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European Precautionary Practice

Les pratiques européennes de précaution

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Table of contents

Sommaire

Vers une évaluation de la mise en œuvre de la précaution en Europe

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Le débat international sur le principe de précaution – ou encore sur l'approche de précaution, comme certains préfèrent l'appeler – a significativement mûri depuis que ce principe a été évoqué pour la première fois comme un élément du différend sur le bœuf aux hormones à l'Organisation mondiale du commerce (OMC) et, ensuite, dans de nombreux forums internationaux sur le commerce, la santé et l'environnement. Les politiques ne se doutaient alors de rien. Tandis que certains continuent à le considérer comme du protectionnisme déguisé, les éléments constitutifs de la précaution se sont progressivement affinés. Parallèlement, un dialogue productif se construit sur sa mise en œuvre et sur les relations qu'il entretient avec les pratiques alternatives traitant explicitement de l'incertitude. Cette dernière est en effet une conséquence inévitable de décisions politiques qui dépendent de plus en plus d'expertises fournies par les chercheurs scientifiques.

Lorsque le débat sur la précaution a commencé, certains défenseurs du principe de précaution, mais aussi certains de ses contradicteurs, ont supposé que la simple invocation de ce principe constituerait des arguments. Il n'est guère surprenant que cela n'ait pas été le cas. Le principe de précaution était alors profondément enchâssé dans les structures administratives des pays qui l'invoquaient, mais nombre des pratiques associées à sa mise en œuvre n'étaient pas encore clairement précisées. Durant les dernières années, dans un processus constant d'articulation, non seulement le principe lui-même, mais aussi les conditions de son application ont été clarifiés. On doit s'en féliciter. L'atelier organisé par l'Iddri à Paris, en décembre 2002, avait pour but de contribuer à ce processus, en se focalisant sur plusieurs aspects de la précaution.

Les défis de la précaution

Les sujets qui émergent sont nombreux et requerront de plus en plus d'attention à mesure que le débat sur la précaution gagnera en maturité.

Le cumul des incertitudes

Des décisions politiques de grande ampleur, qu'elles soient nationales ou internationales, comportent toujours une dimension d'incertitude. Les problèmes ne sont jamais parfaitement définis et les conséquences des choix politiques jamais totalement prévisibles. Dans une situation de précaution, les incertitudes ont tendance à s'accumuler. Il s'agit de celles liées à des connaissances scientifiques non stabilisées, aux différents scénarios possibles pour le développement futur et, enfin, au caractère fondamentalement nouveau des questions qui émergent, pour lesquels nos systèmes philosophiques et religieux ne nous sont pas d'un grand secours. En effet, l'homme est aujourd'hui capable de modifier l'humain et de modifier irréversiblement l'environnement à l'échelle de la planète.

La dimension supranationale des politiques

La mondialisation des échanges économiques, de la science et des technologies, ainsi que le développement des systèmes d'information et de transport à l'échelle du globe, ont doté toutes les questions nécessitant des mesures de précaution d'une dimension internationale, et ceci de manière définitive.

Des échelles de temps très différentes

Les évolutions scientifiques et techniques permettent aujourd'hui d'introduire de nouvelles pratiques et de réaliser de nouveaux objectifs dans un laps de temps très court. De nouvelles générations de produits pénètrent le marché dans une succession très rapide, processus encore accéléré par le commerce et l'investissement internationaux. Ceci étant, les connaissances supplémentaires nécessaires pour évaluer les conséquences potentielles de telles innovations se développent beaucoup plus lentement. En outre, certaines des questions soulevées ne pourront être résolues par la science du fait de leur complexité et de leurs interactions avec des facteurs environnementaux qui ne peuvent pas être étudiés en laboratoire. Ainsi, les conséquences de certaines innovations ne pourront être identifiées que très longtemps après leur introduction.

Le statut évolutif de la science

Les relations entre la science et la société évoluent de manière continue.

En effet, la société nourrit de nouveaux espoirs dans la science, attendant de celle-ci des réponses aux problèmes soulevés par les interactions complexes entre la société et la technique, par exemple les conséquences des modifications de nos modes de consommation ou l'impact des activités humaines sur l'environnement.

Les dynamiques internes à la communauté scientifique changent également. Elles pèsent sur le choix des sujets de recherche, le financement, les objectifs poursuivis, le contrôle de la propriété intellectuelle et la présence, en croissance constante, d'informations scientifiques dans le domaine public et les médias.

Les leçons à tirer de ces modifications sont tout aussi incertaines. Ces incertitudes affectent, en retour, les structures organisant la communauté scientifique ainsi que les priorités reflétées par les budgets publics de recherche, particulièrement à l'échelle européenne.

Conséquences

Pour répondre à ces nouveaux défis, le politique se doit de tout mettre en œuvre pour se préparer à agir à temps, afin que des risques potentiels capable de causer des dommages graves ou irréversibles ne deviennent avérés avant que des actions de précaution n'aient pu être menées. Ceci requiert la création d'instruments pour évaluer les risques potentiels et la mise au point de procédures de consultation des citoyens et des groupes d'intérêt (syndicats, entreprises, associations et collectivités locales).

Les instruments de gestion des risques, comme les fonds d'indemnisation et les systèmes d'assurance, doivent également répondre à ces nouveaux défis. Ils peuvent s'adapter en étendant le champ de leurs activités, en prenant des dispositions d'indemnisation accélérée ou des mesures de prévention de l'aggravation des dommages, une fois les risques matérialisés. Plus généralement se pose la question de la redistribution des responsabilités entre les acteurs, en particulier en modifiant les régimes de responsabilité juridique.

Toutefois, quel que soit le niveau de développement atteint par les institutions de gestion des risques, la responsabilité ultime demeurera celle des politiques et dépendra de la capacité de ces derniers à prendre des décisions en temps utile.

Des outils d'aide à la décision et de gestion des risques

Le processus de consultation

Le processus de consultation fait émerger les questions que peuvent se poser les citoyens, mais également leurs avis sur les risques et sur leur dangerosité. Cependant, de nombreuses questions subsistent sur l'organisation de ces consultations. Elles ont trait aux procédures à utiliser, à la représentativité des résultats obtenus et à la capacité de s'assurer que les problèmes débattus sont bien prioritaires pour les citoyens. Des liens entre les modes de consultation du public et ceux des acteurs économiques doivent être établis pour mettre fin, lorsque cela est possible, aux controverses.

Des informations fiables

Il importe de fournir au public des informations fiables sur l'état des connaissances et les expertises existantes, de manière systé-

matique. Ceci comprend aussi bien les projets de décisions envisagées que le détail du processus de consultation des experts utilisé.

L'expertise

Pour tout sujet relevant de la précaution, l'expertise est confrontée à un dilemme. En effet, s'il est essentiel de disposer de toute l'information nécessaire, celle-ci doit toujours être présentée au politique de façon à la fois accessible et pertinente et permettre l'expression de points de vue différents. Plusieurs niveaux de responsabilité sont alors associés aux résultats de l'expertise. Ils ont trait aux critères de choix des experts, à l'obligation pour les décideurs de rendre compte des avis rendus par les experts et de l'usage qu'ils en font.

L'assurance

L'assurance est une institution qui, traditionnellement, quantifie des risques en établissant des montants d'indemnisation mobilisables dans un fonds constitué par les primes des assurés. L'assurance est aujourd'hui confrontée à de nouveaux risques auxquels elle ne peut pas faire face avec ses outils habituels d'indemnisation des dommages. Ceci introduit un facteur de risque supplémentaire pour les décideurs et la population et requiert que des institutions appropriées puissent maintenir les conséquences des nouveaux risques à des niveaux acceptables.

Une nouvelle culture à acquérir pour le politique

Aujourd'hui plus que jamais, il apparaît nécessaire de prendre des décisions sans se cantonner à une seule représentation possible de l'avenir. A cet effet, des scénarios sont élaborés pour situer la décision dans un cadre qui prend explicitement en compte l'existence de scénarios alternatifs. En pratique, certaines incertitudes sont inhérentes aux réponses que les scientifiques peuvent apporter aux problèmes qui surviennent, tandis que d'autres ont trait aux projections de données, concernant par exemple la démographie, les ressources en eau ou en combustibles fossiles et les migrations. Ces incertitudes augmentent lorsque l'horizon temporel est plus lointain ou que les données considérées sont fortement sensibles à des processus instables. Citons à cet égard les migrations transfrontalières provoquées par des tensions sur les ressources naturelles ou des crises géopolitiques.

Il est indéniable que le degré de complexité des problèmes auxquels les hommes politiques sont confrontés aujourd'hui est très élevé et ne peut que s'accroître. Par conséquent, les décideurs ne peuvent plus attendre des experts qu'ils leur donnent des avis et leur proposent des orientations dénuées d'ambiguïté. Au vu de l'ampleur des questions posées, celles-ci ne peuvent être résolues à la marge. Ceci atténue l'importance d'une expertise trop circonscrite, voire trop détaillée, au profit de la définition d'orientations politiques de grande envergure, dans lesquelles viendront, dans un souci de cohérence, s'insérer des décisions plus ponctuelles.

Pour ce faire, il est nécessaire d'identifier les forces qui limitent la mise en œuvre d'une approche de précaution. Que ces forces reposent sur des facteurs réels ou ressentis comme tels ne fait pas de différence, elles doivent être traitées au cas par cas. Le défi consiste à faire en sorte que la responsabilité politique s'exerce effectivement, de manière à maintenir l'équilibre entre les nombreux intérêts en compétition qui affectent les mesures de précaution. Les décideurs politiques doivent faire preuve d'une grande sagesse de jugement. Cependant, les structures mises en place pour garantir leur responsabilité ne sont pas différentes de celles qui encadrent des décisions réclamant une prudence moindre. De même que le principe de précaution fait partie intégrante de la structure de gouvernance, les mesures existantes pour garantir la responsabilité dans ce domaine ne sont pas différentes de celles qui s'appliquent à d'autres types de décisions. Elles varient d'un pays à l'autre en fonction de l'équilibre constitutionnel de chaque Etat.

La procédure administrative

Dans tous les pays européens, la procédure administrative est régie par des lois et des réglementations extrêmement développées, qui s'appliquent autant aux mesures de précaution qu'aux autres procédures administratives. Ces lois sont destinées à garantir le fondement légal de la prise de décisions, qui se doit donc de reposer sur les avis d'experts disponibles et à lui assurer une transparence convenable, donnant aux parties intéressées des occasions suffisantes de se faire entendre. Pourtant, dans la réalité, les usages diffèrent beaucoup d'un pays à l'autre, reflétant la diversité des influences historiques

qui ont façonné la culture administrative des juridictions respectives. Un des éléments les plus caractéristiques de ces traditions est la ligne qui sépare le contrôle exercé par le politique et la fonction publique. En France, le gouvernement repose sur le système des cabinets, avec une administration séparée jouissant d'une autonomie importante. Les ministres sont censés être membres du Parlement, mais n'y sont pas obligés. En Allemagne, des fonctionnaires « politiques » sont placés au plus haut degré de l'administration, où ils servent d'articulation entre le politique et la fonction publique. Les ministres y sont presque tous membres du Parlement. Le Royaume-Uni a une tradition de quasi-anonymat pour ses fonctionnaires et les ministres doivent être membres d'une des chambres du Parlement. Aux Pays-Bas, les ministres sont à la tête de l'administration et ne sont pas tenus d'être membres du Parlement. Quant à l'Union européenne, elle possède une série de garanties institutionnelles similaires, très influencées à l'origine par les traditions administratives françaises, mais qui ont été modifiées par la suite pour refléter certaines autres coutumes des Etats membres.

Le contrôle parlementaire

Tous les pays d'Europe exercent une sorte de surveillance parlementaire, mais sous des formes très différentes. C'est au Royaume-Uni que les procédures sont les plus récentes et, de l'avis général, les moins efficaces. L'Allemagne dispose de procédures extrêmement développées pour la négociation préliminaire des mesures administratives essentielles avec des commissions parlementaires, qui ont également le pouvoir de surveiller étroitement les budgets. La France et les Pays-Bas se situent entre les deux. Dans toutes les démocraties parlementaires, le gouvernement a besoin du soutien de la majorité parlementaire pour exister, ce qui fait du contrôle du Parlement le premier impératif d'un gouvernement compétent. Il va de soi que cet état de choses impose des limitations à l'exercice d'un contrôle parlementaire. En revanche, le Parlement européen a acquis une autorité croissante, mais celle-ci s'est concentrée sur l'approbation du budget (avec de claires implications sur le contrôle) et la législation. Dans les cas extrêmes, le Parlement européen peut forcer la Commission à démissionner, mais cela n'est guère vraisemblable dans le cadre de l'exercice normal de la discrétion administrative.

Le contrôle judiciaire

Le système judiciaire constitue une strate de surveillance supplémentaire, mais l'exercice de la fonction judiciaire, tout comme l'organisation des procédures, diffère beaucoup d'un pays à l'autre. Au Royaume-Uni, par exemple, la maladie de la vache folle n'a pas entraîné de poursuites judiciaires contre les autorités administratives, alors qu'en France, l'affaire du sang contaminé a donné lieu à un procès retentissant. Pour ce genre de cas, les deux pays statuent dans des cours de juridiction ordinaire, tandis que l'Allemagne possède un système de cours spéciales, qui ont pour seule fonction d'examiner les mesures administratives. Dans tous les pays, les particuliers ont accès aux tribunaux quand ils estiment que des mesures administratives les ont privés de leurs biens sans leur verser de juste dédommagement. Mais les doctrines juridiques varient beaucoup en la matière, allant des traditions anglaises du droit coutumier aux clauses constitutionnelles allemandes stipulant que « la propriété implique des obligations sociétales », une disposition qui peut justifier des mesures administratives importantes.

La politique des groupes d'intérêt

Dans tous les pays de l'Union européenne, les groupes d'intérêt ont fini par jouer un rôle central dans la formation de la politique publique. Ce phénomène est particulièrement prononcé à l'échelle de l'Union européenne, où un degré de transparence moindre a pour conséquence une plus grande influence des groupes d'intérêt bien organisés. L'hypothèse sous-jacente est que les intérêts sont ainsi articulés de manière efficace et contribuent à la pleine discussion de tous les aspects de la plupart des décisions. C'est vrai en particulier dans le domaine des mesures de précaution où l'on peut escompter des mesures décisives quand un intérêt acquiert une importance primordiale, comme dans le cas des dommages forestiers liés aux pluies acides en Allemagne et dans celui de l'exposition au plomb causée par la présence de plomb dans l'essence au Royaume-Uni. C'est encore vrai lorsqu'une mesure de précaution ne rencontre l'opposition d'aucun groupe d'intérêt important. Cela se passe assez souvent dans le secteur agricole, parce que les parties intéressées craignent plus un bouleversement du fragile équilibre des intérêts existants qu'elles n'espèrent obtenir des profits grâce à des innovations promettant des hausses de productivité spectaculaires.

La participation publique

La participation publique est un élément fondamental de la gestion de l'environnement à tous les niveaux. C'est l'un des moyens d'application essentiels des lois environnementales, rappelant que la qualité de l'environnement est l'affaire de tous et que les tentatives de limitation de l'action légale par la propriété ou la géographie se heurtent très rapidement à des problèmes fondamentaux. La participation publique joue aussi un rôle important dans les mesures de précaution, car elle crée un regard sur la responsabilité qui se place en dehors et au-dessus des instances de gouvernance habituelles. Les formes de participation publique varient suivant les pays, mais souvent de façon moins marquée que les autres instances de gestion, parce que leurs modes d'action sont relativement récents, s'influencent mutuellement et se sont fréquemment développés dans un cadre reconnu à l'échelle européenne.

La liberté d'information et la transparence

Les lois qui garantissent la transparence des décisions en matière de précaution favorisent la responsabilité et forment souvent la base de la participation publique. La plupart des pays européens ont des traditions administratives qui protègent généralement les fonctionnaires du regard du public, lequel est plus attentif au Royaume-Uni, mais vigilant partout. Les nouvelles réglementations (souvent environnementales) qui régissent la transparence peuvent se heurter à ces traditions et même rencontrer une certaine hostilité chez les responsables concernés. Plusieurs pays, notamment les Pays-Bas et la France, ont promulgué des réglementations sur la « liberté d'information », mais celles-ci ne sont pas utilisées aussi couramment qu'on pourrait l'imaginer et, dans la pratique, elles se sont beaucoup dérobées.

Ce bref examen de la responsabilité à l'égard des mesures de précaution en Europe montre la diversité des instances mises en œuvre, une variété qui laisse supposer que les décisions importantes peuvent s'accompagner d'un haut niveau de responsabilité. Toutefois, la pluralité des usages témoigne aussi d'une difficulté à obtenir des résultats homogènes d'un pays à l'autre, ce qui laisse, à l'échelle internationale, le soin de choisir entre deux stratégies, la coopération ou la segmentation. La coopération cherche à assurer une uniformité des résultats, fondée sur des procédures communes. La segmentation accepte l'idée qu'une certaine diversité est inévitable, voire, à certains égards, désirable, et que la perte d'efficacité (économique) qu'elle entraîne est tolérable et fait partie du prix à payer pour une prise de décision franche, démocratique et responsable.

Développer des réponses progressives

Lorsque la connaissance est incertaine, les réponses politiques qui reposent sur cette connaissance doivent rester ouvertes, être reconsidérées régulièrement et, si nécessaire, être partiellement ou complètement révisées. Les formes traditionnelles de l'action législative et administrative ne sont pas adaptées à cela, ni les pratiques commerciales. Par exemple, décider de différer l'introduction d'un produit sur le marché équivaut souvent à un abandon. Dans de telles circonstances toutefois, on peut arguer que substituer un produit à un autre ou arrêter l'utilisation d'un produit nouveau, qui n'est pas une grande priorité, peut représenter une alternative plus raisonnable que de permettre sa vente sans information adéquate sur les risques associés.

Pratiquer la précaution est une démarche réflexive par nature. En s'interrogeant à priori sur les conséquences d'une décision, on est conduit à mener une réflexion non seulement sur un produit spécifique dans sa forme finale, par exemple, mais également sur l'ensemble de la chaîne de production et du contrôle administratif, ainsi que sur le fonctionnement du site industriel dont il provient. Cette posture de précaution peut se généraliser à nombre d'actions publiques et privées.

Responsabilité politique et responsabilité juridique

La responsabilité juridique est l'équivalent, du point de vue fonctionnel, de la responsabilité politique dans le secteur privé. Les actions des entreprises privées sont soumises à la loi et au contrôle de ceux qui y participent. Or, bien qu'il n'existe pas de dispositions légales définissant ou limitant les activités des acteurs privés par des mesures de précaution, la responsabilité pour de telles actions demeure intacte. De même, se conformer à des prescriptions légales n'exonère pas un acteur privé de sa responsabilité juridique. Par conséquent, la relation entre précaution et responsabilité est une question

importante qui devra être explorée à l'avenir avec davantage d'attention.

L'exemple de l'amiante est révélateur à cet égard. Les autorités publiques se sont clairement comportées de manière dilatoire dans leur réponse aux risques associés à l'amiante. Mais les compagnies privées qui ont produit et distribué de l'amiante ont eu également une responsabilité écrasante, notamment parce qu'elles n'ont le plus souvent tenu aucun compte des informations disponibles sur ces risques. De nombreuses entreprises ont quitté le marché du fait de leurs activités dans ce domaine, pénalisation ultime pour elles.

L'échelle européenne

La précaution soulève des défis particuliers à l'échelle européenne par rapport à l'échelle internationale. Le degré d'intégration atteint par les pays de l'Union européenne signifie que les risques revêtent forcément un caractère de plus en plus européen. Les décisions de précaution prises par les autorités d'un pays sur un risque potentiel sont presque toujours soumises à un processus européen de révision, qui identifie leurs implications pour les autres Etats membres et considère si des mesures sont alors nécessaires pour s'assurer d'un fonctionnement harmonieux des règles européennes.

L'action proprement européenne en matière de précaution n'existe pas en général par elle-même, mais se produit en réponse aux mesures de précaution prises par un ou plusieurs Etats membres. Cependant, les institutions européennes deviennent un forum où l'on évalue si des telles mesures sont, ou non, appropriées. Dans certaines circonstances, les institutions européennes, particulièrement la Commission, ont l'autorité pour lancer des démarches qui renversent des mesures de précaution lorsque celles-ci ne reflètent pas un consensus européen. Dans d'autres circonstances, ces institutions peuvent étendre des mesures de précaution à tous les Etats membres.

