA informs the German Federal States/Länder about the properties of the substance data and the assessment results. Non-confidential information on the substances is published in the Federal Gazette.

## A8-3.3 Co-operation within Germany

The Federal Ministry of Environment and their subordinated authorities like the BAuA co-operate with the Länder/Federal State authorities in working and sub-working groups on “Chemical Safety”. They exchange information and discuss procedures with regard to enforcement and special enforcement projects as well as questions of how to interpret the Chemicals Act. There are different working groups and sub working groups for different items like technical questions, or legal questions or preparing enforcement facilities for REACH.

In addition to that enforcement authorities and customs service are invited on a regular basis to the BAuA Division 5, to discuss the latest developments within the Chemicals Management process. Combined or bilateral meetings with industry and industry associations are at the same time part of the co-operation.

### A8-3.4 The European Chemicals Agency (ECHA)

With REACH, the role of the CA in the EU Member States will change. The ECHA will be responsible to accept the registration dossiers, to draft decisions in the evaluation procedure, which will be prepared by the CAs. To prepare results in the evaluation process and to come to decisions in the authorisation and restrictions procedure, i.e. scientific reasoning with, a close cooperation with the member states and the committees will be necessary.

The Agency will consist of the following parts: the Director and its Secretariat, the Management Board, the Risk Assessment Committee, the Socio Economic Analysis Committee, the Member State Committee, the Forum, and the Board of Appeal.

Member States have to appoint members to the Member State Committee and the Forum and they are invited to appoint candidates for the risk assessment committee and the socio economic analysis committee. The authorities in the Member States will then help the appointed members of the committees in performing their tasks. Decision making rules are defined in the REACH Regulation in detail.

### A8-3.5 Co-operation on EC-Level

In addition to the staff in the Agency, the Member States Competent Authorities meet several times per year. The Joint meetings regarding new and existing chemicals and the CA-Meeting for Biocides are organised several times per year by the European Commission together with the respective Member State who has the council presidency. The CA-meetings are focused more on general, legal or political issues while Technical Meetings are addressed to scientific and chemical items. Since 2008 the meetings for industrial chemicals will be organised by the ECHA in Helsinki/Finland.

The DNA-meetings for PIC and meetings on POPs or GLP, organised by the European Commission once or twice per year, take place in Brussels.

CLEEN (**C**hemicals **L**egislation **E**uropean **E**nforcement **N**etwork) is a network that co-ordinates and improves the enforcement of EU chemicals legislation. It is basically a network for information exchange and it discusses, in collaboration with the Member States, priorities for enforcement projects in the EU.

Germany is a member of the CLEEN Network, the BAuA Division 5 is the focal point. Under the auspices of CLEEN, chemical inspectorates of the EU Member States discuss priorities and joined enforcement projects, exchange information. In 2006 **Austria** together with **Poland** took over the CLEEN secretariat.

## A8-4 Instruments of International Chemical management - SAICM

The Strategic Approach to International Chemicals Management (SAICM) is a policy framework for international action on chemical hazards under the umbrella of the United Nations, which had been adopted on 6 February 2006 in Dubai, United Arab Emirates. It supports the achievement of the goal agreed at the 2002 Johannesburg World Summit on Sustainable Development of ensuring that, by the year 2020, chemicals are produced and used in ways that minimize significant adverse impacts on the environment and human health.

In Germany the **Federal Environment Agency** (UBA) has been designated as a Strategic Approach national focal point to act as an effective conduit for communication on Strategic Approach matters.

The strategic approach is an overarching policy strategy according to the precautionary principle. It should enable that initial capacity building activities for the implementation of Strategic Approach objectives will be supported by the establishment of the Quick Start Programme (QSP). The QSP contains a voluntary, time-limited trust fund, administered by the United Nations Environment Programme, and may include multilateral, bilateral and other forms of cooperation.
The strategic priorities highlight that the QSP should mobilize resources for national priority initial enabling activities in keeping with the work areas which are in particular the development or updating of national chemical profiles and the identification of capacity needs for sound chemicals management, the development and strengthening of national chemicals management institutions, plans, programmes and activities to implement the Strategic Approach, building upon work conducted to implement international chemicals-related agreements and initiatives, and to undertaking analysis, interagency coordination, and public participation activities directed at enabling the implementation of the Strategic Approach.
An aim of SAICM is to concentrate diverse existing and partly competing activities regarding chemical safety on a global level. Therefore it seems appropriate to use synergy effects and closing gaps by using to a large extent an integral approach that takes into account the Multilateral Environmental Agreements dealing with a certain amount of chemicals with certain properties. The SAICM process is able to establish Chemical Management for all, countries in transition, industrial and less-industrialised countries.

## A8-5 Overview of the United States' Regulatory Regime for Toxic Chemicals and Pesticides Management; Its Relevance to the Contemporary Regulatory Needs of the People's Republic of China

### A8-5.1 Introduction

From the outset, it is important to stress that the United States (US) environmental regulatory regime, though imbued with a precautionary approach, firmly rejects unscientific or chemo phobic regulation and management of toxic chemicals and pesticides. This would include any approach not firmly rooted in science. The U.S. approach to toxic chemicals management both permits a thorough understanding and appreciation of genuine chemical risks and actions to deal with those, as well as concurrent enjoyment of the enormous benefits that chemistry has provided. Modern life and high standards of living that Americans now take for granted, are dependent in part on chemicals. However, Americans also know that full enjoyment of those

living standards also depends upon the sound and safe management of those chemicals and pesticides. TSCA makes clear that it is the intent of Congress that the Administrator of EPA shall carry out the statute in a reasonable and prudent manner and shall consider the environmental but also the social and economic impact of any taken or proposed to be taken.

