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European Proposal
for Chemicals Regulation:
REACH and Beyond

*Proposition de règlement européen
des produits chimiques :
REACH, enjeux et perspectives*

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Proposition de règlement européen des produits chimiques : REACH, enjeux et perspectives

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AVANT-PROPOS

Suite à une demande du Conseil de l'Union européenne, réuni les 24 et 25 juin 1999, la Commission a élaboré un livre blanc, *Stratégie pour la future politique dans le domaine des substances chimiques*, publié le 25 février 2001¹. Le Conseil et le Parlement ont réagi positivement à ce texte, en proposant des amendements visant pour la plupart à renforcer la protection de l'environnement et de la santé et à simplifier la proposition de la Commission. Cette dernière a alors rencontré les parties prenantes et mis en place des groupes d'experts afin de rédiger un projet de règlement. Celui-ci a été rendu public et soumis à consultation sur Internet le 7 mai 2003. Des chefs d'Etats et de gouvernements se sont alors exprimés de manière critique contre ce projet aux Etats-Unis, en Asie, mais également en Europe². Aux très nombreuses réponses reçues par Internet³ se sont rajoutés les réactions et commentaires de lobbies véhiculés par les médias. La Commission a alors publié un texte substantiellement modifié le 29 octobre 2003, proposition de règlement communément appelée proposition REACH⁴. Celle-ci a de nouveau fait l'objet de nombreuses réactions, en particulier au travers des débats sur les études d'impact de REACH sur la santé, l'environnement et l'industrie, commandées par la Commission, les Etats membres et les associations⁵. La proposition REACH sera soumise au Parlement européen en première lecture à l'automne 2005⁶.

Dans le texte qui suit, nous explicitons tout d'abord à quel point la proposition REACH survient dans un contexte de pré-

caution (I). Nous procédons ensuite à un commentaire de cette proposition, en abordant des aspects particuliers (II). Puis, nous évoquons quelques pistes afin de progresser dans la précision du texte actuel (III). Nous revenons ensuite sur la situation des différents acteurs qui jouent et devraient jouer demain un rôle-clé dans les métiers de la chimie, qu'il s'agisse des métiers industriels ou de la recherche, dès lors que l'on s'engage résolument à poursuivre des objectifs de développement durable (IV). Enfin, nous exposons les choix opérés pour l'atelier (V) et présentons brièvement les contributions contenues dans le présent document (VI).

I. Les fondements de la proposition de réglementation européenne des produits chimiques : une situation de précaution par excellence

Le système réglementaire adopté précédemment par l'Union européenne (UE) sur les produits chimiques n'a pas permis d'obtenir des informations substantielles sur les dangers et les risques caractérisant les très nombreux produits chimiques recensés par l'UE, aujourd'hui plus de cent mille (Haigh).

Faute d'avoir été sérieusement évalués au préalable, certains produits se sont révélés notoirement dangereux, comme l'amiante et le DDT. Ils sont désormais interdits dans de nombreux pays industrialisés, en particulier aux Etats-Unis et en Europe⁷. Pour d'autres substances, la nature des risques n'a été que

partiellement identifiée et leurs caractéristiques mal circonscrites, comme par exemple les perturbateurs endocriniens pour lesquels il est encore difficile de définir de manière satisfaisante des tests d'évaluation des risques. L'état des connaissances sur les risques liés aux produits chimiques a trait à plusieurs ensembles de données. Un premier ensemble concerne la manière dont les substances chimiques diffusent dans l'environnement, interagissent avec les systèmes vivants et, éventuellement, se concentrent dans l'air, le sol, les végétaux, chez les animaux et les humains, et l'évolution de ces caractéristiques au cours du temps. Un second ensemble de données a trait au suivi des pathologies chez les humains et les animaux.

L'état actuel des connaissances a permis d'identifier, d'une part, une augmentation de l'incidence, en particulier chez les populations les plus fragiles (nourrissons et personnes âgées), de maladies chroniques – comme l'asthme et certaines allergies, de maladies mortelles – comme le cancer, ainsi que des dysfonctionnements du système reproductif ou du système hormonal ; et, d'autre part, la croissance d'une pollution diffuse de substances chimiques, parfois irréversible lorsqu'il s'agit de polluants persistants s'accumulant dans les systèmes biologiques.

Des débats intenses ont lieu sur les relations entre les évolutions constatées des pollutions environnementales et celles de la santé humaine, qui sont loin de conduire aujourd'hui à des résultats consensuels. Plusieurs éléments rendent la progression de ces débats très difficile.

Tout d'abord, les conclusions des études menées par les Etats et les associations sur l'évolution des caractéristiques sanitaires des populations font l'objet de vives controverses, aussi bien sur l'incidence des pathologies que sur leurs causes. Par exemple, lorsqu'on étudie les évolutions des différents cancers au cours des cinquante dernières années, on se heurte à des difficultés méthodologiques sérieuses⁸. Il est en effet délicat de comparer des corpus de données obtenues dans des contextes différents :

- le nombre et la qualité des diagnostics précoces ont fortement crû, élargissant de ce fait le champ d'investigation des pathologies décelables ;
- les habitudes comportementales évoluent fortement et de manière différenciée selon les classes d'âge ;
- l'environnement des individus, qu'il s'agisse du lieu de vie (sphère domestique,

zone urbaine, campagne...) ou du milieu professionnel, connaît également des modifications importantes.

Ensuite, aux deux extrémités du spectre d'opinions et de sensibilités, deux points de vue, voire deux philosophies, s'affrontent. D'un côté, certains arguent du fait que si des pollutions beaucoup plus intenses et nocives pour l'homme ont existé par le passé, celles-ci ont considérablement diminué, allant de pair avec des améliorations considérables de la santé humaine. Ceci vaut bien sûr pour les pays industrialisés. Par conséquent, les habitants de ces pays, soumis à des taux de pollution beaucoup plus bas aujourd'hui, ne sauraient s'alarmer. Cette constatation ne vaut pas, bien entendu, pour les pays en développement, voire, et pour des raisons différentes, pour les pays émergents ou en transition. D'un autre côté, certains soulignent que si nous vivons dans un monde contrasté, où les pollutions manifestes, c'est-à-dire présentes à des seuils élevés aisément décelables, sont très fortement différenciées selon les pays, on assiste par ailleurs à la croissance de pollutions diffuses, capables parfois de migrations à grande échelle, voire d'accumulation dans les systèmes biologiques. Corrélativement, les constats de la croissance de l'incidence de certaines maladies chroniques mais aussi les fortes présomptions d'augmentation de certains cancers ont donné lieu à de vives inquiétudes et joué un rôle d'alarme. Ces maladies seraient, en effet, soit largement attribuables à des facteurs environnementaux pour les premières, soit favorisées par ces facteurs pour les secondes, facteurs au sein desquels la pollution diffuse par les substances chimiques ne jouerait pas un rôle mineur.

Enfin, il semble que, dans bien des cas, la progression des connaissances sur les relations entre causes et effets pour des pathologies évolutives susceptibles d'être influencées de manière directe ou indirecte par des facteurs environnementaux ne puisse s'opérer que lentement, en particulier dès lors que l'on recherche des énoncés scientifiques certains. Les problèmes méthodologiques sont nombreux et rejoignent, sans surprise, les raisons qui rendent les débats d'experts très peu conclusifs. Citons à cet égard la difficulté à extrapoler à l'homme les résultats de tests toxicologiques effectués sur des animaux, ou encore à mettre en évidence des effets déclenchant ou fragilisant d'une substance pour une pathologie spécifique. La question des effets coopératifs, et donc synergiques, néfastes pour l'environnement

et la santé de substances qui, considérées isolément à des concentrations faibles, ne sont pas préoccupantes (Müller-Herold (a)) est aussi délicate et rend, le cas échéant, la notion d'effet de seuil inopérante. De telles sources d'incertitudes s'ajoutent bien entendu à celles qui proviennent du manque considérable de données sur les caractéristiques toxicologiques et écotoxicologiques des substances, ainsi que sur les conditions d'exposition à celles-ci.

La situation actuelle apparaît par conséquent, au regard des pollutions diffuses de substances chimiques et de l'incertitude scientifique notoire quant à leurs effets sur l'environnement et la santé humaine, comme une situation de précaution par excellence. Dans le cadre de l'Union européenne, le principe de précaution est inscrit dans le traité de Maastricht et a été réaffirmé depuis dans le traité d'Amsterdam, le traité de Nice puis le nouveau traité actuellement soumis à l'approbation des Etats européens. La proposition REACH apparaît clairement comme une application de ce principe (Heyvaert, Reh binder). Il existe en effet des raisons sérieuses de se préoccuper des effets néfastes, potentiels ou avérés, des produits chimiques pour la santé humaine et pour l'environnement : des effets qui peuvent devenir irréversibles lorsque les produits potentiellement dangereux s'accumulent dans les matériaux biologiques ou se manifester à grande échelle si ces substances peuvent parcourir des distances importantes.

Ceci ne retire rien à la gravité de maladies encore très mal soignées, situations auxquelles il est impératif d'apporter des réponses à la mesure des drames qui touchent les populations en développement en de nombreux lieux de la planète. On constate toutefois que les solutions aux problèmes sanitaires et environnementaux majeurs relèvent de mécanismes de solidarité internationaux qui peinent à se mettre en place. Le problème de la lutte contre le paludisme au moyen du DDT est emblématique. La convention de Stockholm, qui engage les parties utilisant le DDT sur leurs territoires à en restreindre strictement l'usage⁹, encourage également les parties à utiliser d'autres méthodes pour combattre le paludisme. A l'évidence, si des efforts conséquents étaient menés pour rechercher, produire et diffuser des médicaments contre cette maladie, ce problème se poserait différemment. Cependant, force est de constater que les efforts dans ce sens sont toujours extrêmement faibles et sous-dimensionnés¹⁰.

II. La proposition REACH

Demander aux entreprises de fournir des données relatives à la dangerosité et aux risques des substances qu'elles produisent, importent ou utilisent est indiscutablement nouveau dans REACH et relève clairement, tout comme la procédure d'autorisation des substances extrêmement préoccupantes, de l'application du principe de précaution (Reh binder). Certains estiment qu'il faut saluer l'initiative instaurant, selon une terminologie en usage dans les discussions relatives au principe de précaution, un renversement de la charge de la preuve, comme cela est recommandé dans la communication de la Commission européenne sur le principe de précaution¹¹. S'il est vrai que la responsabilité tout comme la charge incombant aux entreprises est ici manifeste, ne nous y trompons pas : lorsque le principe de précaution est invoqué, en situation d'incertitude scientifique sur la nature des risques et/ou sur leurs caractéristiques, l'innocuité d'un produit, tout comme la preuve de l'existence d'un risque sont difficiles à établir. Le rôle d'inversion de la charge de la preuve est, par conséquent, avant tout incitatif, les substances potentiellement ou effectivement dangereuses se retrouvant soit retirées du marché par leur producteur, soit restreintes dans leurs usages par le régulateur.

La complexité du texte présenté par la Commission, encore en discussion au Parlement européen, est à l'image du problème traité. Il s'agit en effet de créer un dispositif réglementaire qui permette de rassembler des informations sur toutes les substances chimiques existantes et nouvelles en Europe, selon des procédures normalisées aussi bien sur les dangers que sur les risques environnementaux et sanitaires d'ici 2012.

Dès l'abord, quelques préalables s'imposent. Les substances chimiques – on en dénombre plus de cent mille en Europe et trente mille sont concernées par REACH – sont de nature extrêmement diverse : produits minéraux, produits organiques, métaux, petites molécules ou polymères... Estimer à la fois les dangers et les risques de ces substances n'est pas une tâche aisée, loin s'en faut. Si certaines de leurs propriétés intrinsèques peuvent se mesurer directement en laboratoire, comme la solubilité dans un solvant donné, d'autres ne peuvent qu'être estimées, comme la toxicité pour l'homme, qui requiert l'interprétation et l'extrapolation de tests effectués sur des animaux, démarche à la fois complexe et délicate. Les risques des

substances sont liés aux facteurs d'exposition, donc aux volumes produits, aux types d'usage, au nombre d'utilisateurs, tout au long de la chaîne allant du producteur à l'utilisateur final. Le plus souvent d'ailleurs, le circuit suivi par les substances s'effectue plutôt sur un réseau complexe reliant les producteurs, les utilisateurs et les consommateurs. Par ailleurs, le dispositif REACH s'intéresse à des substances considérées de manière isolée, qu'elles soient ou non insérées dans un produit, et ignore par conséquent les effets synergiques (Müller-Herold (a)).

Le projet initial est donc ambitieux. Le choix des critères à utiliser pour rendre la tâche réalisable de manière efficace et proportionnée est délicat. Par exemple, s'il est tentant de hiérarchiser les produits les plus préoccupants qu'il faudra traiter en priorité selon les risques qu'ils présentent, bien souvent les données disponibles ne permettent pas de les estimer. Par conséquent, la prise en compte à la fois des dangers que présentent ces substances et des volumes produits apparaît plus réaliste. Par ailleurs, faire en sorte que l'ensemble des acteurs, du producteur à l'utilisateur final, exercent leurs responsabilités n'est pas non plus aisé (Rehbinde). REACH choisit de faire peser la responsabilité ultime, ainsi que l'obligation de substitution, sur le producteur initial d'une substance. Or, il n'est pas évident que celui-ci soit toujours en meilleure capacité à cet égard que certains de ses clients.

Des choix ont été opérés dans REACH et nous essaierons de comprendre de façon plus précise, à travers cet atelier, dans quelle mesure le texte en préparation répond de manière cohérente au projet initial.

III. Progresser dans l'élaboration

Que constate-t-on dans l'état actuel des négociations sur la proposition REACH ? Si les différents porteurs d'intérêt – entreprises productrices ou utilisatrices de substances chimiques, syndicats, associations de défense de l'environnement ou de consommateurs – restent aujourd'hui partagés sur le niveau de contrainte réglementaire souhaité pour parvenir au but escompté, leurs opinions ne nous semblent toutefois pas remettre en cause la logique et la cohérence interne de la proposition REACH.

On pourrait bien entendu souhaiter un texte plus simple, et de ce fait plus accessible à la compréhension d'un plus grand nombre, ainsi qu'un calendrier plus resserré pour trai-

ter les produits les plus préoccupants. On pourrait également appeler de ses vœux le développement ou le renforcement de systèmes d'observation de l'environnement (Macrory). On pourrait aussi souhaiter faire un meilleur usage *a priori* des propriétés physico-chimiques accessibles en laboratoire (Hansson, Müller-Herold (b)). Ce raisonnement correspond en effet à une politique de précaution qui s'inscrit en amont de la mise sur le marché des produits. Il nous semble toutefois que la proposition représente une avancée tout à fait significative. Il nous importe alors d'œuvrer pour contribuer à en faire un règlement dont l'application soit la plus efficace, la plus aisée et la plus équitable possible.

Il subsiste aujourd'hui au sein de la proposition des incertitudes de plusieurs natures. Il s'agit en particulier de celles qui relèvent de questions de frontières. L'Europe souhaite jouer ici un rôle exemplaire, voire d'entraînement, vis-à-vis d'autres grands pays producteurs de substances chimiques. Cela étant, plusieurs pays de l'OCDE prennent actuellement des dispositions qui émanent de préoccupations de même nature que REACH sur le manque d'informations sur les substances chimiques et poursuivent des buts très voisins (Musset). Dès lors, les efforts d'harmonisation des initiatives menés dans le cadre de la stratégie internationale des produits chimiques développée par le Programme des Nations unies pour l'environnement prennent tout leur sens et pourront trouver des réponses techniques dans les méthodes d'évaluation, de classement et d'étiquetage harmonisées développées par l'OCDE. La Commission européenne s'est engagée à ce que REACH participe à cet effort d'harmonisation.

Par ailleurs, il apparaît que certaines questions complexes ne pourront trouver de réponses satisfaisantes dans l'immédiat. Il importe alors que le texte permette, voire prévoie, de les traiter dans une période ultérieure ou intègre d'ores et déjà certaines dispositions évolutives (Hansson).

Enfin, d'autres questions trouveront des réponses dans le cadre de la négociation en cours. C'est le cas pour la précision des missions de l'Agence européenne des produits chimiques instaurée par le texte de la Commission, comme des rôles respectifs des Etats membres et des organes communautaires dans l'évaluation et la gestion des risques liés aux substances chimiques. Un autre point important est celui de la mise en commun par les entreprises des données sur les dangers

des substances, dans le respect de la confidentialité pour les informations qui relèvent du secret industriel¹², tout comme celui de la recherche du soutien le mieux adapté aux entreprises de petite taille pour qu'elles puissent répondre à leurs obligations.

Afin d'anticiper les relations que l'Agence européenne des produits chimiques pourra établir avec des autorités nationales similaires ou disposant de l'expertise adéquate, on pourra s'inspirer du modèle des agences communautaires et de leur fonctionnement en réseau (comme la jeune Autorité européenne pour la sécurité des aliments). Une question centrale est celle des ressources en experts, lesquelles seront nécessaires tant au sein des autorités compétentes nationales et européennes que dans les entreprises. Si la réflexion sur les missions à confier à l'Agence doit être séparée, autant que faire se peut, de celle sur les ressources en experts, il est souhaitable en revanche que les Etats membres mutualisent l'état de leurs ressources nationales en matière d'expertise. Identifier, au sein des Etats membres, les domaines dans lesquels les compétences sont les mieux représentées ou, à l'inverse, peu développées permettra d'investir afin de disposer le plus tôt possible d'une capacité d'expertise pour l'évaluation des risques. La mise en place de l'Agence sera très certainement un élément essentiel de cette rationalisation des compétences au sein des vingt-cinq Etats membres.

Le dispositif REACH pose également la question des divers modes d'accès possibles à des données d'expertise privée : dans la recherche de mise en commun de certaines données par les entreprises dans un but d'économie et de diminution des tests sur animaux, tout d'abord ; mais également dans la recherche d'une meilleure exploitation des données existantes. Ainsi, il serait extrêmement utile de réfléchir à comment rendre publique une partie plus importante des données toxicologiques obtenues par les entreprises pharmaceutiques, de par leurs obligations réglementaires. Cela contribuerait très fortement à consolider les connaissances en toxicologie.

IV. Les différents acteurs en présence

Parmi les différents acteurs impliqués dans la négociation REACH, nous avons choisi de nous intéresser plus spécifiquement à ceux qui composent l'industrie chimique européenne. Nous traiterons ensuite d'un

moteur important pour le développement économique de cette industrie, à savoir la recherche et l'innovation.

Les acteurs économiques

La proposition de règlement européen des produits chimiques REACH survient dans un contexte d'accélération mondiale des échanges et de restructurations industrielles importantes sous la pression de plusieurs facteurs – recherche d'économies d'échelle, recentrage des groupes industriels sur leur cœur de métier et diminution du coût du travail. Ces facteurs œuvrent tous à augmenter les valeurs des actions des entreprises et ont pour conséquences des délocalisations de sites industriels vers l'Europe de l'Est et les pays émergents en particulier d'Asie (Gréau). Dans ce contexte, les contraintes réglementaires instaurées pour protéger l'environnement et la santé apparaissent comme l'un des éléments structurants dans les choix stratégiques des entreprises. Ceci vaut pour tous les secteurs et en particulier pour la chimie.

C'est dans ce paysage en pleine mutation, qui pose des défis sociaux et économiques majeurs aux Etats occidentaux qu'un autre défi apparaît lui aussi de plus en plus prégnant. Il importe d'utiliser les ressources naturelles de manière plus efficace et plus économe, en évoluant vers des modes de développement plus respectueux de l'environnement et, partant, de la santé humaine.

Les grandes entreprises européennes du secteur de la chimie, si elles conservent un ancrage fort en Europe, sont aujourd'hui largement internationalisées. En raison de la dynamique économique actuelle, ces entreprises ont une croissance en forte augmentation en Asie en particulier, où se développent des sites de production, mais aussi des unités de recherche et développement. Les évolutions industrielles ont eu pour effet d'inverser la tendance précédente à la diversification de firmes qui avaient réussi à regrouper des activités dans les domaines de l'agroalimentaire, de la pharmacie et de la chimie. Les trois types d'activité, n'ayant pas forcément la même rentabilité, se retrouvent à présent séparés. Ceci n'est pas sans effet sur le tissu industriel qui entoure ces activités. Ainsi, si la création d'une petite unité de production de quelques substances chimiques représente un coût relativement faible pour de nouveaux entrants sur un marché, ce coût augmente si l'on se déplace vers le secteur de la pharmacie en passant par celui de l'agro-

alimentaire. Par ailleurs, on assiste à un éclatement des compétences et des savoir-faire qui aura des conséquences à terme dans les modes d'innovation. A l'intérieur d'un paysage industriel en recomposition permanente et soumis à des tendances lourdes de moyen terme – diversification *versus* concentration et recentrage –, les réglementations environnementales comme REACH devraient toucher les entreprises différemment selon leur taille et leurs moyens. En France, en particulier, coexistent des entreprises productrices ou utilisatrices de produits chimiques de toutes tailles, qui forment un continuum entre ce qu'il est convenu d'appeler les petites et les grandes entreprises. Ce constat milite pour que le règlement REACH édicte des obligations égales, mais permette un accompagnement différencié des entreprises. A ce titre, la mise à disposition de moyens techniques facilitant non seulement l'application des réglementations mais également les innovations apparaît extrêmement souhaitable (Warhurst).

AVANT-PROPOS

Le rôle de la recherche

La recherche, l'innovation et le développement technologique constituent l'un des principaux moteurs de nos sociétés, tant en termes de formation des individus, que d'adaptation aux défis que celles-ci ont à maîtriser, parmi lesquels ceux du développement durable. Moyennant le fait qu'on les traduise en termes de recherche, ces défis – sécurité alimentaire, efficacité énergétique, services essentiels pour tous, protection de l'environnement, amélioration de la santé publique... – font appel à l'évidence à la fois à la recherche fondamentale et à la recherche finalisée (ou orientée).

Or, en dépit de l'impératif systématiquement réaffirmé depuis cinq ans par tous les gouvernements de l'Union européenne de parvenir d'ici à 2010 à consacrer 3 % du produit intérieur brut de leur pays à la recherche, on ne peut que s'attrister de la difficulté des principaux Etats à satisfaire ces engagements. Trop souvent, les premières réductions budgétaires touchent des secteurs qui sont cependant essentiels pour notre avenir. Ceci témoigne d'un manque de volonté et d'une faiblesse récurrente à maintenir l'importance stratégique d'un engagement de l'Etat dans un effort de recherche soutenu, dont les orientations relèvent à la fois de stratégies de long terme pour les programmes de grande ampleur, mais aussi de capacités d'adaptation en fonction de l'avancée des connaissances et des contextes. La

capacité à opérer des choix cohérents et à les maintenir dans la durée suppose que l'on reconnaisse que la recherche dans toutes ses composantes contribue de manière radicale à la vitalité d'une nation.

Si l'on se place dans une perspective historique, il apparaît clair que, depuis la seconde guerre mondiale, l'effort des Etats en matière de recherche a été étroitement associé à celui de l'industrialisation ; ceci vaut aussi pour l'entre-deux-guerres mais avec un rôle moins prégnant de l'Etat (Dahan). Or, on assiste en Europe de l'Ouest à une diminution de plus en plus prononcée du secteur industriel. Dans le même temps, on constate une diminution des soutiens à la recherche. Les restructurations à l'œuvre ne vont pas dans le sens de la conservation de laboratoires privés de tout premier plan – pensons à Bell Labs ou à Dupont aux Etats-Unis à l'époque où certaines entreprises étaient capables de financer une recherche fondamentale d'excellence et d'exploiter les synergies entre ingénieurs et chercheurs.

La chimie n'échappe pas à cette description. Cependant, on observe dans ce domaine une prise de conscience progressive des enjeux du développement durable. Celle-ci croît chez les chercheurs et s'exprime par ailleurs dans des programmes de recherche orientés vers la construction d'une chimie plus respectueuse de l'environnement et de la sécurité et plus efficace, appelée chimie durable (Lattes). Toutefois, quand bien même les efforts consentis produiront leur lot de découvertes et d'innovations *a priori* fort prometteuses, encore faudra-t-il que celles-ci puissent être développées et produites industriellement à des coûts supportables. Or, de telles richesses existent déjà sur les étagères des laboratoires. Dès lors, les efforts devront également se concentrer sur les instruments qui pourront permettre de développer et d'exploiter dans l'industrie des procédés et des produits existants. Cette réflexion vaut pour le secteur de la chimie, comme pour bien d'autres. Pensons à l'ensemble des secteurs concernés par la quête de voies pour réduire les émissions de gaz à effet de serre.

V. Les choix opérés pour l'atelier

Nous avons choisi de ne pas traiter des relations entre la pollution liée aux substances chimiques et la santé humaine. La complexité technique de ces questions (*cf.* I) ne permet pas de les aborder sérieusement

dans le cadre de notre atelier. Celles-ci sont au cœur des recherches menées dans le cadre du Plan Santé Environnement en France¹³. Par ailleurs, des débats centrés sur cette problématique se développent de plus en plus dans notre pays¹⁴. Nous n'approfondirons pas non plus la question des impacts du système REACH pour la puissance publique et les industriels. Suite à une première vague d'études (*cf.* note 5), une seconde série d'études d'impact – sectorielles – a été réalisée¹⁵, dont les résultats ont été publiés récemment et analysés lors d'un atelier de travail entre les Etats membres les 10 et 11 mai à Luxembourg. Ils sont d'ores et déjà beaucoup moins négatifs pour l'industrie que ceux de certaines études précédentes. Là encore, les difficultés méthodologiques soulevées nous ont semblé trop nombreuses pour que nous puissions progresser sur ce sujet lors de notre atelier. Les acteurs ont pu et pourront débattre de ces questions dans d'autres instances.

