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In accordance with Council Regulation (EEC, Euratom) No 354/83 of 1 February 1983 concerning the opening to the public of the historical archives of the European Economic Community and the European Atomic Energy Community (OJ L 43, 15.2.1983, p. 1), as last amended by Council Regulation (EU) 2015/496 of 17 March 2015 (OJ L 79, 27.3.2015, p. 1), this file is open to the public. Where necessary, classified documents in this file have been declassified in conformity with Article 5 of the aforementioned regulation or are considered declassified in conformity with Articles (26.3) and 59(2) of the Commission Decision (EU, Euratom) 2015/444 of 13 March 2015 on the security rules for protecting EU classified information.

In Übereinstimmung mit der Verordnung (EWG, Euratom) Nr. 354/83 des Rates vom 1. Februar 1983 über die Freigabe der historischen Archive der Europäischen Wirtschaftsgemeinschaft und der Europäischen Atomgemeinschaft (ABl. L 43 vom 15.2.1983, S. 1), zuletzt geändert durch die Verordnung (EU) Nr. 2015/496 vom 17. März 2015 (ABl. L 79 vom 25.3.2015, S. 1), ist dieser Akt der Öffentlichkeit zugänglich. Soweit erforderlich, wurden die Verschlusssachen in diesem Akt in Übereinstimmung mit Artikel 5 der genannten Verordnung freigegeben; beziehungsweise werden sie auf Grundlage von Artikel 26(3) und 59(2) der Entscheidung der Kommission (EU, Euratom) 2015/444 vom 13. März 2015 über die Sicherheitsvorschriften für den Schutz von EU-Verschlusssachen als herabgestuft angesehen.

COMMISSION
DES
COMMUNAUTES EUROPEENNES

Secrétariat Général

COM(91)522

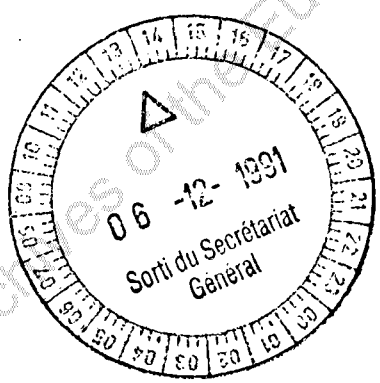
Bruxelles, le 6 décembre 1991

0/91/380

TEXTE F

DEUXIEME RAPPORT DE LA COMMISSION AU CONSEIL ET AU PARLEMENT EUROPEEN EN CE QUI CONCERNE LE BST - PROPOSITION DE DECISION DU CONSEIL

Communication de M. MAC SHARRY



- Cette question est susceptible d'être inscrite à l'ordre du jour d'une prochaine réunion de la Commission.

Destinataires : Membres de la Commission
MM. LEGRAS, KRENZLER, PERISSICH, DEGIMBE, BRINKHORST, FASELLA, BARLEBO-LARSEN, WILLIAMSON, DEWOST

Communication de M. Mac Sharry à la Commission

1. La somatotropine bovine (BST) est une hormone de croissance qui, sous forme recombinante, peut être administrée par injection aux vaches en lactation en vue d'obtenir une augmentation significative de leur rendement en lait (12 % en moyenne).

La BST semble être le produit précurseur de produits biotechnologiques similaires mis au point pour augmenter la production de viande.

2. La décision(1) du Conseil, qui interdit l'administration de BST aux vaches laitières, sauf à des fins expérimentales, expire le 31 décembre 1991. Cette interdiction temporaire a été instaurée pour permettre à la Commission d'élaborer un rapport sur le résultat d'études concernant certains aspects (santé animale, qualité du lait, conséquences économiques, etc.) de l'utilisation de la BST et de faire d'autres propositions si nécessaire à la lumière des conclusions qu'elle en tire. Celles-ci sont exposées dans le rapport ci-joint.

3. En l'absence d'une nouvelle décision du Conseil, les Etats membres sont libres d'autoriser ou d'interdire la BST. Ils sont très embarrassés par le problème de l'agrément de la BST dans les circonstances actuelles. Cela pourrait se traduire par des décisions divergentes au niveau national et un climat d'incertitude générale. Cette situation, à son tour, pourrait avoir de graves implications pour le commerce intracommunautaire et soulever des difficultés à l'extérieur; il faut donc éviter d'en arriver là. Il est probable que les Etats membres partagent ce point de vue.

4. Selon la réglementation actuelle, les demandes d'agrément de la BST, qui est classée comme un médicament vétérinaire, sont examinées en fonction de trois critères, c'est-à-dire la sécurité, la qualité et l'efficacité, qui représentent une condition préalable essentielle pour toute décision d'agrément du produit.

(1) JO n° L 37 du 9.2.1991, p. 39.

Cet examen a été effectué par le Comité des médicaments vétérinaires (CMV), dont l'avis figure à l'annexe III du rapport. Si les résultats concernant la "qualité" et "l'efficacité" n'ont pas soulevé de difficultés, des avis divergents se sont manifestés sur les aspects de la santé animale - qui fait partie du critère "sécurité" -, particulièrement en ce qui concerne l'incidence de la mammite et les réactions provoquées au niveau du site d'injection. Le Comité scientifique vétérinaire (voir paragraphe 5.2 du rapport) dont l'avis figure à l'annexe IV) s'est aussi inquiété de ce que les implications pour la santé animale n'ont pas été analysées avec une attention suffisante. Le Comité a demandé que soient réalisées des études plus complètes.

En ce qui concerne la santé humaine, s'il existe un accord quasi général sur la sécurité de la BST - et le CMV a indiqué que ce produit ne présentait aucun risque pour le consommateur -, on s'est demandé aux Etats-Unis si une attention suffisante avait été accordée à certains aspects du problème immunitaire.

5. En ce qui concerne le volet socio-économique, les études tendent à conclure que l'augmentation possible de la production de lait dans la Communauté, résultant de l'utilisation de la BST, serait de l'ordre de 5 à 10 % selon la régularité d'utilisation du produit. Si cette augmentation a lieu, il faudrait réduire le nombre de vaches de 4 à 6 % pour que les quotas laitiers puissent être respectés. Les hypothèses varient quant à la baisse probable de la consommation de produits laitiers imputable à une réaction défavorable du consommateur; les estimations correspondantes vont d'une réduction modeste à une forte chute pouvant atteindre 20 %, exprimés en équivalent lait.

6. S'il est difficile de prévoir l'ampleur exacte de la réaction des consommateurs, on ne peut négliger la probabilité d'une forte baisse de la consommation des produits laitiers. Les produits "naturels" étant de plus en plus demandés, la réaction du consommateur sera plutôt défavorable à un produit qui peut être associé à une hormone et/ou un traitement hormonal des animaux. Il existe aussi le danger que la situation sera exploitée en faveur de produits d'imitation; la chute de la consommation de beurre, qui s'explique par le lien établi entre les matières grasses non lactiques et le critère de santé, est une illustration du risque potentiel pour les produits laitiers. Les organisations de consommateurs aussi sont opposées à l'autorisation de la BST.

Les exportations communautaires pourraient être gravement menacées aussi sur les marchés de certains pays tiers. De grands importateurs mondiaux peuvent n'être guère disposés à accepter un produit provenant de régions où la BST est autorisée ou bien s'adresser à d'autres fournisseurs. L'impact de la controverse relative à l'ESB sur le marché de la viande bovine représente un précédent malheureux à cet égard. La solution au problème ne réside pas dans l'étiquetage étant donné que le produit recombinant est difficilement détectable et qu'il n'est donc pas possible d'instaurer un régime de contrôle adéquat.

7. Une évolution tendant à encourager le développement de la production agricole pourrait être considérée comme incompatible avec la position adoptée par la Commission au sujet de la réforme de la PAC. En général, cette position mettait l'accent davantage sur l'aspect qualitatif que sur l'aspect quantitatif de la production. Dans le secteur laitier proprement dit, qui est caractérisé par un excédent structurel de quelque 15 % et des coûts qui s'élèvent à environ 6 milliards d'écus par an sous forme d'aides, la réforme encourage une promotion des produits laitiers, une réduction des quotas et la suppression des incitations à produire au-delà des quotas.

La BST n'améliore pas la qualité du lait. Si l'on pouvait normalement escompter des arrangements relatifs aux quotas laitiers qu'ils aboutissent à la fixation d'un plafond de production, dans la pratique, l'utilisation régulière de la BST pourrait engendrer i) une pression accrue en faveur de l'accroissement des quotas et/ou une résistance aux réductions de quotas proposées et ii) un accroissement des difficultés, déjà graves, d'application du système des quotas dans certaines régions de la Communauté.

Pour ce qui concerne les structures agricoles, la BST ne sera probablement utilisée systématiquement que par les grands producteurs, dont la situation économique pourrait en être améliorée et consolidée. Les conclusions d'enquêtes tendent cependant à démontrer que les producteurs sont généralement opposés à l'autorisation de ce produit.

8. Si les facteurs économiques s'opposent à l'autorisation de la BST, au moins pour la durée proposée du régime des quotas laitiers, c'est-à-dire jusqu'en l'an 2000, d'autres considérations militent en faveur d'une approche plus prudente.

Il est nécessaire de conforter le secteur de la biotechnologie, qui sera sensible à toute action pouvant être perçue comme hostile au progrès et à l'innovation et qui pourrait objecter que l'attitude de la Commission est peu cohérente avec sa communication sur la biotechnologie.

Si la Commission a effectivement indiqué dans cette communication qu'elle suivrait normalement l'avis des experts scientifiques dans ce domaine, c'est-à-dire fondé sur les critères de qualité, de sécurité et d'efficacité, elle a aussi précisé qu'elle se réservait le droit de prendre une position différente conformément à d'autres politiques et objectifs communautaires. Une position semblable a été adoptée par la Commission dans ses propositions(2) relatives à de nouvelles procédures d'autorisation des médicaments, lorsqu'il a été reconnu qu'un médicament vétérinaire pouvait ne pas être autorisé si son utilisation était incompatible avec les objectifs de la politique agricole commune.

Le rapport démontre que dans les circonstances actuelles, la BST pourrait avoir des répercussions dommageables pour les marchés et la confiance que le consommateur met dans les produits agricoles.

Une telle situation affecterait à son tour le secteur de la biotechnologie proprement dit, lequel a également intérêt à éviter des conclusions hâtives dans ce domaine.

(2) Proposition de règlement (CEE) du Conseil, établissant des procédures communautaires pour l'autorisation et la surveillance des médicaments à usage humain et à usage vétérinaire et portant création d'une agence européenne pour l'évaluation des médicaments (COM(90) 283 final du 14 novembre 1990).

9. L'aspect extérieur doit également être considéré. En effet, il est difficile d'expliquer aux milieux internationaux une éventuelle divergence des décisions nationales prises par les Etats membres. A l'échelon communautaire, une interdiction de la BST pour une durée indéterminée pourrait être à l'origine de difficultés avec l'administration américaine. Il convient cependant de noter qu'aux Etats-Unis mêmes des positions violemment contradictoires ont été prises à l'égard de ce produit.

De nombreux pays tiers, par exemple les Etats-Unis, la Nouvelle Zélande, le Canada, l'Autriche, la Suisse et les pays nordiques ont grandement intérêt à préserver l'équilibre de leur marché et des produits laitiers et de la viande bovine, et sont confrontés à un dilemme similaire à propos de la BST. Aucun de ces pays n'a encore autorisé la BST à ce jour et la plupart d'entre eux se sont montrés très peu disposés à le faire. Avant d'adopter une quelconque décision définitive au sujet de la BST, la Communauté serait bien inspirée d'envisager la possibilité d'adopter une position commune avec ces pays ainsi qu'avec certains grands pays importateurs.

10. Dans une perspective plus large, les questions relatives au bien-être des animaux se trouvent actuellement au premier plan des préoccupations de la population, ce qui transparaîtra de plus en plus dans l'attitude des consommateurs. Dans le secteur agricole, la Communauté a répondu à cette attente en adoptant plusieurs mesures tendant à protéger les animaux et à garantir une concurrence loyale. Mis à part ces aspects sanitaires, l'interférence entre la biotechnologie et le bien-être des animaux soulève de graves questions éthiques, qui marquent fortement l'opinion publique. Il serait utile de disposer aussi d'une vue objective et fondée sur ces problèmes.