Since the early 1970's, and particularly after the formation of the US Environmental Protection Agency (EPA) in December of 1970, the US has committed substantial resources to the development, elaboration and enforcement of a toxic chemicals management and control regime. The People's Republic of China (PRC), as a major chemical producer, importer and consumer of chemicals, and possessed of a fast-growing domestic chemicals industry, now seeks to strengthen existing structures and create an environmentally sound management system as a key component of future plans for environmental and social progress.

Today, as SEPA plans to prepare a new law/regulation on toxic and hazardous chemicals involving the management of such chemicals for submission to the State Council for approval, the PRC is seeking to glean helpful information from the successful experiences and practices of key developed countries including the US. Much of what the US has done, especially in terms gathering information about toxic chemicals within its borders and the subsequent controls it has imposed with respect to certain substances, is relevant to the situation in the PRC and could be modified to fit the Chinese experience and unique local conditions.

The PRC might focus on those U.S. experiences that could help it to develop a readily available means of auditing or screening what chemicals exist within the PRC and how they are being used. This requires a notification scheme capable of facilitating the review of new chemicals and producing a comprehensive data base of existing substances so that information on which toxic substances are being produced and imported is available - and risks of those substances may be assessed, testing consistent with international standards and protocols and reporting of information relevant to chemicals assessment and management can be required, and further regulatory action pursued where appropriate - including the restriction and even the banning of certain substances where warranted. The desire to invest in such a regime reflects the growing recognition within the PRC that if significant resources are not devoted to the enterprise, given the size of the country and its population and the magnitude of the environmental challenge, an even higher price in terms of environmentally harmful consequences, with potentially severe economic implications, may have to be paid. It is much the same recognition that impelled the US to enact the Toxic Substances Control Act of 1976 (TSCA) and the 1947 Federal Insecticide, Fungicide, and Rodenticide Act as amended.

## A8-5.2 Toxic Substances Control Act (TSCA); 15 U.S.C. Section 2601 et seq.; Implementing Regulations Set Forth at 40 C.F.R., Section 700 et seq.,

### A8-5.2.1 Introduction:

In the United States, the Environmental Protection Agency is responsible for implementing most of TSCA. Under TSCA, EPA is charged with ensuring that chemicals manufactured, imported processed or distributed in commerce, or used or disposed of in the US, do not pose an

unreasonable risk to human health or the environment. It is important to recall that before TSCA was passed just over thirty years ago, it was not known how many chemicals were in commerce in the United States, where chemicals that were in the United States were being produced, or from where they were being imported and in what quantities they were being produced and/or imported.

TSCA established a national program for oversight of toxic chemicals through initiation of a systematic review process for evaluating new chemicals *before* they enter commerce and by creating a set of tools for responding to potential risks from existing chemicals already in commerce. For the very first time, TSCA established as a national policy of the US that the development of adequate data with respect to chemical substances and mixtures, including information on their toxicity and the extent to which people and the environment are exposed to them, is the responsibility of those who manufacture and process such chemical substances and mixtures. With this information potentially available through rulemaking and otherwise, the government can, through its chemical assessment procedures, regulation, and other programs ensure that adequate measures are taken to protect against unreasonable risks to humans and the environment.

TSCA contains provisions which allows the government to regulate any chemical that presents an "unreasonable risk" of harm to human health or the environment. Because of the broad scope of its potential coverage, coupled perhaps with underutilization, it could be referred to as a "sleeping giant." However, though it may be underutilized, the statute is capable of regulating virtually all chemical substances and is the only US environmental statute that can completely ban production of a chemical.

### A8-5.2.2 Key TSCA Provisions of Particular Applicability to the Situation in the PRC

#### A8-5.2.2.1 The TSCA Chemical Substance Inventory

TSCA Section 8 mandates that EPA create and maintain a list of all *existing* chemical substances manufactured or processed in the United States. This "TSCA Chemical Substance Inventory" is used to allow the regulating agency to determine whether any given substance is existing or new. The inventory currently contains over 80,000 existing substances. If the substance is not on the inventory list, it is considered to be "new." The list continues to grow as new chemicals that have been reviewed under EPA's new chemical review program are added. Chemical companies are generally required to notify EPA at least 90 days before beginning manufacture or import of a "new" chemical by submitting a pre-manufacture notice. (See Section 5 discussion below.)

The existing inventory, and how EPA chooses to manage the information reported via periodic updates, is very much about setting priorities in the face of limited resources. This has led to a focus on a subset of chemicals of greatest concern. For Priority setting purposes EPA/OPPT has concentrated its data development and data collection efforts on a subset of approximately 15,000 non-polymeric chemicals reported in the two most recent inventory update cycles and produced in quantities greater than 10,000 pounds per year. The greatest focus is currently on a smaller subset of approximately 3,000 high production volume chemicals produced and/or

imported in annual volumes of 1 million pounds or more across all U.S. companies. In parallel with these undertakings, data development efforts are also focusing on other chemicals of concern, including perfluorooctanoic acid (PFOA) and perflouorooctyl sulfonate (PFOS). All of this information is generally made accessible to the public; however steps are taken to safeguard confidential business information (CBI). However, certain health and safety information is not protected from disclosure under TSCA

#### A8-5.2.2.2 Reporting and Record-Keeping Requirements

Section 8 also establishes extremely broad reporting and record-keeping requirements that provide EPA mechanisms to ensure access to information regarding health or environmental effects associated with chemical substances. This section gives the EPA authority to request a wide variety of information about chemicals or processes that it may not otherwise have authority to investigate under other statutory programs. The Agency can issue rules under TSCA section 8(a) on specific substance or categories of substances requiring the reporting to EPA of hazard and/or exposure-related information, and mandate record-keeping.