Nous avons préféré donner la possibilité à des experts européens de haut niveau de livrer leur éclairage sur d'autres aspects de la proposition REACH. Celle-ci soulève à la fois des questions de principe, de substance et de mise en œuvre. Elles peuvent soit avoir trait au moyen terme dans lequel s'inscrit le processus (2012), soit relever du plus long terme, comme l'insertion du processus REACH dans l'ensemble des initiatives internationales ou encore ses effets sur l'innovation.

Sans s'affranchir d'une analyse critique de la proposition (Macrory), il importe aujourd'hui de situer d'emblée les débats au-delà de pétitions de principe, pour les inscrire au plus près des réalités concrètes et de propositions d'amélioration. L'hypothèse sur laquelle s'appuie notre réflexion consiste donc à gager que les négociations en cours sur la proposition REACH ne remettront pas en cause de manière substantielle la logique du dispositif, d'une part, et le niveau des obligations incombant aux différents acteurs, d'autre part.

Mais dans le même temps, nous ne nous priverons pas d'une réflexion prospective, invitant l'ensemble des acteurs à réfléchir ensemble aux différents scénarios qui pourraient permettre une meilleure prise en compte des défis qui se posent aujourd'hui. Placer la réflexion au-delà d'un horizon trop proche permet de mieux rechercher des modes de complémentarité et de solidarité entre acteurs économiques, puissance publique et citoyens, ainsi qu'au sein même du monde industriel.

Pour y parvenir, il importe tout d'abord de retrouver des logiques économiques plus

raisonnées, si ce n'est plus raisonnables, qui permettent en particulier aux Etats de dégager les moyens nécessaires pour investir dans le futur, tout particulièrement en matière d'éducation et de recherche (Guinot, Lattes).

VI. Les contributions des experts

Le présent document regroupe les textes de neuf auteurs.

Nigel Haigh rappelle l'historique des dispositions législatives qui ont progressivement encadré l'usage des substances chimiques en Europe et les faiblesses de celles-ci.

Laurence Musset présente les travaux menés par l'OCDE sur les substances chimiques et les liens entre ceux-ci et la proposition REACH. Elle évoque également les initiatives menées dans ce domaine par d'autres pays de l'OCDE.

Richard Macrory livre les éléments saillants du rapport réalisé en 2003 par la Royal Commission of Environmental Pollution, commission d'experts indépendants du gouvernement britannique, intitulé *Chemical in Products, Safeguarding the Environment and Human Health*.

Ulrich Müller-Herold illustre la question difficile des effets synergiques des substances chimiques en utilisant un modèle simple et des exemples de la littérature scientifique récente.

Sven Ove Hansson et Christina Rudén montrent que les informations requises par REACH sont insuffisantes pour caractériser les substances produites en faible volume. Ils proposent notamment un moyen pour corriger la faiblesse du dispositif pour les très faibles volumes.

Pour Eckard Rehbinder, la proposition REACH relève de l'application du principe de précaution. Il analyse le régime de responsabilité introduit, la question de la charge de la preuve et la conformité du règlement proposé avec les règles de l'Organisation mondiale du commerce.

Pour Michael Warhurst, les réglementations, dont REACH, sont une composante-clé pour que l'industrie chimique contribue au développement durable. Elles devront cependant être complétées par des investissements dans la chimie durable et des dispositifs d'assistance technique aux entreprises.

François Guinot montre que les défis que rencontre la chimie européenne aujourd'hui, dont la poursuite d'un développement

durable, pourront être relevés à condition que la recherche et l'innovation soient résolument placées au centre des stratégies des Etats et des industries chimiques en Europe afin de faire émerger une chimie nouvelle.

Armand Lattes présente et commente les efforts consentis par les grands pays industrialisés en matière de chimie durable, en particulier pour les biotechnologies, notamment en France et en Europe.

Enfin, si la bibliographie proposée au lecteur à la fin de ce document est modeste, nous l'incitons fortement à consulter les références souvent très riches incluses dans les ouvrages cités.

- 1) COM(2001)88 final.
- 2) Dans une lettre envoyée le 20 septembre 2003 au président de la Commission, Romano Prodi, le Premier Ministre Tony Blair, le Président Jacques Chirac et le Chancelier Gerhard Schröder ont exprimé leurs préoccupations en particulier en matière de compétitivité et d'emploi, mais aussi sur le caractère bureaucratique de la proposition, jugée très difficile à mettre en œuvre.
- 3) Plus de 6000, cf. <http://europa.eu.int/comm/environnement/chemicals/whitepaper.htm>
- 4) Proposition de règlement du Parlement et du Conseil concernant l'enregistrement, l'évaluation et l'autorisation des substances chimiques, ainsi que les restrictions applicables à ces substances (REACH), instituant une agence européenne des produits chimiques et modifiant la directive 1999/45/CE et le règlement (CE) sur les polluants organiques persistants COM(2003) 644 final.
- 5) Durant leur présidence de l'Union européenne, les Pays-Bas ont organisé un atelier à La Haye pour débattre des principales études d'impact réalisées à partir d'un document de synthèse consultable sur Internet : http://www.eu2004-reach.nl/downloads/Comprehensive_Overview-v2.pdf
- 6) Un historique de la genèse puis de la préparation de la proposition REACH ainsi que des réactions qui en ont émaillé les différentes étapes peut être trouvé sur : <http://www.panda.org/downloads/theonlyplanetguide.pdf>
- 7) L'usage du DDT est par ailleurs strictement restreint dans le cadre de la convention de Stockholm, entrée en vigueur en 2004 et ratifiée par plus de 70 pays.
- 8) *Cancer, approche méthodologique du lien avec l'environnement. Une expertise collective de l'Inserm*, Inserm. 2005, 101 p. <http://ist.inserm.fr/basisrapports/cancer2005.html>
- 9) C'est le cas en particulier de la Côte d'Ivoire, l'Ethiopie, la Papouasie-Nouvelle-Guinée et l'Afrique du Sud.
- 10) Rapport de Médecins sans frontières, 13 octobre 2001.
- 11) COM(2000)1.
- 12) Voir à cet égard la proposition *One Substance, One Report* du Royaume Uni et de la Hongrie, ou proposition OSOR.

13) Séminaire de prospective scientifique et de lancement du programme de recherche du Plan national Santé Environnement et du Plan Santé Travail, ministère délégué à la recherche, 31 mars et 1^{er} avril 2005.

14) Deuxièmes rencontres parlementaires *Santé environnement*, Assemblée nationale, 9 décembre 2004.

15) Il s'agit de deux études, l'une commandée par le CEFIC et l'UNICE au consultant KPMG, et l'autre commandée par la Commission à son Centre commun de recherche (CCR) et à l'Institute for prospective technological studies (IPTS), toutes deux rendues publiques le 27 avril 2004.

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L'histoire de la réglementation européenne des produits chimiques

Nigel Haigh

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La législation européenne en matière de produits chimiques s'impose aux politiques nationales. Elle a débuté dans les années 70 et s'est développée selon quatre phases qui se chevauchent, REACH constituant la dernière d'entre elles. Au cours des années 70, un cadre *ad hoc* a été créé, restreignant la commercialisation et l'utilisation de tout produit chimique dont la dangerosité était établie. Ceci se poursuivra avec REACH. Pendant la seconde phase, qui a commencé au début des années 80, aucun produit chimique nouveau n'a pu être commercialisé sans avoir été testé, et les résultats notifiés aux autorités compétentes. C'est ainsi que des informations utiles pour une utilisation moins dangereuse de produits ont pu être collectées et que certains produits n'ont pas été mis sur le marché, alors qu'ils l'auraient été sinon. Durant les années 90, la troisième phase, un programme sur les produits existants a été introduit. Des listes prioritaires de produits chimiques existants et nécessitant une évaluation des risques ont été dressées et les Etats membres se sont partagés leur examen. Ceci a conduit à la publication de stratégies de réduction des risques. Mais celles-ci ont été produites si lentement que la pression pour une réforme majeure des dispositifs existants a crû, donnant lieu à la quatrième phase connue sous le nom de REACH.

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Le programme Produits chimiques de l'OCDE et les aspects principaux de la proposition pour une nouvelle politique européenne des produits chimiques

Laurence Musset

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Le programme de l'OCDE sur les produits chimiques a pour objectif d'aider les pays membres à protéger la santé humaine et l'environnement des risques liés aux produits chimiques de la manière la plus efficace possible. Il comprend le partage du travail et l'harmonisation d'outils performants comme des politiques de gestion des produits chimiques – ce qui permet d'éviter une duplication du travail pour les pays membres comme pour l'industrie. L'évolution du programme reflète les progrès effectués dans les pays de l'OCDE. Cette évolution les a conduits de la gestion des risques posés par quelques substances particulières très préoccupantes au développement d'instruments pour le contrôle des substances chimiques nouvelles, puis à l'évaluation en coopération des substances chimiques existantes. Aux fins d'augmenter l'efficacité globale de la sécurité chimique, l'OCDE travaille aujourd'hui avec certains pays non membres à l'amélioration de la convergence des politiques dans ce domaine.

Les lignes directrices de l'OCDE sur les essais de produits chimiques et les bonnes pratiques de laboratoire sont les deux pierres angulaires de l'acceptation mutuelle de données. Le programme fournit ainsi des documents de référence sur l'évaluation et la gestion des risques. Afin de réduire les coûts et l'utilisation d'animaux de laboratoire, il cherche aussi à faciliter l'adoption dans les textes réglementaires de méthodes de tests alternatives et de méthodologies d'évaluation des données utilisant l'informatique. Le programme contribue de nombreuses façons, par exemple à travers l'harmonisation des critères de classification et d'étiquetage, à la mise en œuvre des recommandations des Nations unies sur la gestion des produits chimiques.

Différents éléments de la proposition REACH, qui constituent des innovations par

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rapport à la législation européenne actuelle, existent déjà dans les politiques sur les produits chimiques des pays de l'Union ou de l'OCDE. Ceci est vrai en particulier pour l'examen systématique des produits chimiques existants et l'importance accordée aux propriétés de persistance et de bioaccumulation. En revanche, la responsabilité de l'industrie pour l'évaluation des risques chimiques et la procédure d'autorisation pour les produits très dangereux constituent des instruments politiques nouveaux. Les interactions entre le programme de l'OCDE sur les produits chimiques et la nouvelle politique européenne devraient donc être nombreuses.

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Les substances chimiques dans les produits. Protéger l'environnement et la santé humaine

Prof. Richard Macrory

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Dans son rapport au gouvernement britannique, *Chemicals in Products: Safeguarding the Environment and Human Health*, publié en 2003, la Commission royale sur la pollution de l'environnement a émis 54 recommandations d'action et de modification de la réglementation des produits chimiques. La Commission royale considère que REACH va prendre trop de temps pour traiter les produits chimiques non encore testés ; elle propose donc un système qui permettrait un « examen rapide » des 30 000 produits chimiques à évaluer en trois ans, plutôt que de soumettre chacun d'entre eux à une analyse plus lente, plus coûteuse et plus complète. La première étape consisterait à dresser la liste des produits chimiques existants sur le marché. Dans une deuxième étape, la dangerosité des produits serait estimée en utilisant des techniques de modélisation moléculaire par ordinateur, ainsi que des méthodes informatiques de revue de la littérature scientifique et de bases de données. Des restrictions d'utilisation seraient ensuite mises en place sur les produits en fonction du niveau de risque qu'ils présentent.

La Commission royale s'attend à ce que la plupart des produits étudiés ne soient pas particulièrement préoccupants. Néanmoins, la production et l'importation de certains produits chimiques classés parmi les plus dangereux devraient être immédiatement interdites. Plusieurs centaines, voire plus d'un millier de produits seront probablement classés comme très, moyennement ou peu dangereux et, par la suite, soumis à une évaluation des risques plus complète. La Commission royale pense que l'évaluation des risques de tous les produits chimiques préoccupants préalablement identifiés pourrait être conduite d'ici 2009. Bien qu'elle ne croie pas que le système qu'elle propose permettra d'identifier tous les produits chimiques néfastes, celui-ci serait plus efficace que l'approche proposée par REACH.

Le rapport recommande aussi que le gouvernement fasse un meilleur usage de la surveillance de l'environnement dans l'identification des produits chimiques dangereux exigeant des actions supplémentaires. La Commission royale souhaiterait que le gouvernement britannique adopte une stratégie capable de réduire de façon permanente et mesurable l'utilisation des produits chimiques dangereux et de leur trouver des substituts moins nocifs. Le rapport estime enfin que donner au public plus d'informations sur les produits chimiques mis sur le marché conduirait les producteurs et les utilisateurs à préférer de tels substituts aux produits dangereux. L'utilisation des produits les plus nocifs devrait être restreinte à certains usages et assujettie à une taxe.

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Au-delà de REACH. Une approche heuristique des effets toxiques de mélanges de substances chimiques présentes à des niveaux tels qu'individuellement aucun effet n'est observé

Prof. Ulrich Müller-Herold

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La règle d'additivité des effets, telle qu'elle est définie dans la proposition REACH (appendice 1b) tend à sous-estimer

systématiquement les risques d'interactions synergiques dans les mélanges de substances chimiques. Nous l'illustrons au moyen d'un modèle simple et d'exemples de la littérature scientifique récente.

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Améliorer les fondements scientifiques des décisions dans le système REACH

Prof. Sven Ove Hansson,
et Christina Rudén

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Une évaluation scientifique des risques d'exposition potentielle ou réelle à un produit chimique n'est possible que si l'on dispose d'un ensemble de connaissances raisonnable sur les propriétés intrinsèques de la ou des substance(s) considérée(s). Un des principaux avantages de la proposition REACH est qu'elle va augmenter notre base de données toxicologiques pour les produits chimiques industriels et consolider ainsi le socle scientifique pour l'évaluation des risques. Toutefois, notre analyse montre que cette amélioration, bien que substantielle, laisse subsister des zones d'ignorance importantes dans l'ensemble des données nécessaires. Les informations exigées par REACH pour les substances produites à moins de 10 tonnes ne sont pas suffisantes pour appliquer aucun des principaux critères de classement scientifique de ces substances, par exemple pour déterminer la toxicité aiguë ou chronique ou leur écotoxicité. Pour des volumes produits inférieurs à 100 tonnes, les informations requises par REACH ne seront d'aucune utilité pour déterminer si le processus d'autorisation de REACH doit être enclenché ou non. Par exemple, pour de tels volumes, on ne demande pas les données qui permettraient de déterminer si les critères définissant les produits persistants bioaccumulatifs et toxiques (PBT) ou très persistants et très bioaccumulatifs (vPvB), potentiellement responsables d'écotoxicité, s'appliquent.

Les tests inclus dans REACH ainsi que d'autres systèmes d'essais réglementaires sont tous soigneusement élaborés en fonction de

principes scientifiques. Cependant, cela ne suffit pas pour rendre un système de tests scientifiquement valide. Par exemple, le mode de combinaison des tests ainsi que les règles déterminant leur chronologie doivent aussi être déterminés en fonction de principes scientifiques. Nous proposons de mener une recherche visant à développer des systèmes de tests fondés sur la science y compris au niveau systémique.

Des efforts particuliers doivent être entrepris pour utiliser prioritairement les propriétés physico-chimiques. De telles données peuvent être obtenues à un coût relativement bas et sans effectuer de nombreux essais sur les animaux. Nous proposons qu'un ensemble de données sur la persistance (P) et le caractère bioaccumulatif (B), suffisant pour appliquer les critères (PBT) et (vPvB), soit requis pour toutes les substances réglementées par REACH.

Nous proposons aussi que les substances pour lesquelles on ne dispose pas des informations scientifiques de base soient classées comme insuffisamment étudiées, et signalées par un label avertissant les consommateurs, un point d'interrogation par exemple. Cela inciterait les sociétés à réaliser volontairement des tests supplémentaires sur les substances produites en petites quantités.

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Les questions légales soulevées par REACH

Prof. Eckard Rehbinder

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La proposition REACH constitue un changement de paradigme pour la réglementation des produits chimiques qui, en principe, ne peut qu'être salué du point de vue de la précaution. Elle soulève néanmoins des questions de droits économiques fondamentaux, de proportionnalité et de conformité avec les règles de l'OMC.

L'introduction d'une procédure d'enregistrement associée à de simples obligations d'information pour les substances existantes peut être justifiée par une « suspicion initiale » de danger et de risque fondée sur notre expé-

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rience des produits chimiques. Il existe de bons arguments politiques pour demander que l'ensemble des obligations d'enregistrement dépende uniquement des résultats de l'évaluation des risques obtenus dans la période précédant l'enregistrement. Cependant, les solutions les plus exigeantes retenues par REACH ne semblent pas imposer de charge excessive sur les producteurs et les importateurs.

L'introduction d'une procédure d'autorisation pour les substances extrêmement dangereuses est associée à des conséquences juridiques plus lourdes, mais elle reste justifiée par la nature spéciale des dangers et des risques considérés.

Imposer un devoir fondamental de diligence incluant l'évaluation et la gestion des risques tout au long de la chaîne de distribution se fonde clairement sur une approche de précaution puisque cela augmente l'ensemble des informations pour l'évaluation et la gestion des risques. Néanmoins, en faisant reposer la responsabilité sur les producteurs, REACH tend à diminuer la responsabilité des autorités publiques. Par conséquent, l'efficacité de REACH dépendra beaucoup des incitations des acteurs le long de la chaîne de distribution à exercer leurs responsabilités.

Le renversement de la charge de la preuve associé aux obligations inhérentes à la procédure d'autorisation se justifie par la nature des risques potentiellement causés et par les garde-fous instaurés au sein du système pour traiter les incertitudes restantes, en particulier la norme de contrôle adéquat plutôt qu'absolu des risques et la prise en compte des bénéfices socio-économiques.

Enfin, REACH est compatible avec l'article XX (b), (g) et le préambule du GATT, car les procédures d'enregistrement et d'autorisation sont nécessaires en tant que telles pour protéger la santé et l'environnement et ne constituent pas une mesure de protectionnisme déguisé et parce que les interventions coûteuses, comme les restrictions et refus d'autorisation pour une substance, doivent être fondées sur une évaluation des risques.

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Les interactions entre la chimie verte, la réglementation et l'industrie dans la poursuite du développement durable

A. Michael Warhurst

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Créer une société durable est un défi énorme pour chacun d'entre nous. Nous devons réduire considérablement notre consommation, effectuer des progrès massifs en matière d'efficacité énergétique et endiguer la pollution de l'environnement. En tant qu'utilisateur de ressources naturelles et pollueur potentiel, mais aussi en tant que producteur de solutions alternatives, l'industrie chimique se trouve au cœur de ces problématiques.

Nous examinons comment la réglementation et les autres modes d'action émanant des gouvernements et de l'industrie chimique, dont la recherche (chimie durable), peuvent concourir à ce que l'industrie constitue une partie de la solution à ces questions.

Afin que l'innovation industrielle aille dans la direction souhaitée – produire des solutions durables, il importe d'agir à trois niveaux différents : volonté, opportunité et capacité à innover.

Rendre la volonté d'innover la plus forte possible est un défi complexe. Une nouvelle réglementation de grande ampleur comme REACH, en infléchissant les activités industrielles, peut contribuer à le relever. De même, en matière d'opportunité, une réglementation comme REACH peut aider à générer des innovations positives de différentes façons, par exemple en décourageant ou en éliminant progressivement les technologies les moins durables, créant ainsi un marché pour des substituts moins dangereux. Certaines règles peuvent aussi rendre plus aisée la création de nouvelles technologies, en réduisant les exigences réglementaires pour de nouvelles substances comme le fait REACH.

Si toute réglementation appelle des changements, ceux-ci ne peuvent se produire que si des alternatives peuvent être trouvées. La chimie durable a un rôle important à jouer à cet égard à travers la découverte, encouragée

par REACH, de nouveaux procédés et de produits plus sûrs et plus respectueux de l'environnement.

Enfin la capacité à innover constitue un réel défi pour beaucoup d'entreprises, surtout les plus petites. S'assurer de l'existence d'une force de travail qualifiée et encourager les sociétés à former leurs employés contribueront à augmenter cette capacité. Beaucoup d'entreprises auront cependant des difficultés à disposer de l'expertise nécessaire, en interne comme en externe. Dans ce cas, une aide technique devra être envisagée, par exemple sur le modèle de ce que propose le Toxics Use Reduction Institute (TURI, Massachusetts) aux Etats-Unis.

► LIRE CONTRIBUTION PAGE 56

Pour une chimie durable

François Guinot

Président de l'Académie des technologies et de la Société de chimie industrielle, Paris, France

Le modèle de développement suivi jusqu'à présent, s'il a magnifiquement contribué au bien-être et à la longévité d'un cinquième de l'humanité, est remis en cause en raison des risques qu'il fait courir à l'espèce humaine. Ce modèle est en voie d'être rejeté au profit d'un autre modèle plus équilibré, alliant de manière indissociable efficacité économique, solidarité humaine et prudence écologique.

La chimie a été l'un des piliers du modèle rejeté aujourd'hui. C'est la raison pour laquelle il apparaît logique à beaucoup de la rejeter en même temps que celui-ci. Ce serait pourtant une erreur stratégique. La chimie sera en effet indispensable à la réussite du développement durable. Elle a toutes les capacités d'adaptation à ce nouveau modèle. La stratégie de Lisbonne, fondée sur la connaissance et l'innovation, devrait conduire l'Europe, berceau de la chimie, à être l'une des régions les plus dynamiques en termes de croissance et d'emploi. Celle-ci doit toutefois prendre conscience que l'émergence d'une chimie nouvelle au service de ce modèle de développement est l'une des clés majeures de son avenir.

► LIRE CONTRIBUTION PAGE 61

La chimie verte au service du développement durable

Prof. Armand Lattes

Président de la Société française de chimie, Paris, France

La chimie doit aujourd'hui répondre à des attentes très diverses, voire contradictoires, de la société : continuer à fournir de nouveaux produits toujours plus performants, contribuer à la croissance économique et à l'emploi et préserver l'environnement.

Ceci implique des réorientations dans l'industrie chimique : des méthodes, procédés et produits plus sûrs, plus efficaces et plus respectueux de l'environnement et de la santé humaine doivent être recherchés. L'Europe en général, et la France en particulier, ne portent pas encore une attention suffisante à cet enjeu si on compare leurs efforts à ceux consentis par les Etats-Unis en termes d'investissements et de formation. On perçoit néanmoins en Europe une amorce de mobilisation en faveur des biotechnologies.

► LIRE CONTRIBUTION PAGE 65

European Proposal for Chemicals Regulation: REACH and Beyond

Claire Weill
Iddri, France

FOREWORD

Following a request from the Council of the European Union at its meeting on 24-25 June 1999, the Commission produced a White Paper on the *Strategy for a Future Chemicals Policy*, which was published 25 February 2001.¹ The Council and Parliament reacted positively to this text and proposed amendments aimed mainly at simplifying it and reinforcing its protection of environment and health. The Commission then met with the stakeholders and established expert groups to propose a draft regulation. The proposal was made public on 7 May 2003, posted on the Commission's Internet site that day, and criticized strongly by heads of state and governments in the United States, Asia, and Europe.² In addition to the numerous e-mail responses,³ the media provided wide coverage of the reactions and comments of various special interest groups. The Commission then published a substantially modified text on 29 October 2003—the regulatory proposal widely known as REACH.⁴ This has once again inspired numerous reactions, especially in the debate about the studies commissioned by various stakeholders (the Commission, Member States, and interest groups) to assess the impact of REACH on health, environment and industry.⁵ The REACH proposal will be submitted to the European Parliament for a first reading in the autumn of 2005.⁶

In the text that follows, we detail first the extent to which the REACH proposal is based upon the precautionary principle (I). We then comment on the proposal, discuss some of its specific aspects (II) and consider several suggestions to complete the current text (III). We next return to the situation of the various

stakeholders who have now and will have key roles in either industrial or research chemistry once a resolute commitment to the objectives of sustainable development is made (IV). Finally we report the choices made for this workshop (V) and briefly present the contributions included in this document (VI).

I. Foundations of the Proposed European Regulation of Chemical Products: The Point of the Precautionary Principle

Under the regulatory system currently used by the European Union (EU) for chemical products, we lack substantial information about the hazards and risks that characterise the huge number of chemical products inventoried by the EU today—more than 100 000 (Haigh).

Failure to ensure serious evaluation before marketing led to the discovery of manifest dangers in widely-used products, including asbestos and DDT. They are now banned in many industrialised countries, in particular in the United States and Europe.⁷ The nature of risks for other agents remains only partially identified, and their characteristics are inadequately defined. Endocrine disrupters furnish one example: tests for use in risk assessment have yet to be satisfactorily defined. Our knowledge about the risks associated with chemical products comes from several types of data. A first group involves the diffusion of chemical substances through the environment,

their interaction with ecosystems and concentration in air, soil, plants, and animals, as well as changes in these characteristics over time. A second type of data derives from the monitoring of diseases in humans and other animals.

We know today that the incidence of a wide variety of disorders is rising, especially for vulnerable populations (children and the elderly): chronic diseases, such as asthma and some allergies, fatal diseases, such as cancer, and dysfunctions of the reproductive and hormonal systems. We also know that diffuse pollution by chemical substances continues to rise and is sometimes irreversible for persistent pollutants accumulating in biological systems.

The relations between the developments observed in environmental pollution and those in human health are hotly debated and consensus is far away. Several factors make it hard for these debates to move forward.