11. Compte tenu des divers points exposés ci-dessus, il est proposé à la Commission de décider :

I) que, eu égard aux positions probablement divergentes des Etats-membres sur la BST, à l'intérêt d'un marché unique et aux difficultés éventuelles vis-à-vis de l'extérieur, l'autorisation de la BST ne

soit pas décidée Etat membre par Etat membre; que le Conseil soit donc invité à statuer sur cette question sur la base d'une proposition de la Commission.

ii) que, eu égard aux divergences d'opinion au sein du CMV et à l'avis du comité scientifique vétérinaire, les aspects de la santé animale/du bien-être des animaux soient précisés. A cette fin, des études complémentaires devraient, si nécessaire, être prévues par la DG VI en coopération avec le CMV et le comité scientifique vétérinaire.

iii) que, compte tenu de l'impact potentiel de la BST et d'autres développements d'ordre biotechnologique dans le secteur des produits animaux, le groupe de conseillers sur les implications éthiques de la biotechnologie, récemment constitué, soit invité à émettre un avis. Cet avis pourrait porter sur les considérations éthiques liées à l'administration, éventuellement stressante pour l'animal, de substances élaborées en vue d'améliorer de façon significative la productivité des animaux d'exploitation dans les cas où l'administration de telles substances n'a aucun effet thérapeutique et que la production supplémentaire obtenue dépasse les besoins.

iv) que, pour tenir compte de l'avis des pays tiers sur ce sujet, des contacts soient pris avec les pays tiers les plus intéressés, c'est-à-dire les grands exportateurs et importateurs mondiaux de produits laitiers ainsi que les pays appliquant des mesures politiques directes de maîtrise de la production dans le secteur laitier, en vue d'examiner les possibilités d'adopter une attitude commune sur la BST.

v) que l'objectif devrait être de préparer une proposition de décision définitive sur la BST pour le 30 juin 1993 en vue d'une décision du Conseil à arrêter dans les 12 mois suivants.

vi) que le rapport et la proposition ci-joints soient envoyés au Conseil en vue de prolonger la période d'évaluation actuelle jusqu'au 30 juin 1994. Ceci donnerait le temps de procéder aux investigations supplémentaires et au Conseil d'arrêter une décision dans le délai prévu.

Projet de proposition

de

DECISION DU CONSEIL

DU

modifiant la décision 90/218/CEE relative à la mise sur le marché et à l'administration de la somatotropine bovine (BST)

LE CONSEIL DES COMMUNAUTES EUROPEENES,

vu le traité institutant la Communauté économique européenne, et notamment son article 43,

vu la proposition de la Commission(1)

vu l'avis du Parlement européen(2)

vu l'avis du comité économique et social(3)

considérant que, dans sa décision 90/218/CEE(4), relative à la mise sur le marché et à l'administration de la somatotropine bovine (BST), modifiée par la décision 91/61/CEE du 4 février 1991, le Conseil a demandé aux Etats membres d'interdire, jusqu'au 31 décembre 1991, l'administration sur leur territoire, par quelque moyen que ce soit, de la somatotropine bovine aux vaches laitières, parce que les effets et les conséquences d'une telle administration n'étaient pas encore suffisamment établis;

considérant que le délai imparti pour étudier ces effets et conséquences s'est avéré trop court; que les recherches mises en oeuvre n'ont abouti que sur les aspects de la qualité et de l'éfficacité du BST; qu'il n'existe, par contre, pas encore de résultats suffisaments précis et réprésentatifs quant aux effets que l'injection du BST pourrait avoir sous l'angle de la santé et du bien-être des animaux; qu'il importe dès lors de continuer de manière approfondie les études afin de disposer d'informations complémentaires tant sur certains aspects de santé et de bien-être des animaux que sur les réactions des consommateurs à l'égard d'utilisation d'une substance destinée à accroître artificiellement la production du lait.

considérant que pour ne pas préjuger du résultat de ces études, il est nécessaire de proroger ultérieurement l'interdiction de mise sur le marché et d'administrer la somatotropine bovine;

A ARRETE LA PRESENTE DECISION :

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(1)
(2)
(3)
(4) JO n° L 116 du 8.5.1990, p. 27

Article premier

La décision 90/218/CEE est modifiée comme suit :

1. L'article 1er est remplacé par le texte suivant :

"Article premier

Nonobstant l'examen scientifique et technique des demandes prescrites par la réglementation communautaire, les Etats membres veillent, jusqu'au 30 juin 1994 à ne pas autoriser la mise sur le marché de la somatotropine bovine et son administration sur leur territoire par quelque moyen que ce soit aux vaches laitières."

2. A l'article 4, les dates du 1er octobre 1991 et du 31 décembre 1991 sont remplacées respectivement par celles du 1er juin 1993 et du 30 juin 1994.

Article 2

Les Etats membres sont destinataires de la présente décision.

Fait à Bruxelles, le

Par le Conseil

CAB/XV/154/91-FR
Orig. : EN

COMMISSION
DES
COMMUNAUTES EUROPEENNES

Direction générale de l'agriculture

VI/B/II.2

Deuxième rapport de la Commission au Conseil et au Parlement sur la somatotropine bovine (BST)

SOMMAIRE

Deuxième rapport de la Commission au Conseil et au Parlement sur la somatotropine bovine (BST)

INTRODUCTION

1. Le 27 septembre 1989, la Commission a présenté un rapport au Conseil et au Parlement sur l'administration de la somatotropine bovine aux vaches laitières en vue d'améliorer la productivité du secteur considéré[1].

Ce rapport propose la fixation d'une période se terminant fin 1990 et devant permettre d'évaluer l'utilisation de BST dans la Communauté. Il indique aussi que cette période représente le délai minimum nécessaire pour apprécier les résultats des études en cours et mettre au point de nouvelles dispositions à adopter quant aux procédures applicables à de tels produits. Par sa décision 90/218/CEE, du 25 avril 1990[2], le Conseil a agréé la demande de la Commission puis, par sa décision du 4 février 1991[3], a accepté un délai supplémentaire, expirant le 31 décembre 1991, était nécessaire pour permettre l'achèvement des études en cours et l'examen de leurs résultats.

2. Le présent rapport doit être considéré en relation avec le premier rapport présenté au Conseil en 1989. Il peut être utile de rappeler que deux compagnies pharmaceutiques (Monsanto, Eli-Lily) ont déposé des demandes de commercialisation de produits contenant la BST r dans la Communauté et que d'autres pourraient être intéressés. A la connaissance de la Commission, certains pays tiers en ont autorisé l'usage. Il s'agit notamment du Mexique, du Brésil, de l'URSS, de la Tchécoslovaquie, de la Bulgarie, de l'Afrique du Sud, de la Namibie et du Zimbabwe. Par ailleurs, aucune autorisation n'a été délivrée aux Etats-Unis, au Canada, en Nouvelle-Zélande, en Autriche, en Suisse et dans les pays scandinaves.

3. Le problème de la BST suscite un intérêt considérable auprès du consommateur, dans l'agriculture et l'industrie. A ce propos, des préoccupations ont été exprimées concernant la sécurité du produit pour l'homme, l'animal et l'environnement, la qualité du lait, les conséquences économiques et sociales dans le secteur agricole, le climat dans lequel se déroulent la recherche et le développement, la concurrence industrielle et les incidences commerciales.

Le présent rapport tente de prendre en considération ces préoccupations et d'analyser les problèmes soulevés selon une approche communautaire globale.

(1) [COM (89) 379 final]
(2) JO n° L 116 du 8. 5.1990, p. 27.
(3) JO n° L 37 du 9. 2.1991, p. 39.

4. Les industries du secteur de la biotechnologie sont soucieuses de préserver la stabilité du cadre réglementaire dans lequel se déroulent leurs activités. La Commission a examiné le problème dans sa récente communication au Parlement et au Conseil : "Promouvoir les conditions de la compétitivité des activités industrielles basées sur la biotechnologie dans la Communauté" [Sec(91) 629 final]. Ce document précise en effet :

"Les produits issus de la biotechnologie ne nécessiteront pas tous des procédures d'évaluation ou d'agrément spécifiques. Pour l'heure, les produits de la biotechnologie sont, dans leur grande majorité, obtenus à l'aide de méthodes traditionnelles (par exemple : fromages, extraits de malt, bières, levures). En ce qui concerne les produits issus de la nouvelle biotechnologie, dont la production implique des manipulations génétiques, chaque produit devra être examiné cas pas cas et évalué comme il convient.

L'approche suivie actuellement par la Communauté, qui se fonde sur l'application correcte et rigoureuse des critères de sécurité, de qualité et d'efficacité, ainsi que sur la législation horizontale applicable, garantit la sécurité et les intérêts économiques du consommateur et permet de protéger l'hygiène humaine, animale et végétale et de l'environnement. En outre, pour assurer la protection du consommateur, il convient de tenir compte également de l'incidence sur l'information et le choix du consommateur.

En règle générale, les décisions doivent être fondées sur des évaluations objectives utilisant des critères clairement définis. Toute incertitude concernant l'acceptation et l'agrément des produits peut avoir pour effet de détourner l'investissement et de décourager l'innovation et le développepent technologique au niveau de l'entreprise. La Communauté doit, d'autre part, donner au public l'assurance que l'industrie est soumise à une réglementation adéquate. Le dynamisme de l'industrie et la confiance du public dépendent de l'aptitude de la Communauté à rassurer les deux parties.

Quand un produit issu de la biotechnologie a fait l'objet d'une analyse, les trois critères traditionnels basés sur une évaluation scientifique s'appliquent. Par leur nature, les aspects socio-économiques doivent être traités selon u ne méthode différente. Cela ne veut pas dire avoir une autre évaluation systématique en complément des trois critères. La Commission suivra normalement un avis scientifique. Cependant, la Commission se réserve le droit de prendre une position différente à la lumière de ses obligations générales de tenir compte des politiques et des objectifs communautaires. Cela peut, dans des cas exceptionnels, conduire à des besoins d'information supplémentaires. Cela peut également, dans des cas exceptionnels, conduire la Commission à proposer que d'autres politiques soient modifiées à la lumière des développements scientifiques.

Des considérations semblables ont été émises à propos de la proposition de la Commission relative à un règlement (CEE) du Conseil établissant des prodécures communautaires pour l'autorisation et la surveillance des médicaments à usage humain et à usage vétérinaire, et portant création d'une agence européenne pour l'évaluation des médicaments, du 14 novembre 1990 (COM90) 283 final), où le point de vue suivant a été exprimé à propos des procédures d'autorisation des médicaments vétérinaires :

"considérant que, dans l'intérêt de la santé publique, il est nécessaire que les décisions d'autorisation de tels médicaments soient prises sur la base des critères scientifiques objectifs de la qualité, de la sécurité et de l'efficacité du médicament concerné, à l'exclusion de toute considération économique ou autre; que les Etats membres devraient toutefois, à titre exceptionnel, être en mesure d'interdire l'utilisation sur leur territoire de médicaments qui portent atteinte à des principes, définis objectifvement, d'ordre public ou de moralité publique; qu'en outre, un médicament à usage vétérinaire ne peut être autorisé par la Communauté si son utilisation contrevient aux règles et aux objectifs établis par la Communauté dans le cadre de la Politique Agricole Commune".

5. Le Parlement européen a également adopté plusieurs résolutions (cf. annexe IV) traitant directement de ce problème. A cet égard, il faut particulièrement noter l'importance des résolutions sur les conséquences de l'introduction de la biotechnologie sur le plan de l'agriculture européenne (16 février 1987) et sur les effet et les risques de l'utilisation des hormones de croissance et de la BST sur la production laitière et la viande (5 juillet 1988). Le sens général du point de vue du Parlement est que les produits biotechnologiques devraient moins viser à augmenter la production et les rendements qu'à améliorer les aspects de qualité et de santé.

6. Pour établir le présent rapport, la Commission a eu recours à un certain nombre d'études et analyses : tout d'abord, au sein du comité des médicaments vétérinaires (procédure de concertation du CMV (directive 87/22/CEE), cf. annexe III), les aspects de sécurité, qualité et efficacité des produits pour lesquels une autorisation de commercialisation est demandée sont examinés.