The Preliminary Assessment Information Rule is one type of section 8(a) information gathering rule that is intended to allow EPA to gather exposure data on chemical substances. TSCA section 8 also provides authority so that EPA can require manufacturers and processors to keep records of significant adverse reactions, including, consumer allegations of personal injury or harm to health, reports of occupational diseases or injuries, and complaints of injury to the environment. The allegations, which must be retained for 5 years (or 30 years if the allegation arises form an employment-related exposure) can provide a means of identifying previously unknown hazards, need only be submitted by manufacturers and processors to EPA upon request.

TSCA section 8(d) requires manufacturers and processors to submit unpublished health and safety studies ("any study of any effect of a chemical substance or mixture on health or the environment") that are in their possession, or known to them but not in their possession, to EPA with respect to the chemicals they propose to manufacture or process. This, among other things, can help EPA to determine which chemicals may present risks that require industry testing under Section 4 (See below). TSCA Section 8 (e) requires chemical manufacturers, processors and distributors to notify EPA immediately of any new (unreported) unpublished information on chemicals that reasonably supports a conclusion of substantial risk of injury to health or the environment. This provision is viewed by EPA as a critical information gathering tool that can serve as an early-warning system for newly found risks. EPA screens the submissions and identifies particular chemicals for further assessment, referral or follow-up. This reporting has also heightened industry awareness of potential chemical risks.

#### A8-5.2.2.3 Regulation of Existing Chemicals

Sections 6 and 7 of TSCA permit EPA to regulate or take other action to protect against unreasonable risk or imminent hazards associated with the manufacture, processing, distribution, use and disposal of chemical substances and mixtures. Events that may trigger such assessment include new monitoring or test data from within EPA, other public or private sector sources, or from other countries. This relatively high standard takes into account the interruption of an

ongoing industrial process which would have higher social costs (job loss, investment in plant and material, etc.) than forbidding or imposing restrictive conditions on new manufacture. Regulation can take the form of prohibiting the manufacture of these substances, or of strictly regulating their use, or both. Prior to taking any such actions, however, EPA must publish a statement in the Federal Register - essentially a cost-benefit analysis – that considers and addresses the effects on health and the magnitude of human exposure, the effects on the environment and the magnitude of environmental exposure, the benefits of using the substance or mixture, the availability of substitutes, and any reasonably ascertainable economic consequences of the action. After considering public comments on the rule-making, EPA has a number of regulatory options. These include prohibition or placement of limitations on the manufacture, processing, distribution, use of disposal of the chemical, or of its use in a concentration in excess of a specified level. There may be imposed specific labeling requirements, or warnings or instructions to be provided prior to use. Whichever action is taken, EPA must use the least burdensome methods to regulate or prohibit the use of chemicals found to present an unreasonable risk. The Agency's actions to ban completely the importation, manufacture and processing of nearly all asbestos-containing products in 1989 were largely overturned by U.S. Courts because, in summary and among other things, the Court found that EPA failed to evaluate the possible health effects of substitute products, and was therefore found to have failed to consider less burdensome regulatory alternatives as TSCA requires.

In fact, there are only a very few existing substances the manufacture, processing, use, distribution in commerce or disposal of which have been regulated under Section 6 to date. These include PCBs, fully halogenated chlorofluorocarbons for aerosol propellant uses, and certain mixtures (metal working fluids) capable of producing nitrosamines (carcinogens). EPA has also used its section 6 authority to regulate the use of hexavalent chromium chemicals in certain heating, ventilation, air conditioning and refrigeration systems and has promulgated regulations to address human exposure to airborne asbestos in school buildings. This regime clearly requires analysis of risks and benefits to support regulatory controls. Some have complained about TSCA section 6's cumbersome nature and its ineffectiveness.

#### A8-5.2.2.4 Regulation of New Chemicals

Section 5 of TSCA creates an effective "gatekeeper" function that can facilitate the identification of concerns and provide authority for the imposition of conditions on the commercialization of new chemicals before they enter commerce. The statute requires any company intending to manufacture or import a *new* chemical substance not on the TSCA Chemical Inventory, to give EPA 90 days notice prior to manufacture or importation by sending a Pre-Manufacture Notification (PMN). PMNs must include any data in the PMN submitter's possession or control on the chemical's health and ecological effects, potential exposures and on their physical and chemical properties. As a result of the Significant New Use Rules (SNURs), PMN requirements now also apply to new or increased use of *existing* chemicals manufactured or processed in, or imported into, the US. Certain genetically modified microorganisms are also considered as new chemicals. The scope of the notification requirements does *not* extend, for example, to mixtures, pesticides, food additives, drugs and cosmetics, very low volume quantities manufactured or imported for research purposes, chemical substances imported solely for export, and chemicals

imported as part of an article. In accordance with U.S. administrative procedure, EPA publishes a short notice in the Federal Register after receiving a PMN, which information is publicly available. If EPA takes no regulatory action on the PMN within a review period, the submitter may commence commercial manufacture or importation without any approval. However, within 30 days of commencing manufacture or import, the submitter must file a notice of commencement of manufacture or import. Once that notification is received, the new substance is added to the TSCA inventory and the chemical is viewed under the statute as an *existing* chemical substance.

This so-called PMN review period (during which the public is also notified) is an aspect of the U.S. regulatory regime that may hold particular interest for regulators in the PRC. It is a process that recognizes the limited resources that even a developed country has available for chemicals assessment and management and that has evolved to focus most effort on the relatively few new chemicals of greatest potential concern, such as those which are structurally related to known chemicals of concern and those about which little is known. The review period is intended to afford EPA the opportunity to assess, on the basis of data submitted by the importer or manufacturer, other information from government data bases, and the existing scientific literature, whether follow-up regulatory controls and/or additional data are needed for assessment to prevent potential unreasonable risks  EPA's review of new chemicals under TSCA Section 5 relies on the knowledge and experience of engineers, scientists, information management specialists and regulators (65 full time staff in 2006) to identify and evaluate concerns.