First, intense controversy surrounds the conclusions of studies conducted by governments and organisations about changes in population health characteristics, including the incidence of different diseases and their causes. For example, serious methodological difficulties impede the study of trends in different cancers over the past 50 years.⁸ It is complicated and difficult to compare data sets obtained in different settings:

- the number of early diagnoses has snowballed, and their quality improved, thereby enlarging the field of investigation of identifiable diseases
- behavior and habits have changed substantially and differentially by age groups
- the environment of individuals, at home (domestic sphere, urban, suburban, rural) and in the workplace, has also undergone important modifications.

From opposite ends of the spectrum of opinions and sensitivity, two points of view—even two philosophies—face one another. At one end, some argue that pollution, once much more intense and harmful for humans, has diminished considerably, at the same time as human health has improved substantially. This is certainly the case for the industrialised countries. Consequently, it is argued that the inhabitants of these countries, where the levels of air and water pollution are much lower than in the past, have no cause for alarm. This observation is inapplicable, of course, for developing countries or even, for different reasons, for the emerging or ‘transition’ countries. Those at the other end of the spectrum point out that while obvious pollution—that is, present at high levels and easily discernible—is

strongly differentiated by country, diffuse pollution is growing. Correlatively, the rising incidence of some chronic diseases and the strong presumption that incidence of some cancers has also climbed are heard as an alarm and have sparked intense worry. These chronic diseases may be largely attributable to environmental factors and the cancers promoted by them; diffuse pollution by chemicals is among the most important of these factors.

Finally, in many cases we observe a notably slow rate of growth in our knowledge about the causal relations between developing diseases and the environmental factors likely to influence or cause them, directly or indirectly, especially when we seek scientific certainty. The numerous methodological problems are unsurprisingly similar to the reasons that the debates of experts are so inconclusive. Issues include the difficulty of extrapolating the results of toxicological tests on animals to humans and of demonstrating the initiating or promoting effects of any given substance for a specific disease. Another major question concerns collaborative and therefore synergistic effects harmful to health and environment of substances that, alone at low concentrations, are of no concern (Müller-Herold (a)). The concept of a threshold appears inoperative in those cases. Another source of uncertainty is the vast amount we do not know about these substances’ toxicological and ecotoxicological characteristics as well as about conditions of exposure to them.

The current situation—diffuse pollution by chemical substances and acknowledged scientific uncertainty about their effects on health and environment—is precisely what the precautionary principle is intended for. It is inscribed in the European Union Maastricht Treaty and has since been reaffirmed in the Treaties of Amsterdam and Nice as well as the newest treaty currently pending approval by the Member States. The REACH proposal clearly appears to apply it (Heyvaert, Reh binder). There are serious reasons to worry about the potential or recognised harmful effects of pollution on human health and the environment, effects that may be irreversible when possibly dangerous products accumulate in biological materials and widespread if these substances can also cover long distances.

None of this detracts from the severity of diseases that are still very poorly managed and that ravage populations in developing countries across the planet. Responses that measure up to the drama of these human situations are imperative. We note nonetheless that the

solutions to major health and environmental problems lie in mechanisms of international cooperation that are being constructed laboriously and with great difficulty. The problem of fighting malaria with DDT is emblematic. The Stockholm Convention, which commits the parties using DDT on their territory to stringent restrictions of its usage,⁹ also encourages them to use other methods to fight malaria. It is evident that if serious efforts were made to find, produce and distribute drugs against this disease, the situation would be very different. But efforts in this direction remain inadequate, especially measured by the magnitude of the problem.¹⁰

II. The REACH Proposal

What is undeniably new in REACH is the requirement that companies provide data about the hazards and risks of the substances they produce, import or use. This choice nonetheless falls clearly within the application of the precautionary principle, as does the procedure for authorisation of substances of very high concern (Rehbinder). Some consider it praiseworthy that this initiative reverses the burden of proof, as the European Commission's communication about the precautionary principle recommended.¹¹ The liability as well as the burden here lie on the producer. Make no mistake: when the precautionary principle is invoked in situations of scientific uncertainty about the nature or characteristics of a risk, the safety of the product is as difficult to establish as the countervailing risk. Inversion of the burden of proof is therefore, above all, an inducement: substances that may be or are certainly dangerous should be withdrawn from the market by their producer or subject to usage restrictions by the regulator.

The complexity of the text presented by the Commission and still under discussion at the European Parliament matches that of the problem it deals with. The goal is to create a regulatory system that will by 2012 collect information about all the environmental and health hazards and risks of existing and new chemical substances in Europe, by standardised procedures.

Several prerequisites appear from the onset. The chemical substances—there are more than 100 000 in Europe and 30 000 are concerned by REACH—are extremely diverse: mineral and organic products, metals, small molecules, polymers, etc. Estimating the hazards and risks of these substances at the same

time is not an easy task. Although some of their intrinsic properties, such as a given solvent's solubility, can be measured directly in the laboratory, only estimates are possible for other properties. Estimating toxicity for humans, for example, requires interpretation and extrapolation of animal tests; it is simultaneously a complex and sensitive procedure. The risks of substances are related to the characteristics of exposure, therefore to the volumes produced, types of use, number of users, all along the chain from producer to end-user. Most often, these substances travel through a complex network that links producers, users, and consumers. The REACH system, by the way, focuses on substances considered in isolation, whether or not they are part of a preparation or product; accordingly it ignores possible synergistic effects (Müller Herold (a)).

The initial proposal is therefore ambitious. The choice of criteria to ensure that the job can be done efficiently and commensurately is sensitive. For example, while it is tempting to rank the products of greatest concern, which should be dealt with most urgently, according to the risks they present, the available data often do not allow us to estimate these risks. Consequently, taking into account simultaneously the hazards of these substances and the volumes produced appears to be a more realistic choice. Nor is it simple to ensure that all of the stakeholders, from the producer through the user, exercise their responsibilities (Rehbinder). REACH chose to place the final responsibility as well as the duty of substitution on the initial producer. It is not evident, however, that the producer is always in a better position than some of his customers to do this.

The current draft of REACH reflects specific choices that were made. This workshop will try to understand more precisely to what extent the text responds consistently to the initial project and its goals.

III. Moving Forward

Where is the REACH proposal at this stage of the negotiations? Various interest groups—companies that produce or use chemical substances, unions, environmental and consumer protection groups—remain divided today about the desirable level of regulatory constraint to apply towards the goal sought, but their opinions do not seem to call into question the logic and internal consistency of the REACH proposal.

We could certainly have wished for a simpler text, easier for more people to understand, as well as a faster schedule for dealing with the products of very high concern. We could also have hoped for the development or reinforcement of environmental monitoring systems (Macrory), together with more effective exploitation of the physicochemical properties accessible in the laboratory (Hansson, Müller-Herold (b)). All of these would have corresponded more completely to the precautionary policy as it should be applied before products are put on the market. This proposal nonetheless seems to us a very significant step forward. It is therefore our task to help make it a regulation with the most effective, equitable and easiest possible application.

Several kinds of uncertainties remain about and within the proposal.

These involve in particular questions about frontiers. Europe seeks here to function as a role model or example for other large countries that produce chemical substances. The steps taken in several OECD countries (Musset) reflect concerns about the lack of data very similar to those that inspired REACH and they pursue very similar goals. The United Nations Environment Program international strategy for chemical products and the efforts at harmonisation it involves thus become meaningful. These efforts may find technical assistance in the harmonised methods of evaluation, classification and labelling developed by OECD. The European Commission is committed to participating in this harmonisation effort through REACH.

Some more complex questions may not find satisfactory responses immediately. It is thus important that the text allow them, or even plan for them, to be dealt with later or that it include from the beginning some adjustable provisions (Hansson).

Finally other questions will be answered during the current negotiations. These will include important details about the tasks of the European Chemicals Agency that the text establishes and the respective roles of the Member States and the community organs in assessing and managing these risks. Other important points are the pooling of hazard data by companies, while maintaining the confidentiality of trade secrets,¹² and support for small businesses to help them meet their obligations.

The model of community agencies and their network operations (such as the recently operational European Food Safety

Authority) may serve as an example for the relations that the European Chemicals Agency establishes with similar national authorities (or those with adequate expertise). An essential issue is the expert resources necessary, within the competent national and European authorities and in industry. While consideration of the tasks to be committed to the Agency should be separated insofar as possible from that of its resources in experts, it is desirable for the member states to cooperate in sharing their national expertise and resources. Identifying within the member states the domains of highest—and inversely most underdeveloped—skills will make it possible to invest effectively to develop capacity for expertise in risk assessment as early as possible. The establishment of the Agency will very certainly be an essential element in this rationalisation of competence within the 25 member states.

The REACH proposal also presents the question of possible modes of access to privately-collected data. The point of pooling data from companies is to save money, reduce the amount of animal testing, and especially maximise the use of the data that exist. Accordingly, it would be extremely useful to consider how to make public a greater portion of the toxicological data that pharmaceutical companies collect in meeting their regulatory obligations. This would greatly reinforce our toxicological knowledge.

IV. Stakeholders

We focus most specifically on European chemical industries. We then deal with an important motor for the economic development of this industry—research and innovation.

Economic Actors

The REACH proposal was made and is being examined in a background of accelerating international trade and substantial industrial restructuring under the pressure of several factors—search for economies of scale, refocusing by industrial groups on their core business, and a reduction in the cost of labor. These factors, which all work to increase the values of company stock, result in outsourcing, that is, the moving of industrial sites towards Eastern Europe and emerging countries, especially in Asia (Gréau). Regulatory constraints set up to protect health

and environment appear in this context to be one element that determines companies' strategic choices. This is true in all industries and especially in chemistry.

In this constantly changing environment of major social and economic challenges to western nations, another increasingly pressing challenge is emerging: the need to use natural resources better, more efficiently, more effectively, and more economically, by moving towards modes of development that are more environmentally friendly and therefore better for human health.

The large European chemistry companies, while they maintain strong roots in Europe, are international today. In today's economic situation, they are growing strongly elsewhere, especially in Asia, where they are developing not only production sites but also research and development units. One effect of industrial changes has been to reverse the earlier trend towards diversification, with firms combining activities in the domains of food-processing, pharmacy, and chemistry. The three activities, which do not necessarily have the same profit levels, are being separated again, which affects their industrial environment significantly. Although a small production unit for several chemicals can be created by a newcomer to the market at a relatively low cost, the cost increases as we move from simple chemicals past food-processing into pharmaceuticals. Moreover the consequent fragmentation of skills and know-how will have long-term consequences on innovation.

Within this constantly changing industrial landscape subject to intermediate-term trends—diversification *versus* concentration and refocusing—environmental regulations such as REACH necessarily affect companies differently, depending on their size and resources. In France, in particular, chemical producers and users of all sizes coexist, forming a continuum between what are conventionally called small and large companies. This observation militates in favor of equal requirements for all under REACH, but with differentiated support, for companies according to their resources to ensure that the overall system operates effectively. As such, making technical resources available to companies to facilitate not only the regulation's application but also innovations would be highly desirable (Warhurst).

The Role of Research

Research, innovation and technological development together constitute one of the

principal motors of our society, one that drives education, training, and adaptation to the challenges that must be mastered. One of these is sustainable development. Translating these challenges—food supply, energy efficiency, essential services for all, environmental protection, and better public health—into research calls simultaneously for basic and applied research.

For the past five years all the governments of the European Union have systematically affirmed the urgency of reaching their research budget goals: 3% of their GNP on research (public and private) by 2010. Sadly, meeting these commitments is proving difficult. Too often, the first budget cuts touch these areas essential for our future. They evidence a lack of willingness and a recurrent weakness: the state does not keep its commitments to sustained research, despite the strategic importance of long-term strategies for large-scale programs and of adaptability to advancing knowledge and changing situations. The ability to make consistent choices and stand by them over time requires a recognition that all the components of research contribute vitally to a nation's vigor.

From a historical perspective it appears clear that since World War II, nations have associated their research and industrialisation efforts; this was also true between the wars, but the State's role was less important then (Dahan). Today, we witness an increasingly pronounced diminution of the industrial sector in Western Europe and a simultaneous reduction in funding for research. The restructuring underway is not preserving the first-class private laboratories—for example Bell Labs or Dupont in the United States—that flourished when some companies financed top-rate basic research and benefited from the synergy between engineers and researchers.

Chemistry fits this description. Nonetheless, awareness of the stakes of sustainable development is evolving progressively. It is growing among researchers and is expressed in research programs directed towards building a more environmentally-friendly, safer and more effective chemistry, called green chemistry (Lattes). Nonetheless, even if these efforts produce a load of discoveries and promising innovations, these will still need to be developed and produced industrially at acceptable costs. The laboratory shelves are already filled with riches, however. Efforts must also concentrate on instruments to enable the development and industrial use of existing processes and products. This is true

for chemistry and many other sectors. Think of all of the fields involved in finding ways to reduce greenhouse gas emissions.

V. Choices for this Workshop

We have chosen not to deal with the relations between chemical pollution and human health. The technical complexity of these questions (*cf.* I) prevents a serious approach to them in the framework of this workshop. They are at the heart of the research now being conducted in France as part of the Environmental Health Plan¹³ and debate here is increasingly focusing on this issue.¹⁴ Nor will we deal in detail with the question of the impact of REACH on public authorities or industry. After a first wave of studies (*cf.* note 5), a second series of sector impact studies took place;¹⁵ their results were published recently and analysed during a workshop of the Member States on 10-11 May in Luxembourg. They are already much less negative for industry than some earlier studies. Here again, the methodological difficulties seem too numerous for us to make progress on this question at our workshop. The participants have debated and can continue to debate these questions in other settings.

Accordingly, we preferred to have high-level European experts provide illumination about other aspects of the REACH proposal. These raise simultaneously questions of principle, substance and implementation. They may deal with the intermediate term—the REACH process through 2012—or the longer term—its integration in international initiatives or its effects on innovation.

While not excluding critical analysis of the proposal (Macrory), we stress the importance today of placing the debate from the outset as close as possible to reality and to proposals for improvement, to keeping it concrete. We are wagering that the negotiations underway will not substantially call into question either the logic of the system or the level of requirements of the various stakeholders.

At the same time, we will look farther ahead; we would like everyone involved to consider together the different scenarios that might help optimise the consideration of the challenges we face today. When we look past the closest horizon, we are more likely to find what we are looking for: ways to improve complementarity and cooperation between economic stakeholders, public authorities and citizens, as well as within the industrial world.

To reach that point, it is first necessary to find the best reasoned economic logic (or even the most reasonable!) that will allow States to commit the resources necessary to invest in the future, most especially in education and research (Guinot, Lattes).

VI. Articles in this Document

This collection brings together the texts of nine authors.

Nigel Haigh reviews the history and weaknesses of the legislative provisions that have progressively governed the use of chemicals in Europe.

Laurence Musset presents the work conducted by OECD on chemicals and the associations between this work and the REACH proposal. She also discusses relevant initiatives by other OECD countries.

Richard Macrory reports on important aspects of the 2003 report by the Royal Commission on Environmental Pollution (a standing committee of independent experts), entitled *Chemicals in Products: Safeguarding the Environment and Human Health*.

Ulrich Müller-Herold sheds light on the difficult question of the synergistic effects of chemicals with a simple model and examples from the recent scientific literature.

Sven Ove Hansson and Christina Rudén show that the information required by REACH is insufficient to characterise substances produced at low volumes. They propose a method for correcting the regulation's weakness for the very low volumes.

Eckard Rehbinder argues that the REACH proposal is an application of the precautionary principle and analyses the liability scheme introduced, the question of the burden of proof and its compatibility with the World Trade Organisation rules.

For Michael Warhurst, regulations, including REACH, are a key component in ensuring that the chemical industry contributes to sustainable development. It must nonetheless be completed by investments in sustainable chemistry and systems to provide technical assistance to companies.

François Guinot shows that the challenges facing European chemistry today, including the pursuit of sustainable development, can be met if both Member States and the European chemical industry place research and innovation firmly at the centre of their strategies to foster the emergence of a new chemistry.

Armand Lattes presents and comments the efforts made toward green chemistry and especially biotechnology by the large industrialised countries (France and the rest of Europe, in particular).

Finally, while the final bibliography proposed for readers at the end of this document is relatively modest, we strongly suggest they consult the references, often very rich, included in those works.

- 1) COM(2001)88 final.
- 2) In a letter dated 20 September 2003 to Romano Prodi, the President of the Commission, Prime Minister Tony Blair, President Jacques Chirac and Chancellor Gerhard Schröder expressed their concerns, especially in relation to competitiveness and jobs, but also about the bureaucratic character of the proposal, considered very difficult to implement.
- 3) More than 6000, cf. <http://europe.eu.int/comm/environment/chemicals/whitepaper.htm>
- 4) Proposal for a Regulation of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency and amending Directive 1999/45/EC and Regulation (EC) on Persistent Organic Pollutants, COM(2003) 644.
- 5) The Netherlands, during its presidency of the European Union, organised a workshop at the Hague to debate the principal impact studies, based on a summary document, which is available on the Internet: http://www.eu2004-reach.nl/downloads/Comprehensive_Overview-v2.pdf
- 6) A history of how the REACH proposal came into being and was prepared as well as reactions at various stages can be found at <http://www.panda.org/downloads/toxics/theonlyplanetguide.pdf>.
- 7) DDT use is tightly restricted as part of the Stockholm Convention, which came into effect in 2004 and has been ratified by more than 70 countries.
- 8) *Cancer, approche méthodologique du lien avec l'environnement. Une expertise collective de l'Inserm*, Inserm 2005, 101pp. <http://ist.inserm.fr/basisrapports/cancer2005.html>
- 9) This is the case in particular for Côte d'Ivoire, Ethiopia, Papua New Guinea and South Africa.
- 10) Report of Médecins Sans Frontières, 13 October 2001.
- 11) COM(2000)1.
- 12) See the proposal by the United Kingdom and Hungary entitled *One Substance, One Report* (the OSOR proposal).
- 13) Seminar of scientific perspectives and launching of the research program of the National Environmental Health Plan and the Workplace Health Plan,

Ministry of Research, 31 March and 1 April 2005.

14) Second parliamentary encounter *Environmental health*, National Assembly, 9 December 2004.

15) There were two studies. In particular, one commissioned by CEFIC and UNICE from KPMG, and the other commissioned by the European Commission from its Joint Research Centre and from the Institute for Prospective Technological Studies (IPTS), both made public on 27 April 2004.

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- (b) Müller-Herold U., Morsini M, Schucht O., and Scheringer M., *Precautionary Pre-Selection of New Organic Chemicals – A Case Study on the Application of the Precautionary Principle in the European Union*, in O.Renn et al.: *The Application of the Precautionary Principle in the European Union*, Part E and Part G; <http://www.sussex.ac.uk/spru/environment/precaupripdfs.html>.
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A Brief History of EU Regulation of Chemicals

Nigel Haigh

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EU chemicals legislation dominates national policies. It began in the 1970s and has evolved in four overlapping phases with REACH constituting the last phase. In the 1970s a framework was created for *ad hoc* restrictions on the marketing and use of any chemical found to be dangerous. This will continue under REACH. Beginning in the 1980s—the second phase—no new chemical could be placed on the market before it had been tested and the results notified. As a result useful information has been provided for safe use and some chemicals were not marketed which otherwise would have been. In the 1990s—the third phase—a programme was introduced for existing chemicals. Priority lists of existing chemicals needing evaluation were drawn up with the work of risk assessment being shared among the Member States. Although this is resulting in published risk reduction strategies, these are being produced so slowly that pressure has grown for a major reform of the existing regimes. This is the fourth phase, called REACH.

► READ PAPER PAGE 29

The OECD Chemicals Programme and some Features of the Proposal for a New EU Chemicals Policy

Laurence Musset

Organisation for Economic and Cooperation and Development (OCDE), Paris, France

The objective of the OECD Chemicals Programme is to assist member countries as effectively as possible in protecting human health and the environment from chemical risks. This is done through the harmonisation of high quality tools and policies for chemicals management, whereby duplication of work for member countries and industry can be avoided, and through work sharing. The evolution of the Programme reflects the progress in OECD countries, from risk management for a

few specific chemicals of high concern, followed by the development of instruments for the control of new chemicals and finally cooperative work on existing chemicals. For global efficiency, the OECD now works with selected non-member countries in order to promote convergence of chemical safety policies.

The OECD Test Guidelines and Good Laboratory Practices are the two keystones of the Mutual Acceptance of Data. The Programme provides guidance documents on risk (assessment and management). To reduce costs and animal use, it also works to facilitate regulatory acceptance of alternative test methods and computer-based data estimation methodologies. In many ways, including its work on harmonisation of classification and labelling criteria, the Programme contributes to the implementation of UN recommendations related to chemicals management.

Several elements of the proposal for REACH are new compared to the current EU legislation, but are already part of the chemicals policy of some EU and/or other OECD countries. This is the case in particular for the systematic examination of existing chemicals and for the high concern for persistence and bioaccumulation properties. On the other hand, industry responsibility for assessing chemical safety and the authorisation procedure for chemicals with very hazardous properties are new features. In many ways, the OECD Chemicals Programme will provide input to the new EU chemicals policy, and vice versa.

► READ PAPER PAGE 33

Chemicals in Products: Safeguarding the Environment and Human Health

Prof. Richard Macrory

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The Royal Commission on Environmental Pollution made 54 recommendations for action and change to chemicals regulation in its report to the UK Government, *Chemicals in Products: Safeguarding the Environment and Human Health*, which was published in 2003. The Royal Commission believe that REACH will take too long to clear the backlog of

ABSTRACTS

untested chemicals and proposes a system that would 'quick check' all 30 000 chemicals within three years, as opposed to subjecting each one of them to a much slower, more expensive and exhaustive analysis. The first step would be to compile a list of chemicals on the market, and the second step to assess them according to hazard with computer-based molecular modelling techniques and computerised methods for searching the scientific literature and databases. Restrictions would then be placed on their use according to the level of risk. The Royal Commission anticipates that most of the chemicals would emerge from this screening as being of no particular concern. However, some of the chemicals in the 'high concern' category might have to be immediately banned from production or importation. Several hundred, and perhaps more than a thousand, would probably be categorised as being of high, medium or low concern and then be subjected to more thorough risk assessment. The Royal Commission believe all of the chemicals of concern identified by the screening could have their risks fully evaluated by 2009. Although the Royal Commission do not believe that such a system would identify every chemical with adverse properties, it would be more effective than the REACH approach. The report also recommends that the government should also make more use of environmental monitoring in identifying chemicals of concern that require further action. The Royal Commission want to see a UK government strategy to achieve a steady, measurable reduction in the use of hazardous chemicals and substitution with safer alternatives. The report argues that giving the public far more information about chemicals on the market would drive producers and users of chemicals towards substituting for risky products others that are inherently safer, and those that are hazardous should be restricted to certain uses and subject to a charge.

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Beyond REACH. A Tutorial Approach to Toxic Effects of Chemical Mixtures at Individual No-Observed-Effect Levels

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It is shown that the 'additivity of effect' rule as provided for by Appendix 1b of REACH systematically underestimates the risks of synergistically acting mixtures of chemicals. This is illustrated with a simple model and examples from the recent scientific literature.

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Improving the Scientific Basis for Decisions in the REACH System

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A science-based risk assessment of potential or actual exposure is only possible when a reasonable amount of knowledge is available about the inherent properties of the substance in question. A major advantage of the REACH proposal is that it will extend our toxicological database for industrial substances and thereby improve the scientific basis of risk assessments. However, our analysis shows that this improvement, although substantial, will still leave large gaps in the data. For substances produced in quantities of less than 10 tonnes, REACH does not require the information necessary for application of any of the major criteria for science-based classifications according to (for example) acute or chronic toxicity or ecotoxicity. For substances produced in quantities of 100 tonnes or less the information required by REACH does not provide any of the information that determines whether or not the REACH authorisation process should be triggered, for example, whether the PBT (persistent, bioaccumulative, and toxic) or the vPvB (very persistent very bioaccumulative) criteria for potential ecotoxicity are applicable.

The tests included in REACH and other regulatory test systems are all carefully constructed according to scientific principles. This does not suffice, however, to make the test system as a whole science-based: the combination of the tests and the rules for how tests follow one another must also be based on scientific principles. We propose research aimed at developing test systems that are science-based on the systemic level.

Special efforts should be made to use physicochemical properties as the first tiers of these test systems. Such data can be obtained at relatively low cost and without extensive animal testing. We propose that a set of persistence and bioaccumulation data, enough to apply the PBT and vPvB criteria, should be requested for all substances regulated by REACH.

We also propose that substances for which basic scientific data is missing should be classified as insufficiently investigated and assigned a warning label, including a warning symbol, such as a question mark. This will provide companies with an incentive to perform voluntary testing of low-volume substances, in addition to the minimum requirements.

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Legal Issues of REACH

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The REACH proposal constitutes a change of paradigm in regulating chemicals that in principle is to be welcomed under the perspective of precaution but which raises questions of fundamental economic rights, proportionality and conformity with WTO rules.

The introduction of a registration procedure for existing substances associated with mere informational obligations can be justified by an 'initial suspicion' of hazard and risk that is based on our experience with chemical substances. While there may be good policy arguments that the full registration obligations should be triggered only by the results of risk screening in the preregistration phase, the more demanding solution of the REACH proposal evidently does not impose excessive burdens on producers or importers. The introduc-

tion of the authorisation procedure for ultra-hazardous substances is associated with more burdensome legal consequences but justified by the special nature of the hazards and risks that are to be addressed.

The imposition of a fundamental duty of care including risk assessment and risk management along the whole supply chain rests on firm precautionary grounds because it extends the information base for risk assessment and management. However, REACH's reliance on producer responsibility tends to blur the responsibility of public authorities. Therefore, much will depend on the incentives the actors along the supply chain have to live up to their responsibility.