Cinq autres études indépendantes ont été entreprises à la demande de la Commission, dont cinq en Allemagne, et notamment :

a) "Recherche en vue de l'amélioration des caractéristiques bactériologiques du lait cru et du lait ayant subi un traitement thermique (vaches traitées à la BST) - nombre accru de cellules somatiques, influence sur la qualité et le rendement, aptitude à la transformation, mammite", effectuée par la Bundesanstalt für Milchforschung, Kiel (1991).

b) "Recherche sur la physiologie de la lactation de la vache laitière" par l'Institut für Physiologie, TU Munich/Weihenstephan (1991).

c) "Les producteurs et consommateurs, facteurs de développement des ventes de lait et de produits laitiers dans la Communauté" par l'IFO-Institut für Wirtschaftsforschung, Munich (1991).

d) "Effets de l'utilisation de la somatotropine sur la consommation de produits laitiers" par l'Institut für Agrarpolitik, Giessen (1991).

La cinquième étude, plus générale, s'intitulait : "Etude de l'effet sur l'élevage de l'utilisation de facteurs de croissance dans l'alimentation animale et d'autres facteurs d'augmentation du rendement" effectuée par CEAS Consultants (Wye) Ltd. (1991) (CEAS I).

En outre, la Commission a examiné les études suivantes : "BST and the consumer : an overview of perception and pratices" (la BST et le consommateur : revue concernant la perception du produit et les pratiques), réalisée par CEAS Consultants (Wye) LtD. (1989) (CEAS II), et "U.S. Dairy Industry at a Crossroad : Biotechnology and Policy Choices" (le secteur laitier américain à la croisée des chemins : biotechnologie et choix politiques), Congress of the United States, Office of Technology Assessment (Congrès américain, bureau d'évaluation technologique) (Washington D.C., mai 1991).

Les services de la Commission ont aussi effectué certains travaux d'analyse.

RESUME ET CONCLUSIONS

6. Le présent rapport concerne à la fois les aspects de sécurité, de qualité et d'efficacité de la somatotropine bovine (BST) recombinante ainsi qu'une évaluation de l'attitude du consommateur et du producteur, des répercussions sur les marchés des produits agricoles, les conséquences budgétaires et l'environnement.

7. Sécurité, qualité et efficacité

Le produit de Monsanto semble répondre aux critères de sécurité, qualité et efficacité, sauf sur la question d'une éventuelle incidence accrue de mammite et de réactions au site d'injection chez la vache laitière traitée à la BST, qui n'a pas reçu de réponse satisfaisante selon les experts de cinq Etats membres.

Pour ce qui concerne la qualité, le produit étudié est conforme aux exigences des directives communautaires. Le comité des médicaments vétérinaires (CMV), qui a analysé le produit de Monsanto, est convaincu que son utilisation n'affecte pas la qualité du lait ou de la viande. Cependant, certains doutes subsistent quant aux implications des nombres accrus de cellules somatiques.

A propos de l'efficacité, on estime que la production de lait des troupeaux laitiers bien conduits augmentera de 12 %. Cependant, cette augmentation sera probablement la même en chiffres absolus pour les vaches à rendement moyen et les vaches à rendement supérieur, donc relativement plus importante pour les vaches à rendement moyen. L'augmentation sera de l'ordre de 2,5 à 5,7 kg par jour.

Enfin, il y a lieu de noter que jusqu'à présent, on n'a pas connaissance d'études exhaustives concernant le bien-être des animaux traités à la BST r.

8. Enquêtes auprès des consommateurs et des producteurs

a) Les enquêtes auprès des consommateurs ont été effectuées dans quatre Etats membres : Allemagne, France, Italie et Royaume-Uni, soit auprès de 70 % de la population de la Communauté.

   Les enquêtes font état de fortes réductions de consommation, variables selon les Etats membres et les divers produits laitiers. Le chiffre le plus faible concerne la France (beurre : environ 10 %) et le plus élevé l'Italie (beurre : environ 26 %).

   L'enquête effectuée en 1989 (CEAS II) pour le compte du National Office of Animal Health du Royaume-Uni indique clairement que

   - les taux de rejet des pratiques de production alimentaire impliquant l'utilisation de produits chimiques sont plus élevés que les taux de rejet concernant toute autre pratique, y compris celles concernant le bien-être des animaux,

- le taux de rejet concernant l'utilisation de la BST est le plus élevé des taux jamais enregistrés.

b) L'enquête auprès des producteurs, effectuée dans six Etats membres (Royaume-Uni, Allemagne, France, Pays-Bas, Danemark et Irlande), pays représentant 52 % des producteurs, 75 % des vaches et environ 80 % de la production laitière, révèle une forte opposition à l'égard de la BST Cette attitude témoigne de l'inquiétude que suscite l'impact virtuel de ce produit sur le marché laitier; la santé animale et le bien-être des animaux représentant des aspects secondaires pour les producteurs.

Si la BST était agréée, de nombreux producteurs seraient favorables à cette nouvelle technique.

9. Marchés des produits agricoles - secteur laitier

a) Consommation

L'incidence sur les marchés de produits agricoles dépendra fortement de l'attitude du consommateur. Si l'évaluation est fondée sur les estimations relatives à la réaction du consommateur, tirée des enquêtes, les incidences sur le marché pourraient être des plus dramatiques (excédents de production et conséquences budgétaires).

Le marché des produits laitiers connaît des difficultés persistantes malgré la réduction des quotas (la dernière réduction de 2 %, décidée dans le cadre des prix de 1991/92, n'a pas été considérée comme suffisante). Ainsi, la Commission a été amenée dans le contexte de ses propositions de réforme, à proposer des réductions des quotas laitiers de 3 % nets supplémentaires en vue de rééquilibrer le marché. Parmi les règles particulières proposées, elle a aussi tenté de décourager tout arrangement, par exemple par le biais de la péréquation des livraisons dans le cadre des prélèvements, susceptible d'entraîner des dépassements de quotas. Toute baisse supplémentaire de la consommation par suite de l'utilisation de la BST aggraverait encore le déséquilibre du marché des produits laitiers caractérisé par un excédent structurel de l'ordre de 15 %.

Plusieurs hypothèses peuvent être envisagées, allant d'une très forte réaction du consommateur, une réaction plus faible que prédite par les enquêtes, voire une situation caractérisée par une réaction légère comme le prévoit une des enquêtes. Toutes les conclusions d'enquêtes prévoient cependant une certaine baisse de la consommation.

L'évolution récente du marché des lactoremplaceurs mérite une attention particulière si l'on envisage d'autoriser la BST. Le secteur des produits lactoremplaceurs a connu une vive croissance ces dernières années, principalement au détriment du beurre, dont la consommation baisse au rythme d'environ 40 000 t par an. Cette croissance a été causée principalement par la réaction du consommateur à des considérations de santé et/ou à une simplification excessive des résultats de travaux de recherche. Si la BST devait être autorisée, il est probable que l'image du lait et des produits laitiers serait gravement ternie pour des considérations de santé attendu que les promoteurs de produits concurrents

exploiteraient sans doute impitoyablement l'affaire de la BST. Dans l'hypothèse d'une forte réduction de la consommation (les résultats de certaines enquêtes tendent à la fixer à 20 %), il y aurait lieu d'opérer une réduction correspondante des quotas avec les conséquences défavorables que cela implique aussi pour le secteur de la viande bovine et l'agriculture en général.

b) Production

La BST pourrait être utilisée régulièrement pendant une partie de la période de lactation. Les producteurs pourraient utiliser le produit dans le cadre de l'achat ou de la location de quotas laitiers à d'autres producteurs, à l'occasion d'une réduction du nombre de vaches ou peut-être encore par une réaction d'anticipation à des situations de pénurie imputables d'autres producteurs, pénurie qu'il serait possible de compenser par des accords de péréquation au niveau de la laiterie.

La BST peut aussi être utilisée comme un moyen tactique de prévenir tout manque à livrer au titre de la quantité de référence individuelle des producteurs, auquel cas le nombre de leurs vaches pourrait rester inchangé.

L'ampleur du régime d'utilisation régulière ou tactique varierait d'un Etat membre à un autre. En effet, l'utilisation de la BST dépend 1) du prix de la BST, 2) du prix du quota supplémentaire, 3) du coût des besoins fourragers supplémentaires et 4) de l'intérêt que présente l'affectation à d'autres usages des terres libérées par la réduction du nombre de vaches.

Indépendamment de la réaction possible du consommateur et compte tenu du niveau actuel des quotas laitiers, une estimation prudente fondée sur l'étude CEAS I laisse entendre qu'à court terme, la BST serait administrée à 20 % des vaches laitières de la Communauté, pendant une période variable de leur lactation. A moyen-long terme (dans les cinq à dix ans à venir), cette proportion passerait à 55 %.

L'utilisation relativement limitée de la BST s'explique essentiellement par le fait qu'il est supposé que des troupeaux de 15 vaches au maximum ne seraient pas traités à la BST de manière régulière à cause de contraintes pratiques (trop peu de vaches) et économiques. A cet égard, l'utilisation régulière de la BST implique un emploi systématique de ce produit pendant une période déterminée ou la plus grande période de la lactation, et pas nécessairement pendant toute cette période.

Sur la base d'une augmentation de la production de 12 % pour 55 % du cheptel de vaches laitières et en admettant que les vaches à faible rendement ne seront pas traitées à la BST, l'augmentation potentielle de la production laitière résultant de l'utilisation de la BST est de l'ordre de 6 à 10 %. Toutefois, d'autres enquêtes tendent à démontrer qu'à moyen terme, un chiffre de 5 % est plus probable.

Un "surcroît" de production laitière n'implique pas nécessairement une augmentation des livraisons, mais représente la part du lait-BST dans la production laitière totale. Cela suppose, dans un système de quotas, une réduction du nombre de vaches laitières, une augmentation des quotas ou un dépassement des quotas existants.

Sur la période de 1992 à 1998, la réduction estimative du nombre de vaches laitières serait de l'ordre de 4 à 6 % en plus de la réduction normale du cheptel laitier (cf. annexe, partie I, chapitre 11).

Le principal avantage pour les producteurs moyens et les grands producteurs, qui jugeraient utile d'utiliser la BST régulièrement, consisterait dans une réduction des coûts de production pour ceux qui réduiraient le nombre de leurs vaches ou des marges accrues pour ceux qui achèteraient ou prendraient en location des quotas supplémentaires ayant appartenu à d'autres producteurs. Les petits producteurs n'utiliseraient normalement pas la BST.

Le système des quotas laitiers atténuerait l'intérêt économique de la BST.

Cependant, deux éléments doivent être considérés. En premier lieu, bien qu'instauré en 1984, le système des quotas n'a pas été correctement mis en oeuvre dans certaines régions de la Communauté et des efforts soutenus seront nécessaires pour ramener les livraisons au niveau des quotas autorisés et l'utilisation éventuelle de la BST n'y contribuerait pour rien. En second lieu, tout instrument tendant à augmenter la quantité de lait produite dans le cadre de ce système crée une pression supplémentaire à l'augmentation des quotas, encourage la fraude au prélèvement supplémentaire et déstabilise les marchés.

10. Autres secteurs agricoles

Parmi les autres spéculations agricoles, celle de la viande bovine est la plus préoccupante.

Pour ce qui concerne la production de viande bovine, une réduction du nombre de vaches suppose une augmentation des abattages, ce qui, à court terme, pourrait aggraver encore la situation déjà fortement déséquilibrée du marché de la viande bovine.

A moyen et à long termes, le remplacement des vaches laitières par des vaches allaitantes et/ou d'autres catégories de bovins à viande aurait un effet également négatif sur l'équilibre du marché de la viande bovine, bien que la réduction du nombre de veaux provenant des troupeaux de vaches laitières tendrait à atténuer le phénomène.

Pour les autres utilisations du sol, les conséquences sont insignifiantes.

11. Environnement et structures

Vu que l'utilisation régulière de la BST ne touchera probablement que les grands troupeaux laitiers (plus de 15 têtes), la production laitière aura sans doute tendance à se concentrer davantage dans les régions de production intensive, engendrant une plus grande contrainte pour les petites exploitations.