If, as a result of its assessment, an "unreasonable risk" is detected or suspected, EPA has the authority to take a number of control actions to prevent or mitigate those risks.  In only about 5% of all cases does EPA determine that some type of controls is necessary for the substance. There are an additional 5% of new chemicals that are voluntarily withdrawn by the notifier, often in the face of EPA action. If the available information is insufficient to permit a reasoned evaluation, EPA may issue a proposed order to prohibit or limit manufacture or import of the substance. EPA may propose a rule limiting or conditioning manufacture or import of the substance or issue "pending the development of information" needed to adequately assess the chemical, or a proposed order, for example, completely banning the manufacture or importation if there is a "reasonable basis to conclude that the manufacture…presents or will present an unreasonable risk of injury to health or the environment." EPA must choose the least burdensome requirement that will adequately protect against the risk which presents a high evidentiary burden. In the United States, in keeping with its elaborate system of checks-and-balances, control actions that EPA might take are subject to review by the courts.

#### A8-5.2.2.5 Mandatory Chemical Testing

TSCA Section 4 was enacted in response to the concern that the effects of many chemical substances and mixtures on human health and the environment were insufficiently characterized or understood. That is a concern that the PRC has today. Section 4 gives EPA authority to require that manufacturers, importers and processors of existing chemicals to conduct testing of any substance or mixture where the Agency finds that there is insufficient data upon which the effects of a chemical on health or the environment can be determined or predicted and testing is

necessary to develop such data. The agency must further find *either* that the chemical substance's or mixture's manufacture, distribution in commerce, processing, use or disposal may present an unreasonable risk of injury to health or the environment *or* it is or will be produced and/or imported in substantial quantities (generally considered to be 1 million pounds per year or more ) and there are human exposure and/or environmental release-related concerns. Those subject to the testing requirement must bear its costs. This section is in keeping with the general objective of TSCA to gather and maintain sufficient information about chemicals to allow government to act if that is warranted, based on a reasonable concern for human health and the environment.

In Section 4(e) of TSCA, Congress created an Interagency Testing Committee ("ITC") to make recommendations to EPA concerning which chemical substances that should be given priority consideration for testing under TSCA. It consists of representatives from many agencies and organizations from across the government and has generally given priority to chemicals about which it has suspicions of toxicity or exposure such as potential carcinogens and for which there is little, if any, testing data on ecological effects, environmental fate, or health effects. Generally, in making its recommendations, the ITC will consider such factors as looking at production volume, quantities released into the environment, the extent of human exposure, existing health effects data and the extent to which testing may result in useful data. Over the past 20 years, the ITC has recommended testing of more than 130 chemicals. EPA is required to act on the recommendation within 12 months of receipt and has issued over 60 so called "Section 4 test rules". The Agency has also made use of consent agreements for testing to avoid lengthy rule-making proceedings. Within 30 days after the effective date of a test rule, each party subject to the rule must either notify EPA that it will conduct testing, submit an application for an exemption, or be covered by regulatory provisions that relieve them of obligations. Should no manufacturer or processor notify EPA that it will conduct testing as required, EPA will notify all subject manufacturers and processors of that fact and 30 days after that, all subject persons manufacture and processing of the chemical will be in violation of the rule. All persons that are subject to testing under section 4 test rules are required to provide equitable testing cost reimbursement to persons who actually conduct the testing, as determined by EPA regulations if no cost sharing arrangement is otherwise agreed to. If after completion of all testing, EPA receives test data or other information indicating that "there may be reasonable basis to conclude that a chemical substance or mixture presents or will present a significant risk of serious or widespread harm to human beings from cancer, gene mutations or birth defects" the EPA must within 180 days initiate the appropriate rulemaking under TSCA Sections 5, 6 or 7 (See above) or publish in the Federal Register reasons for not taking such action. EPA and other Federal Agencies can also can use information developed under TSCA 4 to otherwise support action under TSCA or other regulatory authorities (e.g., Clean Air Act).

#### A8-5.2.2.6 Export and Import into the United States of TSCA-Covered Chemicals

TSCA Sections 12(b) and 13 provide EPA with authority to deal with notifications for exports of certain chemicals and United States Treasury Department (United States Customs Service, which is now part of Customs and Border protection under the Department of Homeland Security) to promulgate rules regarding the importation of certain substances. Section 12(b) requires exporters to notify EPA if they export or intend to export certain chemical substances and

mixtures. The purpose of this section is to inform foreign governments, in a general manner of what EPA knows of the hazards associated with these chemicals and provide information about the nature of TSCA regulatory actions affecting the chemical Under TSCA Section 13, the US Customs Service must refuse entry into the United States of any chemical substance that fails to comply with TSCA. The burden is on importers to certify to US authorities that the chemical substances, mixtures and articles being imported (this could include chemicals, items containing chemicals, materials for recycling, hazardous waste and genetically-engineered micro-organisms) either comply with TSCA, which is a so-called "positive certification" or are not subject to TSCA, which is a so-called "negative certification." Blanket import certificates may be used to certify TSCA compliance for multiple shipments of the same chemical substances over a one year period. If, for example, the chemical is on the TSCA existing chemical inventory list, and all testing and reporting requirements have been complied with, all that need be submitted is a signed positive certification. The Customs Service will detain any shipment containing chemical substances that is not accompanied by an import certificate or, even in cases where a certificate is provided, if it has reasonable grounds to conclude that the shipment is not in compliance.

**A8-5.2.2.7 TSCA Enforcement**

TSCA Sections 11, and 15-17 create enforcement authority for EPA and list prohibited acts, civil and criminal penalties and requirements for enforcement or seizure. Section 11 grants to EPA broad authority to conduct inspections to enforce the Act. Inspection authority extends from all things within the facility where the chemicals are manufactured or stored to any conveyance used to transport the chemical substances. If EPA is denied entry it may seek a search warrant to conduct inspections, or when it considers an surprise inspection crucial to the enforcement goal. In most cases, however, the inspection takes place only after the facility has received a written notice of inspection. EPA is further authorized to issue administrative subpoenas to require the attendance and testimony of witnesses, the production of documents and other information that the EPA deems "necessary."