Les questions de compétence sont cruciales à cet égard. Pour les sujets qui relèvent de la compétence exclusive des Etats membres, les institutions européennes exercent une révision très limitée, qui s'assure de la compatibilité avec les provisions contenues dans les traités, par exemple et évite l'introduction de barrières au marché commun. Cependant, en cas de compétence partagée, l'initiative est prise le plus souvent par un Etat membre, car les institutions européennes ne peuvent généralement pas agir les premières. Enfin, lorsque la compétence relève exclusivement de l'Union européenne, les mesures de précaution doivent être, au moins en théorie, initiées et sanctionnées à l'échelle européenne. En pratique, dans ce cas de figure, les Etats membres continuent à jouer un rôle premier.

Les relations entre la précaution et le régime de commerce multilatéral représentent un problème particulier dans la perspective européenne. Pour la plupart, les premiers forums pour les actions de précaution se situent dans les Etats membres. Comme l'Union européenne possède jusqu'à présent la compétence exclusive en matière de politique commerciale et négocie à l'OMC pour tous les Etats membres, elle doit défendre des mesures de précaution qu'elle n'a pas prises elle-même.

Les articles publiés ici ont été présentés à l'atelier de l'Iddri sur les pratiques européennes de précaution. Ils éclairent certaines des questions qui doivent être prises en considération pour appliquer le principe de précaution, en particulier dans un contexte international.

Claude Henry se demande quand l'information scientifique devient suffisante pour justifier l'action. Il le fait en évoquant deux cas où le rendez-vous critique pour agir a été manqué : l'amiante et les antibiotiques comme facteurs de croissance pour les animaux d'élevage. Il insiste sur l'importance du groupe d'experts intergouvernemental sur l'évolution du climat (GIEC), en tant qu'institution internationale configurée pour éviter de répéter de telles erreurs.

Hervé Le Treut est un membre actif du processus développé par le GIEC. Il décrit certaines des caractéristiques qui contribuent à l'efficacité de celui-ci. S'il note la difficulté de traiter de questions par nature globales, pour lesquelles les gagnants et les perdants à terme sont difficiles à identifier, il souligne que ce sont ces mêmes raisons qui ont conduit à la création du GIEC, institution qui organise l'expertise sur le changement climatique à l'échelle internationale.

Ulrich Müller-Herold examine le rôle joué par les chercheurs dans le processus d'évaluation, par exemple pour ce qui a trait à l'épidémiologie et à l'écotoxicologie. Il évoque les difficultés rencontrées continuellement pour établir des mesures de précaution pour les nouveaux produits chimiques. Il montre comment ces problèmes reflètent les limitations des méthodologies utilisées, ainsi que

les difficultés pour en adopter de nouvelles. Il souligne les tensions qui persistent au sein de la communauté scientifique entre les expérimentateurs et les modélisateurs, qui produisent des évaluations probabilistes.

Monique Eloit fournit une analyse détaillée de l'Agence française de sécurité sanitaire des aliments (Afssa) et de la législation à l'origine de sa création. Elle examine tout particulièrement le lien entre la science et la décision publique.

Gérard Pascal passe en revue le développement de l'intérêt des décideurs pour la science en Europe et les déplacements observés dans la relation entre la recherche et l'élaboration des décisions politiques. Il s'interroge sur l'existence possible d'un équilibre entre les deux, identifiable à un moment donné. Il considère également les stades embryonnaires de développement de certaines formes de l'expertise européenne dans des institutions internationales.

Mae-Wan Ho et Peter Saunders approchent ces sujets sous une forme plus proche de celle du plaidoyer. Ils utilisent le tabac et l'hormone somatotropine bovine (BST), qui augmente la production laitière, comme exemples de l'identification des risques et étendent leur argumentaire aux organismes génétiquement modifiés. Ils soulignent l'importance de développer des structures collectives de décision publique pour les questions de risque et de précaution. En outre, ils insistent sur la distinction entre les mesures de précaution, qui précèdent un événement potentiel, et l'assignation en responsabilité par des procédures judiciaires après l'avènement de celui-ci.

Axel Conrads dresse un tableau de la réponse politique très dure apportée pour une agence qui a failli dans l'exercice de la précaution : le démantèlement de l'Agence fédérale de la santé en Allemagne, suite à sa réaction tardive face à la contamination par le virus du sida par transfusion sanguine, mise en évidence plusieurs années auparavant. Il souligne l'importance du maintien de normes pour l'expertise scientifique ainsi que l'indépendance de celle-ci face aux fortes pressions du secteur privé, bien mieux rémunéré que le secteur public. L'article met en lumière le rôle clé de la direction de l'agence, la nécessité pour celle-ci d'établir des relations appropriées avec les décideurs – dans cet exemple le ministère de la santé –, et propose la mise en place éventuelle d'une structure de contrôle parlementaire de l'agence.

Marie-Laure Tanon examine la directive européenne sur la responsabilité environnementale, résultat d'un long processus. Outre le régime de responsabilité mis en place par la directive et ses limites, elle traite de la définition des dommages couverts et évoque ceux qui ne sont pas encore précisés, comme la restauration de la biodiversité. Elle développe les principaux éléments du compromis obtenu en juin 2003 et analyse à quel degré certaines dispositions de la directive pourraient s'opposer au principe de libre concurrence au sein de l'Union. Elle explique pourquoi la couverture assurantielle n'a pas été rendue obligatoire pour les acteurs économiques et pour quelles raisons des solutions contractuelles apparaissent être la meilleure issue, à l'heure actuelle.

Prises dans leur ensemble, ces contributions constituent une introduction à l'état actuel du débat européen sur la précaution. Celui-ci se caractérise par une attention croissante pour les aspects institutionnels et organisationnels. Or, initialement, ce sujet apparaissait plutôt comme portant sur la manière dont les autorités publiques en Europe parvenaient à certaines décisions. Au cours de l'évolution de la problématique, il est devenu clair qu'il était nécessaire de mieux comprendre les processus en cours, de définir plus précisément certains aspects et de mieux les traduire institutionnellement.

RÉSUMÉS

L'essence du principe de précaution

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De nombreuses formulations du principe de précaution existent. Celles-ci toutefois ne diffèrent pas fondamentalement entre elles. Ce qui est essentiel dans ce principe – reconnaître la nécessité de prendre des décisions fondées sur des informations scientifiques incertaines (ou ambiguës) – est commun à tous les énoncés. Mais qu'entend-on exactement par information scientifique incertaine ? Qu'est-ce qui en outre fait que cette information puisse constituer une base acceptable pour la décision ? Toute hypothèse non falsifiée ne peut être recevable dans ce sens.

A travers les exemples de l'amiante, des antibiotiques facteurs de croissance et des processus de décision en matière de changement climatique, nous essayons d'identifier ce qui conduit à ce qu'un ensemble d'informations scientifiques incertaines puisse et doive être pris en considération dans un processus de décision.

▸ LIRE LA COMMUNICATION PAGE 29

Comment organiser l'expertise à l'échelle internationale ? L'exemple du GIEC

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Le Groupe d'experts intergouvernemental sur l'évolution du climat (GIEC) constitue probablement le meilleur exemple actuel d'élaboration internationale de l'expertise sur un sujet donné. Ce succès a plusieurs causes. Tout d'abord on dispose d'un corpus de données scientifiques indiscutables, qui mettent en évidence la croissance, depuis le début de l'ère industrielle, dans l'atmosphère de la concentration en dioxyde de carbone et en d'autres gaz à effet de serre comme le méthane. En outre, le changement climatique est un problème global pour lequel il est très difficile d'identifier les éventuels futurs gagnants et perdants, ce qui facilite la participation d'experts venant de pays différents.

S'il est nécessaire d'évaluer l'importance des conséquences à attendre des modifications atmosphériques en cours, celles-ci constituent une base solide qui a permis de initier un processus d'expertise et de créer une structure chargée de l'organiser à l'échelon international. Les mandats conférés au GIEC par l'Organisation météorologique mondiale et le Programme des Nations unies sur l'environnement sont très clairs : en faisant régulièrement état des résultats scientifiques publiés, l'activité du GIEC se distingue de l'activité des laboratoires de recherche et doit rester à l'écart du processus de négociation.

Les rapports du GIEC sont élaborés selon un processus précis incluant différents niveaux de rédaction, d'édition et de revue par les experts et les gouvernements (revue des résumés pour décideurs). Le succès du processus suivi par le GIEC, du moins pour le groupe 1, repose sur la préexistence d'une communauté scientifique internationale importante et bien structurée. Toutefois ce système n'est (bien sûr) pas exempt de défauts et reste perfectible (l'exemple pris ici est celui du groupe 1, mais ces remarques peuvent être transposées avec quelques nuances pour les deux autres groupes). Il existe d'abord des difficultés relatives à la diffusion des informations. Ainsi, les résumés pour décideurs résultent d'une sélection puis d'une présentation extrêmement condensée des informations contenues dans le corps du rapport et il s'avère que les choix peuvent très fortement orienter le message, voire le rendre confus pour les décideurs politiques. Cette dernière phase du processus doit donc être bien contrôlée. Par ailleurs, de grands progrès restent à faire pour qualifier et présenter conjointement des incertitudes par nature très différentes. Enfin, il importe de traiter et de rendre compte de façon plus adéquate des opinions scientifiques minoritaires dans les rapports eux-mêmes.

▸ LIRE LA COMMUNICATION PAGE 33

Ambiguïté de type II et approche de précaution : cas des produits chimiques potentiellement dangereux pour l'environnement.

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L'utilisation du principe de précaution comme outil de gestion des risques est aujourd'hui très controversée de part et d'autre de l'Atlantique, notamment par les experts scientifiques. Les controverses opposent les partisans d'une analyse a priori des facteurs de risques à ceux d'une analyse a posteriori des effets soupçonnés. De plus, à plusieurs étapes de l'évaluation des risques, des ambiguïtés apparaissent. L'une, sociopolitique, a trait au constat que l'on peut légitimement interpréter différemment des observations ou des données identiques. Une autre, dite de type II, réside dans la difficulté d'identifier a priori la discipline qui coordonnera le processus de recherche pluridisciplinaire.

Dans l'évaluation classique des effets néfastes des produits chimiques sur l'environnement, ce sont les toxicologues et les écotoxicologues qui, intervenant en bout de chaîne, communiquent les conclusions des études, préfigurant ainsi les mesures à prendre. Or, ce processus ne prend en compte ni l'infinité des effets biologiques possibles des produits chimiques sur les organismes et les écosystèmes, ni la complexité liée à la diversité de l'environnement. Bien que dans le domaine des produits chimiques tous les acteurs, publics et privés, souhaitent une refonte des procédures d'évaluation des risques, peu d'efforts ont été déployés pour développer des outils d'analyse plus efficaces. Face à l'accélération de la mise sur le marché de produits nouveaux et aux échelles de temps très longues pour les dommages qu'ils peuvent causer, il est urgent de développer une approche de précaution comprenant un diagnostic des produits avant leur commercialisation. Pour ce faire, l'auteur propose d'estimer l'étendue du dommage causé à l'environnement par un produit, en analysant trois paramètres au moyen de la chimie environnementale : la persistance du produit dans l'environnement, son potentiel de bioaccumulation et sa mobilité. Le défi consiste à trouver des critères fiables de présélection des produits utilisant des paramètres rapidement accessibles. Il semble que la chimie est plus utile pour l'instant. L'apparition de la toxicogénomique, cependant, peut à nouveau modifier la donne et conduire à un type de responsabilité mixte dans la présélection des produits chimiques.

▸ LIRE LA COMMUNICATION PAGE 36

L'Afssa : éléments de réflexion après quatre ans d'existence

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L'Agence française de sécurité sanitaire des aliments (Afssa), créée en 1998, s'inscrit dans un dispositif global de renforcement de la veille sanitaire et du contrôle de la sécurité sanitaire dans les domaines de l'alimentation, du médicament et de l'environnement. L'Afssa est chargée de trois missions essentielles portant sur l'ensemble de la chaîne de production des aliments destinés à l'homme : l'évaluation des risques, la recherche et l'appui scientifique et technique. Il est aujourd'hui possible d'apporter quelques éléments de réflexion sur les questions génériques qui se posent à l'ensemble des structures chargées, pour tout ou partie, d'évaluer les risques sanitaires liés à l'alimentation qui se créent dans pratiquement chaque pays européen.

Tout d'abord, en créant l'Afssa, le législateur n'a pas souhaité séparer le monde de l'évaluation et celui de la gestion des risques mais plutôt les articuler, en procédant à une meilleure identification des responsabilités. Ainsi, l'agence délivre des avis et des recommandations, y compris en matière de police sanitaire ; elle est consultée sur tout projet de règlement relevant de la sécurité alimentaire ; elle doit être destinataire de l'ensemble des informations et données issues des plans de surveillance et de contrôle.

En second lieu, si l'Afssa n'est pas une autorité indépendante, mais un établissement public administratif sous la tutelle de trois ministres (agriculture, santé, consommation), la loi prévoit plusieurs dispositions

permettant d'organiser une expertise scientifique indépendante (budget public, avis rendus publics, autosaisine, règles encadrant l'organisation de l'expertise, déclarations publiques d'intérêt et mode de choix des experts...).

Enfin, s'il sera difficile d'évaluer l'efficacité de l'agence, car plusieurs dimensions devront être prises en compte (la santé publique, mais aussi les dimensions politique, diplomatique, médiatique, économique et judiciaire), réaliser cet exercice sera essentiel au développement de telles autorités, en particulier pour prévenir et corriger les imperfections et défaillances du système européen en cours de construction.

▸ LIRE LA COMMUNICATION PAGE 40

Relations entre experts scientifiques et décideurs publics dans le domaine de l'alimentation

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Il y a vingt-cinq ans, les travaux d'expertise portant sur les aspects sanitaires de l'alimentation humaine n'intéressaient guère les décideurs politiques, que ce soit à l'échelle nationale ou européenne. Les crises sanitaires qui ont frappé l'Europe et ses Etats membres, ainsi que les interrogations suscitées par les organismes génétiquement modifiés, ont progressivement inversé cette attitude. Les échanges entre experts et décideurs se sont multipliés et les expertises sont devenues extrêmement importantes aux yeux de tous les acteurs, citoyens, médias, décideurs, entreprises. Parallèlement, l'organisation de l'expertise scientifique pour l'évaluation des risques sanitaires liés à l'alimentation humaine a été réformée. En France, l'Agence française de sécurité sanitaire des aliments a été créée en 1998, une de ses principales missions étant d'organiser une évaluation indépendante des risques. A l'échelle européenne, les comités d'experts ont été regroupés en 1997 au sein d'une direction générale non impliquée dans l'organisation et la gestion des filières économiques concernées par l'alimentation.

Jusqu'à la mi-2003, ces comités ont été chapeautés par le Comité scientifique directeur, chargé d'émettre des propositions d'harmonisation des méthodologies d'évaluation des risques alimentaires et sanitaires. Après formalisation des relations entre experts scientifiques et décideurs, ces propositions pourraient également s'appliquer à d'autres comités scientifiques européens ainsi qu'à ceux du Codex Alimentarius, donnant une envergure plus internationale aux réformes européennes en la matière. Cette réorganisation a également permis une réflexion sur l'indépendance et la transparence des activités d'expertise scientifique, qui a débouché sur la création de l'Autorité européenne de sécurité alimentaire, en 2002. Celle-ci devra prioritairement régler la question des modalités de participation des agences nationales à ses travaux.

▸ LIRE LA COMMUNICATION PAGE 43

La science et le principe de précaution

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Le principe de précaution énonce que nous ne devons pas développer ou utiliser une technologie sans être convaincus de son innocuité. Il rencontre des oppositions très vives, en particulier aux Etats-Unis. Dans ce pays, il est souvent présenté comme s'opposant au progrès, comme sanctifiant des arguments non scientifiques, ou encore comme prétexte à des mesures protectionnistes. En outre, ses opposants proposent de résoudre les différends dans ce domaine au tribunal. Or, un tel choix fait prévaloir une appréciation individuelle et au cas par cas des dommages causés, et ne permet d'agir qu'a posteriori.

Les exemples du tabac et de l'hormone laitière somatotropine bovine (BST) permettent de réfuter les arguments énoncés plus haut contre le principe de précaution. Ainsi, si ce principe avait été appliqué au tabac dès son apparition, il n'aurait empêché ni sa dif-

fusion ni son utilisation durant environ quatre cents ans, jusqu'aux premiers résultats épidémiologiques. A partir de là, il aurait permis d'éviter la mort de milliers de personnes, voire bien plus. Par ailleurs, si la dangerosité de l'hormone BST ne peut être mise en évidence en l'absence de groupes test, il existe des résultats et des conclusions scientifiques, qui vont dans le sens de la dangerosité. Or, dans la mesure où cette hormone ne profite qu'à ses producteurs, un pays doit pouvoir estimer lui-même s'il considère les risques acceptables ou non.

En ce qui concerne les organismes génétiquement modifiés, des présomptions multiples, mais aussi des preuves, de danger existent. Le génome qui est aujourd'hui manipulé est loin d'être compris, donc maîtrisé. L'ingénierie génétique crée de nouvelles combinaisons de gènes susceptibles de diffuser dans l'environnement beaucoup plus rapidement que les espèces classiques et de franchir la barrière des espèces. Certaines plantes génétiquement modifiées contiennent des toxines potentiellement allergènes pour l'homme. Enfin, des premiers cas de cancer ont été mis en évidence suite à des thérapies géniques. Le principe de précaution, loin d'être non scientifique, exige davantage de recherches afin de prouver l'innocuité de produits et de processus innovants. Parce qu'il place la responsabilité et le coût de la preuve du côté de ceux qui tirent profit des progrès technologiques, le principe de précaution est contesté.

▸ LIRE LA COMMUNICATION PAGE 47

Le démantèlement de l'Agence fédérale allemande de la santé : un exemple de défaut de précaution institutionnel

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Le scandale du sang contaminé a éclaté en Allemagne en 1993 lorsque la presse a dévoilé que, depuis 1985, 373 personnes avaient été contaminées par le virus du sida suite à des transfusions sanguines. L'Agence fédérale de la santé (BGA) fut alors démantelée, puis réorganisée en 1994. Les structures centralisées qui géraient les sept instituts scientifiques indépendants et l'organe administratif de l'agence ont été supprimés, les instituts devenant des agences fédérales en propre. Cependant, le contrôle et la responsabilité de ces structures demeuraient à l'échelon ministériel. Une commission d'enquête a mis en évidence les défaillances du ministère fédéral de la santé et de l'agence. Ainsi, le BGA a choisi de maintenir constantes les quantités de sang disponibles au détriment du traitement des produits, protégeant dans le même temps les producteurs non commerciaux et les industriels concernés.

Après enquête, ces dysfonctionnements ont été attribués à l'incompétence et à la faiblesse des instances dirigeantes de l'agence, au déficit de transmission des informations provenant des instituts et à la prévalence des intérêts privés et politiques dans les décisions. Le président de l'agence s'était quant à lui principalement investi dans une activité annexe, plus lucrative que sa fonction principale. De son côté, le ministère n'a pas trouvé nécessaire de renforcer ses moyens de lutte contre le sida et a été reconnu responsable des décisions, ou de l'absence de décision, dans l'application de la procédure d'intervention qui avait été lancée.

La réforme de l'agence a surtout visé à renforcer la circulation de l'information au sein de l'administration et à éclaircir les responsabilités de chacun. Mais elle n'a pas eu pour objet de séparer les intérêts publics et privés aux plus hauts échelons de la décision publique.

De son côté, la commission d'enquête a émis les recommandations suivantes. La présence de personnalités fortes à la tête des instituts, chargées d'organiser l'expertise et de garantir son indépendance au regard des pressions économiques et politiques, serait une des clés du système. Ces personnalités devraient être à la fois de bons scientifiques et de bons gestionnaires, capables de traiter des données nombreuses et hétérogènes. En outre, les patients devraient être présents dans le processus participatif. Enfin, une structure parlementaire devrait être mise en place pour veiller à l'indépendance des évaluations produites par l'agence et à la mise en œuvre du principe de précaution.

▸ LIRE LA COMMUNICATION PAGE 53

RÉSUMÉS

La directive sur la responsabilité environnementale

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Le projet de directive sur la responsabilité environnementale adopté par la Commission en janvier 2002 vise à étendre la responsabilité de l'ensemble des acteurs en matière de préjudice écologique pur, le plus mal réparé actuellement par le droit des Etats membres, selon une approche de droit public. Cette démarche est ambitieuse mais également réductrice, car elle laisse de côté le dommage aux personnes et aux biens ainsi que les dommages économiques. En outre, le champ économique couvert se voit limité par plusieurs exclusions importantes : les pollutions diffuses, le transport maritime et les activités utilisant le rayonnement atomique.