Cette concentration peut détériorer encore la situation locale du point de vue de l'environnement. Pour ce qui concerne la production globale d'effluents d'élevage, les conséquences de l'utilisation de la BST seraient significatives si les vaches laitières étaient remplacées par un plus grand nombre de vaches allaitantes et/ou par d'autres catégories de bovins à viande.

12. Réforme de la PAC

Dans sa communication sur l'évolution et l'avenir de la politique agricole commune (de février et juillet 1991), la Commission a conclu que les excédents structurels actuels provenaient pour une large part du fait que l'aide est proportionnelle à la quantité produite.

Le sens général de la communication était que la Communauté devait décourager l'intensification, encourager la qualité et s'efforcer de maintenir un nombre suffisant d'agriculteurs à la terre pour que ceux-ci puissent continuer de remplir une double fonction, celle de producteur de denrées alimentaires et celle de gardien de l'environnement rural.

Dans le secteur laitier, les propositions impliquent une nouvelle réduction nette de 3 % des quotas, des mesures visant à prévenir une réduction des quotas des petits producteurs et une aide promotionnelle tendant à inverser le mouvement de déclin de la consommation de certains produits laitiers, par exemple le beurre. Dans le secteur de la viande bovine, les propositions prévoient des réductions de prix assorties d'une majoration des primes à condition que soient remplis les critères d'extensification et respectés certains plafonds d'aide.

Un régime d'encouragement à la consommation de viande bovine, secteur qui a été particulièrement touché par la polémique sur l'ESB, a également été proposé.

Dans la mesure où la BST tend plutôt à développer la production qu'à améliorer la qualité du produit, elle va à l'encontre des objectifs de la réforme. L'autorisation de la BST, avec les risques qu'elle entraînerait sur le plan de la consommation, paraîtrait incompatible aussi avec la politique de promotion des produits laitiers.

Sur le plan sociostructurel, les producteurs détenteurs de petits troupeaux ne profiteront probablement pas de la BST pour des raisons pratiques et économiques. La BST accélérera probablement aussi la tendance à la réduction du nombre d'élevages laitiers et la tendance à l'exploitation d'un nombre moindre de troupeaux de plus grande taille, plus concentrés dans certaines régions.

L'utilisation de la BST, engendrant un rendement marginal supérieur, sera prise en compte dans l'établissement de la valeur du quota laitier, d'où il sera plus difficile pour les producteurs qui n'utilisent par la BST, d'acquérir des quotas supplémentaires.

Pour ce qui concerne les répercussions sur le marché de la viande bovine, le remplacement des vaches laitières par d'autres bovins à viande affecterait l'équilibre du marché. Les difficultés immédiates pour le marché seraient plus nombreuses en cas de développement rapide de l'utilisation de la BST et entraînerait l'abattage d'un nombre significatif de vaches.

13. Contrôle et étiquetage

Etant donné que l'utilisation de la BST est un sujet d'intérêt public, il serait nécessaire d'envisager des moyens visant à contrôler le respect des règlements communautaires.

a) Le contrôle de la fabrication et de la distribution de la BST ne devrait pas être plus complexe que celui concernant d'autres produits pharmaceutiques. Bien qu'en raison de la nature du produit, son administration semble devoir appeler l'intervention de vétérinaires professionnels, il pourrait être difficile d'imposer cette contrainte dans la pratique.

b) Le dépistage de résidus dans les produits animaux nationaux ou importés ne peut pas s'effectuer correctement avec les techniques et les pratiques courantes, parce que les échantillions contiennent certains taux d'hormones naturelles.

Il n'existe pas actuellement de méthode légale de dépistage de l'hormone BST r administrée aux vaches laitières. Les méthodes actuelles permettent d'effectuer un certain contrôle général, mais supposent le prélèvement d'échantillions de sang à l'étable. A partir de l'exemple de la détection simultanée d'une hormone de croissance et du facteur de croissance IGF 1, il apparaît qu'un taux d'erreur de 20 % est prévisible. Une solution de remplacement envisageable serait l'enregistrement régulier et individuel des graphiques de production de lait.

Toute mesure de contrôle à instaurer se limiterait pratiquement au niveau de l'exploitation, de la pratique vétérinaire et des canaux de distribution pharmaceutique.

Il paraît impossible cependant de répondre aux exigences du consommateur relatives à un système d'étiquetage efficace permettant de distinguer les produits laitiers provenant de vaches traitées à la BST.

Il serait envisageable de prévoir des règles d'étiquetage obligeant à indiquer si la BST a été autorisée dans l'Etat membre d'origine du produit. Une telle exigence ne saurait recueillir de consensus et constituerait une forte incitation à tourner la réglementation.

Cadre législatif

La base actuelle d'une éventuelle décision relative à la BST est la directive 87/22/CEE du Conseil qui prévoit que toute décision dans ce domaine est prise à l'échelon national. Etant donné la sensibilité du problème de la BST, il est évident que pour prendre une décision, les Etats membres seront confrontés à un dilemme considérable. Il est probable aussi que des décisions divergentes seraient de nature à perturber la concurrence dans les échanges intracommunautaires. La justification de telles décisions devant les instances internationales pourrait aussi susciter des difficultés.

Dans ses propositions relatives à de nouvelles procédures d'autorisation de médicaments vétérinaires, la Commission a reconnu les inconvénients d'un système de décision national, particulièrement lorsqu'il s'agit de produits biotechnologiques. Ceci l'a amenée à proposer une procédure d'autorisation communautaire, centralisée, pour de tels cas. Ces

propositions sont actuellement examinées par le Conseil. Une procédure[1] communautaire relative à l'approbation de limites maximales de résidus entrera en vigueur le 1er janvier 1992. Celle-ci prévoit qu'après cette date, les Etats membres ne seront plus autorisés à utiliser des produits tels que la BST en l'absence de limites maximales de résidus fixées par la Commission.

Aspects extérieurs

La plupart des pays tiers qui ont un intérêt vital à maîtriser leur production laitière, comme le Canada ou les marchés d'exportation, comme la Nouvelle Zélande, n'ont pas autorisé la BST. En effet, il est probable que des pays où le consommateur est fortement conscient du problème, seront peu disposés à l'autoriser. Aux Etats-Unis, la Food and Drug Administration n'a pas agréé la BST. Une interdiction totale de la BST dans la Communauté peut être source de difficultés avec les Etats-Unis qui demandent que des produits totalement conformes à des critères scientifiques soient approuvés. Toutefois, la BST a provoqué des controverses aux Etats-Unis où certains Etats comme le Wisconsin et le Minnesota (gros producteurs laitiers) ont adopté une législation visant à introduire un délai de suspension de la BST. Si ces dispositions peuvent devenir caduques par suite du veto du gouverneur - le gouverneur du Wisconsin s'est effectivement opposé au texte de loi en cause -, il n'est pas à exclure que toutes décisions visant à autoriser la BST susciteront de nouvelles polémiques aux Etats-Unis.

Tous les grands producteurs laitiers et pays exportateurs de produits laitiers ont tout particulièrement intérêt à maintenir le niveau de leur consommation et la stabilité de leurs marchés. Si la Communauté a souvent eu tendance à considérer ces pays comme des concurrents, ceux-ci ont, avec la Communauté, un intérêt commun à veiller à ce que le problème de la BST soit traité de telle manière à ne pas porter atteinte à leurs intérêts essentiels.

La Communauté est le plus grand exportateur mondial de produits laitiers; en année normale, elle exporte l'équivalent de 15 % de sa production représentant une valeur à l'exportation de quelque 4 milliards d'écus.

14. Budget

Les incidences budgétaires dépendront pour l'essentiel des effets de l'introduction de la BST sur la consommation. Si l'effet sur la consommation est faible, les conséquences budgétaires ne dépasseront pas quelque 250 millions d'écus par an.

Des enquêtes auprès des consommateurs indiquent que la baisse de la consommation humaine pourrait atteindre 17 millions de t. Dans ce cas, les conséquences financières représenteraient environ 3,5 milliards d'écus par an.

(1) Directive 81/851/CEE, modifiée par la directive 90/676/CEE, et règlement de la Commission 2377/90/CEE (JO L 224, du 18.8.1990, p. 1).

Une troisième hypothèse se situerait entre les deux extrêmes précédentes, avec une baisse de la consommation de quelque 9 millions de t. Dans ce cas, l'incidence financière annuelle serait de l'ordre de 2 milliards d'écus.

15. Conclusions

a) La BST représente un important progrès technologique qui, en raison de l'importance de son effet sur la productivité, des aspects de bien-être des animaux et des effets virtuels sur la consommation et les marchés, ne peut être traitée comme un simple médicament vétérinaire destiné à améliorer le bien-être des animaux.

b) La Communauté doit tout d'abord veiller à ce que, avant d'autoriser des produits, ceux-ci soient sûrs pour l'homme, l'animal et l'environnement. Dans le cas de la BST, si les critères de "qualité" et "d'efficacité" semblent avoir été remplis, certains aspects de la "sécurité" doivent encore être clarifiés. La question des concentrations accrues de l'IGF-1 dans le lait provenant de vaches traitées à la BST en rapport avec la santé humaine a également été soulevée.

La question d'une incidence accrue de mammite et de réactions au point d'injection à suscité des avis divergents parmi les experts. L'utilisation de la BST peut aussi n'être pas compatible avec les efforts déployés par la Communauté en vue de réduire le nombre de cellules somatiques dans le lait destiné à la commercialisation.

Sur un plan plus général, le comité scientifique vétérinaire s'est demandé si les aspects du bien-être des animaux avaient été suffisamment pris en considération à propos de la BST et a demandé des études complémentaires.

c) Dans la pratique, il est impossible de déterminer par l'analyse du lait et des produits laitiers si la BST r a été utilisée. C'est pourquoi il serait impossible, dans le cadre d'un agrément partiel ou conditionnel, de garantir que les règles d'étiquetage ou d'autres dispositions éventuelles ont été respectées.

d) Les organisations de consommateurs sont opposées à l'autorisation de la BST. Des enquêtes auprès des consommateurs révèlent que ceux-ci adoptent une attitude négative à l'égard de la BST, attitude qui devrait se traduire par une chute sensible de la consommation de produits laitiers. Il en résulterait de graves conséquences pour l'agriculture communautaire, pour le secteur laitier en particulier, et pour le budget. Les exportations de produits laitiers et de viande bovine de la Communauté pourraient aussi en souffrir étant donné qu'on ne peut escompter de certains pays tiers qu'ils acceptent les produits provenant d'animaux traités à la BST alors qu'ils sont réticents à en autoriser l'utilisation chez eux.

e) Les propositions relatives à la réforme de la PAC mettent l'accent sur la qualité de la production plutôt que sur l'accumulation d'excédents. Ces propositions s'efforcent aussi de maintenir une structure socio-économique de nature à conserver un nombre suffisant d'agriculteurs

appelés à remplir une double fonction, d'une part celle de producteurs de denrées alimentaires de qualité et, d'autre part, celle de gardiens de l'environnement rural. L'introduction de la BST paraîtrait s'opposer à ces objectifs.

f) Compte tenu des questions en suspens concernant la santé et le bien-être des animaux, de la nécessité de clarifier les aspects éthiques ainsi que d'examiner la possibilité d'une position commune sur ce sujet de la part des principaux pays producteurs, exportateurs et importateurs de produits laitiers, on estime que l'évaluation de tous les éléments du problème requiert un délai supplémentaire. Par ailleurs on pense que, dans l'intérêt d'un marché unique, une décision finale concernant l'autorisation de la BST devrait demeurer de la compétence de la Communauté. Ceci étant, la Commission s'efforcera de présenter ses conclusions finales et une proposition au Conseil pour le 30 juin 1993. Voilà pourquoi il est proposé que la période d'évaluation en cours soit prorogée jusqu'au 30 juin 1994 afin qu'une décision puisse être prise dans le délai convenu.

En conséquence, le projet de décision du Conseil est proposé en annexe.