It is unlawful under TSCA Section 15 to: fail or refuse to comply with a test rule or order; to use for commercial purposes any chemical substance or mixture which the person knows or had reason to know was manufactured, processed, or distributed in violation of the Act; to fail or refuse to establish or maintain records or submit reports or notices or other information; and to fail or refuse to permit entry or inspection as required by Section 11 (See above). EPA can impose civil penalties of up to $27,500 per day for each such violation but most civil penalty proceedings result in negotiated settlements. These are carried out pursuant to a written consent agreement and a consent order. EPA is also authorized to seek criminal penalties against any person who "knowingly or willfully" violates any provision and can seek criminal fines and /or imprisonment of up to one year. US District Courts may also seize and condemn any chemical substance, mixture or product manufactured, processed or distributed in violation of TSCA.

TSCA Section 21 deals with citizen petitions. Any citizen may petition EPA to take action under Section 4 (rules requiring chemical testing); Section 6 (rules imposing substantive controls on chemicals, or Section 8(information gathering rules). The statute also authorizes a citizen-petitioner to request the issuance, amendment or repeal of orders under Section 5(e)

(orders affecting new chemical substances) and Section 6(b)(2) (orders affecting quality control procedures. The Administrator of EPA must either grant the citizen petition or make publicly available the reasons for denial by publishing them in the Federal Register. Within 60 days of denial or no action, petitioners may commence a civil action in a US district court to compel initiation of the requested rulemaking. After hearing the petition, the court can order EPA to initiate the requested action.

Not all chemicals are subject to TSCA. Pesticides are regulated under the Federal Insecticide, Fungicide and Rodenticide Act which is discussed briefly below. Food additives, drugs, cosmetics and medical devices are regulated by the Federal Food Drug and Cosmetics Act, administered by the US Food and Drug Administration has not been included within the scope of this discussion.

### A8-5.3 The Pollution Prevention Act and Voluntary Pollution Prevention Programs

When EPA/OPPT was established in 1977 to implement TSCA, the Agency was generally concerned with control of current sources of pollution and used "end-of-pipeline command and control" approaches. Over the years, this approach has evolved into placing a stronger emphasis on the prevention of pollution at the source. In 1990, the Pollution Prevention Act was passed which sought to reduce or eliminate the creation of pollutants at the source through: increased efficiency in the use of raw materials, energy, water or other resources or protection of natural resources by conservation. "Source reduction" includes any practice that: reduces the amount of hazardous substances that enter any waste stream or are otherwise released into the environment prior to recycling, treatment or disposal. Two Executive Orders, issued by the President have served to incorporate pollution prevention approaches within federal government practice. In 1998, Executive Order 143101: Greening the Government Through Waste Prevention, Recycling and Federal Acquisition, mandated that the federal government, an huge purchaser of goods within the US, adopt environmentally preferable purchasing including with respect to the purchase of chemicals and pesticides. There are also wholly voluntary programs such as "Green Chemistry" which focuses on pollution prevention through the environmentally conscious design of chemical products and processes.

Under the US system, EPA has broad authority for toxic chemical management. Such a broad regulatory authority is important for China to study. When considering TSCA, it is important to bear in mind, especially when considering limitations on resources, that chemical risk reduction activities can have not only statutory, but important voluntary dimensions. EPA, therefore, is both a gatekeeper and guardian against chemical hazards but also a facilitator and promoter of environmental stewardship. In the United States, it has been shown that cost-and time-effective risk management can sometimes be accomplished through voluntary partnerships with broad-based stakeholder groups EPA has frequently acted as a convener, bringing together groups that might not otherwise communicate and cooperate

### A8-5.3.1 Key EPA Public/Private Partnerships that Address Certain Highly Toxic Chemicals

Perfluorinated acids are man-made chemicals with uniquely valuable properties and functionality. Concerns began with perfluorooctyl sulfonate (PFOS) in the late 1990's when reporting under TSCA Section 8(e) indicated that it was persistent, widespread in the environment and caused reproductive/developmental toxicity in animal studies, and was present in humans at low levels. The investigation expanded to include perfluorooctinaoic acid (PFOA) and fluorinated telomers. The main producer in the U.S. of PFOS voluntarily phased out production worldwide between 2000 and 2002. Small quantities continue to be produced overseas by other companies. Significant new use rules under TSCA Section 5(a) were published to restrict the return of these chemicals to the US market. With respect to PFOA, the EPA invited the eight major companies in the industry to commit to achieve, no later than 2010, a 95% reduction in both facility emissions to all media and product content of PFOA. They further committed to work toward the elimination of PFOA by 2015. Polybrominated diphenyl ethers (PBDEs) is a group of brominated flame retardant chemicals that have been of increasing interest to EPA and the US public. Current information suggests that, as a class, they are persistent and may bioaccumulate. EPA is leading a furniture flame retardancy partnership to evaluate alternatives to PBDEs in furniture applications. Also, with respect to lead, the EPA has promulgated regulations that establish hazard standards for lead in residential paint, dust and soil.