Par ailleurs, une analyse approfondie montre que la directive sera difficile à mettre en œuvre, que sa portée effective sur les opérateurs économiques sera limitée et que son action dissuasive devrait être malheureusement faible. En effet, si la directive affiche de prime abord une mise en œuvre énergique du principe pollueur-payeur en annonçant un principe de responsabilité illimitée, sans faute, de toutes les activités réglementées par le droit communautaire de l'environnement, cette ambition est fortement atténuée là encore par de multiples exonérations de responsabilité. Celles-ci portent essentiellement sur toutes les émissions polluantes et les événements autorisés par la réglementation ou par un permis individuel ainsi que sur le risque de développement ; de plus, la charge de la preuve devrait reposer surtout sur les autorités publiques. Enfin, le projet de directive fait peser une responsabilité très lourde sur ces dernières, subsidiairement responsables dans tous les cas – nombreux du fait des exonérations – où la responsabilité ne pourra être identifiée ou mise en œuvre. L'accord politique conclu en juin 2003 lors du Conseil des ministres de l'environnement a supprimé du texte cette responsabilité subsidiaire. Toutefois, la tâche incombant à la puissance publique pour mettre en œuvre la directive sera très grande. Les exonérations pour autorisation administrative et pour risque de développement sont renvoyées au droit des Etats membres, rompant ainsi l'égalité de concurrence. Par ailleurs, l'absence d'obligation d'assurance, présente dans le projet initial, est maintenue.

▸ LIRE LA COMMUNICATION PAGE 58

Precaution in Europe: Towards a More Realistic Assessment

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International debate about the precautionary principle —or the precautionary approach, as some prefer— has matured significantly since it was first presented to unsuspecting trade policy-makers as part of the beef/hormones dispute at the World Trade Organisation (WTO) and subsequently in numerous international trade, health and environmental forums. While some still suspect that it is little more than an excuse for protectionism, the elements of precaution are coming into sharper focus, and with them the beginning of a productive dialogue about its application and its relationship to alternative practices in addressing the uncertainty that is an inevitable consequence of policy-making increasingly reliant for guidance on scientific research.

During the early stages of the debate about the precautionary principle, some-advocates and critics alike —assumed that the simple invocation of the principle could settle arguments. It is hardly surprising that this has not proven to be the case. When the debate about precaution began, the principle was deeply embedded in the scientific and administrative structures of the countries invoking it, but many of the practices associated with its application had not yet been clearly spelled out. In the past few years, a steady process of articulation has clarified not only the principle itself but also the conditions of its application. This is to be welcomed. The workshop organized by Iddri in Paris in December 2002 was intended as another contribution to this process. It focused on several aspects of precaution.

The Challenges of Precaution

A number of issues are emerging that will require further attention as the debate about precaution matures.

Cumulative Uncertainty

Large-scale policy decisions, whether domestic or international, always involve a dimension of uncertainty. The problems are never perfectly defined and the consequences of policy options never totally predictable. In situations characterised by the need for precaution, uncertainties tend to accumulate:

- Uncertainty concerning the state of scientific knowledge
- Uncertainty about various possible scenarios for future developments
- Uncertainty relating to the fundamentally novel character of the issues that are being raised, and for which neither philosophical nor religious systems have ready answers: humans have become capable of modifying what is human and of influencing the environment irreversibly at a planetary level.

The Supranational Dimension of Policies

The globalisation of economic relationships and of science and technology as well as the development of globe-spanning systems of information and transport has endowed most of the issues that require precautionary action with an inescapably international dimension.

Highly Variable Temporal Dimensions

Scientific and technological changes enable the introduction of new practices and the attainment of new objectives at rapid rates. New generations of products enter the market in quick succession, before all of the possible consequences associated with them can be assessed. This process is further accelerated by international trade and investment. The complementary knowledge needed to assess the potential consequences of these innovations develops at a much slower pace. Moreover, some of the issues raised are not susceptible to a science-based response on account of their complexity and their interactions with external environments, factors beyond the ability of any laboratory to test. Finally the consequences of certain innovations may not be identifiable until long after they have been introduced.

Changing Status of Science

The relationship between science and society is not static.

- Society has new expectations for science, from which it anticipates answers to the problems raised by complex interactions between society and technology, for example, the consequences of changes in consumption patterns or of the human impact on the natural environment.
- The internal dynamics of the scientific community are also evolving and affect the choice of research topics, funding, goals, control of intellectual property, and the increased availability of scientific information in the public domain and in the media.
- The lessons to be drawn from these changes are equally uncertain, and these uncertainties affect the organizational structures of the scientific community and the priorities pursued by public research budgets, especially at the European level. The status of those with expertise in public debates has significant consequences for interdisciplinary cooperation and the development of freedom of research.

Consequences

Faced with these new challenges, policymakers must prepare to take timely steps to ensure that risks threatening either serious or irreversible harm do not become established fact before precautionary measures can be taken. This requires the creation of instruments to assess such possible risks and procedures for consulting citizens, interest groups (including unions, professionals, and voluntary associations, as well as local authorities).

The institutions that manage risk, such as indemnification funds and insurance schemes, must adjust to these new challenges as well. Their adaptations may include increases in the scope of coverage, arrangements for accelerated indemnification, and steps to prevent the aggravation of damage once risks have materialised. In the broadest perspective, the question is whether public authorities need to redistribute the responsibilities of the various actors, in particular by adjusting liability regimes.

Yet no matter how highly developed the institutions of risk management become, the ultimate responsibility will remain with policy-makers and will depend on their ability to make political decisions in a timely manner.

Tools to Support Decision-making and Management in Relation to Risk

The Process of Consultation

The process of consultation reveals the questions that the public may have as well as its views on risks and their seriousness. Nonetheless the appropriate organization of consultations presents several questions, namely, what procedures to use, how to deal with the issue of representation, and how to ensure that consultations focus on the key issues. Links between forms of public consultation and the access provided to key economic actors must be established to ensure the eventual closure of controversies.

Information

Information on existing knowledge and expert assessments must be provided systematically and reliably. It must also include proposed policy measures and detail the processes of expert consultation that have been used.

Expert Assessment

The dilemma of expert assessment is that while it is essential to address any issue of precaution and is frequently presented as incorporating all the necessary information, it must still be put in a credible policy context that also permits access to alternative points of view. Several layers of accountability are associated

with expert opinions, including the criteria for choosing experts and the extent to which policy-makers must provide a public accounting of the expert opinions they receive and how they use them.

Insurance

Insurance is traditionally an institution that quantifies risks by establishing prices for distributing them within a risk pool. Insurance is confronted by new risks that overwhelm the processes it uses for managing their economic consequences. This in turn shifts an additional element of risk to policy-makers and the public and requires that appropriate institutions ensure that outcomes remain within acceptable parameters.

The Need for a New Policy Culture

It is more than ever necessary to make decisions that are not constrained by a view of the future that holds no alternatives. For this reason, scenarios are developed for policy-makers to situate decisions within a framework that explicitly takes into account the existence of alternative scenarios. In practice some uncertainties are inherent in the scientific response to problems that arise, while others have to do with the range of variability associated with quantitative projections about topics in demography, water resource availability, fossil fuels, and migratory patterns: this variability increases as the period covered by the projections increases or as the data are highly sensitive to unstable processes. One typical example of these uncertainties involves cross-border migrations caused by the degradation of natural resources or by geopolitical insecurity.

Undeniably the degree of complexity of the problems that policy-makers confront today has grown enormously and can be expected to grow further. Consequently policy-makers can no longer rely on experts to provide them with unambiguous policy prescriptions. A significant shift thus downgrades the relative importance of detailed expertise and elevates in importance the pursuit of broad policy visions that permit the contextualisation of policy options.

It is therefore necessary to identify the forces that limit the possibility of a precautionary approach. It makes no difference whether these forces are based on real or perceived factors; they must be addressed on a case-by-case basis. The challenge is to ensure political accountability so as to maintain a balance between the many competing interests that affect precautionary measures. Policy-makers here must exercise a significant measure of discretion. Nonetheless the structures to ensure their accountability are no different than the structures that apply to decisions with less room for discretion. Just as the precautionary principle is an integral part of the structure of governance, the measures that are available to ensure accountability do not differ from the measures applicable to other decisions. They differ from one country to the next, depending on the specific constitutional balance.

Administrative Procedures

All European countries have highly developed laws and regulations governing administrative procedures. These apply to precautionary measures no less than to other administrative processes. They are designed to ensure that decisions are made in a manner that is firmly grounded in the law and consequently in available expert advice, adequately transparent, with sufficient opportunity for interested parties to be heard. Yet actual practice varies widely from one country to the next; it reflects a range of specific historical influences that have shaped administrative cultures in the different jurisdictions. One of the most characteristic elements of these traditions is the line that separates political oversight and civil service. France has a cabinet system of governance, with a separate administration that enjoys significant autonomy. Ministers are expected to be members of parliament but need not be so. Germany uses "political" civil servants at the highest level of the administration to serve as the hinge between politicians and the civil service. Ministers are almost without exception members of parliament. The United Kingdom has a tradition of virtual anonymity for civil servants. Ministers must be members of one of the Houses of Parliament. In the Netherlands ministers are heads of the administration. They do not need be members of parliament. A similar set of institutional safeguards operates at the European level, originally much influenced by French administrative traditions but subsequently modified to reflect some practices in other member states.

Parliamentary Oversight

All the countries of Europe have some form of parliamentary oversight, but the forms differ widely. The United Kingdom has

the most recent and, by all accounts, the least effective procedures. Germany has highly developed procedures for preliminary negotiation of key administrative actions with parliamentary committees, which also are in a position to monitor budgets very closely. France and the Netherlands lie somewhere in between. In all parliamentary democracies the government requires majority support in parliament to exist —so the control of parliament is the first order of any competent government's business. This clearly limits the ability of parliaments to exercise oversight. The European Parliament has acquired increasing authority, which has focused on budget approval (with obvious implications for oversight) and legislation. In extreme cases, the European Parliament can force the commission to resign but this is hardly likely for the normal exercise of administrative discretion.

Judicial Oversight

The judicial system is an additional layer of oversight, but access to this institution differs widely from country to country as does the organization of judicial procedures. For example, mad cow disease did not lead to any judicial proceedings against administrative authorities in the UK whereas the distribution of tainted blood produced high-profile cases in France. Both countries use courts of general jurisdiction for these purposes but Germany has a system of special courts whose sole function is the review of administrative actions. In all countries, private citizens have access to the courts when they believe that administrative actions have deprived them of their property without just compensation– but the legal doctrines of property differ widely, ranging from the common law traditions of the United Kingdom to the German constitutional stipulation that "property entails societal obligations", a provision that can justify significant administrative action.

Interest Group Politics

Interest groups have come to play a central role in the formation of public policy in all EU countries. This phenomenon is particularly pronounced at the EU level, where less transparency results in more influence for well-organized interests. The underlying assumption is that interests will be effectively articulated and will contribute to the full ventilation of all aspects of most decisions. This is true in particular of precautionary measures, where decisive action is to be expected primarily when some interest attains overwhelming saliency —such as forest damage in the case of acid rain in Germany or exposure to lead from leaded gasoline in the United Kingdom— or when no significant interest group opposes some form of precautionary action —as happens quite frequently in matters pertaining to agriculture because all interested parties fear disruption of the tenuous existing balance of interests more than they expect benefits from innovations that promise dramatic increases in productivity.

Public Participation

Public participation is a fundamental process for environmental management at all levels. It is a basic instrument for implementing environmental law, given that environmental quality is the concern of every person and that attempts to limit legal standing by property or geography run very quickly into major problems. Public participation also plays an important role in precautionary action since it establishes an additional forum for accountability over and above the regular institutions of governance. The forms of public participation vary from country to country, but often not as widely as other institutions of governance because the processes are relatively recent, mutually influenced, and have often developed within a framework agreed upon at European level.

Transparency and Freedom of Information

Requirements ensuring the transparency of precautionary decisions facilitate accountability and often form the basis for public participation. Most European countries have administrative traditions that largely protect civil servants from public scrutiny, most pronounced in the United Kingdom but significant everywhere. New (often environmental) rules governing transparency can conflict with these traditions and even encounter a degree of hostility on the part of the policy-makers concerned. Some countries —notably France and the Netherlands— have enacted "freedom of information" regulations, but these are not used as extensively as might be imagined and they have been significantly restricted in practice.

This brief overview of accountability for precautionary action in Europe indicates the diversity of relevant institutions and processes. It suggests a significant degree of

accountability can be achieved for important decisions. The variety in practice underlines, however, the difficulties in producing consistent outcomes from one country to the next. This leaves the choice of strategies at the international level: cooperation or segmentation. Cooperation seeks to ensure consistency of outcomes based on common procedures. Segmentation accepts that a degree of variety is inevitable, from some perspectives even desirable, and consequent loss of (economic) efficiency is tolerable as part of the price for open, democratic, and accountable decision-making.

Developing Responses that are Progressive and Never Final

When knowledge is uncertain, policy responses based on it need to be open and subject to review and, if necessary, reversal. Traditional forms of administrative or legislative action are not adapted to these requirements, nor are commercial practices. For example, a decision to delay the introduction of a product is often the same as its abandonment. Under these circumstances it may be argued that substituting one product for another or stopping the use of a new product that is not of high priority may represent a more reasonable alternative than permitting its marketing without adequate information on associated risks.

Precautionary practice is reflective by its very nature. Asking whether the consequences of a decision will be acceptable requires confronting a wide range of issues relating to the product chain, to administrative oversight and to the management of industrial installations. This approach can readily extend to a full range of public and private actions.

Public Accountability and Private Liability

Liability is the functional equivalent of accountability in the private sector. The actions of private enterprises are subject to the law and to the control of those who participate in it. Even though there may be no legal requirement for precautionary action to define or limit the actions of private actors, responsibility for these actions remains undiminished. Even compliance with clear legal prescriptions may not absolve a private actor from liability. Consequently the relationship between precaution and liability is an important issue that needs to be explored much more carefully.

The example of asbestos is particularly illuminating in this regard. The public authorities were clearly dilatory in their response to the risks associated with asbestos. But the private companies that produced and distributed asbestos products have faced a crushing liability from their actions —frequently in part because they disregarded information available to them about the risks. Many companies have gone out of business because of their asbestos activities— the ultimate penalty for a private enterprise.

The European Level

Precaution poses particular challenges at the European —as opposed to the broader international— level. The integration achieved between the countries of the European Union necessarily means that risks are also increasingly European in character. Precautionary decisions taken by the authorities in one country about a possible risk almost inevitably result in a European process to review the decision, identify its implications for other member states and consider whether European measures are necessary to ensure the smooth functioning of European policies.

European action on precaution is generally not itself precautionary, but it occurs in response to precautionary action taken by one or more member states. Only rarely is the European Union itself the level of primary precautionary action. In reviewing precautionary measures by member states, however, European institutions inevitably become a forum in which the appropriateness of these measures is considered. Under certain circumstances European institutions, especially the European Commission, have the authority to initiate steps to reverse precautionary measures as not reflecting a European consensus. In other circumstances the European institutions can lead to the extension of precautionary measures to all member states.

Issues of competence are critical in this regard. For matters that fall into the exclusive competence of the member states, European institutions exercise a very limited form of review to ensure compatibility with the provisions of the treaties, for example, to

avoid hidden barriers to the common market. In matters of shared competence, the initiative nonetheless still lies most often with a member state, since European institutions cannot generally initiate the action. In matters within the exclusive competence of the European Union, precautionary action must, at least in theory, be initiated or sanctioned at the European level. In practice, individual member states still play a critical role.

The relationship between precaution and the multilateral trade regime represents a particular problem from the European perspective. Member states are for the most part the primary forum for precautionary action; yet the European Union has exclusive competence for commercial policy and negotiates at the WTO for all member states. It must consequently defend precautionary actions that it did not itself originate.

The Iddri Workshop

The papers that are reproduced here were presented at the Iddri workshop on European precautionary practice. They highlight some of the issues that need to be taken into consideration in applying the precautionary principle, in particular in an international context.

Claude Henry addresses the question of when available scientific information suffices to justify action. He does so by considering two cases where the critical point was clearly missed: asbestos and antibiotics as growth promoters in animal husbandry. He emphasizes the importance of the Intergovernmental Panel on Climate Change (IPCC) as an international institution designed to avoid repeating those mistakes.

Hervé le Treut is an active participant in the IPCC process and describes some of the features that contribute to its effectiveness. He emphasizes the difficulty at addressing issues that are global in character and where winners and losers over time are difficult to identify but also points out that these two characteristics allowed the creation of this institution, which organises expertise on climate change at an international level.

Ulrich Müller-Herold considers the role of researchers themselves in the assessment process in relation, for example, to epidemiology or toxicology. He discusses the continuing difficulties in establishing precautionary policies for new chemicals and how these problems reflect the limitations of established methodologies and the difficulties in agreeing on new ones. He underlines the tensions that persist between experimental scientists and those whose use modeling, and hence probabilistic assessments.

Monique Eloit takes a closer look at the French food safety agency (AFSSA) and the legislation establishing it, with particular concern for the relationship between science and decision-making.

Gérard Pascal reviews the development of policy-makers' interest in science in Europe and the resulting shifts in balance between the research function and the policy development function. He asks whether an equilibrium between them exists that may at some point be identified and considers the embryonic states of development of internationalized forms of European expertise.

Mae-Wan Ho and Peter Saunders approach these issues from a perspective more strongly informed by advocacy. They use tobacco and the bovine growth hormone (bovine somatotropin or BST) that increases milk production as examples of risk identification and extend this argument to genetically modified organisms. They underline the importance of developing collective, public structures of decision-making related to risk and precaution and stress the distinction between precautionary action before a possible event and the subsequent assignment of liability through the judicial process.

Axel Conrads describes the harsh political response to an agency that failed to exercise precaution: the dismantling of the Federal Health Office *(Bundesgesundheitsamt)* in Germany after its tardy response to early evidence of contamination of blood transfusions by the HIV virus. He underlines the importance of maintaining scientific standards and independence in the face of strong pressure from-and much higher salaries in-the private sector. The paper highlights the importance of agency leadership and the need to establish appropriate relationships with policy-makers, in this instance the minister, and a possible structure of parliamentary oversight.

Marie-Laure Tanon looks at the EU directive on environmental liability, which resulted from a process that took many years. She discusses the liability regime introduced and its limits, the definition of damage used in the directive and its relation to matters that it does not clearly classify, such as biodiversity and its preservation and appropriate restoration. She outlines the key issues of the compromise that was finally reached in June

2003 and discusses the degree to which the directive breaks with the principle of the level playing field. She explains why insurance coverage was not required and why contractual solutions continue to be sought for this issue.

Taken together these contributions provide an introduction to the current state of the European debate concerning precaution. It is characterized by increasing attention to the institutional and organizational aspects of a topic that appeared initially to be more a matter of explaining how public authorities in Europe reach certain decisions. In the process it has become clear that a better understanding of these processes is needed and that certain aspects must be more clearly defined and better institutionalized.

ABSTRACTS

The Essence of the Precautionary Principle

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The precautionary principle is formulated in many different ways. However, the differences are not of a fundamental nature. What is fundamental in the principle —i.e. the recognition that decisions must be taken on the basis of uncertain (also called ambiguous) scientific information— is also common to all formulations. But what is meant exactly by uncertain scientific information and what makes it an acceptable basis for decision? Any non-falsified hypothesis might not be deemed acceptable in this sense.

We try to identify what makes an uncertain piece of scientific information acceptable in a decision-making process, drawing from the asbestos, antibiotics as growth promoters and climate change decision processes.

▸ READ PAPER PAGE 29

How Can Expert Advice be Organised on an International Scale? The Case of IPCC

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The Intergovernmental Panel on Climate Change (IPCC) is probably the best current example of the international development of expertise on a given subject. There are several reasons for its success. First, an indisputable corpus of scientific data exists to demonstrate the increased atmospheric concentrations of carbon dioxide and other "greenhouse" gases, such as methane, since the beginning of the industrial era. Moreover, climate change is a global problem and it is not yet possible to determine the potential winners and losers. Both these constraint facilitate the participation of experts from different countries. Although the extent of the consequences to be expected from the atmospheric modifications underway must still be assessed, this corpus constitutes an extremely solid base that has made it possible to begin the process of expert evaluation and to create a body responsible for organising it on an international level. The mandates conferred on the IPCC by the World Meteorologic Organisation and United Nations Environment Program are very clear: by its regular reporting of the published scientific results, the activity of the IPCC is distinguished from that of research laboratories; it must also remain apart from the negotiation process. IPCC's reports are developed according to a specific process that includes different levels of drafting, editing, and review by experts and governments (review of summaries for policy-makers). The success of the IPCC process, at least for Working Group 1, was possible only because a large, well-structured international scientific community already existed. Nonetheless this system is (of course) not defect-free and there is still room for improvement (the example used here is that of Working Group 1, but these comments can be applied, with only several slight changes, for the other two groups). First, there remain problems related to the dissemination of information. For example, the summaries for policy-makers result from the selection and then the extreme condensation of information from the body of the report, and it turns out that these choices can very strongly slant or even confound the message for the political policy-makers. This final phase of the process must therefore be carefully monitored. Another problem is the need to improve the qualification and joint presentation of uncertainties that are by nature very different: we have far to go. Finally, the reports must treat and describe the minority scientific opinions more fully.