ANNEXE :

I Conclusions de l'étude

II Conséquences budgétaires potentielles résultant de l'utilisation de la BST

III Avis du comité des médicaments vétérinaires

IV Résolutions du Parlement

V Extrait de la communication de la Commission au Parlement et au Conseil, intitulée "Promouvoir un environnement concurrentiel pour les activités industrielles fondées sur la biotechnologie dans la Communauté"

ANNEXE

Partie I

* Résultats de l'étude

Partie II

* Conséquences budgétaires résultant de l'utilisation de la BST

Partie III

* Avis du Comité des médicaments vétérinaires

Partie IV

* Avis du Comité vétérinaire scientifique

Partie V

* Extrait de la communication de la Commission au Parlement et au Conseil, intitulée "Promouvoir les conditions de la compétitivité des activités industrielles basées sur la biotechnologie dans la Comunauté"

PARTIE I

RESULTATS DE L'ETUDE

SECURITE, QUALITE ET EFFICACITE

En ce qui concerne les aspects touchant la sécurité, il s'agit de la sécurité pour l'homme, pour l'animal et pour l'environnement. Il s'agit aussi de la qualité des produits alimentaires. La qualité a trait aux caractéristiques chimiques des produits; l'efficacité est liée à la question de savoir si le produit donne bien les résultats revendiqués.

1. BSTr

Les produits à base de BST recombinante peuvent différer légèrement, quant à leurs structures chimiques, de la BST produite par la glande pituitaire, car il peut y avoir un certain nombre d'acides aminés supplémentaires. Chaque produit doit être jugé à l'aune de ses mérites propres. Les acides aminés supplémentaires qui peuvent être produits ne sont toutefois pas susceptibles de modifier la partie active de la molécule et ils ne modifient donc pas l'activité biologique de la BST chez les vaches laitières ou l'inactivité de la BST chez l'homme.

2. Avis du Comité des médicaments vétérinaires (CMV) et autres observations

Le CMV, en mars 1991, a émis son avis sur le produit à base de BSTr dénommé "SOMATECH", présenté par Monsanto.

C'est à ce produit que s'appliquent les jugements qui suivent.

3. Qualité de la BSTr

Le mode de fabrication du produit examiné permet d'obtenir un produit stable homogène, se conservant 18 mois en magasin, conformément aux exigences fixées en matière de qualité par les directives communautaires.

4. Efficacité de la BSTr

Le CMV "estime que le fabricant a mis en évidence l'efficacité du SOMATECH en tant que produit accroissant notablement les rendements laitiers des animaux traités. Cette augmentation des rendements varie en fonction de divers facteurs parmi lesquels la race concernée, l'animal traité, le stade du cycle de lactation auquel le produit est administré et la qualité des techniques d'élevage utilisées; on estime toutefois qu'elle se situe dans la fourchette comprise entre 2,5 et 5,7 kg par jour" (pendant la période de lactation).

L'étude du Congrès des Etats-Unis présente cet aspect sous un jour un peu différent en indiquant que "les utilisateurs réussiraient en moyenne à faire progresser la production de 12 %. L'augmentation de la production par vache accuse toutefois une certaine tendance à l'uniformité en valeur absolue (en nombre de livres) plutôt qu'une évolution proportionnelle à la production normale. Aussi peut-on tabler sur une augmentation du nombre de livres de lait produit (dans des troupeaux gérés de façon comparable) qui sera à peu près du même ordre chez toutes les vaches produisant de 12 000 à 20 000 livres de lait par an".

L'étude CEAS I cite les "progressions comprises entre 15 et 25 % comme étant les plus usuelles. Après l'injection initiale, le rendement laitier s'accroît rapidement et à mesure que le traitement se poursuit, la courbe de lactation chez les animaux traités demeure supérieure et à peu près parallèle à celle enregistrée chez les animaux témoins pendant le reste de la lactation. Certains enregistrements mettent en évidence un élargissement de l'écart à mesure que la pente de la baisse de lactation devient plus aiguë chez les animaux témoins que chez les vaches traitées". Cette dernière observation reflète la possibilité d'un allongement des périodes de lactation, ainsi que l'ont montré les essais.

Ingestion d'aliments

L'étude CEAS I précise : "Ordinairement la prise volontaire d'aliments augmente, mais seulement au terme d'une période comprise entre 5 et 10 semaines après le premier traitement. Lorsque ce phénomène se produit, il compense tout ou partie des déficits nutritionnels antérieurs." Elle indique également que "le traitement à la BST ne retentit pas sur la digestibilité des aliments et [qu]'aucun élément ne donne à penser qu'il améliore l'efficacité sous le rapport de la transformation en lait des nutriments absorbés ou sous celui de l'entretien de l'animal. Toutefois, étant donné l'accroissement de la consommation alimentaire consécutif au traitement à la BST, la proportion de la quantité totale d'aliments consommée qui sert à l'entretien de l'organisme est plus basse. A noter de surcroît qu'il s'agit en quelque sorte d'une "super-ration d'entretien" rapportée à un poids plus élevé de lait produit. Ainsi s'explique l'amélioration de l'efficacité apparente ou brute avec laquelle la nourriture est transformée en lait."

Quant à l'étude américaine, elle conclut : "Pour que l'administration de BST se répercute sur le rendement laitier, il n'est pas nécessaire de recourir à des régimes spéciaux ou à des constituants alimentaires insolites. Des réactions caractérisées ont pu être observées pour les divers types d'alimentation du bétail existant aux Etats-Unis, depuis le pâturage jusqu'aux aliments concentrés, plus répandus. Toutefois, la prise volontaire d'aliments augmente chez les vaches laitières recevant de la BST."

Le bien-fondé de l'observation qui précède peut toutefois dépendre dans une certaine mesure des modalités selon lesquelles la BST serait utilisée, car le rattrapage que les intéressés voudraient obtenir en cas de réduction des quotas serait plus probablement opéré à l'aide de concentrés (CEAS I).

5. Sécurité

5.1. Sécurité pour l'homme

Selon le CMV, le demandeur a apporté la preuve que les résidus de son produit ne présentent aucun risque pour la santé des consommateurs des viandes ou du lait provenant des animaux traités et que l'utilisation du produit peut être admise en toute sécurité sans qu'il faille prévoir une quelconque période de retrait pour les viandes ou pour le lait.

Une question restée en suspens est toutefois abordée dans l'étude américaine en ce qui concerne le niveau du facteur de croissance 1 semblable à l'insuline (IGF-1) dans le lait provenant des vaches traitées à la BST.

"L'importance des quantités accrues d'IGF-1 dans le lait des animaux traités à la BST n'est pas connue avec certitude. Toutefois, la quantité d'IGF-1 ingérée dans un litre de lait est proche de la quantité d'IGF-1 contenue dans la salive avalée quotidiennement par un adulte." (Etude américaine)

5.2. Sécurité chez l'animal

Le CMV n'a pu parvenir à un consensus sur l'acceptabilité du produit considérée sous l'angle de la sécurité des animaux traités. L'avis majoritaire était que le fabricant avait apporté des garanties suffisantes en la matière, mais cinq membres du comité ont estimé qu'il fallait disposer de données supplémentaires sur l'incidence de la mammite et sur l'importance des réactions au niveau du site d'injection et sur l'hygiène de ce site pour être en mesure de formuler des conclusions définitives. Compte tenu des réserves de certaines délégations, le CMV indique dans son avis (points 6 et 7) :

"6. Le comité souhaite insister sur le fait que pour être efficace, l'utilisation du SOMATECH exige de l'exploitant qu'il maintienne une qualité d'élevage supérieure. C'est pourquoi le comité recommande que le produit ne soit mis à la disposition des éleveurs que sur prescription d'un vétérinaire.

7. Le comité juge important de veiller à ce que les résultats du SOMATECH se trouvent confirmés lors de l'utilisation pratique de ce produit dans des conditions d'élevage. A cet effet, le comité recommande d'imposer à la firme une condition préalable à toute autorisation de mise sur le marché du SOMATECH qui consisterait à recueillir et à évaluer tous les effets secondaires du produit qui ont été signalés comme suspects et à élaborer l'autorisation. - Voir l'exposé circonstancié de l'avis dans la partie III de la présente annexe.

Le Comité scientifique vétérinaire de la Commission a lui aussi examiné ces aspects du problème et il a émis l'avis ci-après :

Le comité est préoccupé par le fait que, dans le cadre des discussions consacrées à l'utilisation des produits résultant des procédures biotechnologiques, tels que la somatotropine bovine recombinant, les effets sur le bien-être des animaux traités au moyen de ces produits sont insuffisamment pris en compte. L'utilisation générale d'un nouveau produit de ce type ne devrait pas être autorisée avant que des données suffisantes fournies par des études scientifiques sur le bien-être des animaux ainsi

traités n'aient été rassemblées et analysées. Ces études devraient comprendre la détermination du bien-être des animaux ainsi que l'évaluation de la fréquence des maladies, des troubles physiques, des lésions, du comportement et des processus physiologiques. Les études devraient être menées pendant une période de la vie de l'animal d'une durée au moins égale à la durée la plus longue de son séjour dans l'exploitation et dans des conditions d'élevage diverses. Des études devraient également être effectuées dans des exploitations à orientation commerciale.

Les publications scientifiques disponibles ne mentionnent aucune étude exhaustive consacrée au bien-être des animaux traités à la somatotropine bovine recombinant. Les travaux relatifs aux effets en matière d'incidence des mammites et d'autres affections liées à la production de lait laissent présager l'existence de quelques problèmes de ce type, mais il serait souhaitable de disposer des résultats d'études plus vastes pour cerner la portée de ces problèmes.

5.3. Qualité du produit alimentaire

Chaque groupe d'agents favorisant la croissance se caractérise par une structure chimique et par un mode d'action qui lui sont propres.

a) Le Comité des médicaments vétérinaires qui a étudié l'utilisation de "SOMATECH", le produit Monsanto, admet que l'utilisation de ce produit ne retentit pas sur la qualité du lait ou de la viande, et qu'elle n'aura pas d'effet fâcheux sur la transformation industrielle de ce lait en yaourt ou en fromage.

b) Toutefois, un accroissement du nombre de cellules somatiques ne serait pas sans conséquences sur les normes fixées par la directive 85/397 en ce qui concerne la commercialisation dans la Communauté de lait de

consommation et sur le prix payé aux producteurs pour le lait destiné à la transformation. Un accroissement du nombre de cellules somatiques influe sur la composition du lait, par exemple sur le ratio lactose/sels, facteur qui pourrait retentir sur la qualité du produit et sur le rendement.

c) Les données issues de l'étude effectuée à la demande de la Commission par la Bundesanstalt für Milchforschung, Institut für Hygiene (Directeur : Prof. Dr. W. Heeschen), indique que les "augmentations cycliques", en matière de comptage de cellules somatiques, sont tributaires du comptage initial. C'est pourquoi une évaluation minutieuse de la santé de la mamelle doit figurer parmi les recommandations à suivre avant d'utiliser la BSTr dans un troupeau laitier. Etant donné le risque de dépassement des seuils cytologiques, seuls les troupeaux laitiers dont le comptage cellulaire n'excède pas un ordre de grandeur de 200 000/ml devraient être traités à la BSTr. Cette recommandation se justifie principalement par le fait que la BSTr serait administrée continûment, ce qui n'est pas le cas avec d'autres traitements de ce type faisant appel à des substances pharmacologiquement actives.

5.4. Effets sur l'environnement

Les préoccupations écologiques jouent un rôle important en matière de production animale. Si l'élevage intensif suscite en règle générale certaines craintes en ce qui concerne l'environnement, c'est dans une large mesure en raison des problèmes inhérents au fumier. A noter toutefois que là où ont été introduites des mesures augmentant la productivité, il y a généralement réduction de la quantité de fumier et de méthane produite par animal. Cette évolution tient le plus souvent à la modification des parts de l'alimentation respectivement consacrées à la croissance (production de viande) et à l'énergie (entretien). C'est ainsi que certains facteurs de croissance ont pour effet de piéger une plus grande proportion des substances nutritives aux fins de la transformation en viande, ce qui diminue d'autant les quantités libérées dans l'environnement sous forme d'azote, de phosphore ou de méthane.

A l'instar de ce qui se passe pour les facteurs de croissance, l'utilisation de la BST dans le domaine de la production laitière est susceptible de réduire les émissions de cuivre, d'azote, de phosphore et de méthane. La distribution spatiale de l'émission de fumier est toutefois plus susceptible d'influer sur les difficultés en puissance en matière de pollution.

On pense que seuls les troupeaux laitiers relativement importants (plus de 15 vaches) utiliseront régulièrement la BST, d'où une concentration de la production laitière dans certaines régions, évolution qui aura des conséquences sur l'environnement dans les régions en cause, mais aussi dans les régions où la production laitière baissera.