The reversal of the burden of proof associated with the authorisation requirement is justified by the nature of the potential risks and the safeguards built into the system for addressing remaining uncertainties, especially the standard of adequate rather than absolute control of risk and the authority to consider socio-economic benefits.

Finally, REACH is justified under article XX (b), (g) and the chapeau of the GATT because the registration and authorisation procedure as such is necessary to protect health and the environment and does not constitute a disguised protectionist measure, and because burdensome interventions such as restrictions of substances and the denial of an authorisation must be based on a risk assessment.

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Achieving Sustainability: The Interplay between Green Chemistry, Regulation and Industry

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Achieving a sustainable society is a huge challenge for all of us. We must reduce consumption of material considerably, make a massive improvement in energy efficiency and reverse environmental pollution. As a major user of resources and energy and potential polluter as well as a producer of alternative solutions to these negative effects, the chemical industry is at the core of many of these issues.

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This paper examines the roles of regulation, green chemistry, government and industry itself in making the chemical industry focus on being part of the solution.

Innovation is the key to discovering new, more sustainable ways of doing things, but this innovation must also be channelled in the right direction by taking into account three drivers (willingness, opportunity, capacity) of innovation within industry.

Maximising the willingness for innovation within industry is a complex challenge, and substantial new regulations like REACH can have a role. As for opportunity, a regulation such as REACH can assist in generating positive innovation in number of ways, for example through discouraging or phasing out less sustainable technologies and thus creating a market demand for safer substitutes. It can also make it easier to create new technologies, as REACH does by reducing the regulatory requirements for new substances.

Although regulation creates a demand for change, this demand can only be fulfilled if alternatives can be found. This is a key role of green chemistry, discovering innovative new ways of doing things and creating the safer products that REACH will encourage.

Finally, capacity is a significant challenge for many companies, especially smaller ones. Ensuring an educated workforce, and encouraging companies to train their workers, will assist in generating more capacity. Many businesses will, however, have problems obtaining the necessary in-house or even hired expertise. In this case a technical assistance, like that proposed by the Toxics Use Reduction Institute (TURI), in Massachusetts, USA, might be considered.

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The Case for Sustainable Chemistry

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The development model followed until now, although it led one fifth of humanity to a prosperity and longevity never before known, is

called into question today because of the risks it has imposed on the human species. It is being rejected for another more balanced model that indissociably unites economic efficiency, human solidarity and ecological prudence.

Because chemistry was an important pillar of the old model, many think it logical to reject chemistry together with the model. This would however be a strategic error. Chemistry is essential to the success of the development model now being built. It is entirely capable of adaptation to this new model. If Europe, the birthplace of chemistry, applies the so-called Lisbon strategy, based on knowledge and innovation, it can become one of the most dynamic societies on the planet in terms of growth and jobs. It is essential for Europe to become aware that the emergence of a new chemistry at the service of this development model is a keystone of its future.

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Green Chemistry for Sustainable Development

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Chemistry today must respond to the diverse, even contradictory, expectations of society: continue to furnish new ever more effective products, contribute to economic growth and employment, and preserve the environment. We look at what the proposed European regulation REACH can contribute to the development of a new and sustainable chemistry. The crucial issue of reorienting chemical industry objectives to search for methods, processes and products that are safer, healthier, more efficient, and more environmentally-friendly is not receiving sufficient attention in Europe generally and in France in particular, especially compared with the United States. It requires efforts in terms of investments and professional training that have not yet been provided. We nonetheless see the beginning of mobilization for the biotechnology sector.

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A Brief History of EU Regulation of Chemicals

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In all EU Member States, chemicals policy is dominated by EU legislation more completely than any other branch of environmental policy. There are two reasons. Unlike air and water pollution or nature protection, which have long established national traditions, EU chemicals legislation developed before any Member State had developed a strong tradition of its own. Chemicals policy is also largely about regulating the sale of individual chemicals, and the EU cannot allow national policies to diverge without fragmenting the common market whose creation and preservation has always been a main task of the EU.

Two other preliminary comments need to be made about chemicals policy. First, until recently the subject was little known outside the chemical industry and the limited circle of toxicologists. Only with the new attention to endocrine-disrupting substances did it catch the public's attention. Secondly, if we consider traditional air and water pollution policy to be about controlling emissions of chemicals in the form of waste, chemicals policy is about controlling their use before they become waste. Chemicals policy therefore embodies the preventative and precautionary principles.

This paper deals only with industrial chemicals and not with pesticides and pharmaceuticals which are subject to separate EU legislation. These are intended to be dangerous, e.g. to kill pests. Industrial chemicals, by contrast, are used because they are useful despite sometimes being dangerous. The paper describes the broad evolution of the policy in a first section and the concepts in use in a second section,

before examining more closely the nature of EU regulation of chemicals over time and its possible evolution if the REACH legislation is adopted.

The Four Phases of EU Chemicals Policy

Chemicals policy can be said to have started seriously in 1973 when the OECD Council issued a Decision requiring its member countries to regulate the use of polychlorinated biphenyls (PCBs). This was in response to a number of incidents including poisoned rice oil in Japan and spectacular bird deaths in the Irish Sea. The EU went beyond the binding character of an OECD Council Decision by proposing a Directive to make the OECD Decision uniformly effective in all Member States. It also went further by creating a framework for restricting the marketing and use of any dangerous substance. This was the first of four overlapping phases into which EU chemicals policy can be divided. The proposed comprehensive reform of EU legislation known as REACH (Registration, Evaluation, and Authorisation of Chemicals) is best understood as evolving out of the three earlier phases:

- 1970s. *Ad hoc* restrictions on the marketing and use of chemicals that were known to be harmful (often following tragic accidents).
- 1980s. A systematic and proactive approach to new chemicals which were not allowed onto the market before they had been tested.

- 1990s. A programme for evaluating existing chemicals. Priority lists totalling 140 chemicals have so far been agreed. Of these only a few have so far been evaluated and fewer restricted.

- 2000s (1st Decade?) A proposed consolidation and extension of the earlier phases intended in particular to increase knowledge of the thousands of existing chemicals more quickly than at present and to provide a system that will ban the use of all chemicals 'of very high concern' unless they are expressly authorised. The proposal is known as REACH.

There was a yet earlier phase in the 1960s when the EU adopted Directive 67/548¹ on the classification, packaging and labelling of chemicals. This was before the EU had an environmental policy, and it merely harmonised the labelling requirements introduced by some Member States to protect workers. However, the regime for testing new chemicals (phase 2) was adopted as an amendment of this Directive.

Terminology

The language in which chemicals policy is discussed makes important distinctions often confusing to the non-expert. I therefore offer the following explanations in the knowledge that toxicologists may find them oversimplified.

The word 'chemical' is often used loosely to cover both 'substances' and 'preparations' which are defined more precisely: 'substances' are chemical elements and their compounds, whereas 'preparations' are mixtures or solutions of two or more substances (e.g. paints, inks, and solvents).

'Hazard' is a property intrinsic to a chemical substance, e.g. its toxicity, flammability, corrosivity, or carcinogenicity. 'Risk' on the other hand relates to the likelihood of harm and so depends on exposure which in turn depends on the uses to which a chemical is put. 'Hazard assessment' accordingly means the identification of the adverse effects which a chemical has the capacity to cause. It is a scientific process which may involve tests on laboratory animals. 'Risk assessment' on the other hand is a more difficult process that starts from hazard assessment but also involves exposure assessment. Since information on use and exposure is often limited (and non-existent for new chemicals), risk assessment is subjective and requires expert professional judgement. This distinction is

important. For example the OECD programme on existing chemicals provides information in the form of hazard assessments, whereas the EU existing substances regulation goes further in requiring the more time-consuming risk assessments to be conducted before restrictions can be imposed.

'Risk management' or 'risk reduction measures (or strategies)' are phrases used to describe any one of a number of practical steps to follow hazard or risk assessment. These can range from a total ban to a mere warning label and can include the provision of detailed advice on 'safety data sheets', restrictions on marketing and use, emission controls, setting environmental quality standards, and instituting surveillance programmes.

A 'downstream user' is an industrial user of a chemical, other than the manufacturer or importer, e.g. a paint maker. A consumer is not a 'downstream user'. There are many thousand times more downstream users than manufacturers. Until now, downstream users have not been responsible for contributing to hazard and risk assessments, but they will be more involved under REACH. This is one reason why it is controversial.

From Restrictions to REACH

Phase 1: Restrictions—1978

Directive 76/769² authorised restrictions on the marketing and use of any dangerous substance or preparation. It cannot ban the production of a substance: a separate EU Regulation was adopted when the Montreal Protocol on the ozone layer required a ban on CFC production.

The Directive initially restricted only three chemicals. PCB use could continue only in closed-system electrical equipment; not until nine years later were most uses of PCBs banned. Over the years the Directive has been amended to impose restrictions on many other substances, including asbestos, lead paints, marine anti-fouling paint, cadmium, fire retardants, carcinogens, creosotes, some cements, and chlorinated solvents. Some of these restrictions have been controversial and involved disputes with countries outside the EU, the best example being asbestos.

A few of the restrictions have followed risk assessments carried out under the regimes for both new and existing chemicals (see Phases 2 and 3 below).

Under REACH the provisions of Directive 76/769 will be continued in a modified form: it will also be possible to ban the manufacture of a chemical. In addition REACH will ban all chemicals 'of very high concern' unless they are authorised.

Phase 2: New Chemicals—1981

In the early 1970s a debate developed about the need for an 'early warning' or, as we would now say, a precautionary system for new chemicals, and this found expression in the EU's first environmental action programme, in 1973. This called for controls over new chemicals before their marketing. In the USA this debate led to the Toxic Substances Control Act of 1976 (which also dealt with existing chemicals) and in the EU to Directive 79/831³ (which amended Directive 67/548 for the sixth time).

Directive 79/831 was highly original and, with various subsequent amendments, laid down many of the principles of EU chemicals policy. Some of these had been developed within the OECD. It made a distinction between 'new' and 'existing' chemicals. All chemicals are 'new' unless they are listed in the European Inventory of Commercial Chemical Substances—EINECS⁴—as having been on the EU market before September 1981. This inventory lists more than 100 000 substances.

Since 1981 a manufacturer of a 'new' chemical substance has had to submit the results of tests sufficient to evaluate possible harmful effects and its assessment of the results to the competent national authority. Larger production volume requires submission of more information. The authority sends the information to the European Commission, which sends it to the authorities in all other Member States. Any of these can make enquiries. If no objections are raised within 60 days the manufacturer has assured access to the whole EU market.

Nearly 3000 chemicals have been notified since the scheme began,⁵ and anecdotal evidence suggests that some chemicals which manufacturers began developing have never been marketed because they were found to be more dangerous than expected. This is the precautionary principle at work although the authorities will not have been told. The testing will also have produced information which can enable the chemicals to be used more safely. For these reasons the scheme is thought to have worked well.

The chemical industry supported the Directive when it was proposed—in contrast with REACH today. They could see that a sin-

gle European system was preferable to different testing regimes that might develop in different Member States. Negotiations on the Directive also coincided with the drafting in the USA of rules to implement the Toxic Substances Control Act of 1976. The European chemical industry was fearful that these rules might discriminate against European exports to the USA and wanted a good EU regime so that the EU could negotiate from strength with the USA if necessary. They could see that the size of the EU market meant that the European Commission could negotiate more effectively with US manufacturers than Germany, France, or the UK negotiating separately. The Directive is thus an example of synergy between environmental and trade requirements.

Phase 3: Existing Chemicals—1993

The regime for evaluating existing chemicals developed slowly, not surprisingly given the difficulty of the subject, industrial resistance, and the reservations of some Member States. The need for more information on the thousands of existing chemicals had been recognised in the 2nd, 3rd, and 4th Environmental Action Programmes (of 1977, 1983, and 1987) but it was not till 1990 that the Commission felt able to make a proposal. This was adopted in 1993 as Regulation 793/93 and is known as the Existing Substances Regulation—ESR.⁶ It is because of disappointing progress with ESR that the pressure has grown for REACH.

Briefly ESR requires manufacturers to send only existing data to the Commission. The Commission then draws up priority lists of chemicals needing attention, and work on risk assessment is shared between the Member States. The authorities can then propose risk reduction strategies. More fully these steps are:

- **Data reporting:** Manufacturers submit data—but only what already exists—relevant for an evaluation of risk to the European Chemicals Bureau (ECB). The ECB—established within the EU's Joint Research Centre at Ispra, Italy—manages the International Uniform Chemical Information Database—IUCLID. More information has to be submitted for 'high volume' production chemicals (more than 1000 tonnes per year).

- **Priority setting:** Using the submitted data and taking specific criteria into account, the Commission draws up lists of priority chemicals. By 2000 four lists totalling 140 chemicals had been adopted.

■ **Risk assessment:** Each priority chemical is allocated to a Member State which designates a 'rapporteur' to evaluate the chemical. If a 'base set' of data is not available, the manufacturer must carry out the necessary testing and submit this to the rapporteur within 12 months. The rapporteur evaluates the information and decides whether the manufacturer is to be required to supply further information or carry out further testing. When there are valid reasons for believing that a chemical presents serious risks, a Committee can decide whether supplying this further information is to be obligatory and set time limits for it. The rapporteur then carries out the risk assessment and sends his conclusions to the Commission.

■ **Risk reduction:** The rapporteur's conclusions can suggest a strategy for limiting risk. Any proposed restriction on marketing and use must be accompanied by an analysis of the advantages and drawbacks of the chemical and the availability of replacement chemicals. The recommended strategy can be adopted by the Committee and published. Any recommended restrictions can be proposed by the Commission under Directive 76/769 (see above Phase 1).

The functioning of this system has provoked criticisms which explain the current proposal for reform. By early 2005 only 17 risk reduction strategies had been published and only a few chemicals had been restricted. No one publicly foresaw such slow progress. Industry criticises governments for not providing adequate resources for carrying out risk assessments. Others say that industry is slow to provide information and can use many delaying tactics to gain an extended marketing period. Without reasons for believing that a chemical poses a serious risk, the authorities cannot demand information, and without the necessary information, it is difficult to provide the reasons. For new chemi-

cals, it is in the manufacturer's interest to supply information, since without it marketing is not allowed. For existing chemicals, on the other hand, providing information is not in the manufacturer's interest.

Phase 4: REACH-2009?

REACH is intended to overcome the limitations of the ESR by placing much more responsibility on manufacturers and downstream users to provide useful information about the thousands of chemicals on the market. It also abolishes the distinction between 'new' and 'existing' chemicals, introduces an authorisation system for chemicals of 'of very high concern', e.g. those that are very persistent, and replaces the European Chemicals Bureau with a much larger European Chemicals Agency. It is the longest and most complicated item of environmental legislation to have been proposed so far by the European Commission. It is also the most controversial. In particular, it raises the question of whether sufficient useful information can be provided without excessive burdens being placed on the European chemical industry and without an excessive increase in animal testing.

- 1) Directive 67/548 (OJ L196 16.18.67) (classification, packaging and labelling). The list of substances classified under 15 danger categories is available on the ECB website: ecb.jrc.it
- 2) Directive 76/769 (OJ L262 27.9.76) (restrictions on marketing and use).
- 3) Directive 79/831 (OJ L259 15.10.79) amending for the sixth time Directive 67/548 and now replaced by the seventh amending Directive 92/32 (OJ L154 5.6.92) (new chemicals).
- 4) EINECS is published in OJ C146 15.6.90 and is also available on the ECB website: ecb.jrc.it
- 5) The European List of Notified Chemical Substances (ELINCS) is available on the ECB website: ecb.jrc.it
- 6) Regulation 793/93 (OJ L84 5.4.93) (existing substances-ESR).

The OECD Chemicals Programme and some Features of the Proposal for a New EU Chemicals Policy

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The OECD (Organisation for Economic Cooperation and Development) brings together the largest chemical-producing countries, which are also those that have a major responsibility for global chemical safety. Top policy and technical experts from governments, but also all other stakeholders (industry, trade unions, environmental groups, and animal welfare groups) participate in the work of the Chemicals Programme, which began in 1971. Member countries make the programme decisions by consensus. Council Recommendations and Decisions are legal instruments of the OECD, and the latter are also internationally binding agreements.

Every three years, the 30 OECD member countries decide what the Work Programme on Chemicals will be and thus ensure that it develops to remain consistent with their priorities and needs. More than 10 Council Acts reflect the general trends in chemicals management.

The programme initially focused on specific chemicals known to cause environmental problems, such as PCBs (polychlorinated biphenyls) and mercury. The 1973 OECD Council Decision to restrict the use of PCBs was the first concerted international action to control the risks of a specific chemical.

By the mid-1970s, however, in view of the multinational structure of many chemical companies and the chemicals trade, OECD countries agreed that a more comprehensive strategy was needed. Its two principal objectives were to promote harmonisation of high-

quality chemical-control methodologies, thereby avoiding the duplication of work for member countries and industry as well as the creation of non-tariff barriers to trade, and to address possible transboundary issues associated with chemical production and use. The programme began to develop harmonised instruments that countries could use to assess the hazards and risks of chemicals. These included the Test Guidelines and Good Laboratory Practices, which are core elements of the Council Decisions on Mutual Acceptance of Data (MAD). These instruments were first developed for new chemicals. The point of MAD is that a test carried out using OECD Test Guidelines and following OECD Good Laboratory Practice principles will be accepted by all OECD countries for purposes of assessment. Avoiding duplicative testing through MAD produces yearly savings to governments and industry estimated at US\$ 50-60 million.

In the 1980s, the programme began a systematic investigation of existing high production volume (HPV) chemicals. This was a new approach: the objective was no longer to agree on assessment tools to be used by countries but rather to use comparable methodologies to share the work of producing OECD-approved assessments of HPV chemicals.

An important role of the Chemicals Programme today is to work with selected non-member countries to promote convergence of the chemical safety policies being developed in these countries with those of OECD

countries. According to the 2001 OECD report, *Environmental Outlook for the Chemicals Industry*, which includes projected trends in the chemicals industry through 2020, international trade is expected to increase significantly, and more of the production will shift to non-OECD countries. By 2020 it is expected that these countries will account for 31% of production (compared with 22% currently).

Close co-ordination with the other inter-governmental organisations working in the field of chemicals (FAO, ILO, UNDP, UNEP, UNIDO, UNITAR, WHO¹ and the World Bank) is ensured through the Inter-Organisation Programme for the Sound Management of Chemicals (IOMC), which was established in 1995. OECD work on existing chemicals and its role in the harmonisation of classification and labelling of chemicals are examples of its contribution to the IOMC effort to carry out the recommendations of the 1992 Conference on Environment and Development in Rio (Chapter 19 of Agenda 21) and the Johannesburg Plan of Implementation of the 2002 World Summit on Sustainable Development (Paragraph 23). The IOMC provides useful input to the work of the Intergovernmental Forum on Chemicals Safety (IFCS) and to the development of the UN Strategic Approach to International Chemicals Management (SAICM).

After summarising the content of the OECD Chemicals Programme, we will examine some aspects of the European proposal for chemicals regulation, known as the REACH proposal, and finally discuss the potential relations between the two sets of instruments.

Content of the Chemicals Programme

The Chemicals Programme is part of the wider Environment, Health and Safety (EHS) programme of the OECD, which also includes specific activities related to pesticides, biotechnology, novel food, pollutant release and transfer registers, and chemical accidents (not presented in this paper).

■ **Test Guidelines:** The development and revision of Test Guidelines is the core of the OECD work on chemical hazards, and the level of activity in this area has increased over the past few years, as evidenced by more than 60 projects in the rolling Test Guideline work plan, including in vitro tests. The development of alternative methods that require

fewer or no animals or refine existing methods (or both) can improve testing efficiency (both cost and time) and reduce animal suffering. As part of the special activity on endocrine disrupter testing and assessment, tests for human health and environmental effects are being developed and validated internationally. Key issues to consider are the time needed for developing and finalising Test Guidelines and the extent of validation needed for each new or updated Test Guideline.

■ **(Quantitative) Structure-Activity Relationships [(Q)SARs] and toxicogenomics:** Principles for validation of (Q)SARs for regulatory purposes were recently adopted. The work on toxicogenomics—a computer analysis of gene response to chemical exposure—began with the collection of information on research activities in member countries, in close co-operation with the WHO/ILO/UNEP International Programme on Chemical Safety (IPCS).

■ **Good Laboratory Practice (GLP) and Compliance Monitoring:** Consensus documents on GLP are developed as needed for the interpretation and application of the GLP principles, and training courses for inspectors are held to ensure harmonised inspection procedures. Periodic on-site evaluations of national GLP compliance monitoring programmes are conducted in all MAD partner countries, including non-OECD countries which adhere—or are in the process of adhering—to the Council Decisions on MAD.

■ **MAD and non-members:** OECD works with selected non-member countries that express interest in participating in the MAD system. Participation starts with the non-members' acceptance of data developed under MAD and is followed by their active participation as observers in the work on Test Guidelines and GLP and eventually by their full membership in this part of the Chemicals Programme and the acceptance by the other MAD partners of data developed in these countries.

■ **Harmonised formats for reporting and evaluation:** To facilitate work sharing and information exchange between countries and between programmes, the OECD is harmonising formats to document (i) the data contained in test or (Q)SAR reports and (ii) the evaluation of reports. These harmonised formats (Robust Study Summaries) are prepared for all endpoints covered by OECD Test Guidelines. They will facilitate the submission, review, transmission and storage of

data for new and existing industrial chemicals, biocides and pesticides.

- **Harmonisation of Classification and Labelling:** The Globally Harmonised System of Classification and Labelling of Chemicals (GHS) is based primarily on the Canadian, EU and US systems and on the already harmonised UN Transport Recommendations. The GHS includes: (i) harmonised criteria for classifying substances and mixtures according to their health, environmental and physical hazards; and (ii) harmonised hazard communication elements for labelling (symbols, signal words, hazard statements) and Safety Data Sheets. It does not include lists of classified chemicals or requirements for new tests. The GHS applies to all hazardous industrial chemicals and pesticides. It is expected to be used mostly by chemicals producers and importers; target audiences include consumers, workers, transport workers, and emergency responders.

- The largest part of the GHS was developed under the IOMC umbrella over a ten-year period. The technical work was divided among three focal points: the UN Experts on Transport of Dangerous Goods, the OECD and the ILO. The UN Economic and Social Council (ECOSOC) adopted the GHS in July 2003. The Johannesburg Plan of Implementation encourages countries to implement the GHS as soon as possible and aims to have the system fully operational by 2008. The primary responsibility for maintenance and implementation of the system is now assigned to the UN Sub-Committee of Experts on the GHS. The OECD is the UN focal point for the work related to human health and environmental hazards. OECD work includes update or guidance related to some GHS chapters; it also includes classification criteria and labelling for new endpoints.

- **Exposure Assessment Methods:** Emission Scenario Documents (ESDs) are developed or updated with information from member countries and industry to provide harmonised methods for estimating chemical emissions for various industry and use categories. A project is underway to compare default values and assumptions of the computerised models used in different regulatory contexts.

- **Investigation of Existing Chemicals:** On the basis of a Screening Information Data Set, the OECD produces initial hazard assessments of high production volume (HPV) chemicals, including recommendations regarding the need for further work to be

carried out nationally, regionally or internationally. Since 2001, the pace at which OECD is producing these co-operative assessments of the approximately 5000 HPV chemicals has increased significantly thanks to the contribution of the International Council of Chemicals Associations (ICCA). 500 hazard assessments have been approved, and 150 more chemical assessments are expected to be produced annually. Harmonised hazard assessment methodologies, including the use of 'read across'² and chemical categories, have been approved and are updated as necessary. They can also be used by member countries for their national chemical assessments. In a pilot phase of a globally accessible data repository for hazard data on HPV chemicals, the databases of the US Environmental Protection Agency and the European Commission for their national/regional chemicals programmes will be linked to an OECD Portal. The databases of other countries will be linked to the portal at a later stage.

- **New Chemicals Notification:** OECD work focuses on further elaboration and implementation of the voluntary notification process, parallel to the current country notification processes, to progress towards the ultimate objective of mutual acceptance by countries of new chemicals notifications. The Parallel Process pilot phase began in 2004 and focuses on hazard assessment. International agreement on exposure and risk assessment is much more difficult.

- **Risk Management/Chemical Product Policy/Sustainable Chemistry:** OECD risk management activity is now essentially limited to information exchange for specific chemicals for which regular monitoring of this activity is required. This is currently the case for PFOS (perfluorooctane sulfonate), PFAS (perfluoroalkylsulfonates), PFOA (perfluorooctanoic acid) and their related products, and for brominated flame retardants.

With respect to the Chemical Product Policy, the OECD is exploring how to reduce the risks from products throughout their life cycle. Workshops were held recently on information exchange across chemical supply chains and on service-oriented approaches. A new Workshop on the consideration of chemical safety in green procurement is being prepared.

Until now, OECD work on sustainable chemistry has focused on exchange of information and guidance for R&D (research and development). Some OECD countries have already included sustainable chemistry in

their chemicals management framework, but active promotion of its implementation has not yet started.

Some Features of REACH, the Proposal for a New EU Chemicals Policy

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Several important elements in REACH, innovations with respect to the current EU legislation, deserve attention:

- ❶ the systematic examination of existing chemicals manufactured or imported in volumes over 1 tonne/year;
- ❷ the recognition that persistence and bioaccumulation are properties that justify the same level of concern as carcinogenicity, mutagenicity and reproductive toxicity (CMR);
- ❸ incentives for use of alternatives to testing on animals (in vitro testing and methods based on chemical structure similarities);
- ❹ the obligation to share vertebrate test data;
- ❺ the responsibility of producers, importers and, in some cases, downstream users for assessing chemical safety;
- ❻ the authorisation procedure for chemicals with very hazardous properties.