▸ READ PAPER PAGE 33

Type II Ambiguity and Precautionary Screening with Respect to Large-scale Chemical Threats in the Environment

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The use of the precautionary principle as a tool of risk management is very controversial today on both sides of the Atlantic, and especially among scientific experts. These debates oppose the partisans of an analysis of risk factors before widespread exposure to those who prefer an analysis of any suspected effects *a posteriori*. A further problem is that ambiguities appear at several stages of risk assessments. Sociopolitical ambiguity is related to the variety of legitimate interpretations of identical observations and identical data. Another, which we call here type-II ambiguity, lies in the difficulty of identifying in advance the disciplines that should coordinate the process of multidisciplinary research. In standard assessments of the harmful environmental effects of chemical products, toxicologists and ecotoxicologists intervene at the end of the process; they communicate the study conclusions and thus suggest the measures to be taken. This process does not, however, consider either the infinity of possible biological effects of these chemicals on organisms and ecosystems, or the complexity caused by the indeterminable diversity of the environment itself. All of the actors in this field, public and private, want risk assessment procedures to be overhauled, but few efforts have been made to develop more effective tools of analysis. The acceleration of marketing approvals and the very long time scale of the damage they can cause mean that a precautionary approach is urgently needed; it must include a prescreening of products before they are marketed. The author proposes to estimate the extent of endangerment of the environment by a given product, by analysing three parameters with methods from environmental chemistry: the product's persistence in the environment, its potential for bioaccumulation and its mobility. The challenge lies in finding reliable criteria for the preselection of products with rapidly accessible parameters. At least for now, chemistry appears most appropriate for this purpose. The development of toxicogenomics, nonetheless, may again modify the situation and lead to a type of mixed responsibility for the preselection of these chemical products.

▶ READ PAPER PAGE 36

The AFSSA (French Food Safety Agency): Food for Thought After Four Years

Monique Eloit
AFSSA, France

The French Food Safety Agency (AFSSA), created in 1998, is part of an overall system to strengthen health surveillance and the monitoring of health security in the areas of food, drugs, and the environment. AFSSA is responsible for three essential missions covering the entire chain of production of food intended for human consumption: risk assessment, research, and scientific and technical support. Four years after the agency's establishment, our experience provides some basis for consideration of the questions common to all of the agencies responsible in whole or in part for assessing food-related health risks, agencies now being created in nearly every European country. First, the legislature, in creating AFSSA, did not choose to separate the spheres of risk assessment and risk management, but rather to articulate them by clearly identifying the responsibilities of each. Accordingly, the Agency issues opinions and recommendations, which cover the exercise of public health police powers; it is consulted on all regulatory projects related to food safety; and it must receive all of the information and data collected during administrative surveillance and controls in this area. Second, although AFSSA is not an independent authority but a public administrative establishment supervised by three ministries (agriculture, health, consumer affairs), the statute includes several provisions that enable the agency to obtain, organise and make public independent scientific expert advice (public budget, opinions released to

the public, agenda control, rules governing the organization of expert advisory opinions, public disclosure statements, methods for choosing experts, etc.). Finally, although the various aspects that must be taken into account (public health and also political, diplomatic, media-related, economic and legal dimensions) to assess the Agency's work make this a difficult exercise, it is essential to the development of such agencies. Only in this way can we prevent and correct the flaws and weaknesses in the European system now under construction.

▶ READ PAPER PAGE 40

Relations Between Scientific Experts and Public Policy-makers in the Area of Food

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Twenty-five years ago, the work of experts about the health aspects of human food were essentially devoid of any interest for policy-makers, at either the national or European levels. The health crises that have struck Europe and its member states and the questions raised by genetically modified organisms have progressively reversed this attitude: exchanges between experts and policy-makers have multiplied, and the assessments of experts have become extremely important in the eyes of all —citizens, media, policy-makers, and companies. At the same time, reforms have reorganised the procedures and use of scientific expertise to assess the health risks associated with human food. France created its national food safety agency in 1998 with as one of its principal missions the organisation of independent risk assessments. At the European level, expert committees were regrouped in 1997 into a Directorate-General uninvolved with the food industries. Until mid-2003, these committees were headed by the Scientific Steering Committee, which was also responsible for making proposals to harmonise the methodologies used for food and health risk assessments. Once the relationships between scientific experts and policy-makers are formalised, these proposals may also be applied to the scientific committees of the European Union and of the Codex Alimentarius, thus magnifying the international impact of the European reforms in this area. This reorganisation has also allowed reflection on the independence and transparency of the activities of scientific experts and led to the creation of a European Food Safety Authority in 2002. One of its first tasks must be to define the conditions for the national agencies to participate in its work.

▶ READ PAPER PAGE 43

Science and the Precautionary Principle

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The precautionary principle states that we must not develop or use a technology until we are convinced that it is safe. It has encountered fierce opposition, especially in the United States, where it is often presented as opposition to progress, sanctification of unscientific prejudice, and a pretext for protectionism. Its opponents want to resolve disagreements in this domain in court. Such a choice allows at most an individual case-by-case assessment of any damage and that only after the fact, when the damage is done. The examples of smoking and bovine growth hormone (bovine somatotropin or BST) refute the arguments against the precautionary principle described above. If this principle had been applied to tobacco when its use began, it would not have prevented either its diffusion or its use for approximately four hundred years —until the first epidemiologic findings appeared. Applied at that point, it would have prevented the deaths of many thousands, perhaps millions, of persons. Moreover, although the danger of the BST hormone can be demonstrated only with test groups, well-founded bases for serious concern are plain. To the extent that this hormone benefits no one but its manufacturers, countries must be able to decide for themselves if the risk is acceptable. Similarly, there is evidence

strongly suggesting that genetically modified organisms are hazardous. The genome that is being manipulated is far from well understood and thus far from controllable. Genetic engineering is creating new combinations of genes likely to spread throughout the environment much more rapidly than natural species and to cross the species barrier. Some genetically modified plants contain toxins that may be allergens for humans. Finally, the first cancer cases have been identified among the «successes» of gene therapy. The precautionary principle, rather than unscientific, requires more research in order to prove the safety of new products and processes. It is unsurprising that the precautionary principle is contested for it places this responsibility —and its cost— on those who stand to profit from each technological advance.

▶ READ PAPER PAGE 47

The Dismantling of the German Federal Health Agency: A Case of (Failed) Institutional Precaution

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The contaminated blood scandal erupted in Germany in 1993 when the press revealed that 373 persons had been infected with the HIV virus during blood transfusions since 1985. The Federal Health Office (BGA) was disbanded, to be reorganised in 1994. The central structure that administered the seven independent scientific institutes, the administrative organ was abolished, and the institutes themselves became federal agencies. Nonetheless, they continued to be controlled at the ministerial level. An inquiry board appointed by the parliament identified the failures and dysfunctions in the national Ministry of Health and in the Federal Health Office. Specifically, the BGA chose to maintain a constant quantity of blood available, without insisting on its treatment, thereby protecting both non-profit producers and the commercial companies involved. At the conclusion of the investigation, these malfunctions were attributed to the incompetence and weakness of the Agency's administrators, to the lack of the transmission of information from the institutes, and to the role that private and political interests played in these decisions. The Office president focused principally on his outside activities, more lucrative than his official function. The Ministry, which had not considered it necessary to strengthen its resources against AIDS, was held responsible for its decisions, or absence of decisions, including the action the BGA had begun to plan. The BGA reforms aimed especially at reinforcing the circulation of information within the government and clarifying the responsibilities of each agency. It did not seek, however, to separate public from private interests at the highest echelons of public decision making. The inquiry board made the following recommendations. One key to the system should be the presence of independent heads for the institutes, responsible for organising expert opinions and for guaranteeing their independence from economic and political pressure. They should simultaneously be good scientists and good administrators, able to deal with extremely vast quantities of very heterogeneous data. In addition, patients should be involved in a participatory process. Finally, a parliamentary body should be established to safeguard the independence of the Office's evaluations and the implementation of the precautionary principle.

▶ READ PAPER PAGE 53

The Directive on Environmental Liability

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The proposal for a directive on environmental liability adopted by the European Commission in January 2002 was intended to extend the liability of all of those involved in "pure ecological damage", currently the area of environmental harm for which the public law of member states provides the fewest remedies. This project is ambitious but also reductive, leaving aside as it does damage to persons and property and economic damage. The economic field covered is limited by several important exclusions: diffuse pollution, maritime transportation and activities involv-

ing atomic radiation. Moreover, a detailed analysis shows that the directive will be difficult to implement, its effect on economic operators limited and its dissuasive power unfortunately low. Although the directive starts by energetically implementing the "polluter pays" principle and announcing a principle of unlimited liability, regardless of fault, for all activities regulated by community environmental law, this ambition is strongly attenuated by the many exemptions from liability. These involve essentially all pollutant emissions and events authorized by regulation or an individual license as well as development risks; moreover, the burden of proof will lie most especially on public authorities. The proposal for a directive places another very heavy responsibility on these authorities, secondarily liable in all of the cases —numerous because of the exemptions— in which liability cannot be either identified or implemented. The political agreement reached in June 2003 at the Council of Ministers of the Environment deleted this secondary liability from the text. Nonetheless, implementation of this directive confronts authorities with a huge task. Moreover, exemptions for administrative authorisations and development risk are referred back to the law of member states, a decision hardly conducive to a level European playing field. Finally, the new version still does not require insurance.

▶ READ PAPER PAGE 58

The Essence of the Precautionary Principle

RÉSUMÉ P. 12
ABSTRACT P. 24

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The precautionary principle is formulated in many ways, and differences between them may be significant. However, all formulations have an essential element in common: rational decisions may and should be taken on the basis of uncertain science, despite a "lack of full scientific certainty" or of "conclusive evidence to prove a causal relation between inputs and their effects". "Uncertain" refers to uncertainty in the sense of J.M. Keynes (1921) and F. Knight (1921), i.e. uncertainty that does not boil down to an objective distribution of probabilities. Among all the international agreements, conventions, and declarations that refer to the precautionary principle, one of the most explicit about what serviceable uncertain science might be is the decision by the Appellate Body of the WTO on the hormones case. The Appellate Body discusses the decision previously reached by the relevant WTO Panel: "To the extent that the Panel intended to refer to a process characterized by systematic, disciplined and objective inquiry and analysis, that is, a mode of studying and sorting out facts and opinions, the Panel's statement is unobjectionable. However, to the extent that the Panel purports to exclude from the scope of a risk assessment, in the sense of Article 5.1, all matters not susceptible of quantitative analysis by the empirical or experimental laboratory methods commonly associated with the physical sciences, we believe that the Panel is in error."

Certain science, or fully established science, of the kind the Panel was requiring from the defendant (i.e. the European Union) is well illustrated by the following two examples, one from physics, the other from biology. When a particle beam in a high energy collider is accelerated and then collides with a fixed target of atomic nuclei, the collision products and the directions along which they leave the region of the impact are predicted by quantum mechanics in objective probability terms; these predictions by quantum mechanics are confirmed in statistical frequency terms by the observation of the nature and the trajectories of the products of the collisions. Among the numerous proteins in the human body, one, known as CCR5, functions as a gate for the HIV virus when it is located on the cell surface; this has been established experimentally and is understood theoretically; it is the basis for the development of medicines that shut the gate.

In contrast to these two examples, it is clear that decisions must often be taken without the benefit of scientific knowledge that encompasses a full theoretical understanding of the relevant phenomena (the exact causal links in particular) and completely convincing experimental verification. Think of the possible role of other proteins, the prions, in BSE ("mad cow disease") or the alleged dangers of cellular telephony antennas. How then can we rationally use uncertain or incomplete scientific information? How can we resist the tendency to postpone decisions that may be urgent –because of threatened damaging and irreversible consequences if nothing is done, for example– while keeping to an adequate extent the opportunity of using later, more refined, scientific results?

These questions may be summarized as follows: under which conditions about the available uncertain scientific knowledge is it valid to invoke the precautionary principle? It is obviously not enough to say, as does the UN Framework Convention on Climate Change (1992) –and numerous other official texts– that "lack of full scientific certainty should not be used as a reason for postponing such measures". And it is not enough to rely on the credibility of science as characterized by J. Ziman (2000): "The credibility of science depends as much on how it operates as a collective social enterprise as it does on the principles regulating the type of information that this enterprise accepts and transforms into knowledge."

We shall consider the question in the framework of two well-known cases that are no longer controversial, and then with respect to climate change.

Asbestos

In 1898, i.e. within 20 years of the start-up of asbestos mining, medical inspectors of factories in the UK found strong correlations between bronchial tube and lung injuries, and professional occupations in atmospheres filled with asbestos dust. They went a step further in their analysis. Indeed after observing "the sharp glass-like jagged nature" of the microscopic asbestos particles, they were able to suggest a causal link. These finding were corroborated in 1906 by evidence gathered in the textile industry by the French factory inspectorate; here also the correlations between abnormal death rates and asbestos appeared strong, and causal chains were envisaged. In 1911, British scientists started laboratory experiments with rats exposed to asbestos dust; these results were in line with the previous observations of humans in factories.

The exact nature of the asbestos diseases was not known. Nevertheless, as early as 1918, insurance companies found the scientific knowledge available at the time convincing enough to refuse insurance coverage for asbestos workers: from the point of view of their own interest, that was a precautionary measure. However, the regulatory authorities in the countries most concerned by the processing of asbestos didn't follow suit: they accepted the argument of the industry according to which continuous improvements in the working conditions would eliminate the dust to the point that any danger would also be eliminated. This argument was scientifically unsubstantiated, but looked reasonable and attractive. It even satisfied the majority of insurance companies, who no longer refused coverage, to their present deep regret.

In the thirties asbestos was firmly associated with lung cancer, and in the fifties with mesothelioma (an otherwise very rare cancer of the lining of the chest), this time not only in occupational, but also in environmental circumstances. But it took another forty years, and tens of thousands of disease cases and deaths, before these results were recognized. It can safely be said that the acceptance of the state of scientific knowledge as legitimizing precautionary decisions was long overdue.

Antibiotics as Growth Promoters

The case of antibiotics used as farm animal growth promoters is less spectacular but no less compelling. That antibiotics at subtherapeutic doses could boost the growth of livestock was recognized in the early fifties, and soon exploited on a large scale. Might that be dangerous in any respect? Here the basic science was already well understood, it was Darwinian natural selection; Alexander Fleming himself had warned that misuse of penicillin could have the effect that "microbes are educated to resist penicillin" (interview in the *New York Times* in 1945). But more specific scientific knowledge was required. In particular the following problem had to be tackled: can antibiotics be related to one another to the point that the absorption of one by farm animals increases the resistance to another in the body of consumers of those animals? In 1968, enough experimental results had been obtained in this respect, to allow an advisory committee appointed by the British government, chaired by professor Michael Swann, to recommend the ban of three specific antibiotics in livestock feed because of their chemical proximity to antibiotics used in human medicine. These recommendations were followed neither in the UK nor in the European Union at large.

It was not until more and more farmers became uneasy about the possible consequences of these practices on consumers' confidence that the trend was reversed. And not until 1997 that a Swedish government commission accepted that "the risk for increased resistance associated with the gen-

eral use of antibiotic growth promoters is far from negligible and the potential consequences are serious for both animal and human health". The commission insisted that enough scientific knowledge was available to draw these conclusions, even if all causal links between absorption of one antibiotic by animals and resistance to a related one in the organism of consumers have not yet been fully explained. In 1998 the European Council of Ministers of Agriculture banned four antibiotic growth promoters (including two previously singled by the Swann Commission), as "a precautionary measure to minimize the risk of development of resistant bacteria and to preserve the efficacy of certain antibiotics used in human medicine."

In both cases, it seems that a sound scientific basis had been available a long time before the adequate decisions were taken. That basis was sound in the sense that a good, if incomplete, theoretical model existed, vindicated by much more than anecdotal experimental evidence; it is indeed the kind of basis on which medical decisions are routinely taken. Of course, this is an assessment that benefits from hindsight. What have we to say in a case where we presently have the same brand of scientific knowledge but where the perils might materialize in a more or less distant future?

Climate Change

To this end, we shall consider the Intergovernmental Panel on Climate Change (IPCC) approach to the perspectives of climate change. The expected effects of climate change are warmer temperatures, a more intense and chaotic hydrological cycle, rising sea levels, and possible "surprises", such as a weakened thermohaline circulation (that would reduce the flow of heat carried to Europe by the Gulf Stream). In order to estimate these effects, the IPCC used six greenhouse gas emissions scenarios in various climate models. The results, as presented in the third IPCC report (2001), predict that:

- Carbon dioxide concentrations in 2100 will range between 540 and 970 ppm, i.e., between 1.5 and 2.7 times the present level.
- Global average temperatures over the 1990 to 2100 period will increase by 1.4°C to 5.8°C.
- Global average sea level will rise by 0.09 to 0.88 meters over this century.

These changes would be larger than anything experienced in the past 10 000 years, and would be even larger locally (where exactly is still too uncertain to be mapped). Why such ranges? Because of the uncertainty associated with such critical parameters as:

- Greenhouse gas emissions (that, for example, were larger than expected between 1990 and 2000).
- Impacts of clouds and aerosols (paradoxically, the current emission reduction of SO_2 and NOx are to be regretted in this respect, as the concentrations of these gases in the atmosphere tend to reduce warming).
- Feedback effects from oceans (as regards both temperature and storage of CO_2).
- Natural climate variability.

No probability measure – either objective or subjective – can be assessed for the magnitude of these phenomena, hence for the range of the effects previously mentioned. It is thus clear that the science of climate change is uncertain. But this uncertainty is kept firmly within bounds. These bounds are not provided by the canonical form of scientific investigation as conducted in controlled laboratory conditions, but they are nevertheless the result of a highly methodical, systematically scrutinized production process that leave no room for maverick prophecies. Indeed, the IPCC, as an international and intergovernmental group of experts established by the United Nations and the World Meteorological Organization, is responsible for collecting relevant scientific data, and having them produced when they are lacking. The group uses these data and its members' scientific expertise (in physics, chemistry, biology, economics, etc.) to assess the physico-chemical, ecological and socio-economic consequences of climate change. The experts in the group are chosen by their scientific peers, and the choices are confirmed by their respective governments. Their work is organized as a continuous process, in subgroups set up by field of investigation. They produce interim reports that are discussed with governments and NGOs. But they retain sole responsibility for the contents of their periodic official reports (1990, 1995, 2001). All this shows that the IPCC process contributes to scientific knowledge in a systematically organized, controlled and rigorous way, from both theoretical and empirical points of view.

It is all the more remarkable that the US government rejects this contribution as scientifically unfounded. It has recently developed a plan of its own for investigating and

tackling the perspectives of climate change. This plan has been assessed by an expert panel assembled by the US National Academy of Sciences. According to the New York Times (March 1, 2003): "[The panel] described Mr Bush's plan as a redundant examination of issues that had largely been settled, bereft of vision, executable goals and timetables —in short, little more than a cover-up for inaction". Indeed, this is exactly what the precautionary principle, when rationally invoked, is there to avoid.

1. For an extensive compendium and analysis, see OECD (2002) ; the two quotations are from pages 39 and 41 in that document.

2. For more details about these two cases, see European Environment Agency (2001).

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RÉSUMÉ P. 12
ABSTRACT P. 24

How Can Expertise Be Organised at an International Level? The Case of IPCC

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More than a real analysis, this short contribution may be regarded as testimony from a scientist who was involved as a lead author in the last report of the Intergovernmental Panel on Climate Change (IPCC).

It is a limited contribution to a wider problem: "how can expertise be organised at the international level?" We will first review some of the specificities of the climate change problem, which have had a strong impact on the definition of the IPCC process, and also some of the specificities of the scientific community active on this problem.