En termes de production globale de déchets d'origine animale, l'introduction de la BST aura des conséquences importantes étant donné que des vaches laitières sont remplacées par un nombre supérieur de vaches allaitantes et/ou d'autres bovins à viande. Il y aura toutefois un effet négatif sur l'environnement au niveau local si la production se concentre davantage.

5.5. Sélection génétique

L'adoption de techniques nouvelles peut influencer les stratégies d'élevage et dans l'hypothèse où de nouveaux produits propres à accroître la productivité seraient disponibles et largement adoptés, la réaction commerciale des éleveurs, empreinte de prudence, consisterait à adapter les stratégies de sélection pour tenir compte de la disponibilité de ces techniques.

Il importe d'éviter les distorsions dans le domaine des comparaisons entre les tests de performance des animaux vendus pour la reproduction. Il faut que les acheteurs d'animaux reproducteurs puissent tabler sur la comparabilité immédiate des données de performance qu'ils utilisent pour évaluer les animaux reproducteurs. L'introduction de la BST remettrait en cause les certitudes existant dans ce domaine à moins que les mesures appropriées ne soient prises à l'échelon communautaire.

Des éclaircissements demeurent en outre nécessaires quant aux effets de l'introduction de la BST sur le patrimoine génétique communautaire.

5.6. Bien-être des animaux

Cet aspect du problème a déjà été évoqué à propos de la sécurité pour l'animal.

Les questions liées au bien-être des animaux jouent un rôle majeur dans diverses parties de la Communauté et elles prennent de plus en plus d'importance. Les critères relatifs au bien-être des animaux sont assurément difficiles à définir quantitativement, mais il est clair que la société dans son ensemble est réticente lorsqu'il s'agit d'accepter l'utilisation de techniques qui ne sont guère défendables au regard de ces critères.

Là comme ailleurs, les facteurs inhérents au marché interviennent et une meilleure prise de conscience des méthodes de production a amené le marché à "récompenser" des systèmes moins traumatisants pour les animaux (par exemple élevage en libre parcours pour la production d'oeufs et de volaille et systèmes d'élevage moins intensifs pour la production de viande de veau). La question de savoir si les systèmes moins intensifs sont ou non nécessairement plus "conviviaux" pour les animaux demeure controversée. Les enquêtes effectuées auprès des consommateurs indiquent toutefois que l'utilisation de BSTr serait considérée comme altérant la qualité du lait, dont elle détruirait l'image de produit "naturel".

ENQUETES - ATTITUDES DES CONSOMMATEURS ET DES PRODUCTEURS

6. Introduction

Les préoccupations des consommateurs peuvent être subdivisées en trois catégories : les prix, la qualité (y compris la sécurité) et le choix. Les augmentations de productivité peuvent faire baisser les prix et c'est d'ailleurs là le moteur essentiel du progrès technique que la société s'efforce de promouvoir dans une économie de marché. La qualité est une question plus complexe.

La qualité d'un produit peut recouvrir bien des aspects différents, y compris la méthode de production (ou même l'idée que l'on s'en fait !). Les perceptions du public en matière de qualité sont en corrélation avec le prix et avec les perceptions concernant la santé et la sécurité.

Des instituts de recherche allemands ont entrepris deux enquêtes sur les répercussions que pourrait avoir l'introduction de la BST sur la consommation de lait et de produits laitiers dans la Communauté.

Malgré la marge d'incertitude généralement inhérente à ce genre d'enquête, il est permis de penser que l'écart existant entre la réponse à une question hypothétique et le comportement effectivement adopté dans la réalité ne sera pas suffisant pour en infirmer les résultats.

De fait, les enquêtes illustrent clairement ce que pourrait être l'attitude des consommateurs et des producteurs en cas d'introduction de la BST en l'état actuel des connaissances et de l'information dont on dispose à ce sujet.

7. Enquêtes auprès des consommateurs

a) Le langage utilisé pour diffuser l'information et pour éduquer le public revêt une grande importance lorsqu'il s'agit de déterminer le niveau de compréhension et l'attitude des gens sur tel ou tel sujet.

Il y a lieu de signaler à cet égard que l'étude de l'IFO sur l'attitude du consommateur face à la BST commence par expliquer ce qu'est la BST avant que la question clé ne soit posée aux personnes interrogées.

"Présentation

Vous n'êtes pas sans savoir que la production du lait dans l'organisme d'un animal est un processus biochimique d'une grande complexité. Les chercheurs sont parvenus à imiter un des composés servant à la régulation de la production de lait dans l'organisme. Il s'agit de l'hormone de croissance BST (à ne pas confondre avec les hormones sexuelles destinées à l'engraissement des veaux). Un vaste programme d'expériences a montré que le rendement laitier peut être notablement accru par la BST. Au cours du processus naturel de formation du lait, il y a toujours de petites quantités de BST qui passent dans le lait. La BST présente dans le lait des vaches traitées avec cette substance consiste en un mélange fait d'hormones BST naturelles et d'un apport d'hormones BST étrangères. Au cours des multiples recherches effectuées, aucun risque de quelque nature que ce soit n'a été mis en évidence pour le consommateur, de sorte que l'autorisation du produit ne soulèverait aucune objection fondée sur des considérations sanitaires."

b) Cette enquête de l'IFO sur les consommateurs a été réalisée dans les quatre Etats membres les plus peuplés, à savoir l'Allemagne, la France, l'Italie et le Royaume-Uni. Ces quatre pays représentent 71, 5 % de la population totale de la Communauté des 12. Les résultats ont été regroupés en trois catégories :

- "refus total des produits concernés" (consommation réduite de 100 %),
- "consommation grandement réduite" (de 30 %),
- "consommation légèrement réduite" (de 10 %).

L'enquête a porté sur sept groupes de produits : lait de consommation, boissons à base de lait, tous les types de fromages, beurre, yaourtset produits à base de lait fermenté, crème et produits à base de crème, lait condensé.

L'enquête montre que la réaction des consommateurs de lait et de produits laitiers à l'utilisation en production laitière de l'hormone de croissance BST obtenue par génie génétique impliquerait une réduction de la consommation dans la totalité des quatre pays en cause. Il y a toutefois de grandes dispersions entre les consommateurs et les divers produits/groupes de produits dans les différents Etats membres.

Le pourcentage de consommateurs ayant déclaré qu'ils boycotteraient totalement les produits laitiers concernés était de 17 % en Italie, 13 % en Allemagne, 12 % dans le Royaume-Uni et 8 % en France.

c) Il y a eu un taux très élevé de réponses affirmatives à la question de savoir si les produits fabriqués avec du lait provenant d'exploitations utilisant la BST devaient être clairement étiquetés. En moyenne calculée sur les quatre pays étudiés, plus de 82 % des personnes interrogées se sont prononcées en faveur d'un tel étiquetage, 18 % étant sans opinion ou hostiles à cet étiquetage. Le Royaume-Uni arrivait en tête avec 87 % de réponses positives, devant l'Italie (85 %). Les chiffres correspondants pour l'Allemagne et pour la France étaient respectivement de l'ordre de 80 % et de 77 %.

d) En ce qui concerne le comportement des acheteurs, 45 % des personnes interrogées dans les quatre pays ont indiqué qu'elles privilégieraient en règle générale les produits fabriqués à partir de lait en provenance d'exploitations n'utilisant pas la BST (lait "sans BST"). Cette attitude apparaît très nettement en Italie (57 % des personnes interrogées). Les consommateurs allemands, avec 49 %, se situent au-dessus de la moyenne et les Français juste au-dessous, avec 43 %. En revanche, 29 % seulement des personnes interrogées dans le Royaume-Uni ont exprimé l'intention de privilégier le lait sans BST.

Il y a également une proportion notable de consommateurs qui préféreraient acheter des produits fabriqués à partir de lait en provenance d'exploitations n'utilisant pas la BST, mais seulement à condition que le prix des produits "sans BST" soit acceptable.

e) Le résultat de l'enquête de l'IFO auprès des consommateurs fait apparaître une forte opposition à l'autorisation de la BST. Si nous additionnons tous les groupes de consommateurs ayant indiqué qu'ils réagiraient à une éventuelle admission de la BST en achetant un peu moins de lait, beaucoup moins de lait ou plus de lait du tout, il apparaît que 65 % environ des personnes interrogées modifieraient leurs habitudes en matière de consommation en Allemagne et en Italie et quelque 40 % dans le Royaume-Uni et en France.

Si on extrapole à la Communauté tout entière les résultats de cette enquête effectuée auprès des consommateurs, il apparaît que la consommation baisserait sensiblement. Le groupe des partisans d'un "boycottage total" ferait à lui seul baisser la consommation de quelque 11 millions de tonnes de lait, ce qui correspond à 480 000 tonnes de beurre et 985 000 tonnes de lait écrémé en poudre.

Si l'on prend de surcroît en considération les consommateurs ayant déclaré qu'ils réduiraient leur consommation de 30 %, la demande diminuerait d'environ 17 millions de tonnes, ce qui correspondrait à 750 000 tonnes de beurre et 1,5 million de tonne de lait écrémé en poudre.

Au total, 70 % de l'ensemble des personnes interrogées pensent que l'utilisation de la BST modifierait la qualité des produits laitiers et qu'elle porterait surtout préjudice à leur image de produit sain, "sans additifs", naturel, à leur goût et aux niveaux de substances nutritives et autres composants.

En ce qui concerne les raisons de ne pas acheter, les préoccupations d'ordre sanitaire et le caractère non naturel de la somatotropine ont été les plus fréquemment invoqués (53 %); loin derrière venaient le caractère inadéquat de l'information (14 %) et l'insuffisance des tests et de la recherche (7 %).

f) Etude CEAS (II) de 1989 intitulée "La BST et le consommateur : vue d'ensemble de la perception et des pratiques"

L'étude est fondée sur des enquêtes qui ont été effectués uniquement dans le Royaume-Uni et en Allemagne.

Elle montre que les connaissances des consommateurs sur les pratiques en matière de production laitière sont extrêmement limitées. Elle a néanmoins indiqué dans quelle mesure les consommateurs éviteraient d'acheter du lait s'ils étaient au fait des différentes méthodes de production utilisées. Voici selon les différentes méthodes quelles seraient les proportions de personnes interrogées qui éviteraient d'acheter du lait :

Méthodes de production utilisées	% de personnes interrogées qui éviteraient d'acheter du lait
1. Pratiques d'exploitation intensive normales, par exemple insémination artificielle, traite mécanique	3 - 12
2. Pratiques discutables au regard du bien-être des animaux comme le tarissement thérapeutique des vaches ou le séjour de celles-ci pendant 5 à 6 mois par an sur des aires bétonnées et clôturées	18 - 26
3. Utilisation d'additifs chimiques dans les aliments et d'hormones pour la régulation de la reproduction	33 - 38
4. Utilisation d'hormones (BST) pour la régulation des rendements laitiers	45

Il apparaît clairement que l'utilisation de la BST a été ressentie par les personnes interrogées comme la perspective la plus inquiétante.

g) Etiquetage du lait

Il a déjà été indiqué que les enquêtes effectuées en 1991 auprès des consommateurs attestent une préférence marquée pour un étiquetage mentionnant la BST au cas où celle-ci serait autorisée.

L'étude CEAS (1989) débouchait sur les mêmes conclusions :

"Dans l'hypothèse où l'utilisation commerciale de la BST serait admise, la méthode la plus fréquemment suggérée pour permettre aux consommateurs de choisir entre le lait contenant de la BST et le lait sans BST consisterait à étiqueter le lait en fonction de la méthode de production y afférente. Bien que les fournisseurs de lait ne soient pas actuellement obligés de donner cet étiquetage informatif, il apparaît qu'une majorité de consommateurs y sont favorables."

Cette étude CEAS précise encore que si le lait était étiqueté selon les techniques de production y afférentes, 45 % des personnes interrogées éviteraient le lait produit à l'aide de BST.

Enfin, l'étude CEAS (1989) formule la recommandation suivante :

"Même si l'étiquetage du lait selon la technique de production mise en oeuvre ne devait pas se concrétiser (en raison des grandes difficultés liées aux modalités d'application, au respect de la réglementation et à la clarté de l'étiquetage), il demeure incontestablement nécessaire d'améliorer l'information du consommateur quant à la BST et à la biotechnologie ... L'information, excluant la technicité, devrait être présentée d'une manière neutre par des sources à la fiabilité reconnue."