## A8-5.4 The Federal Insecticide, Fungicide and Rodenticide Act (FIFRA); & U.S.C. Sections 136-136y

The benefits of pesticides are well known and have done much to spare the US from the ravages of disease, crop infestations, noxious animals and weeds. They enable the US to feed itself and to feed others. Since the early 1960's, however, there has also arisen a growing awareness of the hazards as well as the benefits of chemicals. What the US statutory scheme attempts to do and what may be of particular interest to the PRC, is to balance these often conflicting environmental risks and benefits in light of scientific uncertainty. Though many other environmental issues have clearly arisen in the interim, it was probably pesticides and their implications for the food supply and their effects on people in agricultural areas that was the most important reason for the creation of the EPA. Congress first enacted the Federal Insecticide, Fungicide and Rodenticide Act in 1947. In 1970, the function s and many of the personnel assigned to a number of federal agencies with some responsibility for implementing the pesticide laws were all assigned to EPA. Within EPA, FIFRA is administered by the Office of Pesticide Programs (OPP). In 1972, FIFRA was amended and transformed into a comprehensive scheme for the regulation, distribution and sale of pesticide products through passage of the Federal Environmental Pesticide Control Act

At the heart of FIFRA, is the pesticide registration program. Before a pesticide may be manufactured, distributed, or imported, it must be approved by EPA. Registrations are expensive and involve a complex process more akin to a drug registration under the feral food and drug laws (not discussed here) than to the notification required for non-pesticidal chemicals under TSCA, discussed above. All new pesticide products used in the US, with minor exceptions, must first be registered with the EPA. A complete formula, a proposed label, and full description of the tests made and the results obtained upon which the claims are based, must all be submitted. The

registration obtained is very specific and is not valid for all formulations or even uses of a particular chemical. A separate registration is required for each crop or insect on which the pesticide product may be applied as well as for different dosages of the application. Pursuant to FIFRA, several types of pesticide registration have been established

Registrations must be granted unconditionally if the EPA determines that: the composition is such as to warrant the proposed claims for it; the labeling and other material required to be submitted comply with FIFRA; it will perform its intended function without unreasonable adverse effects on the environment and, when used in accordance with widespread and commonly recognized practice, it will not generally cause "unreasonable adverse effects on the environment" (this phrase is defined elsewhere in the statute to mean "any unreasonable risk to man or the environment taking into account the economic, social and environmental costs and benefits of the use of the pesticides). The registration is valid for 15 years and automatically expires unless there is a petition for renewal. Though the States may not permit any sale or use of pesticides prohibited under FIFRA, states may provide for additional uses of federally registered pesticides to meet "special local needs". These state uses are, however, subject to possible disapproval by EPA.

Until the 1972 amendments, the US federal government had no control over the actual use of a pesticide once it left a manufacturer or distributor properly labeled. In reality, however, a chemical that could be safe for use on a dry field might be environmentally hazardous if applied in a marshy area. Other pesticides might be too dangerous for general use but could be used safely by trained professionals using special equipment. The amendments limit certain uses to qualified individuals. A pesticide may be placed into a restricted category that is only available to certified applicators.

To facilitate its registration and product labeling decisions, EPA has promulgated elaborate requirements for the numerous scientific studies that it directs pesticide manufacturers to conduct to obtain and maintain registrations for pesticide products. In accordance with EPA regulations, pesticide registration studies must be conducted in compliance with good laboratory practice (GLP) requirements. This is intended to ensure the quality and integrity of all data submitted to EPA in support of pesticide registrations.

Re-registration is a review of existing pesticide registrations for a pesticide active ingredient to determine whether those registrations meet the statutory standard, or whether any registered products should be canceled or their use modified or limited. It also identifies data gaps in the database that supported registration, and acts as a screening process to select pesticides for more intense review. EPA also has broad authority under the statute to require existing registrants to submit additional test data that is identified by EPA as necessary to support the continued registration of a pesticide. EPA may suspend the registration of any registrant who fails to take appropriate steps to respond to a notice for such data.

While the registration process is key, the tool available to EPA that draws the most public attention is cancellation of a pesticide registration. The cancellation process is used to initiate a

review of a substance suspected of posing a substantial question of safety to humans or the environment. While cancellation proceedings are pending, the product may continue to manufactured and shipped in commerce. The cancellation order itself, though final if not challenged within 30 days, usually leads to a public hearing or scientific review committee or both and the process culminating in cancellation can be quite lengthy. A suspension order is an immediate ban on the production and distribution of a pesticide and is mandated when a product constitutes an imminent hazard to humans or the environment and may be invoked at any time. An "emergency suspension" is the strongest environmental action EPA can take under FIFRA. It immediately halts all uses, sales and distribution of the pesticide. The EPA may only use this procedure when it determines that an emergency exists and time does not permit a hearing prior to suspension of use. EPA may also order that sales be halted when claims are made about a pesticide that are unsupported by the registration. Cancellation and suspension decisions are meant to apply only in the US because the risk-benefit calculations applied to the challenged pesticides are based upon conditions in that country and would not necessarily be valid abroad where there are different risks and benefits. An important question faced by EPA following a cancellation or suspension action is whether to recall those products already in commerce. Generally, EPA has allowed banned pesticides to be used until remaining supplied are exhausted and does not subject them to recall.

If at any time after the registration of a pesticide, the registrant has additional factual information regarding unreasonable adverse effects on the pesticide on the environment, the registrant is required to submit that information to EPA. Types of information that must be reported include toxicological studies in ecological studies, human epidemiological and exposure studies, and toxic or adverse effect incident reports. There are also significant record-keeping requirements. These include that the producer keep certain records regarding the shipment of all pesticides and active ingredients used in producing pesticides. A pesticide registrant/producer must keep documents including the inventory records for the types and amounts of registered pesticides produced, records regarding the disposal of pesticides or active ingredients, records of tests conducted on human beings, and records containing research data.