A Global Problem

A first important characteristic of climate change is that it is by nature a global problem. Greenhouse gas emissions have the same impact wherever they are emitted from, which means that a CO_2 molecule emitted by any country in the world has the same impact on the global climate. On the contrary, the local impacts of this greenhouse gas are very different but cannot be localised very accurately. These facts strongly constrain the expertise process. Because it is difficult to predict which countries will win or loose from the greenhouse problem, a strong general concern has emerged, at least through the scientific community, and has led to some global thinking and expertise more than for other problems.

Another important feature is the existence at the origin of the scientific problem of strong evidences in number of hard undeniable facts. The increasing atmospheric content in greenhouse gases has been measured over several decades. The *International Geophysical Year* in 1957 provided the means to carry out the first CO_2 measurements in the atmosphere, and already in the early seventies, it was clear that there was a trend in the CO_2 concentration but also in the concentration of other gases such as methane. We have extended our measures backward into the past and we know that these trends began with the industrial era and are due to human behaviour. There is a need to discuss the importance of those changes but they constitute a very strong starting basis for the expertise process, enough to motivate international bodies to create a dedicated structure such as the IPCC.

The IPCC was given a very clear mandate by its sponsors (the United Nations Environment Programme, and the World Meteorological Organisation-WMO): to review the existing science on climate change. The limits of this mandate must be stressed: the IPCC activity has been kept separate from the development of the existing research effort —although of course the IPCC was able to build and capitalise on this existing research effort. This has had important consequences from a methodological point of view, as developed in the next paragraph. The IPCC, on the other hand, has also been kept independent from the actual negotiation process, which means that the IPCC has managed to play a role at the interface between the scientific community and the

negotiation process, remaining (for the most part) independent from both.

The Role of the Scientific Community

How Can Such an Expertise Process Work?

It is important to stress first that it must rely on an active and organized scientific community. Let us consider the first difficult problem linked with the review process: how can we identify the potential experts? How will they be selected? This can be done in a somewhat consensual way only because the scientific community has for a long time been organised at some international level. Indeed, a strong characteristic of the community working in the fields of the physical, chemical or biological environment of the earth is that its activities have been coordinated by international efforts since the seventies at least. I have mentioned the *International Geophysical Year* in 1957, which is one of the key starting dates for international cooperation. Presently, at least two major programs organize the sciences of the global environment: the World Climate Research Program, sponsored by WMO, which is more focused on physical measurements and understanding whereas the International Geosphere Biosphere Program (IGPP), sponsored by the International Council of Scientific Unions (ICSU), has expanded the research to biological, chemistry and the human dimensions of the problem. The credibility of the IPCC would have been much poorer if it had not been able to capitalise on the credibility of this organised scientific community.

The necessity of a pre-existing scientific community can also be seen in the technical process leading to the writing of the reports. The first step is to carry out a review of the published literature. Note that by "published literature", one means the published *and* peer reviewed literature. The IPCC has been very strict on that. Only published scientific information has appeared in its reports: all the material that went into the summaries distributed to decision-makers has been based on material already listed in the complete IPCC report, itself based on published literature exclusively. All material and all figures based on published papers were rejected from the different IPCC publications at the end of the process. The respect of these procedures of peer reviewing, the role of the scientific associations which edit the various journals, all this constitutes the basic structure that serves to organize the scientific community: it is also one of the bases on which the IPCC has chosen to establish its credibility.

The IPCC process contains another review process, by governments and experts, concerning this time the choice of the scientific material that has been selected by the contributing and lead authors for their first draft. The IPCC has evolved in how to treat these different reviews and comments. For the last report editors were appointed for each chapter. They were independent from the actual authors and in charge of looking after the correct handling of the many reviews.

Finally the last step is the approval of the summaries by a general assembly (where all countries are represented), with a vote of the text line by line or paragraph by paragraph. This very careful approval of the written material is one of the best characteristics of the IPCC mechanism.

Limitations

In spite of all this care such an approach is not exempt from possible biases and limitations.

Before discussing them it may be important to recall that there were in fact three groups in the IPCC process:

- One concerning the science of the climate change, based on what we may call "hard science" (physics, biology).
- Another concerning the impact of climate change. This was more difficult from a methodological point of view because it was based on predictions, which are not completely safe, of what may be the local consequences of climate change, and drawing on some inputs from the social sciences: what is important in term of climate change? What is not important?
- A third group was in charge of making the link with social sciences in order to evaluate the economic component of future scenarios, both to understand future greenhouse gas emissions in case no action is taken and to examine possible measures to mitigate those emissions.

Some of the remarks below may apply more closely to the science group, Group 1, although they correspond with some nuances to problems encountered by all three groups.

A key difficulty to be stressed is of course the diffusion of the information. After this huge process, the information is condensed into the few pages of a summary and then a few key illustrations. The figure showing the temperature record, for example, has played an important role in the appreciation of the conclusions of the IPCC process in 2001. It shows the global temperature change throughout the 21st century. Two diagrams have been used: one is starting from present conditions. The second one is a diagram showing information starting from 1860. Although the information provided by those two diagrams is strictly the same for the part concerning the future ahead of us, they are clearly different in terms of impact because the second diagram shows more clearly the difference between what we can expect in the future and what has happened in the past. The IPCC has also added two shadings on those diagrams: dark shading, which represents the uncertainty resulting from the different scenarios of climate change, e.g., the different hypotheses concerning future energy use; and a lighter shading, which is a measure of the difference between different physical models. Visually percieving those two kinds of uncertainties, which are very different (one is related to how we understand the physical world, the other to how we will behave in the future) has had a strong impact on the perception of the problem by the general public, the decision-makers and the media. It has led, to my mind, to a number of confusion. The details in the diffusion of the information from a consensus report such as the ICPC report are extremely important: one has to be very cautious about who controls them.

Another source of difficulties in the IPCC process has been the handling of uncertainty: the examples I have just discussed also point out this problem. This is a very general concern: from the hard evidence discussed at the beginning, and as we move towards the real impacts of those scientific problems on societies, towards the real information that might help decision makers, we have to face a number of added uncertainties which are very different in nature. Finding a convenient metric to qualify these uncertainties is difficult and, in my opinion, IPCC has not completely succeeded. There is a huge difference in terms of decision-making between a moderate risk that can occur frequently in a random manner, and the remote but real possibility of a true catastrophe. Providing this information to decision-makers in an adequate and well agreed manner is something which requires some further thinking and is probably one of the weaknesses of the existing IPCC report.

The last point I would like to mention is the difficulty for an IPCC-like process to adequately treat minority opinions. This is again essential. The IPCC report has played an important role in the public debate over climate change. But in spite of it, and to consider only the situation in France, the media have highlighted a large number of instances of so-called conflicting information about the possibility of a climate change. A part of it is due to non-expert people speaking about a science they do not know. But part of it is also constituted of criticisms from the scientific community concerning information or points of view which are almost always contained in the main IPCC report but have not made their way into the summaries, that condensed the information that is transmitted to the media or the decision makers. That these arguments, concerns, and nuances from authorised scientists are more easily expressed in the mass media than in the outcome of the expertise procedure should be a source of worry because it leads to a confusion between expert and non-expert views in the public perception.

In summary, the IPCC probably constitutes the best and most successful example so far of international scientific expertise on a given subject. This success is the result of rather specific conditions which we have tried to emphasize. It does not constitute a perfect example of what should be done: the IPCC process is also affected by limitations that need to be reduced in the future.

RÉSUMÉ P. 13
ABSTRACT P. 25

Type II Ambiguity and Precautionary Screening with Respect to Large-scale Chemical Threats in the Environment

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Risk and Ambiguity

In risk assessment socio-political ambiguity denotes the variability of legitimate interpretations based on identical observations or data assessments[1]. Many of the disputes in the fields of risk analysis and management do not refer to differences in methodology, but to the question of what a presumed risk means for human health and environmental protection: Does it involve perceptions of major potential harm? Is it associated with significant institutional conflict or political mobilisation? Are there issues of "distributional equity" or signs of "social amplification" in the news media?

At present, electrosmog may serve as an illustrative example. The scientific mainstream, on the one hand, is predominantly sceptical about the adverse effects of low-frequency electromagnetic fields and the insurance business widely classifies them as "phantom risks." Segments of the general public and of the news media, on the other hand, electromagnetic fields are seen as major sources of impairment, including carcinogenicity.

In contrast to socio-political ambiguity –which will be referred to type I– there is a second form of ambiguity which applies to risk research itself. This second type of ambiguity has to do with the way sciences organize the inquiry of a potential risk. A potential environmental threat such as climate change or ozone depletion does not appear in scientific terms from the very beginning. Instead, it appears as a potential fact of everyday life that necessarily has to be reformulated as a scientific problem prior to scientific investigation. However, due to the highly-specialized, "balkanized" structure of the scientific world it is not clear *a priori* which of the conceivable disciplines will take ultimate responsibility in the shaping of a presumably multidisciplinary research process[2]. This type of ambiguity will be called type II.

The history of the greenhouse gases and climate change may serve as an illustration for type II ambiguity. In the early eighties they were seen mainly as problems of environmental chemistry. It was then that the chemical dynamics of the greenhouse gases in the atmosphere were at stake. However, once some probably dominant chemical mechanisms had become plausible, the main interest shifted to prediction: would there be a climate change at all? And if so, to what extent could it be influenced by reductions of greenhouse gas emissions? As environmental chemistry does not offer an obvious route to the investigation of these problems, the leading responsibility changed from chemistry to the group of "modellers" who purport to synthesize all the relevant knowledge[3].

Precautionary Action and Chemical Assessment

The appraisal of potential adverse effects of new and existing chemicals is one of the

most tedious and costly burdens of innovation in the chemical industry. Although both industry and regulatory agencies have called for an overhaul of the relevant procedures, there is no general demand for the development of new and more efficient assessment tools by regulatory authorities. The recently published EU White Paper on a Strategy for a Future Chemicals Policy[4], for example, exclusively mentions classical risk assessment in connection with a quest for more data, more regulation, more costs and more responsibility for industry.

As we intend to look at the situation under the aspect of type II ambiguity, it is imperative to take a short look at standard chemical assessment. This can be summarized as a four-step procedure.

1. *Substance properties and emissions.* The first step starts with the characterization of chemicals in terms of their physicochemical properties, such as the vapour pressure, the octanol-water partition coefficient, the Henry's law coefficient and rate constants for the various degradation processes in the environment. These chemical properties reflect intrinsic chemical properties of the chemicals in question.

2. *Exposure.* After emission, many different kinds of transport and transformation processes take place in the environment. The processes are governed by the intrinsic properties of a chemical in combination with environmental factors such as temperature, humidity, presence or absence of oxygen, etc.; they determine the concentrations at which the chemicals occur in the environment and to which organisms or ecosystems they are exposed.

3. *Effects.* Exposure to chemicals causes a variety of effects in the environment, which are investigated by methods of toxicology and ecotoxicology. Here, it is the objective to causally relate effects to concentrations and to derive dose-effect relationships that, in turn, are used to define threshold values for the occurrence of adverse effects.

4. *Prediction.* The scientific results thus derived are assumed to reliably predict a chemical's environmental fate and impact.

This practice was carefully discussed by Scheringer who emphasizes the impossibility of testing the reliability of the above assessment scheme under real environmental conditions. This has to do with an aspect Scheringer calls overcomplexity: overcomplexity due to the virtual infinity of possible biological effects in organisms and ecosystems and overcomplexity due to the undeterminable diversity of the environment itself.

The sequential nature of the assessment scheme, on the other hand, implies almost inevitably that the overall outcome of chemical risk assessment is dominated by toxicology and (to a lesser extent) by ecotoxicology (i.e. the disciplines doing the concluding synthesis of the relevant results). In more technical terms, one speaks of so-called toxicological and ecotoxicological "endpoints"[5] that are controlled by these disciplines. It is the endpoints which trigger regulatory decisions.

However, in view of these observations, one is confronted with the paradoxical situation that toxicology is the relevant discipline in chemical assessment in spite of the fact that the major insufficiencies of the overall procedure are due to the impossibility for toxicology to properly deal with biospheric overcomplexity. To some extent the situation is comparable to forensic psychiatry— many people criticize it, but some discipline has to do the job.

In the eighties, the quasi-monopolistic situation of toxicology was slightly changed when "ozone depletion potential" and "global warming potential" were established as novel, non-toxicological assessment endpoints. One realized that not only biological objects should be protected, but also non-living structures such as the atmosphere. However, as these new endpoints were again effect-based, this new and extended perspective was essentially in line with the earlier development. One simply had to think of the atmosphere as a novel kind of "organism" or ecosystem to be protected.

Exposure-based Precautionary Pre-screening of New Chemicals

Precaution-type arguments can be identified at several places in standard chemical assessment, particularly in the case of the well-known "safety" or "assessment" factors that contribute to the final result. Pre-screening is an entirely different type of precautionary action. It can be seen as a reaction to the problem of divergent time scales. On the one hand one observes the ever-accelerating pace of technical innovation. On the other hand it can take decades before adverse effects appear in man or the environment and there may be another decade between a first suspicion and its full scientific confirmation. However, even then

it can take considerable time before management measures remove adverse effects of failed innovations. For some humans or species full scientific clarification may come too late. The problem of divergent time scales calls for a kind of precautionary prescreening that tries to identify cases where immediate reaction is urgent.

With regard to chemicals, one remembers that their presence is a necessary condition for adverse effects. This simple logical fact gives exposure and persistence a special importance: if it turns out, possibly a long time after release, that an apparently inconspicuous persistent compound has negative biological effects, it is impossible to eliminate it from the environment. The resulting situation would be unmanageable because even immediate phasing out may not ameliorate the situation quickly enough for some species. The PCBs and the European otter *(Lutra lutra)* can be regarded as a typical example of this scenario.

These facts have been used to propose a general approach to environmental precaution by controlling necessary factors of adverse effects instead of controlling risks directly[6]. The approach recognizes the fact that the probability of an adverse effect factorizes into the probability of a chemical being at a given place and the conditional probability of the adverse effects, given its presence at said place. In the language of standard chemical assessment one would say that the probability of adverse effects factorizes as a given exposure and the probability of (toxic) effects.

In order to be as specific as possible, however, one has to take into account that longevity alone does not lead to possibly unmanageable situations (see e.g. concrete, bitumen, plastics, etc.). It is only in combination with other controlling necessary factors such as mobility and/or bio-accumulation that persistence is a significant indicator for possible large-scale environmental threats.

Screening out chemicals with high persistence, mobility, or bio-accumulation potential is a type of precautionary prescreening proposed by several authors. The corresponding parameters can be determined from chemical information alone. In this setting, persistence, mobility, and bioaccumulation potential appear as endpoints of an exposure-based assessment which can be done by chemistry alone, without referring to toxicology or ecotoxicology.

A Case of Type II Ambiguity?

The precautionary principle as a management tool is still highly controversial, both in the United States and in Europe. Although there are too many pros and cons to be briefly summarized[7], it can be said that many critical objections come from the risk assessment community: as risk denotes the combination of probability times magnitude of adverse effects, risk assessment in its standard form is necessarily effect-based. This is contrary to exposure-based assessment approaches, such as precautionary prescreening, which may explain a sometimes far-reaching lack of understanding as well as the calls for so-called “sound science”, which occasionally appears as synonymous with effect-based assessment. In this perspective the debate is shaped as a controversy between the mainstream of an established community and a dissident minority.

With respect to precautionary pre-selection of chemicals, things can be viewed from a second, largely different, perspective; “exposure-based” means environmental chemistry and “effect-based” means toxicology. It is notable that the toxicology community is reluctant with respect to precautionary pre-selection. Evidently, it is not toxicology which controls the corresponding endpoints. To be clear, exposure assessment is part of standard chemical assessment, and standard chemical assessment will continue to have toxicological endpoints and to play its present-day regulatory role for chemicals surviving the foregoing precautionary selection. The essential difference is the promotion of exposure to an endpoint in the small and novel field of precautionary pre-screening. In this perspective, the debate appears as a type II ambiguity between environmental chemistry and toxicology: will there be a shift in disciplinary leadership or will toxicology extend its leading role to precautionary pre-screening of chemicals?

For this question it is crucial whether toxicology and ecotoxicology overcome the overcomplexity problem. Is it possible to find novel and sufficiently reliable endpoints allowing for rapid and reliable pre-screening? It seems that the new field of toxicogenomics, which looks at gene expression or expression patterns, could open up new vistas. This would lead to a situation of mixed responsibility for pre-selection. In addition to exposure-based endpoints, there would be new toxicodynamical endpoints, and chemicals might be screened out by either of them.

Acknowledgment

The author gratefully recognizes critical remarks by S. Funtowicz pertaining to problems of ignorance, uncertainty and ambiguity in risk research.

1. Klinke A. & O. Renn, 2002. A New Approach to Risk Evaluation and Management: Risk-Based, Precaution-Based, and Discourse-Based Strategies. *Risk Analysis* 22, 1071-1094 (2002), p 1086.

2. This problem was brought to the author's attention by Silvio Funtowicz.

3. This shift in disciplinary leadership was emphasized by Silvio Funtowicz, who also raised the question of what kind of science modelling really is. There seems to be some literature about tensions between empirical scientists (natural and social) and modellers.

4. CEC, COM (2001) 88 final, Brussels 27.2.2001.

5. Comp. Glenn W. Suter II, 1993. *Ecological Risk Assessment*. Lewis Publishers, Chelsea (Michigan), Chapter 2.

6. U. Müller-Herold, 1996. Measures of Endangerment. The Geneva Papers of Risk and Insurance, 80, 383-392. In an introductory address the editors write: "Müller-Herold's paper introduces a conceptual alternative to risk analysis as the basis of risk management. Risk denotes the combination of probability times magnitude of adverse effects. Conventional management strategies are designed to reduce either one of the two components. Müller-Herold argues that the precautionary principle in environmental policy making requires an approach that implies management steps at an earlier stage. His target is what he calls "endangerment". Controlling endangerment means controlling the scope and range of the potential for damage. He develops a taxonomy of endangerment that comprises two main factors: spatial extension and persistence over time. These two factors determine the degree of endangerment regardless of their strength of destructive potential."

7. For a first orientation the reader is referred to a special issue on the precautionary principle of the journal *Human and Ecological Risk Assessment*, Vol. 5, 1999.

The French Food Safety Agency (AFSSA) Food for Thought After Four Years

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Nearly every European country has now created an agency responsible in whole or part for assessing the health risks associated with food. Because of the institutional and administrative specificities of each country, the forms of the agencies vary widely. They constitute as many responses to two common questions raised by the establishment of such bodies: the nature of the organisational and institutional relations between risk assessment and risk management, and the extent of their independence from politics and business. A third question, after several years of operation, is the system's effectiveness in regard to its objectives.

Four years after AFSSA's establishment, our experience provides food for thought about the system established. We shall apply ourselves to that task here after describing very briefly the AFSSA's objectives and operating methods.

AFSSA: Objectives and Organisation

The French Food Safety Agency (AFSSA) was created by Law No. 98-535 of 1 July 1998, a statute intended to reinforce health surveillance and the safety of products intended for human use. Under the primary authority of the Ministry of Health, this law established a broad system of health security. Food was only one topic targeted: at the same time, the legislature created the French Drug Agency (AFSSAPS); this led in 1999 to a redefinition of the functions of the French Transplant Agency, set up in 1994. At the same time, the agencies dealing with blood safety were also reorganised. Finally, two years later, the law of 9 May 2001 completed this system by creating a French Agency of Environmental Health (AFSSE) and the Institute of Radioprotection and Nuclear Safety (IRSN) —a merger of the Office of Protection against Ionising Radiation (OPRI) and the Institute of Nuclear Protection and Safety (IPSN).

Within this System, AFSSA Was Assigned Three Essential Tasks

Because AFSSA primary objective was to help protect consumers, its first mission is risk assessment, in this field that requires particular skills: AFSSA deals with the entire food chain. This ranges from animal health, although it has no direct impact on human health, through the delivery to consumers of food products. AFSSA thus covers all of the stages of production, transformation and distribution. AFSSA must also assess nutritional risks. Its scientific expertise may thus cover balanced diets, obesity in children, salt and sugar intake, etc. (all of which is useful for its participation in a national public health nutritional program).

The second major mission is research, and the third scientific and technical support. One particularity of the latter for France is that the Agency on its establishment incorporated 13 existing laboratories distributed across the country, organised either by production branch (pork, poultry,

bees, etc.), or by cross-sectional themes (for example, dairy products, zoonoses). These were previously attached directly to either the Ministry of Agriculture or the Ministry of Health (hydrology laboratory). Our aim was thus to establish close links between the spheres of scientific assessment and of research, so that research priorities might include the scientific questions identified during assessments and the scientific knowledge acquired in the Agency's laboratories could directly feed into and assist the assessment work.