L'étude américaine elle aussi abordait cette question.

8. Enquête auprès des producteurs

a) L'enquête auprès des producteurs a été effectuée dans six Etats membres : Allemagne, France, Royaume-Uni, Pays-Bas, Danemark et Irlande. Les six pays en cause totalisent à peine moins de 52 % des producteurs de lait de la Communauté et environ les trois quarts de son cheptel de vaches laitières (EUR 12).

La somatotropine bovine (BST) est un problème dont la perception varie selon les Etats membres et, dans une moindre mesure, d'une région à l'autre dans un même Etat membre. Comme on pouvait s'y attendre, les producteurs laitiers ayant des troupeaux importants sont plus sensibilisés que ceux ayant de petits troupeaux.

Les producteurs étaient invités à se prononcer sur les aspects suivants de la BST :
- faut-il en autoriser l'utilisation ?
- l'utiliseraient-ils dans leurs propres troupeaux ?
- l'utiliseraient-ils s'il y avait une différence en matière de prix et de débouchés selon que le lait produit l'est avec ou sans BST ?

b) Le résultat le plus frappant de l'enquête a été un rejet sans équivoque des initiatives tendant à permettre l'utilisation de la BST. Il n'y a eu qu'une petite minorité de personnes interrogées en faveur de l'enregistrement de la BST, la grande majorité souhaitant une interdiction. Cette observation s'applique même à la France et à l'Irlande, où la BST est pourtant généralement mieux acceptée : dans ces deux pays, il n'y a qu'une catégorie d'exploitation où le pourcentage "pour une interdiction" représente moins de deux fois le pourcentage "pour l'enregistrement".

Il est tout aussi frappant de constater qu'il n'y aurait qu'une minorité de producteurs pour utiliser immédiatement la BST si cette hormone devait être autorisée. A noter toutefois qu'il n'y a pas non plus de majorité nette (c'est-à-dire plus de 50 %, sauf dans le Royaume-Uni) de producteurs qui renonceraient à la BST en tout état de cause. Une proportion similaire de producteurs envisagent de se donner un délai de réflexion pour voir si leurs craintes en matière de bien-être des animaux peuvent être apaisées, quels sont les avantages commerciaux et surtout s'il peut y avoir des conséquences fâcheuses sur l'évolution du marché des produits laitiers, après quoi ils arrêteront leur décision pour ou contre l'utilisation de la BST.

c) Les résultats de l'enquête reflètent l'incertitude qui subsiste quant aux réactions des consommateurs précédemment exposées. Il est manifeste que les producteurs s'inquiètent beaucoup d'éventuelles répercussions négatives sur le marché, de sorte que leur opposition ne constitue pas une surprise.

Le problème de la santé ou du bien-être des animaux n'arrive qu'en seconde position dans l'ordre des préoccupations.

L'observation qui précède est confirmée par le résultat de l'enquête indiquant que dans l'hypothèse où la BST serait autorisée, les producteurs de lait y recourraient à relativement brève échéance.

9. EFFET SUR LE MARCHE DU LAIT

Cet effet sera dans une large mesure tributaire de deux facteurs, à savoir les taux d'adoption et la réaction des consommateurs.

a) Il a déjà été indiqué que plusieurs scénarios différents peuvent être envisagés en matière de réaction des consommateurs.

L'enquête de l'IFO auprès des consommateurs pronostique une baisse de 18 millions de tonnes de la consommation, alors que l'étude CEAS II prévoit une réaction un peu moins brutale. L'étude américaine s'articule autour de deux possibilités : a) consommation en baisse de 10 % à titre permanent; b) baisse transitoire de la consommation, de 10 % également. L'étude américaine ne cherche pas à justifier ces hypothèses, mais se borne à les utiliser pour évaluer les conséquences économiques et budgétaires.

Chaque diminution de 1 % de la consommation de lait dans la Communauté équivaut à 46 000 tonnes de beurre et 89 000 tonnes de lait écrémé en poudre. Les débouchés extracommunautaires ne pouvant guère être accrus sans qu'il en résulte des effets budgétaires et commerciaux négatifs, la moindre baisse de la consommation interne dans la Communauté nécessiterait une révision à la baisse des quotas laitiers.

Un autre aspect à ne pas perdre de vue en ce qui concerne la BST est celui des lactoremplaceurs.

Dans le troisième rapport de la Commission au Conseil concernant "Evolution du marché des produits laitiers et des produits concurrents" (Sec(91)1297) figurent en particulier les observations suivantes :

- accroissement de la consommation de fromage et stabilisation de la consommation de lait et de produits laitiers;

- fléchissement considérable de la consommation domestique de beurre, en particulier dans les Etats membres où les produits concurrents sont les mieux implantés;

- augmentation importante des ventes de mélanges de matières grasses lactiques et non lactiques;

- permanence d'une certaine confusion dans l'esprit des consommateurs, entretenue par les dénominations, l'étiquetage et la disposition des produits laitiers et des produits concurrents dans les magasins.

Une expansion très importante a été observée pendant les dernières années dans le secteur des lactoremplaceurs, en particulier les matières grasses jaunes, et plus récemment dans le secteur des fromages. Cette croissance a surtout tenu au trouble suscité chez les consommateurs par des griefs sanitaires infondés et/ou par une simplification excessive des résultats de la recherche, notamment dans le domaine des maladies cardiaques et de leurs causes. C'est ainsi que l'industrie des lactoremplaceurs en est venue à user de messages publicitaires ambigus et passionnels.

Si la BST devait être autorisée, il ne serait pas exclu que cette industrie tente de pousser encore son avantage en utilisant des moyens publicitaires de cette nature.

b) En ce qui concerne les taux d'adoption, il règne une très grande incertitude.

(i) Dans le cadre de l'étude américaine, une enquête effectuée chez les éleveurs de bétail laitier a montre que quelque 50 % des personnes interrogées adopteraient la BST pendant sa première année de disponibilité dans le commerce, et que la proportion monterait à 80 % dans un délai de trois ans. La plupart des spécialistes, largement tributaires d'études de ce type, se sont accordés à penser que l'adoption de la BST devrait être relativement rapide. Il faut toutefois être conscient du caractère aléatoire que présente le recours aux enquêtes pour prévoir ce que pourraient être les taux d'adoption d'une technique qui n'est pas encore disponible.

La même étude indique d'autre part :

"A noter en outre que les nouvelles technologies laitières n'ont pas été en général rapidement adoptées. C'est ainsi que la technique de l'insémination artificielle, commercialement disponible depuis plus de 40 ans, n'est utilisée que par 65 à 70 % des éleveurs de bétail laitier."

L'étude américaine se fonde sur ces divers éléments pour pronostiquer que les taux d'adoption devraient s'établir au bout de cinq ans dans une fourchette comprise entre 25 et 26 % selon la région et au bout de dix ans dans une fourchette comprise entre 31 et 67 %, toujours selon la région.

(ii) L'étude CEAS (1) propose une analyse prenant en considération le système des quotas laitiers et le prix probable de la BST.

La conclusion de cette analyse est que la BST ne devrait pas être très largement adoptée et utilisée dans la pratique.

L'étude indique de surcroît :

"La décision d'utiliser ou non la BST et le choix des vaches auxquelles cette hormone sera administrée seront arrêtés par chaque éleveur en fonction de sa perception des risques et des avantages ainsi que de son attitude à l'égard de la nouvelle technique. Chaque exploitant appréciera la situation à sa manière, mais il y a lieu de penser que l'adoption procédera de la prise en considération des éléments ci-après :

- avantage de la BST (reflétant partiellement la rentabilité existante du troupeau et champ des possibilités qui s'offrent pour réaffecter les ressources libérées);
- prix de la BST;
- aptitude à la gestion;
- taille du troupeau.

Compte tenu des restrictions que subit la production du fait des quotas laitiers et si lon considère que la BST est censée accroître de 12 % le rendcement moyen et que la BST devra être vendue à un prix raisonnablement

rémunérateur, et il y a lieu de penser que la pression qui s'exercera pour développer l'utilisation de la BST dans la Communauté restera limitée.

La production laitière globale imputable à la mise en oeuvre de la BST représenterait 1,2 % de la production totale à court terme et 5 % à longue échéance si l'on admet que les résultats enregistrés pour les cinq Etats membres sont représentatifs de la Communauté des Douze.

La réduction de l'effectif de vaches consécutive à l'utilisation régulière de la BST est estimée à 0,5 % à court terme, chiffre qui monterait à 3,6 % à moyen terme.

Les données qui précèdent seraient l'aboutissement de plusieurs facteurs conjugués : utilisation régulière de la BST, transfert de quotas probable au profit de troupeaux plus importants, réduction du nombre de vaches dans le cadre d'un quota fixe et utilisation de la BST par de petits exploitants laitiers soucieux d'éviter une diminution de leur quota.

Il semble que l'existence des quotas laitiers joue un rôle significatif non seulement en limitant la production globale, mais aussi en raison de la capitalisation de la valeur d'un quota laitier appartenant à une exploitation. Le prix du quota constitue un coût supplémentaire que tout exploitant doit acquitter s'il cherche à utiliser plus largement la BST."

Ces calculs pèchent peut-être par excès de prudence.

Une estimation différente, fondée sur les chiffres de l'étude CEAS, débouche sur une conclusion différente en ce qui concerne l'augmentation de la production laitière.

D'après l'étude CEAS II (1989) :

- L'utilisation de la BST fera en moyenne progresser de 12 % les rendements;

- à moyen ou à long terme, 55 % des vaches recevront de la BST.

En conséquence, il est permis de penser que l'accroissement de laproduction laitière pourrait se situer quelque part entre les deux scénarios suivants :

a) Si l'on admet que 55 % des vaches assurent 55 % de la production laitière, l'augmentation s'établit à $\frac{55 \times 12}{100} = 6,6$ %.

b) Etant donné que la BST serait exclusivement administrée aux vaches à rendement moyen ou élevé et que celles-ci assurent quelque 80 % de la production laitière, l'accroissement serait en réalité de 9,6 %.

10. Effet sur le marché de la viande bovine

L'effet exercé sur le marché de la viande bovine dépendra également des hypothèses retenues en matière de consommation et de taux d'adoption. Si la consommation baisse notablement et que cette évolution débouche sur la

décision d'adapter les quotas laitiers en conséquence, des vaches laitières seront abattues et on enregistra à court terme une augmentation de la production de viande bovine.

Si l'on écarte en revanche l'hypothèse d'une baisse sensible de la consommation, le marché de la viande bovine sera moins affecté.

Une baisse de moitié du prix de la BST se traduirait par une régression plus importante de l'effectif de vaches laitières. Une évolution en ce sens s'étalera toutefois sur un certain nombre d'années, qui variera en fonction du taux d'administration de la BST.

La diminution du nombre de vaches libérera des superficies pour d'autres spéculations, c'est-à-dire soit pour des productions végétales, soit plus probablement pour la production de viande bovine.

Le précédent des réductions de quotas laitiers donne à penser que des vaches laitières seront remplacées par des bovins à viande; dans cette hypothèse, la production totale de viande bovine devrait augmenter à long terme, essentiellement parce que les vaches de boucherie ont un rendement en viande plus élevé que les vaches laitières.

Il n'est cependant pas exclu, comme on a récemment pu le constater ici ou là, que des éleveurs de bétail laitier qui réduisent leurs troupeaux laitiers remplacent les vaches laitières non seulement par des vaches allaitantes, mais aussi par d'autres bovins à viande tels que des bouvillons ou des taurillons. S'ils veulent maintenir leurs revenus, les intéressés se voient obligés de remplacer les vaches laitières dont ils se défont par un nombre supérieur de bovins à viande. La vérification de l'hypothèse se solderait par une forte augmentation de la production de viande bovine.

11. BST - Effet sur les effectifs de vaches

Année	Production en millions de tonnes	Pas de BST	Effectif de vaches (en milliers de têtes) Administration de BST	
			20 % à court terme	55 % à long terme

V.O.