The first four elements have already been addressed by some OECD countries. Canada, before the EU, started a systematic examination of all substances on its domestic list of manufactured or imported chemicals. Japan accords great importance to persistence and bioaccumulation (toxicity data for new substances are only required for non-degradable substances). Persistent, bioaccumulative and toxic (PBT) substances are also categorised under the Canadian Environmental Protection Act. In the US, the Pollution Prevention Framework, a compilation of computer-based methods for predicting risk-related information, also includes a screening tool that provides estimates of potential for persistence, bioaccumulation and chronic fish toxicity. The US has long used similarities in chemical structure for assessing new chemicals. Sharing data is already an obligation in a few EU Member States; companies and consortia in the EU, in other OECD countries and in the OECD programme on HPV chemicals investigation have experience in this data-sharing.

Item 5, allocating responsibility to industry for assessing chemical safety, has been pol-

icy in the US and some EU member states for several years: chemical companies are asked to submit draft hazard or risk assessments. This is also the case for the OECD HPV chemicals programme; however, although member countries agreed that draft hazard assessments can be submitted directly by industry to the OECD for review by an expert group before endorsement, the companies have not yet used this option but continue to work with a sponsor country. The EU proposal goes further than these current practices, all of which include a review process by the authorities. REACH does provide for an evaluation of certain testing proposals and priority substances, but there is no review process for most registered chemicals. The authorisation procedure for chemicals with very hazardous properties is a new instrument; until now, authorisation procedures were only used to address specific chemical uses that were expected to present risks, that is, such uses as pharmaceutical products, biocides or other pesticides.

The OECD and the Implementation of REACH

The OECD Chemicals Programme already plays an important part in current EU industrial chemical legislation. For example, the EU has adopted new and updated OECD Test Guidelines and OECD GLP principles into its own legislation without modifications.

OECD work on the harmonisation of classification and labelling criteria is relevant to the future EU chemical legislation since an authorisation procedure is planned for substances classified as carcinogenic, mutagenic and toxic to reproduction (CMR) and the EU is expected to implement the GHS. REACH provides that international hazard assessments should be used in its implementation; this would apply to substances already investigated by the OECD. The OECD work on chemical structure similarities—(Q)SARs, ‘read across’, analogs or categories—will help reduce costs and animal use in the EU. In addition to the development of in-vitro tests, they will allow a shift from requirements for data from many animal tests to information requirements. Given the quantity of chemicals for which chemical companies will have to provide information under REACH, this work should be very useful for the EU.

OECD Emission Scenario Documents may need to be supplemented with informa-

tion on risk management measures if they are to be used for the EU safety assessment. The harmonised formats for data reporting (Robust Study Summaries) are sufficiently detailed to make it generally unnecessary to refer to the original test report to evaluate hazards or to review a hazard assessment; the EU is closely involved in the development of these harmonised formats at the OECD, and the European Commission plans to use them for the registration of chemicals.

The OECD work on new chemicals may be less relevant to REACH, which will require new chemicals registration only for volumes over 1 ton/year and initial marketing will no longer be subject to the authorities' assessment of a dossier. Other OECD countries (US, Canada, Australia and Japan), on the contrary, will continue to assess these notification dossiers before marketing or manufacturing. The OECD work on reduced notification requirements for polymers may however be used in the future by the European Commission, when it considers how to address polymers.

In one way or another (and more likely in many ways), the EU will continue to provide input to the OECD and work for their mutual benefit. Draft Article 117 on cooperation with third countries and international

organisations already provides a good basis for cooperation.

1) Food and Agriculture Organisation, International Labour Organisation, United Nations Development Programme, United Nations Industrial Development Organisation, United Nations Institute for Training and Research, World Health Organisation

2) This is a method of evaluation that uses for a given substance hazard data for another substance in the same chemical family with a similar chemical structure. This is based on the principal of structure-activity relations.

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 Test Guidelines
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 Good Laboratory Practice
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Chemicals in Products: Safeguarding the Environment and Human Health

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The Twenty-fourth Report of the Royal Commission on Environmental Pollution

The Royal Commission on Environmental Pollution is an independent standing body established in 1970. It provides advice on environmental issues to the Queen, government, Parliament, the devolved administrations and the public. The Commission has freedom to consider and advise on any matter it chooses; the government can also ask it for advice on specific topics. The Commission is funded by the Department of Environment, Food and Rural Affairs, on behalf of the UK government and the devolved administrations. The Members of the Royal Commission on Pollution are drawn from a variety of backgrounds in academia, industry and public life. The primary function of the Commission is to contribute to environmental policy development in the longer term by providing an authoritative factual basis for policy-making and debate and by setting new policy agendas and priorities. Its advice is mainly given in the form of reports, which are the outcome of major studies. The Royal Commission on Environmental Pollution's Twenty-fourth Report, *Chemicals in Products: Safeguarding the Environment and Human Health*, was published on 26 June 2003.

There is a long history of serious environmental concerns associated with chemicals that were initially thought to be beneficial and without significant risk. The Royal Commission first raised concerns over the envi-

ronmental impact of chemical products in 1972 [2] and will do so again in a report on pesticides due to be published shortly. Despite efforts (outlined by Nigel Haigh [1]) over the years by the UK and other governments to manage possible risks from chemical use, major doubts persist about the effectiveness of present policies in protecting the health of ecosystems and humans from unintended long-term effects. The RCEP also believes that the new REACH system under the current European Commission proposal will be too cumbersome and time-consuming to be able to cope with the large number of chemicals within its scope. It may take decades to work through the vast number of substances, and the criteria set within REACH are not sufficient to trigger early reviews of problem chemicals. The Royal Commission believes that a substantial paradigm shift is required to rectify this situation.

The Nature of the Problem

All chemicals have the potential to be harmful, and some have properties and patterns of use that allow them to reach compartments of the environment that are vulnerable. Chemicals that are released into the environment during use or disposal of products create more diffuse sources of pollution than those released accidentally during the production process. Their effects are thus more pervasive and more difficult to detect and correlate with adverse effects on the

environment and human health. Any proposed new system will have to deal with the large number of existing chemicals on the market in greater than laboratory-scale quantities, between 30 000 to 100 000 chemicals, depending on the definition used. Of these, less than 5% fall into categories that are approved for specific uses such as food additives, pesticides, biocides or pharmaceuticals. The rest can be used unless specifically regulated against. As outlined by Nigel Haigh [1], there is a distinct lack of data for the majority of these existing chemicals, and only a small fraction has been subject to risk assessment. Even where data are available there remain limitations and uncertainties in hazard evaluation and the risk assessment process itself. Much of the evidence that the Royal Commission received for the Chemicals Study indicated areas of ignorance and uncertainty in data reliability, validity of risk assessment assumptions and basic understanding of environmental processes and effects.

Shifting the Paradigm

Given the inherent uncertainties about the way chemicals interact with the environment, it makes sense to assume that the continuing use of large numbers of synthetic chemicals will lead to serious effects, which we cannot predict on the basis of our current or foreseeable understanding of these processes. There are two main reasons for the current high levels of uncertainty about the environmental effects of chemicals. The first reason, already outlined, is the lack of adequate information about the hazards presented by most of the chemicals currently on the market. This must be addressed as a matter of urgency, as recognised by REACH. Where REACH fails is that it has been insufficiently radical in its approach to the actual process of assessing the hazards and risks from chemicals. The infeasibility of carrying on with traditional approaches for hazard and risk assessment results from not fully exploiting new technologies and advances in computational assessment techniques. This is a potentially serious failing.

The second reason is more fundamental: our understanding of environmental processes and the way that chemicals interact with the physical and biological environment is far from complete. Furthermore, because of the complex and fluctuating nature of the environments into which chemicals are

released, providing descriptions of behaviour that will encompass all relevant vulnerable situations is extremely problematic. A sensible approach to this uncertainty would be one of precaution—to reduce the hazard wherever we have an opportunity to do so. The report states that the UK government should adopt the substitution of hazardous chemicals by those less hazardous or by non-chemical alternatives as a core goal of its chemicals policy.

In many cases, substitution depends on actors throughout supply chains and broader policy instruments—one cannot only depend on ‘top-down’ regulatory decision-making or management activities within individual companies.

This principle of substitution underpins many of the other recommendations made in the report, including: better provision of information about chemicals that are on the market and their hazards; the use of assessment and monitoring programmes to inform corporate or regulatory decisions; a much improved flow of hazard information along the supply chain, underpinned by legislation; and a government-sponsored programme of testing chemical products.

A New Approach

The Report makes a total of 54 recommendations; it proposes a new approach for assessing and managing risks of synthetic chemicals, ways of encouraging the substitution of hazardous chemicals with less hazardous ones, and improvements to administrative arrangements. The alternative process the report recommends comprises four inter-linked steps—listing, sorting, evaluation and action. Two features span the whole process: the incorporation of public values and the integration of environmental monitoring. In our Twenty-first Report, *Setting Environmental Standards*, the Royal Commission proposed a conceptual framework for environmental policy that involves several complementary and interrelated components, including scientific evidence, risk assessment and economic appraisal [3]. The Royal Commission recognised that all components would be characterised by uncertainty or indeterminacy and might be influenced by different interests and beliefs. It is essential for uncertainties and different premises to be explicit in the policy process, and a key recommendation of the Twenty-first Report was that people’s values be inte-

grated into each critical stage of decision-making, including framing the problem under consideration.

In the present system, the links between environmental monitoring and risk assessment are rudimentary, and proposals such as REACH appear to do little to put that right. We recommend that monitoring be an integral part of the whole process of assessing both the potential and actual environmental impact of chemicals that are on the market. We have advocated the adoption of a reconnaissance monitoring¹ approach, through tighter integration of chemical and biological surveillance and the intelligent use of sophisticated new techniques to provide the data needed for detecting unexpected adverse effects. Those responsible for overseeing the regulatory control of chemicals must have clearly defined routes through which they can influence environmental and monitoring programmes to deliver the required information, and that information must be integrated into the assessment process at all stages. An inefficient and fragmented approach to monitoring may continue if improvements are not made to the systematic co-ordination of the relevant activities of the various Directorates-General of the European Commission, as well as between the multiple regulatory authorities typically present within a Member State.

Step 1: A list of marketed chemicals

At present, there is no list of chemical substances available in the UK, although in the light of our report the Chemical Industry Association has agreed to compile such a list. The existence of a list is an essential pre-requisite to efficient enforcement of chemicals legislation. Open public access to the list would be an important first stage in improving transparency of the process, and the list would be a factor in the design or re-alignment of environmental monitoring programmes. As information is gathered about chemicals that are on the list and the decisions taken about whether or not to restrict them to certain approved uses, the information and the decisions should be added to the list.

Step 2: Sorting to select chemicals

It is not realistic to expect a comprehensive risk assessment to be carried out on all of the tens of thousands of chemicals currently on the market. This would involve

detailed analyses of the pathways and fates of chemicals once released into the environment, as well as comprehensive and expensive testing of the effects on living organisms and the environment. A system that identifies chemicals of concern for further investigation is essential. It should be based on simple criteria that reflect both hazard and exposure and can be applied quickly to all these chemicals. Two widely-used criteria that reflect exposure are persistence (the resistance of a chemical to degradation by environmental processes) and bioaccumulation (its tendency to concentrate in the fatty tissues of organisms). Information about persistence, bioaccumulation and toxicity is available for many chemicals and these data should be first brought together by the exploitation of advanced methods of searching available literature and databases. This should be augmented by a system pioneered in the pharmaceutical industry and based on advanced computational techniques that identify molecules with particular physiological properties. Although such techniques would not resolve the uncertainties alluded to earlier, it would ensure that the properties of every chemical were systematically examined. On the basis of this information some chemicals would be selected, against carefully chosen criteria, for further evaluation. Those not selected would remain under review—that is, they would be re-evaluated in the light of any information arising from the environmental reconnaissance monitoring, from improvements in screening technology, or from new insights into the properties and behaviour of chemicals.

Step 3: Evaluation of selected chemicals

On the basis of the sorting data, criteria should be devised for the rapid identification of highly hazardous chemicals, for which immediate action is required without further investigation. The criteria for identifying such chemicals (e.g. in cases when synthetic chemicals are found in elevated concentrations in humans) should be selected in the light of open debate; this is not a decision to be made solely by experts. However, most chemicals will require further evaluation. It will be necessary to gather detailed information on the toxicological profiles and exposures that result from use. Determining chemical properties might require further testing, although the report advocates the use of computational techniques wherever available and the development of new computational techniques where they do not yet exist. This is for both

ethical and practical reasons. The drawbacks of the classic *in vivo* toxicology endpoint approach are discussed at some length in the report, but the decisions to move to *in vitro* and *in silico* tests should be made on a case-by-case basis following transparent discussion. The evaluation stage should result in the assignment of a chemical to one of three categories—high, medium or low concern—or in a decision that the chemical is not, after all, of immediate concern.

Step 4: Risk management action

One of the main criticisms that we have heard about the present regulatory regime for chemicals is the length of time from the first indication that a chemical is harmful to any action to curtail that harm—typically several years. REACH, when it comes into force, will introduce approval for use for a subset of chemicals identified as highly hazardous (the authorisation process)—this seems to us to be the correct way forward—but it needs to be introduced more quickly than is planned for REACH.

In addition to guiding risk management decision-making, the categorisation system proposed in our Report would also be used to implement a chemicals charge. Chemicals placed in the category of highest concern would face severe restrictions on their use and the highest level of the chemicals charge. In some cases, a total ban on the production or importation of the chemical would be required. Medium concern chemicals would be restricted to certain uses and attract a lower charge. Those in the low concern category might not need to be restricted—but would still attract a charge. Information about the category to which a chemical has been assigned must be made available throughout the supply chain, including the public, so that customers can consider it in making purchasing decisions and assessing their potential liabilities if they choose to use chemicals with a particular hazard rating. Thus, the chemicals assessment and management process will provide both regulatory control over the chemicals of particular concern and a driver for the process of substitution that we have recommended.

The Future of Chemicals Regulation

Regulation flowing from chemicals policy usually needs to be accepted and endorsed at EU level, and this has been a major obstacle

to the adoption of new regulatory policies in individual Member States, including the UK. We believe that the length of time that it will take for REACH to have any effect and the widespread criticisms of its efficiency and effectiveness mean that it is inappropriate for the government simply to wait for the new EU regime to come into force. There is now a good opportunity for the UK, jointly with like-minded Member States, to come forward with coherent proposals for new legislation, possibly interim legislation pending further development of the REACH proposals, within the EU.

The Report recommends new administrative arrangements to provide a much more coherent framework for the assessment, management and monitoring of chemical risks. In the case of the UK, this includes the formation of a new body, a chemicals safety co-ordination unit, which would have a specific remit to oversee the implementation of the recommendations made in the Report and provide a clear strategic drive towards substitution. This body would be responsible for overseeing the publication of the list, conducting the initial preliminary sorting by available information and computational techniques, and securing information from industry for further evaluation of chemicals identified as of concern. Industry would be required to undertake further testing on these chemicals. The industry would also pay fees to the government body for the initial assessment of the chemicals into the categories. Further substances of concern may be identified through monitoring rather than the sorting or evaluation exercises. The increases in monitoring to achieve this would be paid for through the chemicals charge and the aforementioned fees.

All chemicals currently on the UK market should be reviewed by 2006 according to the sorting process that we have recommended. All the chemicals selected by that process as being potentially harmful should then be fully evaluated by 2009. A government strategy should be in place within the next two or three years to achieve a steady, measurable reduction in the overall use of hazardous chemicals. A comprehensive programme of research should be promoted jointly by industry and government to expand new approaches to risk assessment to reduce uncertainty in our understanding of the behaviour and fate of chemicals and their interaction with the physical and biological environment. However, whilst acknowledging the problems of the current system and accepting the validity of some of the individ-

ual recommendations in the report [4], the UK government has not yet accepted either the need for a new framework for managing chemical risks or that the system suggested under REACH will not solve the problem.

PAPERS

1) Reconnaissance monitoring aims to determine what chemicals are present in the environment and whether a change in the health status or function of the ecosystem, the quality of a habitat, the functional integrity of an ecological community or the level of harm to individuals or populations of organisms in the environment is due to chemicals or attributable to some other cause.

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Beyond REACH. A Tutorial Approach to Toxic Effects of Chemical Mixtures at Individual No-Observed-Effect Levels

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RÉSUMÉ P. 14
ABSTRACT P. 26

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Traditionally, toxicological interest and regulatory activities focus on the properties of single substances. Consistent with this approach, the main body of the REACH document consists of more than one thousand pages on single substances whereas there is but one annex (1b)—one and a half pages long—on mixtures of substances (so-called preparations) [1]. According to Annex 1b the assessment of mixtures is identical to the procedure prescribed for single substances: “The chemical safety assessment for a preparation shall be based on the information on the individual substances in the preparation contained in the technical dossier and/or the information communicated by the supplier in the safety data sheet. It shall also be based on the information available on the preparation itself.” Annex 1b ends with section 4.3: “Assuming additivity of effects, then for each route of human exposure and each human population and for each environmental sphere, the estimation of the exposure level to the preparation is the sum of the estimates of the exposure level to each substance in the preparation [2].”

Human beings and other living organisms are rarely exposed to single substances. On the contrary, there is growing insight that in some situations, toxicological properties of mixtures pose unsolved problems of considerable scientific and practical interest. This applies to consumer products such as cigarettes with hundreds of chemical additives, each in a very low concentration, as well as to environmental pollution, such as the ecotoxicological effects of ground-water contami-

nated with pesticides and herbicides or of wastewaters. The discrepancies between the high concentrations of estrogenic chemicals that are needed to elicit effects in laboratory tests and their low concentration levels in wastewaters or in the environment have impelled the widespread belief that mixtures pose no particular risk to human health and wildlife. This belief is largely based on the assumption of additivity of effects.

On the other hand, the ongoing observations of sexual dysplasias in fish and amphibians need explanations. There are indisputably situations where the “effect of a mixture does not equal the arithmetic sum of the effects of its individual components [6].” In particular this applies to synergistic drug effects [3]. In this case the relevant conceptual alternative to additivity of effects is additivity of concentrations.

Cooperative Binding and Synergistic Drug Effects

If several molecules of the same type bind to different sites of a macromolecule it can occur that the binding for the first molecules is less strong than for the subsequent ones. This effect is called positive cooperative binding. The significant fact about positive cooperativity is the sharp response of the binding curve to a small change in the molecule concentration. In mathematical terms this corresponds to an S-shaped, so-called sigmoid binding curve. The binding of oxygen to

hemoglobin is the classic example of cooperative binding [4].

A quantitative measure for cooperative binding is p , the Hill coefficient. If c is the concentration of the binding molecule in question, the fraction r of the occupied binding sites is usually described by the Hill equation:

$$r = \frac{c^p}{1+c^p} \quad (1)$$

We see in Figure 1 that the binding curve for $p = 1$ is non-sigmoidal. Accordingly, there is no cooperative binding. For increasing values of $p > 1$, however, the binding curve becomes more and more sigmoidal. Independently of p , the binding r approaches 1 for high concentrations of the binding molecule. At $c = 1$ there is half-maximal binding, i.e., $r = 1/2$. (This implies that concentrations are measured in units of reference concentrations related to half-maximal binding).

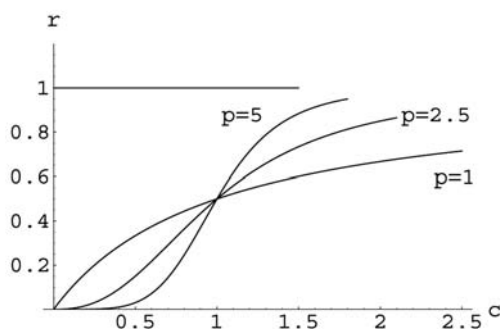


Figure 1: Binding curve for different values of the Hill coefficient p .

A behavior formally similar to cooperative binding to macromolecules is synergy in toxicological dose-effect curves. In this case r is the observed effect and c is either a dose given to an individual or the environmental concentration to which individuals are exposed. The unit of c is again related to half-maximal effects. In contrast to cooperative binding, however, the toxicological Hill coefficient is but a phenomenological parameter without mechanistic interpretation. To characterize the no-effect level, c_{no} is defined here¹ as the concentration that produces 1/100 of the half-maximal effect in equation (1):

$$\frac{1}{100} \frac{1}{2} = \frac{c_{no}^p}{1+c_{no}^p} \quad (2)$$

Solving for c_{no} yields $c_{no} = \sqrt[p]{1/199}$.

Now assume a set of different chemicals leading to the same effect via the same mechanism and with similar Hill coefficients (the requirements for so-called concentration additivity). We now ask: how many of these chemicals must be combined in a mixture at individual no-observed-effect concentrations to produce a significant, say half-maximal effect. Let n be this number of chemicals. The effective total concentration c_{eff} is then the sum of the individual no-observed-effect concentrations. In other words: $c_{eff} = n c_{no}$. Inserting c_{eff} into eq. (1) and requiring half-maximal binding ($r = 1/2$)

$$\frac{1}{2} = \frac{(nc_{no})^p}{1+(nc_{no})^p} \quad (3)$$

yields the main result:

$$n = 1/c_{no} \quad (4)$$

In other words:

$$n = \sqrt[p]{199} \quad \text{or} \quad p = \ln 199 / \ln n \quad (5)$$

It follows from equation (5) that $n < 2$ for $p > 7.6$. Accordingly, in this case, a combination of only 2 chemicals at no-observed-effect concentrations suffices to produce half-maximal effects.

Kortenkamp's Xeno-Estrogen Example

In a remarkable paper *Something from 'nothing'*, Andreas Kortenkamp and coworkers demonstrated that "eight weak estrogenic chemicals combined at no-observed-effect concentrations produce[d] significant mixture effects [5]." Using the yeast estrogen screen assay they showed that eight xeno-estrogens with measured average Hill coefficients of about 2.6 are sufficient to produce substantial effects despite individual no-effect concentrations. Equation (5) and Figure 2 now easily allow us to understand this effect: at a Hill coefficient of $p = 2.6$, $n = 7.7$. Accordingly, 8 is the minimum number of xeno-estrogens to generate the prescribed effect.

Before transferring these results to other chemicals and assays, we must ensure that a Hill coefficient of 2.6 is not exceptionally high. The measurements by Niederer *et al.* [6] for three different endpoints in algae (chlorophyll fluorescence, growth recovery, and glutathione depletion) with a group of 6 reactive

electrophilic chemicals (organochlorides and epoxides)—yielded three values of p between 1 and 2; six values between 2 and 4; seven values between 4 and 10; and two values larger than 10, with a maximum of 21 for 1,2-epoxybutane. These results raise doubts that high Hill coefficients are so exotic as to justify a general assumption of additivity of effects.

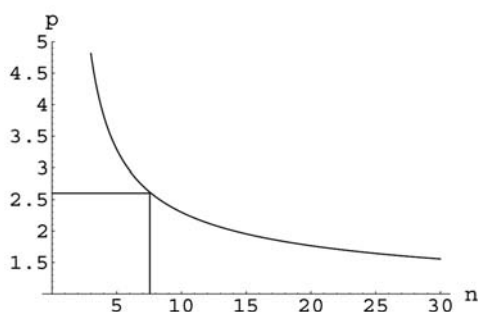


Figure 2: Number n of mixture constituents at no-observed-effect concentrations required for a half-maximal total effect as a function of the Hill coefficient p according to Eq. (5). For xeno-estrogens with average Hill coefficients of 2.6, $n = 7.7$. Consequently, Kortenkamp and his coworkers could demonstrate significant effects with a mixture of eight xeno-estrogens.

Concluding Remarks

One may object that these findings are laboratory results with little bearing on real-life situations. As early as 1980, however, masculinization in fish was detected after exposure to pulp mill effluents in the US: exposed female mosquito fish (*Gambusia spp.*) developed anal fins to a gonopodium normally seen only in males. This anomaly was reproduced in experiments with newly hatched fry exposed to these effluents. Males, on the other hand, did not respond to comparable exposure. Originally, it was conjectured that androstene-dione is the androgenically active compound in pulp mill effluents, but it was shown later that this compound, although present, is not a dominant androgen. The active components have not yet been identified [7].

In a recently published paper, Anders Svenson and Ann-Sofie Allard examined pulp and paper mill effluents for in vitro androgenicity testing with a recombinant yeast-based androgen receptor assay [8]. They discovered low levels of androgenic effects but were not able to identify single androgenic compounds. Using indirect methods they plausibly suggested that

the androgens originated in decaying (soft) wood. It is tempting to suggest that the great variety of (phenolic) transformation products of humic matter may be responsible for the androgenic effect, even though the individual androgenic potential of each is weak.

Real-life toxic effects of mixtures at individual no-observed-effect levels, accordingly, are observable through measurement and so they are not completely out of scientific reach. But they are out of REACH.

1) The standard method for the determination of no-observed effect levels is Dunnett's test. The method used here corresponds to the so-called E01 level. Numerically, both values are largely equivalent. For details comp. Silva *et al.* [5]

Acknowledgments

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Improving the Scientific Basis for Decisions in the REACH System

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In current debates on chemicals policies, a strange paradox can be observed in attitudes towards the use of science in public policy-making. Some participants in these debates put strong emphasis on what they call 'sound science'. For a scientist, it is obvious that to make science and its applications as sound as possible, we should collect as much scientific information as possible and ensure that our judgments are based on scientific information as complete and as robust as possible. In the field of chemical risk assessment, this would imply the collection of as much data as possible about the substances in question. However—and this is the paradox—precisely those discussants who speak up in favour of 'sound science' tend to be those least willing to support efforts to substantially extend the scientific basis of risk assessment by obtaining more toxicological data about substances in use.