The Agency also has specific responsibilities for veterinary drugs. It includes the national Agency of veterinary drugs, which handles applications for marketing authorisations and adverse drug reaction reporting and can inspect veterinary drug manufacturing plants. The Agency therefore exerts both assessment and risk management functions in this area.

AFSSA has a staff of nearly 900 and calls on several hundred experts. Its annual budget is roughly €90 million.

Some Thoughts about the System Established by AFSSA

In the light of four years of experience, several points merit discussion. This is especially important since the law of 1 July 1998, which created AFSSA, planned its own revision at the end of five years, that is, in 2004.

The Principle of Separation between Risk Assessment and Risk Management

This often-repeated principle was one of the objectives underlying the Agency's creation. Nonetheless, the law organises very close links between risk assessment and management. Three examples illustrate this here.

First, the law provides that the Agency may issue not only opinions but also recommendations to the competent authorities; it may even suggest specific measures of health police power. The exercise of the "police power" in France is very clearly an act of pure management. This type of recommendation, which like all scientific opinions must be made public, leaves the final separation between the domains of evaluation and of management very tenuous.

Second, the Agency must be consulted about any regulations proposed by the government in the domain of food safety and it must express its opinion on the adequacy of the proposed measures for the asserted health objectives.

Finally, the Agency must receive all of the information and data collected during the surveillance and control in this area by various authorities. This provision is intended to ensure that the reality in the field, especially how decisions are actually applied, is integrated into scientific evaluations, together with more basic or academic scientific knowledge.

In conclusion, the legislature, in approving these provisions, specifically chose not to separate the spheres of risk assessment and risk management. It decided instead to improve the allocation of tasks and responsibilities between each of these two partners. When the law is revised in 2004, we will see whether the legislature is satisfied with the results of this initial decision.

The Independence of the System

Here we will discuss the influences that may affect experts during the risk assessment process: these may come from politicians, from the business world, or even simply from public opinion, especially via the media.

It must be recalled first of all that AFSSA is not an independent authority but a public administrative Agency, directly supervised by three ministers (agriculture, health, and consumer affairs). They allocate the Agency's budget and name its managing director, who can be dismissed at any moment. At least in the French legal sense, therefore, it is not an independent authority. On the other hand, the law creating the Agency includes several provisions that enable it to obtain, organise and make public independent scientific expert advice.

Accordingly, all of the Agency's opinions and recommendations must be made public, by managing director; this is not a option for the Minister receiving the opinion or recommendation.

Moreover, not only the government may request opinions: consumer associations may also invoke the Agency's jurisdiction, but industry may not. The Agency may also choose to examine subjects that it considers important in the area of food safety, even if the government does not seek its advice on these points. This control of its own agenda is a powerful guarantee of the independence of the opinions rendered.

The Agency Budget Is Entirely Public.

Finally, the independence of the expert advisory opinions is guaranteed by several strict rules that govern and constrain the process.

These assessments are not conducted solely in-house; scientists outside of AFSSA conduct much of this work. The Agency is aided by ten committees of experts on various broad topics. This subject division is almost identical to that for the expert committees at the European level. AFSSA followed the procedures described below to appoint these committees: a public call for applications as broad and transparent as possible sought candidates through different channels (mail, but also by Internet, intended to reach a public in universities and public research institutes). With the aid of the Agency's scientific council, applications were analysed according to several criteria (initial training, job experience, dependence or independence in previous work for the private sector). Finally, the applications received —more than 700— were analyzed from this point of view. Intentionally, most of the persons selected came from the public research sector and had very diverse perspectives (to ensure representation of different points of view for some subjects). We also sought to renew the population of experts to obtain a balance between those with and without experience in advisory groups.

The experts chosen were legally required to report all interests (competing or otherwise) in the area, either personal or for the research unit to which they belong. Accordingly they must report all work or funding from the private sector. The Agency publishes these competing-interest declarations. Nonetheless, expert committees do not include only public sector researchers who have never had any relations with the business world. In some areas (for example, that of materials in contact with foodstuffs), French public expertise is extremely limited. It is therefore necessary to call on pre-existing industrial scientific expertise.

The Efficacy of the System

Assessing the efficacy of the system is perhaps the most difficult task, especially if the question is posed only in the following terms: is the new system more effective? Has it increased the level of food safety for consumers?

It is not easy to find clear answers in the area of food, which is the object of sharply differing opinions. Some claim that food has never been healthier and that this has had positive effects on the population's health and longevity. At the same time, a very vague feeling that food is dangerous has developed and is magnified regularly by different episodes (dioxins, mad cow disease, contaminated Coca Cola, etc).

To determine whether the system is more effective in terms of consumer safety would require that we establish and monitor several epidemiologic criteria, indicators of the incidence of relevant diseases, such as food-related cancers and variants of Kreuzfeld-Jacob disease. Epidemiologic forecasts in this area, however, are highly limited in their usefulness: it is very difficult to establish a direct link between disease and specific food, because of the enormous variety of food available and the huge number of interventions (handling, transformation, distribution) that it undergoes between manufacture and consumption. AFSSA naturally relies on collaborations, in particular with the National Institute of Public Health Surveillance.

Nonetheless, public health is not the only dimension to take into account. Other important dimensions are:

- political: the appearance of bovine spongiform encephalopathy led to the resignation of two government ministers in Germany;
- diplomatic: disputes take place between Great Britain and France and between Great Britain and the European Community during the embargo on British beef;
- media: food-related crises systematically receive massive media attention;
- economic: the economic stakes are considerable, during crises (dramatic drops in consumption) and in calm periods, as normalisation occurs;
- judicial, when, as is increasingly often the case, various parties seek to hold others liable —criminally or civilly.

All of these factors make it extremely difficult to evaluate the food-safety system. Nonetheless, this exercise is essential, not only for France as part of the revision of the law of 1 July 1998, but also in the many industrialised countries developing similar agencies and at the European level, for the European Food Safety Authority. We must act now to avoid discovering the system's flaws and weaknesses too late.

RÉSUMÉ P. 14
ABSTRACT P. 26

Relations between Scientific Experts and Public Policy-makers in the Area of Food

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The relations between human food and public health are in some ways unique. This text deals with several aspects of the fundamental changes that have affected the relations between scientific experts and political as well as administrative policy-makers in this domain. We first describe the different stages that have marked this development and led to the system that we know today. Then we present the organisation of the various expert committees at the national, European and international levels and discuss how it affects their relations with decision-makers. Finally we propose several desirable reforms in the area.

Stages of Development

Policy-makers are Not Interested

In France just twenty-five years ago, the scientists responsible for expert evaluations of health aspects of human food performed their tasks serenely, sending regular reports to committees of official experts. These committees relied on this information to make proposals to the public authorities, who then made regulatory decisions. It was during this period that the High Council for Public Health fought for more than a decade for the publication of these opinions. Its almost unbroken string of failures shows the lack of importance then attributed by political circles to the transparency and communication of the activities, work and opinions of scientific experts.

In one case, in 1992, the food and nutrition section of the Council called attention to the risks of bovine products, related to "mad cow disease" for humans; the first case of this disease in France had been reported in March 1991. No action followed this alert, which was never published. Since then parliamentary inquiry boards have paid attention.

These observations for France are equally applicable to the European Union for the same period: those responsible for deciding public policy seemed to consider themselves above the worries of scientific experts and were uninterested in their work. Only very rarely did the chair of a European scientific committee meet the Director-General responsible for the issues covered by his or her committee. Exchanges were limited to technical discussions with administrative officials, at best office or division heads.

At the European level (this was not systematically the case in France) several scientific committees were attached to the Commission Directorates-General that handled the relevant economic sectors. For example, the Veterinary Scientific Committee, and the Animal Food Scientific Committee were both attached to the Directorate-General of Agriculture.

When the mad cow scandal broke out, it was probably the mixture of the scientific evaluation of the risks and their management that led to the ensuing crisis of confidence in some European institutions. Several dysfunctions were found to mar the relations between the Veterinary Scientific Committee and the Directorate-General of Agriculture.

Experts did not receive from the DG some important files with highly relevant scientific information. Draft opinions prepared by the DG were distributed to the Veterinary Scientific Committee at the beginning of sessions. These operational anomalies in the expertise process shook the Commission brutally. At the end, the Commission completely overhauled the scientific committees involved in the areas of risk assessment for public health and food.

Nonetheless, these are examples, not the general state of things. Political policy-makers could in some cases pay very careful attention to opinions issued by the expert committees and be very respectful of their independence. The Human Food Scientific Committee had excellent relations with the Directorate-General of Industry and the Internal Market, to which it was attached for many years. This committee was never strongly pressured to issue an opinion that would have had favorable economic and prejudicial health consequences.

The Progressive Development of Exchanges Between Policy-makers and Experts

When the first genetically modified organisms (GMOs) used as food or components of food appeared on the North American market and the first applications for their use arrived at the European Commission, new questions and new responsibilities, beyond those associated with BSE, weighed on the EU's scientific committees. Consumer interest augmented abruptly, and citizens little by little began to seek explanations from administrative and political policy-makers, who then turned towards the scientists in whom they showed somewhat more interest than in the past.

A new era began in the relations between scientific experts and policy-makers. As part of the reorganisation of the scientific committees mentioned above, a Scientific Steering Committee was created to coordinate the other scientific committees. All were attached to what is now the Directorate-General for Health and Consumer Protection. Regular meetings were then organised between the chair of this steering committee and the Director-General. These meetings were intended to enable each to understand the other's concerns and working methods better and to help ensure that the scientific committees' responses to the questions of the Commission and of administrative and political policy-makers were adequate and relevant.

The relations between the scientific committee chairs and the policy-makers, including political policy-makers, slowly became much more frequent, for example, during discussions on the lifting of the British beef embargo in 1999.

At the same time, the media have become ever more pressing, not to say troublesome: requests for interviews have multiplied, coming from all over the world. This places further pressures on scientists.

The Organisation of Expert Committees

The organisation of different committees of experts, French, European and international, has important consequences on the nature of their relations with policy-makers.

France: the Example of AFSSA

In accordance with an old French tradition, three ministries are systematically involved in the supervision of institutions that express scientific opinions related to food safety. These are the Ministries of Health, of Agriculture and of Finance (through the Secretary of State responsible for consumer affairs). Following this tradition, AFSSA, which is organised in ten committees of scientific experts, reports to three political departments.

This agency constitutes important progress over the previous French situation. Nonetheless, the legislature has set a serious trap for these committees by requiring them to assess all legislative and regulatory texts. When such a request is submitted to a committee of experts, they will not only have to submit a scientific opinion assessing risks but will also be directly involved in their management. This pitfall should be considered by the upcoming revision of the statute that established AFSSA (the 1998 law intended to reinforce health surveillance and the safety of products intended for human use).

Europe and the World

Among the changes at the European level, we have already mentioned the creation of a Scientific Steering Committee. One of the major concerns of this committee has been to harmonise the approaches of other specialised scientific committees: the Human Food Committee, the two veterinary

committees, as well as those for animal food, for plants, for drugs and medical devices, for cosmetics and for ecotoxicology and the environment. These committees, for historic reasons related to the sector they cover, apply slightly different methods for risk assessments.

This organisation of scientific committees, attached to the Directorate-General for Health and Consumer Protection (SANCO), will remain in place until the European Food Safety Authority (EFSA) becomes operational. DG SANCO makes no decisions about economic matters related to the food industry or agriculture. It manages the administrative duties and leadership of the various scientific committee organised into specialised working groups.

No administrative or political policy-makers exist at an international level. Nonetheless, the World Trade Organisation relies on the opinions of Codex Alimentarius, a United Nations organisation working under the joint aegis of the FAO and WHO. Codex Alimentarius is organised into different committees, one of which focuses on food additives and contaminants. These committees are composed of experts who represent their governments, and they in turn rely on groups of independent scientific experts, for example, the Joint FAO/WHO Expert Committee on Food Additives (JECFA); its experts do not represent their country, but work in their individual capacities. There is no institutional setting where the JECFA scientific experts meet the members of Codex Alimentarius.

Dealing with these questions on an international scale requires awareness of the many pressures exerted on the committees to protect various economic interests. These become clear through what we might call "government science" arguments, several illustrated during different clashes between the United States and the European Union. There is no real scientific debate about hormones in meat, since the scientific file of European Union was essentially empty: it was a different sort of confrontation. Europe took its position for reasons that were not purely scientific and public health-related. Similarly, in the discussions about international standards for dioxins and mycotoxins, economic interests underlay the scientific positions argued within JECFA.

It is thus very important for experts to know the reasons they are called upon and the economic consequences of their opinions. Nonetheless their work ought to be limited to strictly scientific considerations, and other bodies should deal with questions of a political, economic and commercial order.

Harmonise Assessment Methods and Develop Dialogue

Procedure and Harmonisation of Risk Assessment Methods

The Scientific Steering Committee of the European Union has established a task force to submit proposals for the harmonisation of risk assessment methods in the areas of food and health. Once the relationships between scientific experts and policy-makers are formalised, these proposals could also be applied to other scientific committees of the European Union and of the Codex Alimentarius, thus magnifying the international impact of this harmonisation.

In addition, for policy-makers to be in a position to make decisions based on adequate knowledge, in as effective and informed a manner as possible, several conditions should be fulfilled:

- The scientific uncertainties about risk must be expressed clearly, in homogeneous language and using a shared vocabulary. In particular, the various hypotheses on which the experts' analyses and opinions are based must be presented clearly and the level of uncertainty and the plausibility of the knowledge described clearly.
- Different proposals for risk management should be associated, where appropriate, with the different levels of risk considered.
- It is appropriate to ensure that the questions directed at scientists truly come within their field of competence and that the scientists' response is relevant to the question and understandable by the policy-makers. The dialogues and the continuing interchanges between scientists and policy-makers then become truly important.
- The separation between risk assessment and management is desirable, but continued interactions between risk assessors and managers remain essential.
- Communication during the expert assessment can be crucial: it must be conducted with attention to clarity, not only for the policy-makers, but also the public and the media.
- Finally, policy-makers should specify the extent to which scientists' opinions are taken into account for regulatory or legislative decisions.

Scientists, Policy-makers, Citizens: How They Can Work Together

A dialogue between political leaders and experts is essential, but dialogue and consultation do not mean a transfer of responsibility: responsibility for decisions at the end of the day belongs to the political decision-makers. In this regard, the expert committees should insofar as possible be protected from political and economic pressures.

This concern for the independence of the expert assessment process is accompanied by concern for transparency. For example, when it was decided to ban animal meal, consumers and citizens should have learned that:

- this ban was taking place at a point when these were already much less dangerous than they had been (before 1996);
- environmental questions were associated with their storage;
- some decisions in the battle against mad cow disease must inevitably have substantial economic and social consequences.

A debate on the latter question should have been organised in each member state of the European Union and Union-wide.

We note finally that, despite all of the warnings by the Scientific Steering Committee to Spain, Italy and Germany about the possibility of mad cow disease in their countries, they took no measures until the first animal was affected —or discovered.

Conclusion

Despite all the dysfunctions brought to light by the health crises that have struck Europe and its member states, the European health system finally functioned satisfactorily, overall. Determinant in that success, nonetheless, was the reform of the organisation of the scientific expertise that conducts risk assessments: these were brought together within a Directorate-General not involved in the organisation of agriculture, the food industry or food distribution. This organisation, which began in 1997, also allowed reflection on the independence and transparency of the activities of scientific experts, and led to the creation of a European Food Safety Authority in 2002. This step was certainly progress in the development of the European system. One of the fundamental issues facing the Authority is the question of the ways in which national agencies can participate in its work, so that it may benefit from the skills available and avoid wasting resources, without being influenced by the pressure of member states concerned about defending particular interests.

Science and the Precautionary Principle

RÉSUMÉ P. 14
ABSTRACT P. 26

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The precautionary principle is basically a statement that we should not go ahead with a new technology, or persist with an old one, unless we are convinced it is safe. This sounds such an obviously sensible idea that we might expect it to be accepted by almost everyone and without question. Yet it has aroused fierce opposition especially, but by no means only, in the USA. Some claim it is nothing more than an admonition that we should be careful —and so says nothing that is not already accepted— while at the same time others argue that it is so powerful that if it were applied it would stop progress dead in its tracks. It is said to sanctify unscientific prejudice, and to be a mere cover for protectionism.

Here we refute these charges, using as illustrations two well known cases: tobacco and bovine somatotropin (BST). If the precautionary principle had been applied in these cases, it would have made a considerable difference, and for the better. We then discuss briefly how the principle can be applied to two current issues, climate change and genetic modification.

The Precautionary Principle

While there is no definitive statement of the precautionary principle, and while its opponents often set up and demolish straw man versions of it, there is a general consensus among its advocates of what it is. A typical example is the Wingspread statement[1]:

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

This formulation immediately deals with two of the common objections that are raised. First, the principle does not support unscientific prejudice. To say that the potential hazards do not have to be *fully* established scientifically makes it clear that the principle is precisely about cases where there is scientific evidence. The European Commission states this explicitly in its Communication on the Precautionary Principle[2], writing that it applies "where preliminary objective scientific evaluation indicates that there are reasonable grounds for concern..."

Second, the principle is about the burden of proof. It is not an algorithm for taking decisions, any more than the legal principle that the burden of proof in a criminal trial lies with the prosecution makes it unnecessary to have a jury to consider the evidence and come to a decision. It is a part of decision making, not a substitute for it.

Moreover, like the legal principle, the precautionary principle does not demand absolute proof. A jury is not supposed to convict only on the balance of probabilities, which is the criterion appropriate for civil actions, but it does not need absolute proof that the defendant is guilty. It must only be convinced "beyond reasonable doubt". And

what constitutes reasonable doubt in any given situation is also a matter for the jury to decide. The precautionary principle would no more stop all technological progress than the principle of the burden of proof makes it impossible to obtain convictions in the criminal courts[3].

The Precautionary Principle and the Courts

Many opponents of the precautionary principle argue that the issues it is meant to deal with are better decided in the courts. As we might expect, this view is especially common in the USA, a highly litigious nation, but it is found in other countries as well.

Now redress through the courts has obvious disadvantages. It is very expensive, generally well beyond the means of the private citizen. It can also be very slow, especially when a large corporation is involved: think how long the Bhopal case has dragged on. It is also primarily retrospective: one can only sue after the damage has been done. It is good that people who are dying of lung cancer can obtain damages from tobacco manufacturers, but it would have been far better if they had not been induced to smoke in the first place.

We see from this example, however, that the precautionary principle and the legal processes are not alternatives. They can be used together. The actions against the tobacco manufacturers succeeded only because of the evidence that the companies were aware of the dangers and did nothing about them. If the precautionary principle had been applied, then the companies' liability would date from the much earlier time when the scientific evidence was suggesting that there could be a real danger. Exactly what would be the critical date would have to be decided in the courts, but clearly many more smokers would be eligible for compensation, or at least their survivors would be.

The precautionary principle could have made an even more important contribution than that, because while lawsuits are necessarily retrospective, legal liability does have a prospective effect. It leads us not to act in ways that are likely to result in our being sued some time in the future. In this respect, legal liability is similar to regulation, except that instead of acting within explicit rules that are set down by governments, individuals and companies are influenced by their judgement of the consequences if things go wrong. Driving without insurance is against the law in most countries, but most of us are even more concerned about the very large damages we might have to pay if we caused a serious accident.

It is interesting to consider how the history of tobacco would have been affected if the precautionary principle had been applied throughout. Despite what its more vehement opponents may say, the principle would not have prevented tobacco from being introduced into England by Sir Walter Raleigh. It would have had no effect at all until about 60 years ago, because before then there was no scientific evidence of harm. Women were discouraged from smoking because it was not ladylike, rather than because it was possibly dangerous. We are told that when Sir Richard Doll's group was trying to discover why lung cancer was becoming so much more common in UK in the mid-twentieth century, they thought it might be due to the emissions from the much larger number of motor vehicles that had recently come into use, and were surprised to find the correlation with cigarette smoking.

Once the epidemiological evidence was published, however, the precautionary principle would have made a significant difference. Governments would not have felt obliged to wait until there was a known mechanism linking smoking and lung cancer —a "smoking gun", so to speak. They would have become involved much earlier, and the restrictions on tobacco advertising, the large increases in excise duties in countries such as the UK, and the bans on smoking in public places might have come into effect many years before they did. More individuals would have been aware of the risk they were taking, and would have given up smoking.

The manufacturers too would have had to do more than they did. Once the evidence that smoking might be harmful was strong enough, they would have been required to carry out research to try to establish that it was not. Their failure to show this, and we can be in no doubt that they would have failed, would have been a further reason for both governments and individuals to act. Whether it would also have led the manufacturers to act on their own accord is another matter: the record of their behaviour in North America and Europe and their present expansion into Asia suggest not. This is a further reason for applying the precautionary principle. Those who are producing something new, or whose existing product is now giving cause for concern, have an obvi-

ous incentive to push ahead. Putting on to them the burden of proof of safety can balance the pressures.