A pesticide may only be imported into the US if it is registered under FIFRA and a Notice of Arrival is completed prior to the shipment's arrival in the United States. A pesticide, or active ingredient used in a pesticide, may be exported from the US when prepared or packaged according to the specifications of the foreign purchaser subject to the producer meeting certain FIFRA requirements including the labeling requirements (labeling must include the information that the pesticide or active ingredient is not registered for use in the US and appear in English and in the language of the country of import) and books and records requirements. The US is not yet a party to the Stockholm (POPs) or Rotterdam (PIC) Conventions though it has signed both treaties and played leading roles in their negotiation in the 1990s. US instruments of ratification have not yet been deposited because implementing legislation amending FIFRA and TSCA, which would allow the United States to fully meet its obligations under those instruments, has not yet been passed by both houses of the US Congress. This is largely due to continuing controversy over legislative provisions regarding the manner in which that legislation would deal with the addition of other "POPs" chemicals beyond the so-called "dirty dozen," none of which

are still in commerce within the United States. That said, the United States as a signatory to both the PIC and POPs Conventions, upholds their object and purpose by cooperating fully with Parties implementing the convention. Moreover, the statute provides that any person exporting a pesticide not registered under FIFRA shall obtain a "foreign purchaser acknowledgment statement" from the purchaser stating that the purchaser understands that such pesticide is not registered in the United States and cannot be sold in the United States consistent with US law. This requirement can be satisfied annually or on a per-shipment basis and foreign purchaser statements have to be filed with EPA according to deadlines specified by regulation. An unregistered pesticide may be transferred within the US solely for export if it meets the labeling and packaging requirements of US regulation and the foreign purchaser has signed the acknowledgment statement.

The precursor to any enforcement action is likely to be either an inspection or a subpoena form EPA. EPA's employees may inspect facilities where pesticides are held for distribution or sale or where cancelled or suspended pesticide products are being held. EPA may also obtain and execute warrants to enter, inspect and copy records that are required to be maintained.

Under FIFRA, It is unlawful for any person to sell or distribute a pesticide that: is unregistered; though registered, is accompanied by claims different from those approved by EPA; has not been colored or discolored if coloration is required; or that is adulterated or misbranded. A pesticide is misbranded if, for example, it bears any false or misleading statement or does not contain directions for use adequate to protect human health and the environment. Adulteration occurs when the strength or purity of the pesticide differs from that stated on the label or if any substance has been substituted in whole or in part for the pesticide, or if any valuable component of the pesticide is not present. EPA is authorized to bring a seizure action in federal district court against a pesticide that violates any of these requirements. EPA also has the authority to issue "stop-sale" or "removal" orders to prevent the sale, distribution, or use of a pesticide, or require the removal of a pesticide, that is in violation of FIFRA. Fines may be imposed for these violations. However, EPA may also bring criminal charges against a registrant, applicant or producer who knowingly violates any provision of the law with penalties ranging up to $50,000 and/or 1 year in prison. It is important to note that in many cases, EPA and the defendant are able to reach a settlement in conference and sign a written "consent agreement" that is filed at the conclusion of the case along with a consent order . The consent agreement, which settles the matter, usually includes, among other provisions: a stipulation that EPA has jurisdiction over the subject matter alleged in the complaint; a statement that the respondent admits, or neither admits nor denies, the factual allegations in the complaint; a recitation of the amount and terms for payment of a penalty, and the justification for such a penalty and of any other terms and conditions that are part of the settlement; and a statement that the respondent will not contest EPA's reliance on the consent agreement and consent order as demonstrating a prior violation in a future enforcement action.

The 1996 Food Quality Protection Act (FQPA) amended FIFRA (and other pesticide law) to establish a more consistent regulatory agenda grounded in science by (i) mandating a single, health-based standard for all pesticides in all foods; (ii) providing special protections for infants

and children; (iii) expediting the approval of safer pesticides; and (iv) requiring periodic reevaluation of pesticide registrations and tolerances (maximum permitted residues on food) to ensure that the scientific data supporting pesticide registrations will remain up-to-date in the future. By 2006, after ten years, over 99% of the tolerance reassessments were completed by EPA.

### A8-5.5 The Federal Emergency Planning and Community Right-to-Know Act (EPCRA)

EPCRA was signed into law on October 17, 1986 and codifies the concept that residents in a community have a right to know about the presence in their community of particularly hazardous substances that could be released into the environment. The primary purpose of the law is to provide the U.S. public with access to information concerning hazardous chemicals present in the community and to use such information to adopt local emergency response plans in the event of a chemical release. EPCRA both compels the establishment of state and local emergency planning bodies as well as the development and implementation of local emergency plans. It further requires certain facilities to provide detailed reports on the presence and health effects of specified chemicals and releases.

A facility must engage in emergency planning based on the presence of an "extremely hazardous substance" (EHS) only if that substance exists at the facility in an amount greater than its threshold planning quantity (TPQ). This amount will be different for each EHS. If the facility has that amount, it must meet all of the emergency planning requirements. However, if the EHS exists in forms where it constitutes less than one percent by weight if a compound or a mixture, it is regarded a de minimis and its volume is not considered in determining where the TPQ level has been met.

If such amounts of an EHS are present at a facility, its owner/operator shall, within sixty days, notify the State Emergency Response Commission (SERC) that the facility is covered by the emergency planning requirements of the law. The facility then appoints an emergency response coordinator and notifies the Local Emergency Planning Committee (LEPC). The LEPC must be notified of any changes occurring at the facility that may affect community planning. Each LEPC is required to prepare (and annually update) an emergency plan. Information to be included in the program includes identification of emergency equipment and facilities available in the community and at each covered facility as well as evacuation plans and methods and schedules for carrying out such plans.

A facility owner/operator may be required to notify federal, state or local authorities upon the release of specified substances from the facility unless it is fully contained and only persons within the facility are exposed. The owner/operator must immediately notify the community emergency coordinator of the LEPC and the SERC of any reportable release. The EPA has made available summaries of the Toxic Release Inventory (TRI) data covering a number of industrial sectors on the internet. The TRI contains the EPCRA pollutant release data.

EPCRA contains so-called "citizen suit provisions" which permit "any person" to commence a civil action against a facility owner or operator for various violations of the statute.