A possible explanation of the paradox is that the phrase 'sound science' does not refer to the soundness of scientific judgment but to a particular attitude to decision-making under scientific uncertainty. The use of 'sound science' as a political slogan seems to have its origin in The Advancement of Sound Science Coalition (TASSC) set up by the Phillip Morris Company in 1993. Its major task was to promote the view that the evidence for health risks from passive smoking was insufficient for regulatory action (Mooney 2004).

When scientists refer to improving the scientific basis for risk assessments, what we mean is simply enlarging the database and extending our capability to use it to make good

risk assessments. A science-based risk assessment of potential or actual exposure is only possible if we have a reasonable amount of knowledge about the inherent properties of the substance in question.

How Far Does REACH Take Us?

The REACH proposal will extend our toxicological database for industrial substances, and it will therefore improve the scientific basis of risk assessments. But how far will it take us? How well informed will we be about the effects of a substance when we have the data about it that is required by REACH? A good way to illuminate this issue is to compare the required data sets to the data needed to classify a substance according to defined criteria. The classification and labelling directive (dir 67/548) contains such criteria, as does REACH itself (criteria for authorisation). Let us consider in turn some of the major effect criteria.

Figures 1-4 (pp. 50-51) summarise the test criteria in REACH. The required data are listed to the left. The black and white arrows indicate how test requirements will change for 'existing' (respectively 'new') substances, i.e. substances notified to the Commission before (respectively after) the 18th of September 1981. Test requirements also depend on the annual production volume, which is classified into one of five ranges. REACH abolishes the previous distinction between test requirements for 'existing' and 'new' substances. Tests required by REACH, for each production volume category,

are thus those up to and including the point where the black and white arrows meet. Data requirements for the classification and authorisation criteria are indicated to the right.

- Acute toxicity (Figure 1, p. 50): For substances produced at a volume of 10 tonnes or more, REACH requires enough data to enable application of the classification criteria for skin and eye irritation and acute (mammalian) toxicity. For substances with a volume of less than 10 tonnes, the criteria for acute effects on mammals cannot be applied. In other words, REACH does not require enough data to determine whether or not these substances should be labelled for acute toxicity.

- Carcinogenicity (Figure 1, p. 50): The test data generally required in any production volume do not allow application of the criteria for the carcinogenicity classification.

- Reproductive toxicity (Figure 2, p. 50): Data required in REACH are sufficient for classification of developmental toxicity for substances produced in volumes of 10 tonnes or more. Classification for adverse effects on fertility is based on data required only for substances produced at a volume of at least 100 tonnes.

- Ecotoxicity (Figures 3 and 4, p. 51): The data required in REACH will be enough to apply the classification criteria for aquatic toxicity to substances with production volumes of 10 tonnes or more. The REACH system specifies criteria for classifying substances as persistent, bioaccumulating and toxic (PBT) and very persistent and very bioaccumulating (vPvB). But the data needed to apply these criteria are required only for substances produced at volumes of 100 tonnes or more.

In summary, implementation of REACH will increase data requirements for 'existing' chemicals substantially. However, for substances produced at volumes below 10 tonnes, the required information is insufficient to apply any of the classification or authorisation criteria under consideration here. Only for substances produced at a volume of 100 tonnes or more is information required that can trigger the REACH authorisation process.

Priority-Setting According to Production Volume

The general criterion for priority setting in REACH, as well as in the current regulations, is each chemical's production volume. Production volume is used to assign different test

requirements to substances. The rationale for this criterion is that large production volumes increase the potential for exposure and therefore the risk associated with the substance. This is a sensible argument, but there are at least three problems with this priority-setting criterion. First, it is not known to what degree production volume actually predicts exposure. Secondly there are indications that chemicals with low toxicity may be overrepresented among high-volume substances (Cunningham and Rosenkranz 2001). Thirdly, the lower exposure predicted for low-volume substances refers to aggregate (total exposure), not individual, exposures. Even if the total production volume is low, exposure to a low-volume substance may very well be (and often is) limited to fewer people who are exposed to large doses of the substance, in their workplace, for example.

In this perspective, it is important to look beyond the production volume criterion and discuss how the system can be further developed to optimise the testing requirements.

Science-Based Test Systems

REACH and other regulatory applications use many different toxicological tests that are combined into test systems. A test system contains several tests as well as rules for when and in what order the different tests should be applied. Most test systems are tiered, which means that the initial tests are used to determine the need for further testing, often in several stages. Different substances will take different paths in the test system, depending on the outcome of the tests to which they are successively subjected.

The tests included in currently used test systems are all carefully constructed according to scientific principles. However, for a test system to be science-based, it is not sufficient that each individual test be based on science. In addition, the test system as a whole, i.e. the combination of the tests and the rules for how tests follow one another, must also be based on scientific principles. This is a weak point in current test systems: scientific principles were used in the construction of individual tests, but the systemic level is largely based on more intuitive judgments.

One of the major goals of our research in this field is to develop test systems that are science-based on the systems level as well as the test level. Two major approaches can be used to achieve this, one mechanistic and one decision-theoretical. The mechanistic approach

uses knowledge about toxicological mechanisms in a systematic way; its objective is to identify the relevant decision parameters as efficiently as possible. This approach depends on a thorough basic understanding of how chemical agents behave and react in biological systems. Mechanistic knowledge is available for specific substance groups, typically pharmaceuticals, but is very scarce for other types of substances, such as industrial chemicals.

Toxicological risk is composed of the combined effect of (1) exposure and (2) the chemical's inherent capacity to cause adverse effects (its hazards). To improve exposure assessment methods, we need to learn more about the underlying mechanisms of exposure, and to improve the hazard assessment we need to know more about the relation between the information obtainable from the different tests used in a test system and human or ecological risk.¹ Examples of such relations of interest are the hypothetical relations between persistency, exposure, and risk. Is a chemical's high potential to persist in the environment related in any meaningful way to exposure or risk, and are persistent chemicals prone to certain types of toxicity due to their potential for long-term exposure? Scientific validation of such relations would provide knowledge that could have important implications for the design of test systems (and test requirements) for persistent chemicals. Knowledge of toxicological mechanisms is needed to determine if the tests under consideration are at all relevant for the toxic effects that we want to prognosticate.

Mechanistic knowledge can also provide us with well-founded presumptions about whether test outcomes should be regarded as independent of one another. If two tests furnish indicators of different effects that are independent of one another, the result from one test is not predictive of the outcome of the other. In this case, findings from one of the tests does not justify failure to conduct the other test. Such tests should preferably be arranged at the same time.

In contrast, if two tests provide indicators of the same effect, results from one may be relevant to the need for the other. For example, positive mutagenicity test results in most cases increase the need for carcinogenicity tests. When tests are related in this way, they should in general be arranged consecutively in a test system, and it may be adequate to use one of them as a screening test to determine whether or not the other should be performed.

The decision-theoretical approach to the design of test systems should be based on information from what we propose to call cor-

relations toxicology, i.e. studies of the correlations between different test outcomes and (when available) the correlation between test outcomes and results from epidemiologic and field studies. Statistical information from the tests that have been performed can be used to determine the predictive power not only of individual tests but also of combinations of tests in a test system.

In our view the best result can be achieved by a combination of the mechanistic and the decision-theoretical approaches. The aim of this research should be to develop science-based test systems, i.e. tiered systems that have a solid base in toxicology and decision theory.

We also believe that special efforts should be made to use physicochemical properties as first tiers. There are several reasons for this. Both the fate and behaviour in the environment (e.g. partitioning, persistency and ability to bioaccumulate) differ for substances with different chemical characteristics, which also require different approaches to testing (e.g. due to their solubility in water) and pose different risks (e.g. acute or long-term effects). Data on these properties can be obtained without extensive animal testing. We have therefore proposed that a set of persistence and bioaccumulation data, enough to apply the corresponding criteria, should be requested for all substances regulated by REACH (Hansson and Rudén 2004). This will make it possible to determine whether or not the substance is persistent and bioaccumulative or even very persistent and very bioaccumulative according to the relevant criteria in the current REACH proposal.

Incentives for Voluntary Testing

In addition to the minimum legally-required tests, manufacturers may choose to conduct other tests to improve the scientific data set available for a substance. Ideally, regulatory systems should encourage such additional testing, since it will contribute to decreasing health and environmental risks. Unfortunately, the present system not only does not do this, but deters such testing.

In the classification and labelling system (dir 67/548), additional data about the properties of a substance can lead to a stricter, but almost never to a less strict classification (see Hansson and Rudén 2003). Strict classifications tends to diminish the marketability of substances. Companies responsible for producing and marketing chemicals thus often have something to lose, but almost never any-

thing to gain in economic terms, from subjecting their products to testing. The classification and labelling system thus has an incentive structure that discourages rather than encourages toxicity testing. The proposed REACH system does not change this counterproductive incentive structure.

One way to improve the regulatory system in this respect is to introduce an additional dimension and a new classification category into the classification and labelling system—the dimension of toxicological ignorance and the category of insufficiently investigated. Substances classified in this category should be assigned a warning label, including a warning symbol, such as a question mark, as an indication of potential danger. See Figure 5 (p. 51) for an example of what the new labelling might look like (Hansson and Rudén 2003).

The classification of a substance as toxic, dangerous to the environment, etc. is a competitive disadvantage, and classification as insufficiently investigated would be expected to have a similar effect. Companies producing a low-volume chemical will however be able to attain the competitive advantage of not having to ‘question-mark’ it. They can do this by submitting the substance to a certain level of testing above the minimal requirements.

The criteria for classification as insufficiently investigated should be based on a minimal list of test data. A balance must be struck to avoid so many products carrying the new symbol that the public will tend to ignore it. In our view, the data requirements in REACH for substances produced in quantities less than 10 tonnes per year are not so onerous as to deter the desire for exemption from classification as ‘insufficiently investigated’. On the other hand, it would be unrealistic to set the limit higher than the proposed requirements for production volumes exceeding 10 tonnes per year. The limit for question-marking should be set at, or somewhat below, the data set required for substances produced in quantities exceeding 10 tonnes. A case can be made for evaluating and reconsidering these criteria at regular intervals.

The question-mark label will inform the user of chemicals that the substance may have unknown hazardous properties. Chemical safety consists not only in avoiding known problems but also in avoiding as far as possible exposures with unknown or uncertain effects on health and the environment. To achieve

this, a rational chemicals policy must make full use of science. This means that all types of scientific information should be used, including information about what remains uninvestigated or for other reasons uncertain.

Conclusion

In summary, the proposed REACH system is an important step towards a system that will ensure sustainable development with regard to the use of chemical substances. This task, however, is so vast that it would be unrealistic to believe that it could be solved in one single reform. It is therefore no surprise that despite the progress that REACH should engender, it will not solve all problems. The most pressing remaining issue is that of generating sufficient information for science-based risk assessment of chemicals produced in low volumes.

1) In most cases it is not possible to determine the relevance of a single test or a test system in relation to effects in humans or entire ecosystems. Instead reference tests, such as a well-established long-term in vivo test, must often be used, as the so-called gold standard (Hartung et al 2004). Validation is possible through comparison with a well-established combination of tests.

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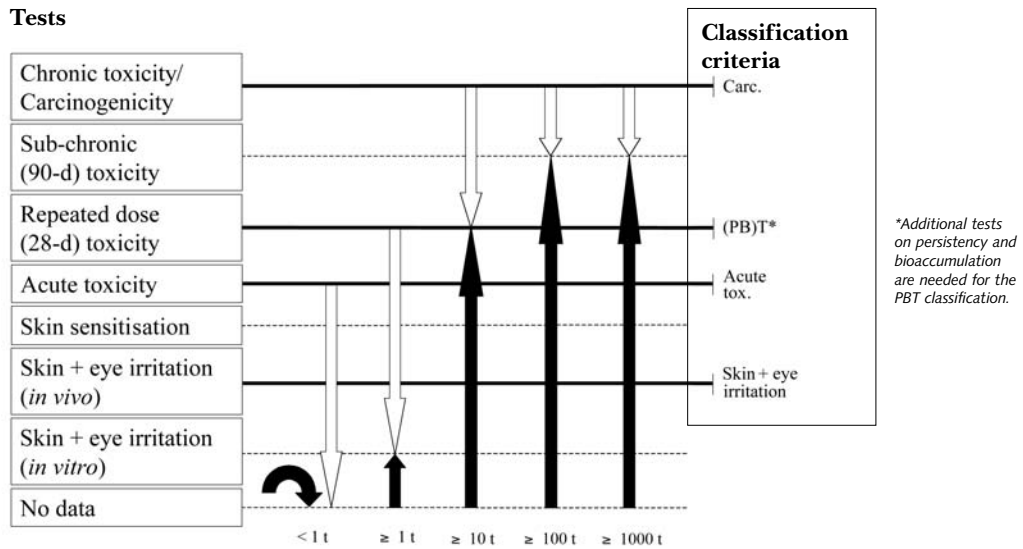


Figure 1. Data requirements and classification and authorisation criteria for general toxicity including carcinogenicity. Data requirements are listed to the left, with increasing requirements upwards. Requirements for the classification and authorisation criteria are indicated to the far right in the dia-

gram. The black arrows indicate how test requirements will change for 'existing' substances, for each of the production volume categories indicated at the bottom of the diagram. Hence, for substances in the volume category ≥ 1000 tonnes, the present level of data requirements is 'no data', and with

REACH the level 'Sub-chronic (90-d) toxicity' will be reached. The white arrows indicate how test requirements will change for 'new' substances. Tests required by REACH for the respective production volume category are hence thus those up to and including the point where the arrows meet.

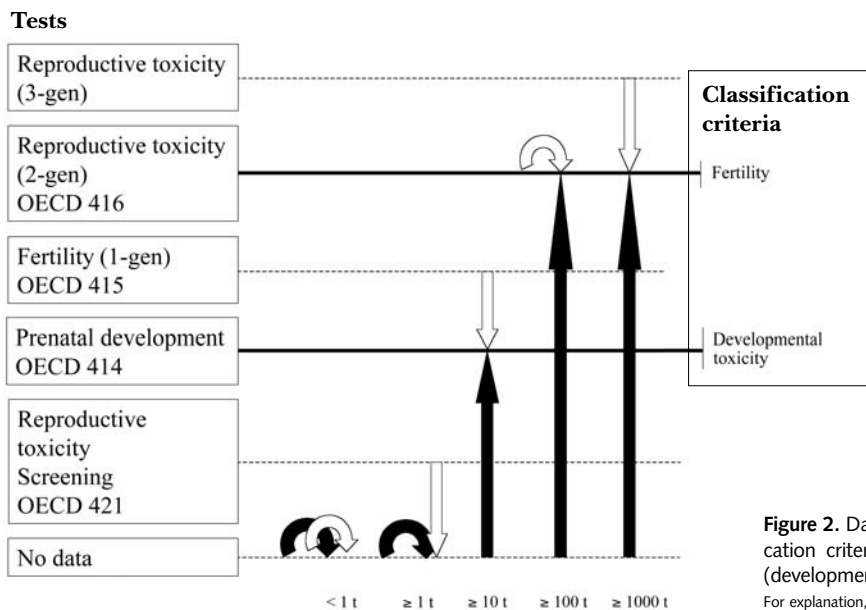


Figure 2. Data requirements and classification criteria for reproductive toxicity (developmental toxicity and fertility). For explanation, see Figure 1.

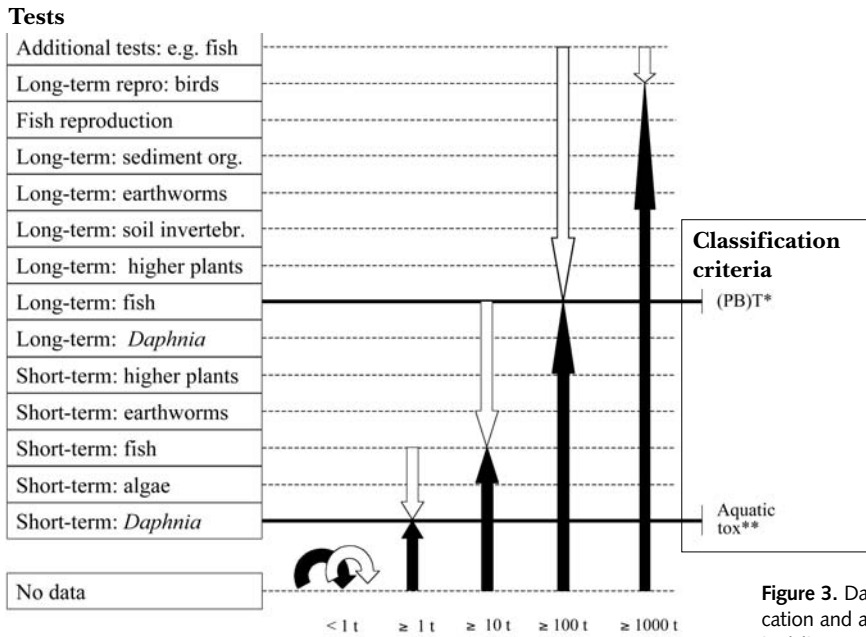


Figure 3. Data requirements and classification and authorisation criteria for ecotoxicity. For explanation, see Figure 1.

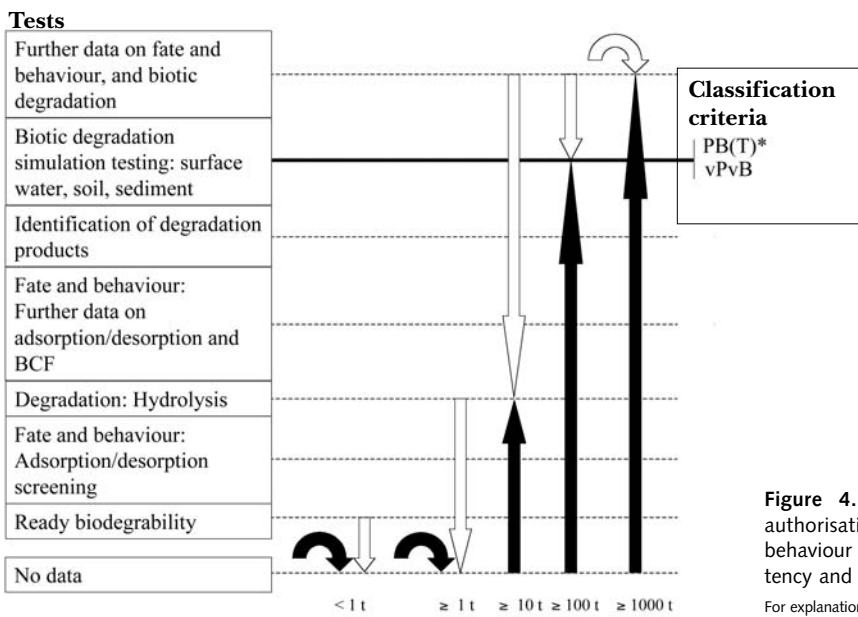


Figure 4. Data requirements and authorisation criteria for fate and behaviour in the environment (persistence and bioaccumulation). For explanation, see Figure 1.



Figure 5. The proposed new warning label for insufficiently investigated substances (on a yellow background).

Legal Issues of REACH

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The Commission's proposed regulation for the registration, evaluation, authorisation and control of chemicals (REACH) is a response to the failures of current EU chemicals regulation, which has focused unilaterally on new substances and has not assessed nearly enough of the 30 000 existing substances produced in relatively high volumes. While REACH is to be welcomed from the perspective of precaution, it raises questions of fundamental economic rights, proportionality and conformity with WTO rules.

Registration and Authorisation as Means of Implementing the Precautionary Principle: Justification and Limits

REACH reorients EU chemical policy towards implementation of the precautionary principle set forth in article 174(2) EC Treaty. The introduction of a comprehensive registration procedure entailing data collection and testing obligations for new and existing substances and of an authorisation procedure for ultra-hazardous substances constitutes an environmentally desirable specification of the precautionary principle in its core meaning, as a policy for coping with scientific uncertainty about hazards and risks. The intensive regulatory scrutiny of the very few new substances is severely disproportionate to the lack of regulatory concern for the many existing substances, which cover a market share of about 99 percent. Experi-

ence with the latter certainly does not justify regulatory neglect as a pragmatic response to the high economic and administrative costs of regulation—even if the qualification of the situation as 'toxic ignorance' is an overstatement.

However, it is generally recognised that the precautionary principle is subject to legal limitations. The bases of these limitations are the right to free movement of goods (article 28 EC Treaty), other fundamental economic rights, including the right to free exercise of economic activities and possibly the guarantee of property. Regulations that interfere with these freedoms or rights must be justified by the pursuance of a legitimate Community objective and violate neither the principle of proportionality nor the right to equal protection. The European Court of Justice accords European regulatory agencies a wide margin of discretion in the field of economic and other complex regulatory policy and will hold that regulations violate article 28 EC Treaty or fundamental economic rights only when agency findings are clearly erroneous in law or fact or otherwise clearly unreasonable. Considering the precautionary principle specifically, the European Court of First Instance has held that precautionary measures cannot be justified by merely hypothetical risk considerations based on assumptions that are not yet scientifically verified.¹ Rather, the available data must provide reasonable grounds for concern. This requirement must be interpreted, however, according to the kind and extent of intervention.

Introduction of a registration procedure for existing substances can be justified, based on our experience with chemical substances, by an 'initial suspicion' of a hazard and risk to human health or the environment. Since the direct legal consequences of the registration requirements are limited to provision of information, further obligations such as a full risk assessment are triggered only by a finding of hazardous properties and significant risk; marketability is not affected at all. Accordingly, the regulatory burden imposed by REACH appears at first glance to be proportionate. Nevertheless, there are some doubts in this respect. Cost/benefit estimates for the new registration system vary considerably, but there is no denying that innovative flexibility and the cost level for chemicals production will be deeply affected by REACH because the mandatory entry of existing substances into the registration system is triggered at a relatively low production volume. The impact may be even more serious on small and medium-sized enterprises, which manufacture the bulk of the special chemicals typically produced in small quantities, as well as on downstream users. Market volume here may be such that the costs incurred by compliance would be prohibitive. The industry proposal to mandate full registration only when justified by the results of a risk screening undertaken by the producer in the pre-registration phase is clearly a less burdensome but also less effective alternative. The proposal assumes an information level which can ultimately be reached only after completing the registration process. Furthermore, production volume serves as a proxy for extent of exposure, and thus to some extent potential risk is considered a triggering factor. Finally, the rigour of the system is tempered by transitional periods for phase-in and the step-sequence procedure. All told, the present REACH approach may not be an optimal solution but from a legal point of view it can hardly be considered excessively burdensome.

The authorisation procedure for ultra-hazardous substances requires stronger justification because the product's continued marketability is at issue. The imposition of an authorisation requirement is based solely on the existence of a hazard, with exposure data relevant only for setting priorities. However, as the comparison with authorisation procedures for pharmaceuticals, pesticides and biocides shows, special kinds of hazards justify closer scrutiny. The authorisation prerequisites ensure that only significant risks to human health and the environment due to

inadequately controllable dispersal and exposure, rather than the mere existence of a hazard, justify banning or restricting production, use, or marketing. Together with the availability of authorisation on the basis of socio-economic benefits, the authorisation procedure constitutes a balanced accommodation of environmental and health concerns and economic interests.

A major criticism of REACH from the perspective of proportionality is its principle that every individual producer must go through the registration procedure, including testing, risk assessment and risk management, unless several producers voluntarily establish a consortium. REACH requires sharing existing test data and cost. There are also incentives to cooperate in other testing. While it may be true that the competing concept of 'one substance, one registration' would avoid costs for both industry and governments, its implementation implies the establishment of mandatory consortia and the allocation of tasks within a consortium by the authority. From a competition point of view, any form of consortium is objectionable because it increases market transparency, which is undesirable at least in narrow oligopolies, and because it serves as a forum to coordinate the consortium members' activities on the market.

Producer vs. Governmental Responsibility

The imposition of a fundamental duty of care including risk assessment and risk management along the entire supply chain is a major regulatory innovation. It rests on firm precautionary grounds because it extends the information base for risk management and closes gaps in protection that existing law has tolerated. Moreover, the fundamental duty of care can also be based on the polluter-pays principle if this principle of environmental policy is, as it should be, conceived as a principle that governs material responsibility and not only attribution of the costs of regulation. Actors in the supply chain are the source of the potential adverse effects created by the production, marketing and use of chemicals. As such, and due to their proximity to exposure to these chemicals, they are in a key position to control the relevant risks. The parallel to product liability under private law, the legitimacy of which we take for granted, is obvious.

Again, however, this does not mean that REACH is necessarily an optimal solution in

this respect. REACH's reliance on producer responsibility tends to blur the responsibility of public authorities. The power of the authorities to verify submissions in the proposed regulation is somewhat underdeveloped. The dossier submitted by the registrant can be reviewed for completeness, and additional information and testing can be required if warranted. Yet REACH is not at all clear about the authorities' powers regarding registrations that are materially deficient or risks that even the chemical safety report indicates are inadequately controlled. Arguably, apart from requesting additional information, decisions for tackling such problems can only be taken through the committee procedure, which means that the marketing of substances associated with considerable risks could continue for quite some time. In addition it must be underlined that the complex evaluation process for deciding upon restrictions will create an enormous workload for the authorities. Regulatory failure of the kind we have experienced in the regulation of existing substances appears almost inevitable.