Thus not only are two major objections to the precautionary principle contradictory, they each fail separately. If the principle had been applied to tobacco right from the beginning, it would not have prevented it from being introduced and used for almost four hundred years. As the scientific evidence started to accumulate, however, the reduction in smoking would have occurred sooner than it did, and thousands, possibly millions of lives would have been saved.

The Precautionary Principle and Uncertainty: The case of BST

The evidence that smoking is harmful is now overwhelming. To see how the precautionary principle operates when the evidence is not conclusive, we turn to the case of bovine somatotropin (BST), a hormone that, when fed to cattle, increases milk yields by about 10%. It is permitted in the USA but not in most other countries.

In 1997, the European Union banned the import of products from cattle that have been treated with BST, on the grounds of safety. The Americans took the case to the WTO, claiming that the issue was not one of safety at all. They argued that there was no known example of humans being affected by BST, and that the EU's action was merely a device to close their markets to produce from the USA.

In its original decision, the WTO gave the EU a year to provide evidence of harm to humans. If they could not do this, the ban would have to be lifted. This is a clear example of how the precautionary principle can make a real difference, because had the principle been invoked, the WTO would have been very unlikely to make such a ruling. In fact, the WTO was applying what we might call the antiprecautionary principle: it is for society to show that something is dangerous, not for the innovator to show it is safe.

Now it is true that there is no known example of humans being affected by BST. But it does not follow that there is no danger. First of all, many harmful effects take a long time to become obvious. The harmful effects of tobacco occur only after many years of smoking. Besides, if BST is harmful to humans, it will be very difficult to establish this because there is no control group. The original work on lung cancer was possible only because many people smoked and many people did not, and the researchers knew which were which. This is not possible with something that almost everyone consumes —apart from vegetarians, and their diets differ from others' in more than just BST.

There are, however, good scientific grounds for being concerned that BST might be harmful. They arise from the fact that BST is a hormone, i.e. a signal substance. It therefore has to be present only in very small concentrations to have a significant effect. It is not, to be sure, a human hormone, but hormones do not only act in the organism in which they originate. An example is the femininisation of fish in rivers in which there is a minute concentration of oestrogen, a human hormone. It enters the water system in the urine of women who are taking contraceptive pills, and it is not eliminated by the sewage treatment processes.

It has been found, however, that BST does not replicate the activity of human growth hormone (hGH) because it does not interact with the hGH receptors. Unfortunately, that is not enough to establish that it is safe, because hormones typically have effects other than their primary one. We always have to ask what else are they doing, and whether they are modifying the effects of other hormones.

BST has been found to stimulate the production of "insulin-like growth factors" (IGF-I and IGF-II) in the liver. These in turn are involved in many physiological processes including cell growth and tumor production. Unlike BST itself, bovine IGF-I is identical to the human form and survives pasteurisation. It is present in ordinary milk but in higher concentration in milk from cattle that have been treated with BST. High normal levels of IGF-I in humans are associated with a greater risk of cancer development, though it is not known whether the IGF-I is a cause or merely a marker[4].

Thus the evidence is that BST itself is largely destroyed by pasteurisation and would not act like human growth hormone even if it were not. On the other hand, there is cause for concern about the raised level of IGF-I in cattle treated with BST. There may be other secondary effects of BST in cattle or even in humans that we do not know about because no one has looked for them: it is not easy to discover how one hormone interacts with another.

The question is whether in the light of this evidence we are sufficiently confident

that the use of BST does not pose a risk to human health that we should allow the sale of milk products from cattle that have been treated with it. And even if some countries decide that the risk is acceptable, is the evidence strong enough that the WTO is justified in refusing to allow the rest of us to decide for ourselves?

There is of course also the issue of animal welfare, but here there is no need to invoke the precautionary principle because the harmful consequences of BST treatment, including an increase in mastitis and in foot and reproductive problems, are well known. Cattle with mastitis are, of course, treated with antibiotics and that adds to the danger to human health because it contributes to the development of antibiotic resistance in pathogens.

Finally we have to consider the other side of the argument, the possible benefits. Whenever we are trying to protect ourselves against harm, whether we are using the precautionary principle or not, we have to ask what the protection will cost, what are the benefits we are foregoing.

If the world were starving because of a shortage of milk, then we might weigh up the costs and the benefits and decide that, even using the precautionary principle, the best decision was to allow BST. But there is already a surplus of milk, so much so that, for example, the European Union has developed an elaborate system of quotas to reduce production.

The only benefits from the use of BST are to the companies that produce the hormone. Given that, the evidence is surely sufficient to convince us that it should not be used, and even more so that the WTO should not force it (more or less literally) down the throats of those that do not want to consume the products of cattle that have been treated with it.

In the event, the WTO backed off, and decided to postpone taking a decision on BST. The result is that the EU is allowed to maintain its ban, but at the same time no precedent has been set; presumably this was the intention. We await further developments.

Climate Change

Climate change may not appear to come under the scope of the precautionary principle because hardly anyone doubts that the Earth is getting warmer, that the chief cause of this is the burning of fossil fuels, and that as a result, the climate will change. Areas that are now fertile will become dry, and the sea level will rise and flood a great deal of land that is now occupied. Northern Europe, on the other hand, may become much colder if the influx of fresh water into the North Atlantic stops the Gulf Stream.

That much is well established. There is, however, a further possibility. The Earth's climate is a large, complex nonlinear dynamical system, and it is well known that such systems often behave in ways that are difficult to predict. In particular, when they are perturbed, they do not always respond by a change more or less proportional to the perturbation. They may hardly change at all, or they may undergo changes that are large, abrupt and, at least in the short term, irreversible[5].

We know that there have already been many abrupt changes in the climate. About 13,000 years ago, for example, the temperature in Greenland increased by about 8° C in a decade. It also increased rapidly in other parts of the Earth, but it is only for Greenland that we have the ice core data that give such an accurate measure.

We are at present perturbing the climate by causing a large increase in the concentration of carbon dioxide in the atmosphere. This has already led to a significant warming and there seems hardly any doubt that the temperature will rise still further, with estimates ranging from 1.5° C to 5° C over the next century. What will happen after that probably depends on whether or not we continue to pour greenhouse gases into the atmosphere. If there is nothing more drastic than a gradual rise, we, or rather our descendents, may be able to reverse the process.

What we do not know is whether we are about to trigger a much larger increase. The precautionary principle tells us that in balancing the damage that may result from global warming against the cost of keeping it under control (it is already too late to counter the effects of our actions in the last century) we should take into account the possibility that the increase in temperature may be considerably greater than has been estimated, and that, if it is, it will probably be very difficult to bring it down again even by a drastic reduction in the emission of greenhouse gases.

Genetic Modification

The issue of genetically modified organisms (GMOs) is a very complex one and can only be mentioned in an article of this

length[6]. But it cries out for application of the precautionary principle, if only because so much damage can still be prevented at this stage.

The most commonly raised objection to the introduction of genetically modified crops is ecological, that the genes may spread to other species. That is indeed a danger; more than that, it has already happened. In Canada and the United States, the genes that make oil seed rape tolerant to herbicides have spread to crops and weeds, which end up tolerant to multiple herbicides. That makes the herbicides useless and the weeds harder to control than before.

But while the ecological problems are real, and have attracted the most attention, they are by no means the whole story. The technology itself is a cause for concern. To be sure, hardly anyone is likely to die immediately after eating GM food. Apart from acute toxins and allergens, any harmful effects are likely to appear only in the longer term. There is evidence that many of the Bt toxins engineered into GM crops as biopesticides are actual or potential allergens for human beings, and toxic to a wide range of beneficial species. But it will be very hard to identify these and other effects by epidemiological studies because there is no control group.

We are often told that GM foods must be safe because Americans have been eating them for years. But if there have been harmful effects, with no control group how would we know? If all Americans are eating GM foods, none but the most immediate harmful effects are likely to be recognised.

There is evidence strongly suggesting that GMOs are hazardous. First, transgenic DNA is not, as is so often claimed, "just the same as natural breeding." It is different. For example, when researchers created mutants for herbicide tolerance both by genetic engineering and by conventional mutagenesis, they found that the transgenes were up to 30 times more likely to spread to wild-type plants[7]. The more rapid spreading of transgenes is a potential hazard in itself, but what is crucial here is the demonstration that the transgene was different. Genetic engineering is not merely reproducing what happens in nature, and it is creating new combinations of genes that have never existed.

Transgenic DNA can also be transferred (horizontally) to unrelated species, to bacteria in the soil or in the gut and to cells of all animals including humans[8]. When mice were fed viral or transgenic DNA, not only was the DNA not completely degraded in the gut (as we used to be assured it would be), it passed through the wall of the intestine into the blood stream and even became incorporated in the genome of some mouse cells[9]. When fed to pregnant mice, the foreign DNA was found in some cells of the foetuses and newborn, showing it had gone through the placenta[10].

The researchers raised concerns over the possibility that transgenic DNA integrated into human cells could result in mutations and trigger cancer, as we did[11]. This prediction has sadly become reality in the first cancer cases identified among the handful of 'successes' in gene therapy at the end of 2002. These patients were exposed to transgenic DNA similar in construction to those in GM foods.

The technology by which many GMOs are made is inherently dangerous, also because it often involves the creation, directly or indirectly, of super-viruses, which, unlike most natural viruses, are capable of crossing species barriers.

Genetic engineering further relies on the assumption that the piece of DNA that is transferred from one organism into a totally different one —from a fish to a tomato, for example— will have precisely the same effect in the second organism that it did in the first, and no other. This flies in the face of our modern understanding of genetics and of developmental biology. Organisms are a lot more complicated than that. Molecular biologists have long since given up defining a gene in terms of a more or less contiguous stretch of DNA. This alone raises the question of what exactly it is that is transferred.

We have a long way to go before we understand how the genome works, except that it is remarkably fluid and dynamic as it responds to multiple levels of feedback from the environment, to maintain itself constant or to change as appropriate to ecological challenges[12]. That makes it an interesting time to be a biologist, but it also means that in genetic engineering we are playing with a system we do not understand.

What are the benefits? We are often told that we must push ahead with the technology because otherwise millions of people in the developing world will starve. But there is easily enough food to feed everyone, and the best estimates are that using only conventional crops that will remain the case for at least 25 years and probably far into the future as well[13]. If people are starving —and millions are— that is not because there is not enough food but because it is not getting to them.

The problem of hunger is a problem not of production but of distribution. And distribution is not helped if we shift from small scale, local farming, where food is produced by the people who need it, to large agri-business. Yet it is the latter that genetic modification is designed to promote. Monoculture increases susceptibility to disease and pests, whereas smaller scale bio-diverse farming practices can mitigate the problem to the point where there is no need even to consider genetic modification as a solution[14].

Genetic modification may offer the opportunity for improving crops at some future time. The precautionary principle does not rule this out, nor does it exclude properly contained research to develop new varieties. It does, however, require that we should not press ahead with commercial crops until we have carried out the research necessary to establish that the technology we are using is safe.

Conclusion

The precautionary principle is neither so weak that it is empty nor so strong that it would stop the progress of technology. Far from being unscientific, it is based on science and it generally requires that more good science, not less, be undertaken so that sweeping assurances of safety can be replaced by solid evidence. The principle does, however, place more of the responsibility for safety on those who stand to profit if the technology goes ahead, rather than on those who will have to bear the costs if things go wrong. It is not really surprising that there are some who oppose it, however weak the arguments on their side may be.

1. The statement was the outcome of a meeting held at Wingspread, the headquarters of the Johnson Foundation in Racine, Wisconsin, in 1998.

2. COM (2000) 1 *Communication from the commission on the precautionary principle*. European Commission, Brussels, 2 February, 2000.

3. See P.T. Saunders, 2000: Use and Abuse of the Precautionary Principle. *ISIS News* (now *Science in Society*) issue 6.

4. See for example the summary of the talk to the WTO Risk Analysis Workshop, June 2000 by J. Moynagh of the European Commission, available on the web at: www.wto.org/english/tratop_e/sps_e/risk00_e/risk00_e.htm.

5. See the report of the Committee on Abrupt Climate Change (and others) *Abrupt Climate Change: Inevitable Surprises*. National Academy Press, Washington, 2003.

6. See M.W. Ho, 1999. *Genetic Engineering, Dream or Nightmare?* Gill & Macmillan, Dublin; or M.W. Ho, 2003. Living with the Fluid Genome ISIS and TWN. London and Penang..

7. See M.W. Ho, 2002. Horizontal gene transfer special. *Science in Society* 16, 27-30.

8. Bergelson J, Purrington CB, Wichmann G, 1998. Promiscuity in transgenic plants. *Nature* 395, 25.

9. Schubbert R, Rentz D, Schmitz B and Döerfler W., 1997. *Foreign M13 DNA ingested by mice reaches peripheral leukocytes, spleen and liver via the intestinal wall mucosa and can be covalently linked to mouse DNA.* Proc. Nat. Acad. Sci. USA, 94, 961-6.

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RÉSUMÉ P. 15
ABSTRACT P. 27

The Dismantling of the German Federal Health Agency: A Case of (Failed) Institutional Precaution

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In October 1993, the *Bundesgesundheitsamt* (BGA), the internationally well-reputed German Federal Health Office, was dismantled by the Minister who supervised it. The dismantling of an institution considered among the top public health agencies in the world attracted a great deal of attention worldwide. The case of the BGA, besides highlighting political issues in the field of health and precaution, illustrates the failures that loom in the field of precaution and its institutional implementation. Examination of the circumstances surrounding the failure of the BGA should therefore help us to identify institutional characteristics that might guarantee the successful implementation and safeguarding of precaution. Accordingly, we will outline the facts of the 'scandal of AIDS-contaminated blood' and explore explanations that may account for the institutional disaster. As a conclusion, we will enumerate the lessons for institutions in the field of precaution.

Prologue: Dismantling of a Dysfunctional Agency

Before October 1993, suspicion had been repeatedly raised that AIDS might have been transmitted in HIV-contaminated blood to haemophiliacs and patients undergoing blood transfusions during operations and that the responsible institutions had not guarded against this possibility. Relying on information forwarded by the BGA, the Minister repeatedly declared that no cases of infection through blood products had been reported since the development of an AIDS test and a process to inactivate viruses, i.e., since 1985. In October 1993, the public learned from the press that many cases of AIDS infection had in fact followed treatment with blood products-in the end 373 people had apparently been infected with AIDS in this way since 1985.

Investigations discovered that officials in the BGA, which was responsible for supervising and ensuring the safety of all medicinal products, had been informed of these cases, but that this information never left the relevant agency departments. The President of the BGA, his vice-president, and the competent senior Ministry official had never learned of the spread of AIDS through blood products.

In any case, the scandal of AIDS-contaminated blood was only the last act in a series of incidents that indicated growing inefficiency, laxity and incompetence in this agency that had over its 100-year history contributed to the fame of the German public health sector.

As a consequence, the Minister, presumably eager to avoid his own dismissal, announced the dismantling of the agency in October 1993. A reorganisation in June 1994 broke the BGA down into its component parts.

As a federal superior agency *(Bundesoberbehörde)* the BGA had been organisationally separated from the ministry, but subject to ministerial directives even for the assessment

of technical and medicinal matters. With a president at its helm, the BGA had been composed of an administrative body and seven largely independent scientific institutes, each with its own director.

The reform eliminated the federating and central structures; the components became superior federal agencies on their own, and some functions were merged. Under the new structure, however, the institutes remained as subject to ministerial control and as accountable to the Ministry as the single BGA had been.

Findings of the Inquiry Board

Failures within the Agency

In October 1993, the *Deutsche Bundestag* established an inquiry board to investigate the agency's failures. The board's final report (*BT-Drucksache* 12/8591) accused the agency of years of negligence in its task of protecting the blood supply from AIDS and hepatitis.

The board found (*BT-Drucksache* 12/8591, p. 189-191) that the BGA had continued to approve non-inactivated blood products until 1985, even there had been sufficient reason to consider AIDS to be an infectious disease since 1982. Thus the BGA contravened the German Medical Preparations Act (*Arzneimittelgesetz*, AMG), which requires precautionary measures in case of a "reasonable suspicion of a risk", (§§ 30 sec. 1, 25 sec. 2, No 5 AMG), defined to encompass cases of scientific uncertainties (Rehmann, Wolfgang: *Arzneimittelgesetz*, München 1999, § 5 para. 2).

Moreover, although the BGA had all the relevant facts, it did not provide clear information for patients nor did it recall old products. The board found evidence that such measures had been discussed internally and that at least for certain products the *Stufenplanverfahren*, the administrative process for an action, had begun. However, after a hearing that included public-sector and industry experts as well as representatives of non-commercial blood suppliers, the process stopped and the proposed measures were withdrawn. Moreover, the initial lenient measures that had been taken were also withdrawn in part, on the objection of the pharmaceutical industry and the protests of the non-commercial blood-suppliers (*BT-Drucksache* 12/8591, p. 129-146).

Therefore, the BGA did not taken measures that were needed because: firstly, it failed to assess the risk appropriately; secondly, it attributed too much importance to the quantitative aspects of the blood supply; thirdly, it wanted to avoid driving the non-profit suppliers, who could not have inactivated their products, out of the market; and lastly —albeit mentioned rather discreetly by the inquiry board— the BGA may also have overemphasised the economic interests of the industry concerned (cf. *BT-Drucksache* 12/8591, p. 129-146).

Involvement of the Ministry of Health

The inquiry board also found evidence of negligence within the Federal Ministry of Health. The Ministry had failed to recognise the need to develop AIDS expertise within the BGA -although this lack had been pointed out explicitly and repeatedly to officials, even by representatives of the pharmaceutical industry (*BT-Drucksache* 12/8591, p. 233)

Equally fatally, the relevant senior official in the Ministry of Health was obviously in completely over his head in this matter, as illustrated by his production of a memorandum supposed to show that blood-products *had been inactivated* since 1984 —a measure that had never been imposed on suppliers, although it had been discussed internally (*BT-Drucksache* 12/8591, p. 237).

Finally, the Ministry was assumed to be largely responsible for administrative decisions that were and that were not taken in the course of the *Stufenplanverfahren.* The board did not, however, clarify details of the Ministry's involvement in these decisions (*BT-Drucksache* 12/8591, p. 197, cf. p. 129-146).

Structural Deficits

The inquiry board also looked into the institutional structures that led to these inappropriate decisions. The report identified three sets of structural problems that seemed to account for the disaster:

i) weaknesses related to staff,

ii) deficits in the flow of information, and

iii) pressure from political and private interest groups.

The board dealt with five staff issues. First of all, it cited the lack of expertise reflected in the agency's inept risk assessment (*BT-Drucksache* 12/8591, p. 189-191).

Second, the recruitment of top-level scientists and doctors was hampered by the low

level of public salaries and by the repressive atmosphere inside the institution, which treated critical independent voices as trouble-makers rather than supporting them and thereby drove them out (*BT-Drucksache* 12/8591, p. 237-238).

Third, the board named weak leadership as a major precondition for the agency's shortcomings. It found that appointments to the positions of institute directors and president went to people unqualified to fill such positions —an assessment that seemed particularly true with regard to the president of the agency at the time, who had explained to the inquiry board that it was his "philosophy" to rely on to the "responsibility of the pharmaceutical entrepreneurs" because the agency should be only a "moderating spectator" (*BT-Drucksache* 12/8591, p. 234).

Fourth, the board looked at the imbalance of income between officials and private industry employees and concluded that agency officials might feel degraded and psychologically weakened in dealing with counterparts whose salaries were ten- to twenty-fold higher (*BT-Drucksache* 12/8591, p. 237).

Fifth, the board did not find evidence of bribery. Nonetheless, the former BGA president, for example, had spent a considerable amount of his time on well-paid secondary jobs. Over the past ten years, one quarter of all BGA scientists had worked on secondary private contracts, often with the pharmaceutical industry. The board therefore considered whether such practices might not affect the quality of the agency's work and its independence. Given the much higher salaries available in private industry, however, the board concluded that outstanding scientists and physicians could be attracted to leading positions in the public sector only if they were allowed to generate additional income for themselves as private consultants (*BT-Drucksache* 12/8591, p. 234-244).

Problems were identified in the flow of information between the institutes and between the institutes and the president. Outside observers perceived a sense of independence and also rivalry between the institutes. As a consequence, the BGA-institutes, although accountable to BGA-headquarters and to the Minister, often provided inadequate information to both (*BT-Drucksache* 12/8591, p. 234-236).