## A8-5.6 US Involvement in International Efforts to Promote the Environmentally-Sound Management of Chemicals; Cooperative Efforts between the US and the PRC

Multilateral environmental agreements and arrangements are negotiated by the United States under the leadership of the State Department and its Bureau of Oceans and International Environmental and Scientific Affairs. These negotiations are always undertaken in close cooperation with the EPA and/or other relevant technical and scientific agencies and components of the US government. As most of these international environmental regimes affect goods-in-commerce, there is also often involvement from the Office of the US Trade Representative and the Commerce Department. In the US experience, full coordination among all agencies that have jurisdiction over any aspect of policy that might be affected by an environmental regime, including particularly economic, trade, foreign and national security policies, is required to ensure a workable and successful outcome.

The United States has played a leadership role in the international negotiation of a number of chemicals management regimes where it was clear that *only* international action engaged in by most, if not all, of the world's major emitters, was required to address the concern. Prime examples of this would be the Montreal Protocol for the Protection of the Ozone Layer, that successfully promoted the international phase out of ozone-depleting chemicals and pesticides. The United States has been a Party to that treaty for over 15 years and though some ozone-depleting substances have proven difficult to phase-out on the schedule agreed to initially (a prime example of a widely used pesticide that is effective and has few effective and environmentally sound substitutes in certain regions of the world, is the nematocide, methyl bromide which has proven difficult for the United States to phase out as quickly as desired), international action has made significant progress in alleviating the international problem. Another example of where global action is *necessary* is the Stockholm Convention on Persistent Organic Pollutants (POPs) which seeks to prohibit or restrict the production, use, release and/or transboundary movement of, certain identified POPs which can travel long distances in the environment, are persistent, bio-accumulative, and can have severely adverse human health or environmental effects. Here again, given the long range transport of POPs, only a global solution can have the desired environmental and health effect. The Rotterdam Convention on Prior Informed Consent (PIC) for certain toxic chemicals and pesticides, constructs an international regime that gives the recipient of those chemical substances that the international community has agreed should be added to a so-called "PIC list" the opportunity, prior to import, to refuse them. Strictly speaking, an international regime, might not be necessary in this case, were each country to adopt this type of an arrangement into its domestic laws, as the United States had already done under FIFRA. See above. However for reasons of efficiency, uniformity-of-approach, and to ensure that such regimes are wisely adopted and can function together, an agreement such as the PIC is extremely useful in promoting sound chemicals management world-wide. The United States has signed both the Stockholm and Rotterdam agreements and intends to ratify both; it attends the conferences of the parties and various working groups as an observer.

The United States, along with the PRC and Germany have participated fully in the development of a Strategic Approach to International Chemicals Management (SAICM) which was developed

under the auspices of the United Nations Environmental Program (UNEP) and in coordination with the Intergovernmental Forum on Chemical Safety (IFCS). Among other things, the non-binding output is intended to provide information to countries with incomplete chemical management regimes and/or those who wish to strengthen such regimes, with options for doing so. The Organization for Economic Cooperation and Development, consisting of 30 industrialized developed countries, has a number of chemicals programs in which the United States actively participates. These include the Screening Information Data Set (SIDS) to facilitate the investigation of high production volume chemicals, the globally harmonized system of classification and labeling (GHS) to promote better exchange of information on the hazards of chemicals to human health and the environment, and a proposed Mutual Acceptance of Notifications process in response to concern over the need to better align new chemicals systems in the global market. Also, there is the OECD Test Guidelines Program, a foundation of which is the Mutual Acceptance of Data (MAD) agreement among OECD countries to accept the test guideline-run studies for review regardless of where the study is performed.

The PRC and the US have an important, growing, almost 30 year-old, bi-lateral environmental relationship that has led to significant cooperation in the chemicals management arena. The two most important pillars of this relationship is the US-PRC Agreement on Cooperation in Science and Technology dated January 31, 1979, and the Memorandum of Understanding between EPA and SEPA on scientific and technical cooperation in the field of the environment dated December 8, 2003. Under the MOU, a joint EPA-SEPA Committee on Environmental Cooperation is charged with developing cooperative activities on pollution for POPs and other toxic substances. The concept is further elaborated in Annex 3 to the MOU. EPA and SEPA are also currently engaged in a "Toxics Strategy" that is intended to implement Annex 3.

Within the Toxics Strategy, in addition to joint work to address pollution from unintentional POPs (dioxins and furans) and pesticides (lindane), mercury, PCBs and PBTs, there is a chemicals management component. This component includes risk assessment training for industrial chemicals that will include selecting modes and identifying assumptions. It also includes providing SEPA with a better understanding of EPA's New Chemicals Program which is designed, as described herein, to prevent environmental risks before they occur. There will also be collaboration on the management of risks associated with particular existing chemicals of concern, such as PFOA and PDBE's. The US will share program strategies for working with industry through voluntary means to provide health and safety data on high production volume chemicals and efforts to make basic screening-level data available to the public.

There is also collaboration in the area of pesticide management, including harmonization of risk assessment, and enhancement of regulatory capacity. This includes guidance for the private sector in the PRC to develop basic data for the risk assessment process and development of procedures for the evaluation and determination of appropriate internationally harmonized pesticide residue levels on foods. There will also be work to improve regulatory decision making capacity and collaboration on the establishment of good laboratory practices (GLPs) for the development of data used in the risk assessment process, as well as development of a GLP compliance monitoring program which will support sound pesticide risk management.

## A8-5.7 Conclusion

Consistent with the joint work in the area of chemicals management that the US and the PRC are already undertaking, this exercise and the further review and study of US regulatory experiences and paradigms should provide a relevant template for chemical and pesticides management in the PRC, as it works to strengthen its regime and further develop its regulatory capacity. A number of US chemicals management practices are well suited to a nation faced with the challenge of setting priorities and making progress in key areas but constrained by limited resources.