If this assessment is correct, much will depend on the incentives for actors along the supply chain to live up to their responsibility voluntarily. Producers have an interest in ensuring maximum market share, keeping downstream users from turning to other raw chemicals, and avoiding damage to their reputation on the market as a result of a wrong classification. Moreover they have of course an interest in avoiding civil liability. These provide powerful incentives to comply with the obligation to conduct a scientifically correct risk assessment, determine adequate risk management measures in the CSR (chemical safety report) and furnish sufficient information to users down the supply chain. On the other hand, depending on compliance costs, a 'wait-and-see' approach cannot be ruled out, especially by downstream users. These will often not be able to bear the costs of preparing a separate CSR because the costs exceed the price they can get on the market over a period of several years. They may be also reluctant, however, to supply data on uses and exposures to the producer, who may be an actual or at least potential competitor in their market.

Burden of Proof

REACH also poses the problem of the burden of proof. The producers' obligation to collect and generate the requisite hazard

and risk data for the registration procedure can hardly be deemed excessive. To impose restrictions the authority would be required to show an unacceptable risk to human health or the environment. This standard is clearly higher than that set by the European Court of Justice in the *Toolex Alpha²* case, where it held that a precautionary assessment based on incomplete data but not mere hypothetical risk considerations may justify restrictions.

Genuine problems of burden of proof only arise in the authorisation procedure. REACH provides for a tiered solution. Proof of the trigger facts, i.e. ultra-hazardous properties, lies with the Community institutions. The authorisation can nonetheless be granted if the risks presented by the substance are adequately controlled or if the socio-economic benefits outweigh the risks and there are no suitable alternatives. Article 57(2), (3) expressly refers to documentation of adequate risk control and proof of net benefit and implies that the burden of proof lies on the producer.

In light of the right to free exercise of an economic activity, any imposition of the burden of proof on private actors is problematic independently of whether the state intervenes or decides to grant the requisite authorisation. In the relationship between the citizen and the state, the rule of law requires in principle that the burden of justification be attributed to the state unless there are cogent public policy reasons to the contrary. In light of the precautionary principle and given the special nature of the hazards associated with substances that will be subject to authorisation under REACH and of the potential risks of dispersal and exposure, reversal of the burden of proof is not excessively burdensome. This was recognised by the European Court of First Instance with respect to pharmaceuticals and is true of ultra-hazardous chemicals in general.³ Of course EU institutions retain responsibility for the application of law, especially the evaluation of risks, and REACH so provides. The remaining questions are whether clarification is needed about whether any remaining uncertainties do or do not automatically result in denial of the authorisation or whether such automatic denial might be a legitimate specification of the level of protection. In this connection it must be underlined that under REACH the risk need only be adequately rather than absolutely controlled and that in the absence of proof of such control, balancing occurs to the extent that the socio-economic benefits can over-

ride the remaining uncertainties. With these safeguards, the burden of proof imposed by the regulation appears reasonable and by no means excessive.

WTO Issues

Finally, the WTO implications of REACH are a possible source of concern, as the early intervention by the US government demonstrates. The introduction of the registration and authorisation procedure for existing substances is not a sanitary or phytosanitary measure in the meaning of the SPS Agreement but can be challenged as not necessary to protect human health or the environment or as a disguised protectionist measure under article XX lit (b) or (g) and the chapeau of article XX GATT. The first question is whether the possible risk to human health presented by existing substances is sufficient to subject foreign producers to the registration requirement with the obligations associated with it or whether there are less burdensome alternatives. The precautionary principle as such is not recognised under GATT. However, recent practice of WTO dispute settlement bodies relating to the SPS Agreement and article XX (g) GATT (Hormones case, Shrimp Turtle case, Asbestos case) tends to uphold precautionary action where it is reasonable, considering its contribution to solving a particular problem, the weight of the interest to be protected and the extent of burdens imposed on international trade. Simple data collection, generation and assessment obligations arguably meet this

test although the doubts raised under EU constitutional law are also relevant here. The argument that REACH is a disguised protectionist measure is clearly fallacious. The authorisation procedure for ultra-hazardous substances appears justified in the light of undisputed parallels in the fields of pharmaceuticals and pesticides. Any more extensive obligations are risk-based. In particular, the most burdensome interventions, namely restrictions of substances and the denial of an authorisation, must be based on a scientifically valid risk assessment. This ensures conformity with GATT.

REACH also establishes an obligation of registration for substances in products classified as hazardous, provided that the substance as such is not registered and is intended under normal or foreseeable circumstances to enter into the environment during use. This obligation clearly aims at foreign producers and importers of foreign finished products. While this constitutes unequal treatment under article III GATT, it only results in the closing of gaps of protection and a limited equalisation of requirements since like domestic products can only be sold and used on the market where the substances they contain have been registered. Therefore, article XX GATT arguably does not prohibit this kind of regulation.

1) Toolex Alpha, case C-473/98, 11.7.2000, 2000 ECR I-5681 Nos. 40-45 (precautionary principle)

2) Pfizer, case T-13/99, 11.9.2002, 2002 ECR II-3305 Nos. 143-146, 152, 160-162 (against mere hypothetical risk considerations).

3) Artégodan, case T-74/00, 26.11.2002, 2002 ECR II-4945 Nos. 181-195 (pharmaceuticals).

Achieving Sustainability: The Interplay between Green Chemistry, Regulation and Industry

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Achieving a sustainable society is a huge challenge for all of us. We must reduce consumption of material considerably, make a massive improvement in energy efficiency and reverse environmental pollution. The chemical industry is at the core of many of these issues—on the negative side, it is a major user of resources and energy, and many of its products cause persistent pollution of the environment. On the positive side, it is chemistry that will create many of the solutions, for example through assisting the development of more efficient renewable energy sources (e.g. solar cells), developing closed-loops for resources and inventing safer products.

This paper focuses on the question—How can society ensure that the chemical industry focuses on being part of the solution to the sustainability challenge, rather than a major element of the problem?—examining in particular the role of regulation, innovation, green chemistry, government and the industry itself.

Innovation as a Route to Sustainability

It is clear that society needs to develop new ways of doing things, and new products to do them with—this will require considerable innovation. It is also clear that European industry will need to be innovative in order to be competitive. There are many lower-cost producers of chemicals across the world, particularly in Asia. It is not possible for European industry to compete on labour costs with such coun-

tries—they must have some other ‘added value’ in their products. This is what innovation can provide.

Innovation is frequently mentioned in the debate over European regulation, but it is less often examined in depth. Innovation is not just about ‘inventing new things’. Innovation, and what drives it, is made up a number of elements.

Innovation itself has two components [1]:

The ‘rate’ of innovation is the quantity of innovations produced over a given period of time. This tends to be fairly easy to measure, for example, by the number of new patents, new chemicals or new products on the market.

The ‘direction’ of innovation is related to the quality of innovation produced. This is much more difficult to measure, as it depends on judgment and values. In these cases, the key question is whether the new innovation increases or reduces sustainability.

Sometimes this is easy to determine: a new energy-intensive or waste-intensive product, for example, is unlikely to be increasing sustainability.

Other examples are more complex—for instance, the replacement of ozone-depleting CFC refrigerants with HFC greenhouse gases.

Innovation is not evenly distributed—one company might be very innovative, whilst another might be more dependent on existing products. Some sectors will have more innovative companies than others; some countries will have more innovative companies than others.

Innovation theory states that three factors are required for innovation to happen [2]:

- **Willingness:** Is the company aware that other solutions exist? Are they prepared to change what they do, or are they happier continuing the way they always have done?

- **Opportunity:** A demand for a new solution exists, due to new regulatory requirements, pressure from customers, workers or other stakeholders or opportunities to reduce costs. At the same time, a technology must exist or be able to be developed to fulfil this demand.

- **Capacity:** The company has access to sources of knowledge about new techniques, and the skills necessary to take these new techniques and implement them effectively.

These three factors are discussed—with particular reference to REACH—in the sections that follow.

Willingness to Innovate

Maximising the willingness for innovation within industry is a complex challenge. For example, a trade association or a government can have a role in persuading companies that the status quo is not an option (e.g. due to competition from China).

In London, UK, a government-funded campaign called ‘London Innovation’ has been launched to encourage London companies to be more innovative. Through adverts on the London Underground, workshops, and information supply, they aim to encourage businesses to think about innovation [3]: “The bottom line is this: If you don’t innovate today, your business may not be around tomorrow.”

In addition, a substantial new regulation such as REACH has the power to force companies to change what they are doing. A clear indication that change is essential to comply with legislation is usually enough to convince all layers of a company that change is needed. The ‘London Innovation’ website makes a similar point in one of its 10 top tips for innovation: “7: Let threats to your business drive your innovation. Convert fear of a competitive product or service into an idea for a new, superior product or service of your own.”

Opportunity to Innovate

As for opportunity, there are a number of ways in which a regulation such as REACH can assist in generating positive innovation, for example through:

- **Discouraging or phasing out less sustainable technologies,** as REACH does through various elements that discourage (or in some cases phase out) more hazardous chemicals. For example, any chemicals that meet the criteria for requiring authorisation will effectively be on a ‘black list’, and may in the future be subject to the authorisation process itself, which will create extra costs for those who wish to continue using them. This will create a market demand for safer substitutes.

- **Making it easier to create new technologies.** REACH does this through increasing the threshold for registering a new chemical from a production volume of 10 kg/year in the current system to 1 tonne/year. REACH also provides exemptions for production and process orientated research and development.

Although regulation creates a demand for change, this demand can only be fulfilled if alternatives can be found. This is a key role of green chemistry, discovering innovative new ways of doing things, creating the safer products that REACH will encourage. Green chemistry is, however, a relatively young movement, and it has not yet penetrated widely into chemical research in either academia or industry. It is clear that a range of measures are necessary in order to promote it and its application, including increasing the funding available for green chemistry research, developing green chemistry education for new chemists in universities, and promotion of and education on green chemistry for both industry and academia.

Capacity to Innovate

Finally, capacity is a significant challenge for many companies, especially smaller ones. Ensuring an educated workforce and encouraging companies to train their workers will assist in generating more capacity. Many businesses will, however, have problems obtaining the necessary in-house expertise.

Some businesses will hire consultants to provide expertise, but this will be too expensive for many. In Massachusetts, USA, the Toxics Use Reduction Institute (TURI) supports businesses in discovering and testing alternative substances [4]. TURI is funded through a fee on the companies using the most hazardous chemicals and is thus able to give free or low-cost advice and training.

This approach could provide a model for similar approaches within Europe. For example, TURI-like assistance could be funded

through development aid for a region. Such technical assistance will often be required to provide a bridge between green chemistry research and practical implementation within companies. It should also provide direct benefits in creating competitive companies that are leading, not following, market changes.

Innovation, Regulatory Cost and the Impact on Competitiveness

Regulation is often portrayed as an enemy of competitiveness. This portrayal depends on the 'common sense' approach that if industry has to conform with lots of regulations they are less likely to spend time innovating and that they are likely to move their plants away from regions with more regulations.

However, these assumptions have been challenged by many of those who have studied the issue. For example, the Harvard economist Michael Porter suggested an alternative relationship in 1995 [5]: "Companies can improve resource productivity by producing existing products more efficiently or by making products that are more valuable to customers—products customers are willing to pay more for. Increasingly, the nations and companies that are most competitive are not those with access to the lowest-cost inputs but those that employ the most advanced technology and methods in using their inputs.

Environmental progress demands that companies innovate to raise resource productivity—and that is precisely what the new challenges of global competition demand. A truly competitive industry is more likely to take up a new standard as a challenge and respond to it with innovation. An uncompetitive industry, on the other hand, may not be oriented toward innovation and thus may be tempted to fight all regulation."

In reality, competitiveness involves many different factors, including issues as diverse as levels of education, level of corruption and macro-economic environment. The World Economic Forum publishes an annual list, which ranks the Growth Competitiveness Index of many of the world's nations. The top seven nations on this list in the 2004 study were as follows [6]: Finland > US > Sweden > Taiwan > Denmark > Norway = Singapore.

These ratings are particularly interesting as four of the top seven countries are bound

by EU product regulations—Finland, Sweden and Denmark are EU Member States, and Norway is a member of the European Economic Area and must apply all EU internal market legislation (including REACH). It is also interesting to note that these are Nordic countries—a region which has a tradition of strong environmental regulation and social support.

China is the country most often mentioned in the competitiveness debate in Europe. There is undoubtedly plenty of cheap labour available in China, but overall competitiveness relates to much more than labour costs, and the World Economic Forum places China at number 46.

Clearly, EU businesses must compete with those in China—but they will not do it through cutting wages or through a race to the bottom on regulation. As Digby Jones, the Director General of the UK business lobby group the Confederation of British Industry put it [7]: "We've got to drive toward getting everyone's skill levels up [...]. If you're trying to compete only on price, you will fail, and you will go bust and China will have your lunch. If you move into innovation, and high value-added [products], you have nothing to worry about. Britain has got a tremendous future."

Costs of REACH and Impact on Innovation

Following on from the general issue of regulation and competitiveness, one of the arguments frequently used by industry is that the cost of complying with REACH will take resources away from research and development. If true, this would mean that REACH would reduce innovation, rather than increase it, as has been argued above.

Leaving aside the issue of whether research and development funds are really reduced as a result of regulatory compliance costs (rather than the funding coming from price changes, reduced profit etc), REACH is only likely to have such an impact if costs of compliance are significantly higher than normal variability in costs.

A few reports (for example, the studies by Arthur D. Little in Germany [8] and by Mercer Consulting in France [9]) have claimed that REACH costs will be very high. However, these studies have been widely criticized by economists [10] [11] [1] [12], though they have been remarkably persistent in the political debate.

Other economic studies have found costs similar to those calculated by the European Commission [13] and have then compared

them with other variable business costs, concluding that the changes in costs as a result of REACH will not be significant [12]: “Price changes of the same magnitude as the costs of REACH are commonplace in industry, and do not prevent profitable operation. The spot price of crude oil varies by a greater percentage in almost every week, while the EU-15 price index for all intermediate manufactured goods varies by a greater percentage in almost every month.”

Such research suggests that the overall cost impact of REACH will not be significant. Therefore its main financial impact is likely to be on those chemicals with the worst properties, the use of which will be discouraged by various REACH mechanisms including authorisation. Such an impact is desirable in order to create the motivation for companies to innovate towards safer chemicals.

New Opportunities for Innovation Created by Supply Chain Restructuring Due to REACH

A major regulatory proposal such as REACH has the potential to modify supply chains and thereby create new opportunities for companies to innovate and develop value-added products. Companies that respond to these opportunities should benefit from REACH; companies that are not willing to innovate may suffer negative effects.

REACH promotes closer links between producers and users, as the producer will usually need to define safe use for downstream users. Close contact between producers and customers has been shown to promote innovation [1]. REACH also changes the distribution of costs in the value chain because it increases producer responsibility:

Chemical producers and importers will need to do more hazard and risk assessment of their chemicals, but they should have the expertise to do this.

Downstream users will be able to reduce their safety assessment costs, freeing them to focus on the service provided by chemicals, which is their area of speciality.

These changes will create new opportunities for innovation in the supply chain, as the players adjust their roles to take advantage of the new system. For example:

- Chemical producers and importers will be encouraged to create and assess new exposure scenarios, promoting new uses of their products.

- Formulators and distributors will have new opportunities to produce exposure scenarios to support their own customers, for example in sectoral or niche markets.

- Downstream users will be able to innovate with uses of chemicals, knowing that the uses will be safe if they follow exposure scenarios in the Chemical Safety Reports.

Conclusions

The world faces a massive challenge in achieving a more sustainable future, and it is clear that Europe, as a major developed economy with a commitment to sustainability, has a responsibility for leading this transformation. However, this role as a leader should benefit rather than burden European companies, as they will be at the leading edge of the move to sustainability, as first movers into more sustainable technologies.

Europe is not going to compete in the global economy on the basis of low labour costs; it must instead provide more sustainable products. To encourage this transformation, Europe needs good, sustainability-orientated regulation, such as REACH. REACH will assist innovation through a combination of focussed deregulation, a re-ordering of the value chain and promotion of safer chemicals.

However, to maximise the speed of innovation towards improved products, government assistance could be provided in two key areas:

- Research and education in green chemistry.

- Provision of technical support to assist companies in moving towards safer alternatives. This support will be particularly useful to SMEs and should also generate other benefits, such as reduced waste-handling costs and improved worker health.

REACH also has a role to play in improving the global sustainability of the chemical industry. Clearly, REACH will encourage (and to some extent force) European companies to produce safer, more sustainable products. Outside Europe, companies that wish to export products to Europe will need to consider how they meet the REACH challenge. Even companies trading exclusively outside the EU will be affected, as they will have to compete with products produced by companies from Europe or active in Europe.

In addition, REACH is stimulating a debate on chemicals policy outside Europe, for example in the USA, where a recent

stakeholder conference on *Framing a Future Chemicals Policy* was heavily influenced by REACH [14].

Sustainability is not easy. Creating more efficient methods for providing services to society is part of the solution, but not the whole solution. Sustainable consumption of resources will not be achieved if more efficient production methods lead to higher rates of use, resulting in higher overall consumption. However, dealing with the issue of sustainable consumption requires a lot more than just the creation of a new chemicals policy...

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The Case for Sustainable Chemistry

PAPERS

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The world being 'globalised' today is looking for a new model of development, one able to combine economic efficiency, human solidarity, and ecological prudence. These three indissociable components would make it noticeably different from the model followed until now, which has very rarely combined any two of these components, never all three. It has nonetheless led one fifth of humanity to a level of prosperity and longevity never before known. Today, however, its consequences—whether proven, presaged, or feared—on the maintenance of conditions appropriate to human life, biodiversity and a well-regulated planet (that is, climatic changes, exhaustion of natural resources, and pollution) create justified fears for the future. After centuries of deprivation, another quarter of humanity (the Chinese and, tomorrow, the Indians) is moving up to the First World's table to share the fruits of progress. This will make the current model of development impossible.

Preserving the already compromised natural balance of the planet we share imposes solidarity between us even as we strive for the economic growth essential to all nations. The failure of this solidarity must engender unprecedented conflicts. This solidarity, one of the three indissociable components of sustainable development, calls for a break with the current model. Chemistry is one pillar of this model. Coloring agents, manufactured textiles (of initially natural or synthetic materials), chemical fertilisers, plastics, paints, pharmaceuticals for humans and animals, pest control products, new materials—the history of industrialisation and development could be

written with its milestones marked as chemical innovations.

Despite or perhaps because of these close associations, this rejection of the current model includes a refusal of the chemistry that has served it well. This rejection is spread throughout Europe unequally but fairly strongly and obeys an apparent logic that masks a major strategic mistake. We must go beyond appearances and show how chemistry, one of the most effective factors in the model already consigned to yesterday, will be a decisive factor in the success of the sustainable development under construction.

Beyond the European regulation of chemical products—REACH, we will then understand that Europe should have other and larger ambitions for chemistry: instead of steeling itself at heavy cost to try to restore its tarnished image in this outdated model, European chemistry, scientists and manufacturers alike, should, on the contrary, affirmatively and with exemplary transparency set forth how it intends to work for and serve the sustainable development we hope for.

Persistent Reserves about the Role of Chemistry

The rejection of chemistry is essentially related to the perception that it is contrary to nature. It mastered nature's alphabet (atoms) and learnt to talk its language (synthesis) the better to dominate it. Philosophers of science have spent much time studying this opposition

between natural and artificial, the difficulty in understanding that two products with different origins—one natural, one manufactured—can be identical [1].

Fundamentally, chemistry is associated with the idea of transgression, of sin. This was true long ago for alchemy. The alchemist sought to control a divine attribute: time. The transmutation of base metals into gold was only an acceleration of ordinary phenomena in the nature God created. The alchemist could not succeed without asceticism to bring him close to the divine Creator. Gold, the elixir of long life, is incorruptibility, the purity of the being that resists time. The Faustian pact with the Devil is never far away from the desire to imitate God, and there, to some extent, modern chemistry meets up with alchemical philosophy: it captures nature's language and draws considerable power from its efficacy.

One noteworthy example is found in the circumstances surrounding the synthesis of ammonia, which opened up access to nitrogen fertilizers at the beginning of the last century. At that time the consensus among specialists was that the rapid increase of the world population would, because of a shortage of cereal grains, lead inevitably to famines, which, playing their 'usual' regulatory role, would be more massive than ever. That is, the supply of guano from Chile, the principal source of nitrogen for crops, would soon be exhausted. It had taken many centuries for the excrement and cadavers of these sea birds to constitute this precious natural resource, and it was being spent much faster than it could be rebuilt.

Fritz Haber's synthesis of ammonia released humanity from this worry. He was a benefactor of humanity and the entire world praised the man who 'made bread with air.' Like the alchemist, he mastered time by making products similar to natural ones but much faster than nature could. He also mastered space. Nature concentrated these products in inconvenient locations. Thanks to Haber, we can produce them where we want them. He won the Nobel Prize in 1918.¹

By that time, however, he had already designed and enthusiastically supervised the use of chemical weapons (chlorine, phosgene, and mustard gas); and in 1919, he was on an allied list of war criminals for this role. He sincerely sought to spare lives in using these new weapons (which the enemy did not have) to reduce the duration of the war. After using chemistry to prevent famines and starvation, he sought to use it to hasten the end of a war that had bogged down.

This story illustrates the dualism of science and technology, which can serve both good and evil. This is true for chemistry as for any instrument in human hands—from a machete to nuclear energy. The choice of good or evil depends on the human, not the tool.

But chemistry is particular in that it uses nature's own language. Its products, whether identical or similar to or different from those of nature, interfere with nature's own products and affect the balance that holds them together and that we too often ignore. This is all the more the case in that their efficiency, which we recognized as a factor in their development, leads to their production in quantity, by tens or hundreds of millions of tons each year. The chemist, having mastered the language of creation, sometimes forgets his status as a creation and yields to the temptation of equating himself with the Creator. He does not recognize the damage his creativity can cause the creatures of this earth—himself included. Once again, imitation of the 'Creator' can open the door to the Devil.

The Limits of Efficiency

The combination of efficacy and efficiency was the most valued attribute in the old model. It remains necessary in the emerging model but will not be alone an adequate criterion of sustainable development.

In 1996, at the Fourth International Chemical Industry Forum [2], I reckoned that chemistry would soon follow in all its applications the pathway it had already taken in health. Jean Bernard considers that effective medicine began in 1936 with the sulphonamides, the first therapeutic weapons capable of limiting the massive human losses caused by infectious diseases. The next quarter-century saw the discovery of anti-infectious, antiparasitic, and antibiotic agents whose efficacy revolutionized therapeutics: the diseases that slaughtered humanity without any age distinctions finally found treatments. When survival is at stake, efficacy takes precedence. Thus during this period, efficacy was naturally the predominant criterion for evaluating new treatment agents.

Then in 1962 came thalidomide. This hypnotic drug, prescribed against nausea in pregnant women, induced the birth of thousands of infants with phocomelia.² Regulatory tests until then did not mandate a sufficient assessment of teratogenicity or testing with an optically pure isomer (thalidomide was a racemic drug and the teratogenic effect came from the 'ineffective' isomer).³

Since this catastrophe, tolerance is considered as important as efficacy, but it is, we have discovered, much more difficult to assess. Efficacy comes—very schematically—from the drug's interaction with its biological target. Tolerance takes into account all the ways the drug affects and interferes with the life system to which the target belongs and its environment.

Tolerance then is the concept of environmental impact, in all its complexity. This approach has profoundly modified the process of drug research and development, considerably increased development costs and substantially restructured the international pharmaceutical industry.

Efficacy is now an outdated concept that has been replaced by therapeutic benefit, which assesses the relation between efficacy against the target disease and treatment's harmful effects. Therapeutic benefit is the primary criterion for marketing approval and also determines in part the drug's price. I continue to believe that other applications of chemistry will follow the same course.

When everything had to be rebuilt after the second world war, unprecedented prosperity and growth followed (*les Trente Glorieuses*), and they were based on efficiency. At that time, we thought little of what economic theory has come to call negative externalities. These are the harmful consequences of an activity, the disadvantages and costs that are borne by someone other than those who profit from the activity. Strong growth and full employment led everyone to feel they benefited from industrial activities. After the years of deprivation, not much value was attributed to the purity of river water or of air, to silence or to the beauty of a place. In any case, they were not measured. In 1976, the accidental release of dioxins at Seveso was, it seems to me, for industrial chemistry the equivalent of what thalidomide was for the pharmaceutical industry. Except for one small girl whose face was branded by chloracne, there were no victims and so it was much less dramatic. There was only the enormous cost of crude soil remediation, compensation to nearby residents—in brief, a sudden consciousness of the value of the environment and industrial responsibility for negative externalities.

From then on, regulations multiplied. Undeniably they improved the security of industrial installations considerably and created within large industrial groups a culture of safety and environmental protection. Today, industrial chemistry is among the

safest industries. The costs of these regulations have weighed down the profitability of this industry. Unlikely pharmaceuticals, chemistry rarely sells its products according to the value of their use but rather at a very competitive market price that is closely linked to production costs. Bringing the oldest chemical sites, that is, European sites, into compliance has been a heavy burden that has disadvantaged European chemistry relative to its competition.

New Chemistry for Europe

The scale of the REACH regulations under discussion is unprecedented. The question we have a right to ask is if whether this impressive regulatory corpus will serve the old or the new model of development, whether it represents one of the last series of constraints imposed on a dying model of chemistry or a lever to move a new European chemistry into position as a decisive factor in sustainable development. In the first hypothesis, this regulation applies only to the chemical industry within the European Union and risks precipitating its decline. In the second, however, it should support the strategy of innovation that Europe needs.

The probability of decline must not be neglected. Europe, the cradle of chemistry, has seen its portion of the international market dwindle from 32% quite recently to 28% today, and some forecasts reduce it to 16% in the next ten years. Halving this market share in fifteen years will have dramatic consequences in terms of strategy and jobs. This decline is not, however, inevitable if we frame REACH according to what could, above all, determine the future of Europe: innovation must become an obsession for Europeans. The regulation must serve this obsession.