Although the board mentioned this mainly in passing, all these factors need to be considered against a background of two types of extreme political pressure: the electorate's intense response to health and especially AIDS issues, and enormous pressure from interest groups, due to the extraordinary value of the pharmaceutical market (*BT-Drucksache* 12/8591, p. 253-254).

Approaches to an Explanation

There is no single explanation to account for the failure of the BGA. Based on this case, at least four issues may be considered to be crucial for the functioning of an institution in the field of precaution.

Accountability

The Minister's rapid decision to dismantle the agency and subject the institutes to the direct control of his ministry reflected his conclusion that lack of ministerial control and a culture of independence within the institutes explain the BGA's failure. His reform was concerned with enforcing the 'lines of responsibility' between himself and the civil servants and addressed only the information flow problems between the agency and the ministry. It ignored the poor organisation inside the institutes and their weaknesses in relation to the industry.

Regulatory Capture

To a large extent, theories on regulatory capture formulated by Stigler and Peltzmann in the early 1970s (cf. Stigler, George: "The Theory of Economic Regulation", in *Bell Journal of Economics and Management Science* (2) 1971, p. 3-21 and Pelzmann, Sam: "Toward a More General Theory of Regulation", in *Journal of Law and Economics* (1) 1976, p. 211-240) seem to account for the deficits identified. According to this theory, a regulatory agency is 'captured', when it *disregards the common good in favour of the regulated private interest.* To some extent, the agency's informational deficits account for this phenomenon: the regulator depends on information from the regulated enterprises, which may distort it and thus induce inappropriate decisions. The theory's fundamental claim, however, is that capture occurs without the wilful intent of the regulatory agency. The regulator rather becomes gradually entwined with the business of the regulated and tends to be easily influenced by it in the course of normal day-to-day business. Here, capture is the *identification of an agency with its industry.* The regulator feels responsible for the success of the industry. He is therefore prone to defer to the wishes it expresses.

Such 'co-operation' is considered a precondition for smooth regulation and the constant supply of the markets. In extreme cases, the regulator might *identify the economic interest of the regulated with the general public interest.*

Capture is facilitated when agencies lack expertise and leadership, both defects identified in the case of the BGA. These weaknesses, the theory suggests, are produced by 'political appointments' and the limited funding available for public service agencies. The theory holds that even when regulators do not take on secondary jobs that constitute a direct conflict of interest, they may be dominated by the wrong incentives. In particular, the potential of future high-paying jobs with regulated firms may make regulators interested in staying on good terms with them. To these aspects must be added the extraordinary amounts of money that are spent by interest groups on political parties as well as for consultants, lawyers, advertisements, and lobbying to which the individual public servant is constantly exposed and eventually might —even unintentionally— succumb (cf. Balzer-Schnurbus, Sabine: *Ökonomische Theorie der Regulierung unter besonderer Berücksichtigung öffentlicher Unternehmen*, München 1992).

Scientific Independence

The experts invited to a parliamentary hearing to discuss the Minister's reform placed significant importance on the issue of scientific independence and the independence of scientific decisions from ministerial interference. The parliamentary hearing raised the following issues:

In scientific matters the institutes must be entirely free from any political interference. A clear separation of political normative decisions from scientific medicinal assessments is indispensable for consumer protection based strictly on scientific facts.

The experts stressed that finding reputable scientists and dedicated staff depends less on higher funding than on good working conditions. Competent scientists fled the BGA because the Ministry increasingly interfered with scientific decisions. To illustrate this claim, they pointed to the case of salmonellae-contaminated eggs in 1992: the BGA had recommended —based on scientific findings— the cooling of eggs from the 10th day onwards to avoid contamination with salmonellae. For political reasons, however, the ministry favoured a term of 18 days. Despite the refusal of BGA officials to change their advice, the agency was obliged to set the more generous term by directive of the ministry —and to keep the reason for the decision secret. Generally speaking, keeping quiet became the primary obligation within the agency.

The experts also urged that leadership positions of the institutes go to high-ranking experts *who are also* strong independent characters. Large institutions need the leadership of an individual who can function not only as a scientist, but also as a manager of such an institution. The challenge of the position is to master the huge quantities of knowledge and information that must remain accessible, be updated, advanced, and brought into co-operative structures such as projects, rather than departments (*Wortprotokoll 90. Sitzung des Ausschusses für Gesundheit*, p. 1-23).

These suggestions are supported by what is seen as the central institutional requirement for precaution in the literature. In his work on administrative decisions and risk assessment, Di Fabio stresses that risk assessment requires public agencies to interact with the outside while inside these agencies, decisions are reached by experts *who are not incorporated into public administration*, that is, either external experts or staff of the agency whose scientific work is not subject to ministerial directives. Di Fabio consequently envisioned the successor of the BGA as an agency at the centre of administrative risk assessment only in terms of organising this assessment and transferring scientific knowledge into the final mandatory decision. The traditional doctrine of political control with clear lines between the minister and the civil servants, he claims, has been rendered obsolete by the risks of modern technology (cf. Di Fabio, Udo: "Das Arzneimittelrecht als Repräsentant der Risikoverwaltung", in *Die Verwaltung* 1994 (27), p. 352-357).

Participation and Pluralistic Bodies

This issue can be reduced to the question of how, in concrete terms, a risk assessment should be carried out and how appropriate results can be ensured.

The law, in general, only provides open legal terms such as "reasonable scientific possibility" or "reasonable scientific probability". However, these terms must be objectified and applied to concrete cases. In international contexts, according to scholars, objectifying the subjective thresholds of the precautionary principle requires the establishment of pluralistic scientific bodies with a high degree of credibility. Precaution requires approaches

of "balanced representation" (cf. Marr, Simon: *The Precautionary Principle in the Law of the Sea*, Kluwer Law International, 2003).

In contrast, the current design of the *Stufenplanverfahren,* the central administrative proceeding required for an intervention under the German Medical Preparations Act, *one-sidedly* provides only for the inclusion of the pharmaceutical industry in written procedures and hearings, but leaves patients and consumers unheard. The independent expert mandated by the inquiry board to review the structures in the BGA consequently supported the idea of participatory approaches, so that stronger representation of patients might possibly counterbalance the pressure currently exerted only by producers (*BT-Drucksache* 12/8591, p. 603).

Lessons to be Learned: Institutional Criteria for Precaution

The purpose of this paper is not to give a full account of the lengthy discussion about the re-organisation of the BGA —a discussion that is still going on- but rather to draw some lessons from this case about institutional characteristics that might guarantee precaution. The following points should be considered:

First: agencies need to be strengthened against regulatory capture through the careful selection of agency staff. In particular directors and senior officials must be both high-ranking scientists and dedicated to consumer protection. 'Political appointments' are likely to stack an agency in terms of capture -while a reputed and dedicated director could protect his agency staff from the inevitable pressures of interest groups.

Second: administrative decisions relating to risk require an independent scientific vote; i.e., risk assessments must be kept clear from any political and hierarchical interference. Scientific independence and the scientific quality of work may also make up for lower salaries and thus strengthen the regulator against capture.

Third: the organisation of risk management requires flat hierarchies to ease the flow of information, to manage huge quantities of administrative transactions efficiently, and to keep the knowledge and information available in the agency accessible and within co-operative structures such as projects, rather than departments. Joint management by a high-ranking scientist and a professional administrator with excellent information skills might be an advisable solution.

The German parliament enacted the legislative proposal of the Ministry of Health as presented. However, it added —quite unconventionally— an "attributive statement" that stated its "assumption" that the act granted scientific institutions independence from political interference, and that the Minister's role was limited to defining priorities and deciding on actions based on the agencies' scientific results. A parliamentary watchdog might also be included in our discussion as an institution that may help to safeguarde independent risk assessment and the implementation of the precautionary principle.

The European Directive on Environmental Liability

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The General Framework

Like any liability scheme, the one for environmental liability established by the directive focuses on situations where, despite preventive measures, environmental damage occurred. It also governs some situations of imminent damage. While it may appear in advance to be an economic sanction of inadequate prevention, in reality, it increases the financial consequences of environmental damage with the aim of serving as a tool of dissuasion, and therefore of preventing risky conduct. Unfortunately, a detailed analysis shows that the directive will be difficult to implement, its effect on economic operators limited, and its dissuasive action low.

After briefly describing the directive's contents and objectives, we will take a critical approach to the liability scheme it would institute for economic operators and public authorities. To remain as simple as possible, this analysis considers the Commission's initial text of January 2002, which was internally consistent. We will conclude by briefly discussing the major lines of the political accord reached in June 2003.

The Directive's Ambitions

The proposal for a directive on environmental liability adopted by the European Commission in January 2002 was intended to extend the liability of all economic operators involved in "pure ecological damage".

Ecological Damage

Traditionally, environmental damage covers several concepts:

- Damage to persons and property through damage to environmental media: This includes, for example, individual health impairment associated with air pollution. Property damage can include the contamination of farmland by heavy metals, which makes the land less valuable or the crops unsaleable.
- The economic losses associated with environmental damage: for example, the effects of oil spills on professional fishermen.
- Finally, damage to the environment itself: water pollution and degradation of aquatic ecosystems that depend on the water, disappearance of an ecosystem such as a wetlands area, diminution of some species as their habitat disappears or is damaged, etc.

The directive focuses exclusively on this last component, which it calls incorrectly, at least in French legal terminology, environmental damage. French doctrine calls this *pure ecological damage,* terminology that we use hereafter to avoid confusion. The project is ambitious but also reductive. It is ambitious because pure ecological damage is, as the Commission's comparative studies have shown, the area of environmental harm for which the civil law of member states provides the fewest remedies, if indeed it provides any at all. This pure ecological damage is not totally unknown in French law, but remedies are often symbolic: the civil or administrative

judge often does not know how to approach it. The directive therefore seeks to fill a large void and sets about this courageously, despite the conceptual difficulties raised by remedies for such damage. The approach is nonetheless reductive, for it leaves aside completely environmental damage to people and property and economic damage, which are generally the most extensive and the most expensive to repair. Moreover, in most ecological disasters, they require immediate remedies.

As an example, consider the recent damage from an incinerator near Albertville in France, which was emitting excess amounts of dioxins. The damages observed were harm to human health (contaminated breast milk) and to property (farm land banned from agricultural uses for a long period, destruction of cow's milk). Financial compensation for both is relatively easy. The pure ecological damage caused by this incinerator, on the other hand, is probable but poorly known: it undoubtedly contaminated natural media, the local water in particular, and harmed wild fauna and flora. It is the effective repair of the so-called classic damages —damage to people and property— that would have the greatest dissuasive effect, because of its financial cost. Nonetheless, in the framework of standard civil or administrative liability, these remedies are neither easy nor complete, because of the specificity of the damages involved. There is much room for progress in this domain, but the directive begins instead by excluding these damages from its field of application.

The Economic Field Covered

At first, the directive's aspiration for economic coverage also seems strong. Unlike previous instruments, it covers not only the activities most dangerous to the environment, but all economic activity. The definitions designate all activities –public or private, industrial or agricultural, for– or not-for-profit– and exclude only domestic, strictly private activities. In this vast field, it distinguishes activities regulated by Community environmental law (listed in its Appendix I), which it subjects to a no-fault liability scheme, from the other activities, for which fault is relevant.

Several exclusions severely limit this field, however. The first example is what is called diffuse pollution, which is in any case poorly defined. Although it is difficult from a practical point of view to apply a scheme of individualised liability to these, this legal exclusion will undoubtedly encourage operators to hide behind it in every instance involving multiple pollution sources and difficult proof of causality. The same is true for maritime transportation: everything governed by the various conventions of the International Maritime Organisation (IMO) concerning ship owners' liability is excluded from the directive's coverage. Finally, all activities involving atomic radiation are also excluded, that is, the exploitation of nuclear energy but also industrial and medical uses of radioactivity.

The reasons for this exclusion are serious and reasonable, based as they are on the existence of an international system applicable beyond the European Community. But nonetheless, two of the main industrial sources of ecological catastrophes —oil spills and nuclear power plants— are not covered: public opinion will find this very difficult to understand. Furthermore, agricultural pollution can be hidden behind diffuse pollution.

Thus, although the directive expresses the ambition to cover an important legal void, its choices lead to coverage that is actually quite limited.

The Liability Scheme

Limited Liability of Economic Operators

The directive starts by energetically implementing the "polluter pays" principle and announcing a principle of unlimited liability, regardless of fault, of all activities regulated by community environmental law. These are numerous given the abundance of community directives, which already regulate almost all aspects of activities that might affect the environment. Nonetheless, this liability in principle is again strongly attenuated by numerous exceptions.

Exemption from liability is thus foreseen for all polluting emissions and events that were authorised by regulation or by an individual permit for the activity. The second exception concerns development risks, that is, the damages claimed to have been unpredictable when the activity began, based upon the available ecological, scientific and technical knowledge.

The third substantial weakening of the scheme comes from its allocation of the burden of proof: the public authorities must prove the causal association between the

damage identified and the activity causing it, since the entire scheme is one of public law. We find here one of the traditional difficulties in attributing environmental liability: causality. Finally, in addition to the activities listed in Appendix I, there is also a partial exemption for those activities whose liability covers only one component of pure ecological damage —damage to species and habitats, defined by the directive Natura 2000.

Of all of these restrictions, the exemption for development risks seems to us the most directly contrary to the implementation of a precautionary approach by economic operators. By definition, the principle of no-fault —or objective— liability supposes that the risk belongs to the actor who benefits economically from the activity and not on those who did not decide to conduct the activity that caused the damage, whether the latter are the tax-payers, the users, or the victims. This basis for exemption is especially troubling in that it was until now essentially unknown to French civil or administrative law. It was recently introduced in the French civil code by the transposition of the 1985 directive on product liability. The directive on environmental liability therefore (and paradoxically) threatens to open a second, much larger breach in the precautionary principle by applying it to the administrative law coverage of activities requiring special permits: classified plants, waste, chemical products, etc.

Burdens on Public Authorities

Public authorities intervene at every stage of the directive's implementation, for imminent damage as well as for repair of damage that has occurred. In addition to the requirement of results associated with any directive, this one adds explicit clauses that invoke the liability of the public authorities in many cases. The laudable objective is to ensure that damages are repaired, especially when the operator cannot be held liable, for the Commission has no illusion about the effective likelihood of invoking operators' liability very often.

The many exemptions already mentioned thus are thus turned against the public authorities: the directive designates them as responsible for repair when the operator causing the damage cannot be identified (as for some of the diffuse pollutions), does not have the funds to repair, is exempted from liability under the directive (in particular administrative authorisation or development risk), is not at fault (for all the activities except those listed in appendix I), and in cases of force majeure or acts of war. The responsibility thus transferred may be combined with the rules practiced by the Commission and the jurisprudence of the Court of Justice of the European Communities that insist on results in the implementation of a directive, an obligation especially strong in environmental matters. This mechanism has been designated as the "secondary liability of public authorities".

This governmental liability appears so heavy and so systematic that we might even wonder if it will not have the perverse effect of discouraging prevention by operators.

Financial Coverage

The Commission's proposal neither limits environmental liability nor requires mandatory insurance. To assess the realism of this option, we should recall that:

- all international liability schemes include mandatory insurance unless they set a (low) ceiling on liability
- the German law of 1990, innovative in instituting mandatory financial coverage for damage caused by hazardous industries, has not yet been applied today because no insurance is available, even though the law applies only to standard damages;
- in France, no industrial activity, except for the nuclear industry, is required to have mandatory insurance coverage of its tort liability;
- the environmental liability established by this directive is entirely new, so that it is difficult for insurance companies to calculate the risks.

We thus understand that this position, as unsatisfactory as it is on paper, is in reality the least bad solution, for by maximising the contractual freedom of parties it may promote the development of an insurance market. Based on experience, the Commission may subsequently modify on the directive.

Appraisal of the Commission's Initial Proposal

Finally, leaving aside the Commission's wise position concerning insurance, the principal proposals of the initial directive, combined with the dynamics of these proposals in the intermediate term and of community issues overall would, in our opinion, have reinforced a trend already well advanced in recent years: the increased attribution to society as a whole of environment risks.

The Political Agreement of June 2003

The negotiations with the Council were accompanied by intensive work and numerous counter-proposals. Against all expectations and due to the energetic commitment of the Greek presidency, these led after eighteen months to a political agreement.

France conducted an intense campaign at the EU and in bilateral administrative and political contacts to eliminate the secondary liability of public authorities from the text: success was due to the demonstration of extreme firmness on this position and to progressive support from several important delegations —Great Britain, Germany, and then Italy.

The common position of the Council deviates from the initial text described above on two major points:

- secondary liability has been entirely eliminated (although the current draft does not express this quite perfectly), but the text naturally leaves heavy burdens on public authorities for implementing the directive and monitoring its application.
- the exemptions for administrative authorisation and development risk divided the Council in half, both equally intransigent in their positions! The only possible solution was to refer these two exemptions, total or partial, to the law of each member state. This decision is hardly conducive to the official goal of a level European playing field and it will continue to be a source of difficulties, especially for the transposition of the directive, with each country waiting to see the positions of the others to define their own.

This political accord nonetheless constitutes a major satisfaction for France, since the text's major defect has been corrected. Even though many difficulties and insufficiencies remain, the merit of this text is to launch an initiative to implement environmental liability that conforms with the "polluter pays" principle. This concept can now develop over the years: it is alas certain that damages requiring remedies will continue to occur!

Biographies

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Axel Conrads studied law and politics in Bonn and Lausanne. After his graduation from the University of Bonn he received a Masters in Public Policy at University College, London, with an emphasis on economic policy instruments and organisational issues of government and administration. During his legal training, he worked for the home office of the Land Berlin in the working group for administrative reforms and reorganisation and with the German Technical Cooperation group in Pretoria on the democratisation of South African legal and administrative institutions. He received his law degree in February 2002 and has since worked for Ecologic on institutional issues in the field of environmental politics, environmental policy integration and issues in environmental law.

Monique Eloit

Monique Eloit has been adjunct director to the managing director of AFSSA, the French food safety agency, since its creation in 1999. She is responsible for coordinating the agency-wide objectives and for monitoring the procedures that organise relations and exchange of information with the relevant directorate-generals —health; food; competition, consumer affairs, and fraud prevention. She was responsible for setting up the laboratory planning office, which she directed. This office plans, coordinates, follows up and assesses all of the activities of the Agency's laboratories.

Claude Henry

Claude Henry is research director at the National Center for Scientific Research (CNRS). From 1977 to 1999, he was professor of public economics at the École Polytechnique. He was awarded the silver medal of the CNRS for his work on uncertainty and irreversibility. For twenty years, he was co-editor of the *Journal of Public Economics*; he is a member of the Council for Economic Analysis and President of the scientific board of the IDDRI.

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Hervé le Treut is a physicist, alumnus of the Ecole normale supérieure in Paris. He is research director at CNRS, the French national centre for scientific research, where he directs the Laboratoire de météorologie dynamique (laboratory for dynamic meteorology) and teaches at the Ecole polytechnique. He is one of the lead authors of the reports of Group 1 of the Intergovernmental Panel on Climate Change (IPCC).

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Ulrich Müller-Herold is a member of the Department of Environmental Sciences at ETH Zurich and leads the "ecological risk prevention"

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Gérard Pascal

Since 1998, Gérard Pascal has been a scientific director at INRA, the French national institute for agronomic research. He created the nutrition research department, which he headed from 1989 through 1992 and then from 1996 to 1998. A member of the Biomolecular Engineering Committee since its creation in 1986, he chaired the section on nutrition of the High Council of Public Health from 1988 to 1992, the scientific council of the French Food Safety Agency until 2002 and the European Scientific Committee for Human Food from 1992 through 1997. He has also served as an expert at the World Health Organisation since 1993 and currently chairs the European Union Scientific Steering Committee.

Peter Saunders

Peter Saunders is Professor of applied mathematics at King's College, London University. His present research is chiefly into complex systems and physiological control, though he has also written on the precautionary principle and global warming. He has been a council member of both the London Mathematical Society and the European Mathematical Society and is presently on the council of the UK Parliamentary and Scientific Committee. He is Honorary Secretary of the campaigning organisation Save British Science.

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Mae-Wan Ho obtained her PhD in biochemistry at the University of Hong Kong and was a postdoctoral fellow in neurosciences at the University of California, San Diego.

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Claire Weill

Claire Weill is a physicist who conducted experimental research activities and teached condensed matter physics and statistical physics for 15 years.

In 1999 she joined the French task force for climate change for three years. She is now in charge of the program "Uncertainty, Precaution and Risk Management" at IDDRI, in Paris.