The history of chemistry proves that it can adapt to this evolution, on condition that the markets' responses support it economically. We have seen how swiftly tetraethyl lead was abandoned (for ethers) in gasoline, and fluorocarbons in refrigeration. The evolution of chemistry towards specific functionalities is a move in the right direction. While chemical products were mass-produced to serve multiple uses, the products of the new chemistry must become the basis for functionalities specific to them.

Indeed, the general evolution of chemistry is moving in the right direction. Some of these new directions include: soft chemistry, capable of what the chemistry of fire

produced before only at 'infernal' temperature or pressure conditions; the alliance of mineral and organic chemistry in 'designing' products with preconceived properties; the alliance of biocatalysis and traditional chemical processes; the conception of biodegradable products that reflect a new integration of time into the concept of the chemical product (and this is also a better integration to nature).

The science of chemistry will also lead us to a better understanding of the extraordinarily complex systems that maintain life on our planet.

By placing this new chemistry at the service of all the other branches of activities, with an obsession for innovation, Europe will have some chance of implementing its so-called Lisbon strategy. Energy, transportation, homes, health, leisure, textiles, agriculture, telecommunications—there is no activity whose future does not depend on our ability to blow up the technological barriers that cannot disappear without help from this new chemistry.

My urgent wish is for us to witness the development of a European awareness of the need to place the science and technologies of chemistry at the heart of a European strategy of research and innovation.

- 1) The prize was not presented until 1920.
- 2) Developmental anomaly during pregnancy causing atrophy of the limbs such that the individual's hands and feet stem directly on the trunk.
- 3) Some chemical molecules are mirror images, with the same angle plan of light polarization but in opposite directions. These are called isomers. A mixture of the equal parts of two isomers is called racemic, as opposed to an optically pure isomer.

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Green Chemistry for Sustainable Development

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The principal role of chemistry is to research and design substances to improve the living conditions of the world's population. Chemistry, unloved stepchild of the natural sciences, strives to copy nature and goes still further, creating objects and products that do not exist, using methods that nature cannot. Because people have difficulty accepting this transgression and are afraid of its consequences, chemical products are considered dangerous.

At the beginning of this new century, chemistry must respond to three major societal needs:

- furnish new products and improve existing ones
- contribute substantially to economic activity (the chemical industry in France employs 240 000 persons, around 1 million when related jobs are included; annual sales are 83 billion euros)
- preserve the environment.

The latter factor has grown and today it must be placed at the top of the list of chemists' concerns. Research and production are thus being directed towards clean substances and processes. This new strategy is considered a source of innovations that help companies grow rather than as a possible drain on their balance sheet.

Governments have reacted differently to this situation:

- The United States is promoting the concept of 'Responsible Care' and companies participate in voluntary actions to limit the

risks or disadvantages associated with the preparation or use of chemical products.

- Europe is pursuing sustainable development and has suggested an application of the precautionary principle that will impose on industry the constraining rules set forth in the proposed REACH regulation. These rules apply to the preparation and importation of chemical products and vary in their details as a function of quantity.

The chemical industry is generally favourable to this new European policy. They have nonetheless proposed modifications to make REACH efficient and practicable for all.

Approaches such as REACH move towards a radical change in how people think and oblige its participants to evolve towards a novel system of research, innovation and development. It goes beyond the current trend of 'eco-efficiency', which aims at controlling pollution by such palliative methods as recycling with selective sorting and enters the era of 'ecodesign', where every new product must be designed, even before its manufacture, as a function of its life cycle and end-of-life fate.

Green or Sustainable Chemistry

The concept of sustainable development was defined in 1987 at the United Nations, based on the principles of the Swedish movement Natural Step. To respond as effectively as possible to the concern for it, green—or sustainable—chemistry appeared at the begin-

ning of the 1990s, when it was included in the US Pollution Prevention Act, a statute that called on the US Environmental Protection Agency to establish and administer a source reduction program. The generally accepted definition is the following: “green chemistry is the design of chemical products and processes that reduce or eliminate the use and generation of hazardous substances” (EPA & ACS, Green Chemistry Institute).

The scope of action of this concept is broad and applies to all the sectors where chemistry plays any role. For example:

- transportation: the production of ‘clean’ fuel and the development of novel materials that reduce vehicles’ weight
- medicine, where we hope to design and manufacture not only new drugs but also biomaterials and prostheses that will remain viable in the body for long periods
- textiles, where new fibers will be designed from biodegradable materials

- agriculture, through the use of pesticides and fertilisers that protect farmers’ health and the environment.

Principles of Green Chemistry

In practice, green chemistry is defined by the application of twelve principles, which can be classified into four research themes:

- ❶ design clean products that use biomass resources when possible
- ❷ imagine clean methods inspired by biomimetic processes or biotechnologies
- ❸ reduce energy expenses by using biomass resources and biotechnologies
- ❹ improve safety through effective analytic monitoring.

These four research themes highlight the use of agricultural resources (‘plants as plants’) and industrial biotechnology processes, but sustainable (or green) chemistry is not limited to this one recommendation. The other

12 Principles of Green Chemistry

1 Prevent waste: Design chemical syntheses to prevent waste, leaving no waste to treat or clean up.

2 Design safer chemicals and products: Design chemical products to be fully effective, yet have little or no toxicity.

3 Design less hazardous chemical syntheses: Design syntheses to use and generate substances with little or no toxicity to humans and the environment.

4 Use renewable feedstocks: Use raw materials and feedstocks that are renewable rather than depleting. Renewable feedstocks are often made from agricultural products or are the wastes of other processes; depleting feedstocks are made from fossil fuels (petroleum, natural gas, or coal) or are mined.

5 Use catalysts, not stoichiometric reagents: Minimize waste by using catalytic reactions. Catalysts are used in small amounts and can carry out a single reaction many times. They are preferable to stoichiometric reagents, which are used in excess and work only once.

6 Avoid chemical derivatives: Avoid using blocking or protecting groups or any temporary modifications if possible. Derivatives use additional reagents and generate waste.

7 Maximize atom economy: Design syntheses so that the final product contains the maximum proportion of the starting materials. There should be few, if any, wasted atoms.

8 Use safer solvents and reaction conditions: Avoid using solvents, separation agents, or other auxiliary chemicals. If these chemicals are necessary, use innocuous chemicals.

9 Increase energy efficiency: Run chemical reactions at ambient temperature and pressure whenever possible.

10 Design chemicals and products to degrade after use: Design chemical products to break down to innocuous substances after use so that they do not accumulate in the environment.

11 Analyze in real time to prevent pollution: Include in-process real-time monitoring and control during syntheses to minimize or eliminate the formation of byproducts.

12 Minimize the potential for accidents: Design chemicals and their forms (solid, liquid, or gas) to minimize the potential for chemical accidents including explosions, fires, and releases to the environment.

principles also modify the ways that chemists and chemical companies think and act. These changes presuppose a strong commitment by them, an ethic that they must assimilate from their entry into our discipline. Education is therefore an essential component of this strategy. Young people rank environmental problems as extremely important: greening chemistry will undoubtedly be attractive to them, because the challenges are intellectually stimulating and the stakes for sustainable development enormous.

The chemical industry has already adopted some of the recommendations of green chemistry. In a perspective of innovations (inevitable in an international economy) and environmental protection, this multi-faceted strategy should become the rule.

European and French Initiatives

In January 2004 the European Union launched an Action Plan for environmental technologies and then created a technology platform (initiative) for sustainable chemistry, presented in July 2004 by the European Research Commissioner.

This platform covers four domains:

- ① industrial (or white) biotechnologies
- ② materials technologies, especially nanotechnologies
- ③ reaction and process design
- ④ new innovation and applications that develop green chemistry in the areas of health, safety, environment, education, training and research-industry collaboration.

The 7th European Research and Development Framework Programme (FP7) included the technology platforms among its instruments so that the initiative for sustainable chemistry is assured of continuity. Calls for proposals for the FP6 also planned financial support for this platform's activities. Several research teams in France are working in different fields in this domain, but without any coordination. Similarly, several chemical companies have followed this orientation at least in part.

At the institutional level sustainable chemistry is supported by different decision levels:

- the current chemistry report by the Ministry of Research sets sustainable chemistry as one of its three priorities, stressing its role in industrial biotechnology, catalysis and analysis
- the Ministry of Industry's strategic high committee for the future of the chemical

industry by 2015 chose sustainable chemistry as one of its recommendations in the domain of Research–Innovation

- finally, the French Federation of Chemists, which includes three French learned societies—the French Chemistry Society, the Industrial Chemistry Society and the French Society of Process Engineering—have launched a large multiyear program of information about and training in green chemistry.

Increasingly Larger International Initiatives

It is time for the European Union as a whole and France in particular to recognise the enormous stakes of the commitments of industrial and research chemists in this new form of chemistry. From 1983 to 2001, 3235 of 10 000 American patents mentioned sustainable chemistry. 65% of these patents came from the United States, but only 24% from Europe (8% from Japan)!

Scientific publications also cover this field; the English Royal Society of Chemistry has published a specialist journal entitled *Green Chemistry* for the past seven years, while several more general scientific journals (for example *Science*) devote special sections or special issues to green chemistry.

Several universities throughout the world have added programmes in green chemistry to their curricula. Accordingly, in the United States, the Green Chemistry Institute contributes within the American Chemical Society to the pedagogical dissemination of the concept of green chemistry, while in the United Kingdom, Japan, Italy and Australia, specialised centers offer training on this subject.

Annual public investment in Research and Development is approximately 100 million US dollars in the US and approximately the same sum in Japan. Although it is hard to compare these figures with European or French contributions, which until now have not distinguished support for green chemistry from other support for environmental chemistry, we can nonetheless assume that the US and Japan spend considerably more than either France or even the European Union in this area.

The US Presidential Green Chemistry Challenge Award Program, which has just celebrated its tenth anniversary, awards prizes each year to the best industrial or academic work. This award functions as an eloquent measure of industrial efforts.

We note several examples of projects underway in US industry:

- Du Pont de Nemours is spending 275 million dollars to develop polymer synthesis in supercritical CO₂ (non-polluting reaction medium).

- Dow's Midland site made a single investment in green chemistry of 3.1 million dollars, which enabled it to save 5.4 million dollars a year and reduce the volume of 26 toxic emissions by 43%.

- 3 M reduced its hazardous waste emissions by 800 000 tons in 25 years, and by switching to safer alternatives to the solvents used until then, they saved approximately 827 million dollars.

To support these efforts, the federal government accorded substantial subsidies to companies taking this route in 2004. Accordingly, Dow Chemical received 10 million dollars to study plant science, harvest processes, materials treatments and the development of interesting applications. Similarly, Rohm and Haas obtained an allocation of 2.75 million dollars.

Is Biotechnology the Future of Chemistry?

The four preferred research themes of green chemistry show the important role in its strategy played by biotechnologies and the exploitation of raw biomass materials, whether natural biomass or agricultural products or their waste.

Only a small proportion of biomass is used today (less than 10%), although given the approaching exhaustion/depletion of oil reserves, it might be considered an important source of raw materials.

Moreover the processes used in biotechnologies are generally more protective of the environment than those of standard industrial chemistry. Reactions take place in mild temperature and pressure conditions, and reaction media are generally aqueous, thereby eliminating the sources of pollution associated with solvent use.

A final important point is the need for natural catalytic processes that use extremely efficient and selective catalysts—enzymes, which are already used, for example, in detergent formulations. Observation of their structure and modes of action stimulates chemists to reproduce them artificially or, at least, to synthesise models capable of fulfilling the same functions. Green chemistry therefore leads scientists to imitate nature not only in its products, but also in its tech-

niques. Finally, the combination of processes from biotechnology and standard chemistry may be expressed in the performance of syntheses effectuated in several stages to take advantage of their complementarity.

Targets of Industrial Biotechnology

Industrial biotechnology can play a role in all areas of the chemical industry:

- ① Basic chemistry, with, for example, the preparation of biofuels:

- ethanol, by fermentation (in 2001, 250 000 hl/year in France, but 40 million hl/year in the United States.)

- biodiesel oil, from plant or animal oils. In 2004, in the United States, production reached 80 million gallons, and demand should reach 125 million gallons in the years to come.

- ② Specialty chemistry, where we find both natural products (vitamins B2, B9...) and raw materials to prepare polymers (acrylamide, lactic acid), biopolymers (Rhodia's xanthan gum) and biopesticides.

- ③ Fine chemistry, where biotechnologies have become essential in pharmaceuticals.

But all this represents only a small proportion of the potential of applied biotechnologies in chemistry: more than 300 products are thus accessible. At the beginning of this century, the United States set as objectives for the year 2020 that biotechnologies would meet 25% of its requirements in organic chemical products and 10% of its fuel requirements and that in the long run, they would account for more than 90% of all chemical products and 50% of energy needs.

Position of Europe and France

Europe is far behind the United States. It is not a question of skills—from 1994 through 1999 there were 349 000 European publications compared with 345 000 in the United States—nor is it associated with the number of biotechnology companies—1879 in the European Union and 1455 in the United States.

This delay is reflected by its economic performance: sales in Europe are one-quarter of those in the United States, and many fewer patents are issued (in 2000 the percentage of patent applications at the European patent office was 9% for the United States and only 3.8% for the EU).

In France approximately 250 companies are working in this area. Their primary objective is the preparation of therapeutic products.

In the US, 324 biotechnology companies are publicly traded, compared with only 106 in Europe—48 of them in Great Britain and only 4 in France. In 2002, of 23 leading companies worldwide, only six were European: none was French!

Why have we not gone further, why have neither researchers nor industry explored all the possibilities open to them?

The first explanation is economic: as long as the price of oil allows (and it will need to climb very high for that to stop!) competition will always be unfavourable for biotechnology products. Moreover the chemical industry is responsible for only 7% of the consumption of petroleum and its increasing scarcity is therefore felt only to a minor extent. The use of coal (at least three centuries of reserves!) for which we have had adequate technologies since the beginning of the 20th century complicates the problem further. Moreover in this domain, company costs for research and development are already high, while revenues, at the beginning, are limited. Companies rely on risk capital, which places the United States and Canada at the head of the list, while risk capital has only begun to develop in France.

Risk Capital for Biotechnology
2001 (% of GNP)

Canada	0.045
United States	0.035
Belgium	0.025
Germany	0.025
Denmark	0.022
France	0.005

The second reason is related to the quality of consumer products: chemical industries have optimised the properties, especially the stability, of petrochemical products. So far, biotechnology products do not generally have comparable properties.

Cultural and training issues also play a role: it is here that the application of the principles of green chemistry should enable positive action for the environment.

The new French research agency plans to spend 350 million euros in 2005 for the general research budget, aiming for a growth that will allow a budget of 10 billion euros through 2010 (financed by privatisation). Priority will

go to the life sciences, which includes biotechnology. We can reasonably hope that these funds will be significantly greater than the 5 million euros spent in 2004 by the National Science Fund on design and sustainable development, only a small part of which went to green chemistry.

Conclusion

Application of the principles of green chemistry is accompanied in many cases by a new way of thinking. These principles must be translated into a new source of innovation, in synthetic and analytic chemistry as well as in process engineering. There is no doubt that it will also facilitate popular acceptance of chemistry and can lead to better industrial competitiveness.

University professors must include this concept and its principles in their curricula; this topic should have a positive effect on students' motivation and make our discipline more attractive.

Information about green chemistry must also be disseminated to educate the public and shows them the environmental-friendly orientation it implies.

Adoption of this strategy—which is at the same time a philosophy—must be extended finally to all the countries concerned, including (and especially) the emerging countries. This requires international activity on the scale of the environmental problems our generation must solve.

In summary, what green chemistry is about after all is compliance with the ethical code of the chemist, as expressed by the American Chemical Society: “Chemists have a professional responsibility to serve the public interest and welfare and to further knowledge of science. Chemists should be concerned with the health and welfare of co-workers, consumers and the community... Chemists should understand and anticipate the environmental consequences of their work. Chemists have a responsibility to avoid pollution and to protect the environment”.

1) Definition of green chemistry to be found by the EPA, http://www.epa.gov/greenchemistry/whats_gc.html

or by the American Chemist Society: <http://www.chemistry.org/portal/a/c/s/1/acdisplay.html?DOC=greenchemistryinstitute/index.html>

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Biographies

► **François Guinot** is President of the Académie des technologies. He trained as a chemical engineer (ENSCM) and has doctorates in physical sciences and in economics. As executive director of R & D and Strategy at Rhône Poulenc Santé, he completely renovated its R & D activity—its tools, methods and teams (he directed the development of Taxotère® and Lovenox®). He next became Managing Director of Rhône Poulenc Santé, then President and Managing Director of Rhône Poulenc Chemistry, and then Managing Director of bioMérieux and President of Transgène holding. He is President of the French Society of Industrial Chemistry, and Vice-President of the French Federation of Chemists.

► **Nigel Haigh** was for many years Director of the Institute for European Environmental Policy (IEEP) in London before retiring in 1998. He continues as editor of IEEP's *Manual of Environmental Policy: the EU and Britain*. This is a loose-leaf volume that is updated every six months and which describes all EU environmental legislation—including chemicals—and its impact in Britain. He has

published extensively on many aspects of European environmental policy. He was a founding member of the European Environmental Bureau and was a Vice-President from 1975 to 1979. Currently he is a member of the Management Board of the European Environment Agency, appointed by the European Parliament.

► **Sven Ove Hansson** is a professor and head of the Department of Philosophy and the History of Technology at the Royal Institute of Technology, Stockholm. He is programme manager of the interdisciplinary research programme NewS (New Strategy for risk assessment and management of chemicals). His publications on risk include *Setting the Limit. Occupational Health Standards and the Limits of Science* (Oxford University Press 1998) and numerous articles in international journals. <http://www.infra.kth.se/~soh>

► Professor emeritus at the Université Paul Sabatier (Toulouse 3), **Armand Lattes** is an organic chemist specialising in aqueous reaction systems. His current research applies green chemistry to chemical

decontamination and the environment. He works, in particular, on the development of strategies for destruction of chemical weapons and systems for detecting military toxins. Former chairman of the NATO committee Environment and Earth, he is currently president of the French Chemistry Society and the French Federation of Chemists, member of the Committee of Prevention and Precaution at the Ministry of Ecology and Sustainable Development, of the RITMER (marine pollution) research bureau at the Ministry of Research and of the strategic committee for the future of chemical industry by 2015, at the Ministry of Industry.

► **Richard Macrory** CBE was the first Professor of Environmental Law in the UK. He is currently Professor of Environmental Law at University College London. Prior to this, he was Director of the Environmental Change Unit at the University of Oxford and held a number of positions at Imperial College. Richard Macrory was a member of the Royal Commission on Environmental Pollution from 1992 through 2003 and until recently a board member of the

Environment Agency of England and Wales. He is editor-in-chief of the *Journal of Environmental Law* (Oxford University Press) and legal correspondent for ENDS Report. He is a Vice-President of the National Society for Clean Air. In 2001-2003 he was elected chairman of the Steering Group of the European Environmental Advisory Councils. He has been a Specialist Adviser to the House of Lords Select Committee on European Communities; Specialist Adviser to the House of Commons Environment Committee and a consultant to the Hong Kong Government. He has also produced research and consultancy reports for the European Commission.

► Professor **Ulrich Müller-Herold** is a member of the Department of Environmental Sciences at the Swiss Federal Institute of Technology (ETH) Zürich and leads the Ecological risk prevention research group. He originally trained as a theoretical chemist, and his current scientific activities deal with the scientific foundations of the precautionary principle. In 2005 he published a paper presenting a systematic filter series approach to precautionary regulation of chemicals with respect to global risks (*Environmental Science and Technology* 39, 683-691). At ETH Zürich, he teaches thermodynamics and risk theory for students of environmental science. Professor Müller-Herold is chairman of the board of directors of the journal *GAIA, Ecological Perspectives for Science and Society*.

► Trained as a chemical engineer, **Laurence Musset** worked on general environmental issues at the

French Center for Scientific Research (CNRS) from 1974 to 1988, before moving to the Ministry of the Environment to work on chemicals until 1995. She then became the Head of the Chemical Substances and Preparations Office, in charge of new chemicals, existing substances and biocides for the Ministry. In that role she participated in the negotiations leading to three international conventions on chemicals and in the EU discussions on REACH. Since May 2003, she has been Principal Administrator at OECD, Environment, Health and Safety Division, in charge of harmonization of classification and labelling, new chemicals and risk management.

► Professor **Eckard Rehbinder** teaches Business Law, Environmental Law and Comparative Law at the Law Faculty of the University of Frankfurt. He was Director of the Research Center for Environmental Law (1987-2000) and chaired the German Council of Environmental Advisors (1996-2000). He is also member of a number of national and international environmental policy and law bodies and the author of numerous books and articles on German, European and comparative environmental law, including extensive coverage of toxic substances regulation.

► **Christina Rudén** is a PhD in toxicology (Karolinska Institutet) and a senior researcher at the Department of Philosophy and the History of Technology at the Royal Institute of Technology, Stockholm. She leads the synthesis project of the NewS programme. Her main research area is regulatory toxicology. <http://www.infra.kth.se/~cr/>

► Dr **A. Michael Warhurst** has been working for the Lowell Centre for Sustainable Production, Massachusetts, USA, since January 2005, as project manager of the Chemicals Science and Policy project. His work involves the analysis of how chemicals management methods can contribute to achievement of the goal of sustainable production.

His particular expertise as a biochemist is on REACH, on which he has been working since the EU started reviewing its chemicals regulations in 1998, first as an expert for Friends of the Earth, London, UK, then from 2002 on, as Toxics Senior Programme Officer at the World Wildlife Fund's European Policy Office in Brussels, Belgium. He is a member of the Editorial Board of the journal *Green Chemistry*.

► **Claire Weill** is a physicist who conducted experimental research activities and taught condensed matter physics and statistical physics for 15 years. In 1999 she joined the French task force for climate change. Since 2002 she has directed the programme on uncertainty, precaution and risks.

Programme

IDDDRI Workshop

European Proposal for Chemicals Regulation: REACH and Beyond

*Proposition de règlement européen des produits chimiques :
REACH, enjeux et perspectives*

Maison de la Chimie, 28, rue Saint-Dominique, Paris – June 15/15 juin, 2005

8:30-9:00 RECEPTION AND COFFEE

9:00-9:15 OPENING
Laurence TUBIANA, Director, IDDDRI and **Claire WEILL**, Senior Advisor, IDDDRI, Paris, France

9:15-10:15 **Panel I. Context**

Chair: **Claude HENRY**, Research Director, CNRS, Econometry Laboratory, Ecole Polytechnique, Paris, France

- ▶ History of EU Regulation of Chemicals, **Nigel HAIGH**, Former director, Institute for European Environmental Policy, London, United Kingdom.
- ▶ The OECD Chemicals Programme, **Laurence MUSSET**, Principal Administrator, OECD, Environment, Health and Safety Division, Paris, France
- ▶ Viewpoint of the Royal Commission of Environmental Pollution (RCEP), Prof. **Richard MACRORY**, former Member of the RCEP, University College, London, United Kingdom

10:15-12:00 **Panel II. REACH, Science and Expertise**

Chair: **Claire WEILL**, Senior Advisor, IDDDRI, Paris, France

- ▶ Introduction: **Catherine DAY**, Director General, DG Environment, European Commission, Brussels, Belgium
- ▶ Improving the Scientific Basis for Decisions in the REACH System, Prof. **Sven Ove HANSSON**, Royal Institute of Technology, Stockholm, Sweden
- ▶ REACH in Context: Open Questions, Prof. **Ulrich MÜLLER-HEROLD**, Swiss Federal Institute of Technology, Zurich, Switzerland
- ▶ Discussion introduced by **Mans LÖNNROTH**, MISTRA, former State Secretary, Ministry of Environment, Sweden

12:00-13:30 LUNCH

13:30-14:30

Panel II (continued). REACH, Responsibility and LiabilityChair: **Laurence TUBIANA**, Director, IDDRI, Paris, France

- ▶ Legal Issues of REACH, Prof. **Eckard REHBINDER**, Goethe University, Frankfurt am Main, Germany
- ▶ REACH and Precaution, **Veerle HEYVAERT**, London School of Economics, London, United Kingdom
- ▶ Discussion introduced by **Corinne LEPAGE**, lawyer, former Minister of the Environment, France

14:30-16:30

Panel III. Research, Industry and Sustainable Development: Looking ForwardChair: **Guy OURISSON**, former President, French Academy of Sciences, Paris, France

- ▶ Achieving Sustainability: The Interplay between Green Chemistry, Regulation and Industry, **A. Michael WARHURST**, Lowell Centre for Sustainable Production, Lowell, MA, United States
- ▶ For a Sustainable Chemistry, **François GUINOT**, President, French Academy of Technology; President, French Society for Industrial Chemistry, Paris, France
- ▶ Viewpoint of **Bernard MEUNIER**, President, French National Center of Scientific Research (CNRS), Paris, France
- ▶ Viewpoint of **Colin HUMPHRIS**, Executive Director, European Chemical Industry Council (CEFIC), Brussels, Belgium
- ▶ Discussion introduced by **Linda LANZILLOTTA**, University of Rome, former Secretary general of the Prime Minister's Office, Italy

16:30

Conclusion**Mans LÖNNROTH**, MISTRA, former State Secretary, Ministry of Environment, Sweden

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Iddri was founded in 2001 as a research consortium and became a non-governmental organisation in 2003.

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- Support scientific groups working on sustainable development through the promotion of research and multidisciplinary expertise on new issues in sustainable development.
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