NOTE : Les projections ci-dessus sont fondées sur une production demeurant constante et sur des rendements laitiers moyens en hausse de 75 kg par an hors utilisation de la BST.

Données statistiques concernant la Communauté des Douze, ex-RDA comprise.

PARTIE II

CONSEQUENCES BUDGETAIRES POTENTIELLES RESULTANT DE L'UTILISATION DE LA B.S.T.

CONSEQUENCES BUDGETAIRES POTENTIELLES RESULTANT
DE L'UTILISATION DE LA B.S.T.

L'adoption et le développement de l'utilisation de la B.S.T. auraient d'importantes répercussions sur les marchés agricoles au niveau de l'offre aussi bien que de la demande, avec une incidence correspondante sur le budget communautaire.

Les éventuelles conséquences pour le budget annuel sont exposées ci-dessous. Les hypothèses utilisées sont fondées sur la politique actuelle et ne tiennent donc pas compte des propositions récemment formulées par la Commission en ce qui concerne la réforme de la PAC.

L'approvisionnement en produits agricoles

L'adoption et le développement de l'utilisation de la BST débouchera sur un accroissement du rendement moyen de la popupulation de vaches laitières de la Communauté. La production laitière globale de la Communauté étant limitée par le système des quotas, une hausse du rendement moyen entraînera une réduction du nombre de vaches laitières. Les scénarios possibles suivants peuvent être envisagés au sujet de l'évolution du taux d'utilisation de la BST dans la population de vaches laitières:

a) expansion rapide de l'utilisation de la BST atteignant 20 % du cheptel laitier;

b) outre le taux immédiatement atteint de 20 % du cheptel, l'utilisation s'étend par la suite à raison de 7 % supplémentaires par années pendant une période de cinq ans, de sorte qu'en fin de compte la BST est utilisée sur 55 % du cheptel total.

Dans l'hypothèse d'un accroissement du rendement laitier par vache de 12 % en cas d'utilisation de la BST, la réduction du nombre de vaches laitières qui en résulterait serait la suivante:

		1000 têtes
a)	utilisation sur 20 % du cheptel	- 540
b)	utilisation sur 55 % du cheptel	- 1280

- Vaches de races à viande supplémentaires

En supposant que 75 % de la réduction totale du cheptel de vaches laitières soient remplacés par des vaches de races à viande pour maintenir la production de viande bovine au même niveau, le nombre de vaches allaitantes éligibles à la prime de 40 écus par animal dans le cadre du régime communautaire augmentera.

Le nombre supplémentaire de vaches éligibles et les coûts budgétaires qui en découlent sont les suivants:

a) 540 000 têtes x 75% = 405 000 têtes x 40 écus/tête x 1 145 (DT) = = 18,5 millions d'écus (B)
b) 1 280 000 têtes x 75% = 960 000 têtes x 40 écus/tête x 1,145 (DT) = = 44,0 millions d'écus (B)

- Production supplémentaire de viande bovine (temporaire)

La conversion des élevages laitiers en élevages à viande limitera la réduction du nombre total de vaches de la façon suivante:

Diminution nette du nombre de vaches:
a) 540 000 - 405 000 = 135 000 têtes
b) 1 280 000 - 960 000 = 320 000 têtes

La diminution nette du nombre de vaches aura pour effet une augmentation de la production de viande bovine résultant de l'abattage de ces animaux. Les quantités supplémentaires de viande et le coût budgétaire qui risquent d'en découler (achat par l'intervention) sont les suivants:

a) 135 000 têtes x 300 kg/tête = 40 500 t x 2 035 écus/t x 1,145 (DT) = = 94,4 millions d'écus (B)
b) 320 000 têtes x 300 kg/tête = 96 000 t x 2 035 écus/t x 1,145 (DT) = = 223,7 millions d'écus (B)

Ces coûts ne devront cependant être supportés que pendant la période du passage à l'adoption de la BST et auront donc une incidence exceptionnelle, éventuellement répartie sur plusieurs années, dans le cas de l'hypothèse b).

- Libération de terres disponibles pour d'autres productions agricoles

La diminution nette du nombre de vaches aura également pour effet de libérer des terres et d'autres ressources actuellement consacrées à l'élevage laitier et de les rendre disponibles pour la production d'autres produits agricoles. En supposant une charge moyenne de pâturage de 1,5 vache laitière à l'hectare, les terres potentiellement libérées peuvent être estimées comme suit:

a) 135 000 têtes x 1,5 tête/ha = 202 500 ha
b) 320 000 têtes x 1,5 tête/ha = 480 000 ha.

La production de céréales peut représenter une des utilisations de remplacement de ces terres. Compte tenu des rendements moyens actuels de la Communauté de 4,6 tonnes à l'hectare, la production supplémentaire de céréales et, de ce fait, les coûts budgétaires additionnels (achat par l'intervention) seraient les suivants:

a) 202 500 ha x 4,6 t/ha = 930 000 t (arrondies) x 128 écus/t x x 1,145 (DT) = 136,3 millions d'écus (B)
b) 480 000 ha x 4,6 t/ha = 2 210 000 t (arrondies) x 128 écus/t x x 1,145 t/ha = 323,9 millions d'écus (B)

Considérations relatives à la demande

L'enquête menée sur la réaction des consommateurs révèle que l'utilisation de la BST pourrait entraîner une baisse de la consommation communautaire de lait et de produits laitiers de près de 17 millions de tonnes d'équivalent lait (une diminution de près de 20 % de la consommation actuelle estimée à 90 millions de tonnes environ).

Si cette baisse se produisait, elle équivaudrait à une production annuelle supplémentaire d'environ 780 000 tonnes de beurre et de près de 1,45 million de tonnes de lait écrémé en poudre. Le coût budgétaire de l'achat par l'intervention des quantités en cause s'élèverait à 3 200 millions d'écus environ.

D'autre part, si, comme l'indique l'étude américaine sur la BST, la baisse de la consommation (temporaire ou permanente) devait être limitée à 10 % (-9 millions de tonnes), le coût budgétaire de l'achat par l'intervention des quantités supplémentaires correspondantes de beurre et de lait écrémé en poudre atteindrait 1 700 million d'écus environ.

Conclusion

Sur la base des scénarios possibles exposés ci-dessus, l'introduction de la BST pourrait avoir les répercussions budgétaires annuelles suivantes:

1. Réduction de la demande d'environ 20 %

	Millions d'écus (B) (chiffre arr.) a)	b)
Versements supplémentaires prime vache allaitante	+ 20	+ 45
Production supplémentaire de céréales	+ 135	+ 325
Baisse de la consommation (- 20 %) de lait et de produits laitiers	+ 3 200	+ 3 200
TOTAL*)	+ 3 355	+ 3 570

2. Réduction de la demande d'environ 10 %

	Millions d'écus (B) (chiffre arr.) a)	b)
Versements supplémentaires prime vache allaitante	+ 20	+ 45
Production supplémentaire de céréales	+ 135	+ 325
Baisse de la consommation (- 10 %) de lait et de produits laitiers	+ 1 700	+ 1 700
TOTAL *)	+ 1 855	+ 2 070

*) A l'exclusion des coûts supplémentaires résultant de la hausse temporaire de la production de viande bovine due à la réduction nette transitoire du nombre de vaches.

PARTIE III

AVIS DU COMITE DES MEDICAMENTS VETERINAIRES

Comité des médicaments vétérinaires

Avis du comité des médicaments vétérinaires
concernant une demande d'autorisation de mise sur le marché,
présentée par la firme MONSANTO, relative au SOMATECH
(précédemment Sométribove), somatotropine bovine recombinant

(Procédure de concertation du CMV (directive 87/22/CEE) demande n° 1)

INTRODUCTION

Le 24 août 1987, conformément à l'article 2 de la directive 87/22/CEE, la France a saisi le CMV pour avis au sujet d'une demande d'autorisation de mise sur le marché, présentée par la firme Monsanto, relative au SOMATECH, somatotropine bovine recombinant, dont l'administration aux vaches laitières est prévue à 14 jours d'intervalle afin d'augmenter les rendements laitiers. La firme Monsanto a par la suite adressé des demandes relatives au même produit à l'Italie et au Royaume-Uni.

La demande a été examinée les 24 et 25 novembre 1987 par le comité chargé de la biotechnologie et de la médecine vétérinaire au cours d'une réunion ad hoc. Celui-ci a fait remarquer qu'il existait des différences entre la documentation présentée à la France et celle adressée au Royaume-Uni. Conformément à l'article 3 de la directive 87/22/CEE, il a invité la firme à renvoyer deux dossiers identiques aux Etats membres concernés et a suspendu l'examen de la demande.

Le 23 février 1988, les autorités françaises ont accepté une demande modifiée, puis des exemplaires de la demande intégrale ont été mis à la disposition de tous les Etats membres et du comité.

Le 16 juin 1988, à l'occasion d'une deuxième réunion ad hoc sur la biotechnologie et la médecine vétérinaire, la demande modifiée a fait l'objet d'une discussion avant d'être examinée par le comité lui-même le 17 juin. Ce dernier a considéré que les informations fournies par la firme n'étaient pas suffisantes pour déterminer si le produit satisfaisait aux critères préalables à toute autorisation établis par les directives 81/851/CEE et 81/852/CEE relatives à l'harmonisation des législations des Etats membres en matière de médicaments vétérinaires. Le comité a donc élaboré une série complète de questions qui a été transmise à la firme immédiatement après la réunion du 17 juin.

En juillet 1989, la firme a présenté à tous les Etats membres sa réponse initiale comprenant plus de 22 000 pages de données supplémentaires. Cependant, compte tenu des difficultés à établir une corrélation entre les données contenues dans la demande originale de la firme et les nouvelles informations figurant dans sa réponse, le comité a estimé que cette demande était inacceptable aux fins d'une évaluation. La firme a soumis une nouvelle réponse en décembre 1989.

Cette réponse a fait l'objet d'une discussion détaillée au comité lors de la réunion des 17 et 18 mai 1990 qui lui a permis de conclure que plusieurs réponses de la firme relatives à la qualité et à certains aspects biotechnologiques du produit ainsi qu'à la sécurité de celui-ci chez les espèces cibles n'apportaient toujours pas satisfaction. Ces conclusions ont été communiquées à la firme qui a accepté de présenter de nouveaux documents; ceux-ci ont été distribués en deux fois à tous les Etats membres, aux mois de juin et d'août 1990. Le 19 septembre 1990, des représentants de la firme ont assisté à une audition devant le comité, au cours de laquelle ils ont non seulement répondu aux questions des Etats membres, mais aussi confirmé qu'à l'exception de certaines questions posées pendant l'audition auxquelles ils apporteraient de nouvelles réponses écrites, toutes les données appropriées relatives au produit, qu'elles fussent favorables ou pas, avaient été mises à la disposition du comité. Les réponses à ces questions en suspens ont été distribuées à tous les Etats membres à la fin du mois d'octobre 1990.

La discussion concernant la demande s'est poursuivie les 26 et 28 novembre 1990 et les 15 et 16 janvier 1991 à l'occasion de réunions du CMV. Le comité a adopté l'avis suivant lors de sa réunion des 19 et 20 mars 1991.

AVIS DU COMITE DES MEDICAMENTS VETERINAIRES CONCERNANT LE SOMATECH

1. La majorité des membres du comité considèrent que le produit SOMATECH répond aux critères préalables à toute autorisation prévus dans les directives 81/851/CEE et 81/852/CEE.

2. Le comité estime que le fabricant a démontré qu'il était capable d'élaborer un produit stable et homogène d'une durée de conservation de 18 mois, conformément aux exigences de qualité établies par les directives communautaires, en utilisant un procédé biotechnologique bien maîtrisé. Toutefois, cette entreprise doit fournir au comité les résultats de l'essai sur l'ADN du plasmide mené sur les vingt premiers lots produits à échelle industrielle après autorisation.

3. Le comité considère que le demandeur a mis en évidence la capacité du SOMATECH d'augmenter considérablement les rendements laitiers des vaches traitées. L'importance de cette augmentation dépend, entre autres, de la race des vaches traitées, de l'individu soumis au traitement, du stade auquel le produit est administré dans le cycle de lactation et de la qualité des techniques d'élevage utilisées, mais on peut l'évaluer entre 2,7 et 5,7 kg par jour.

4. Le comité estime que le demandeur a prouvé que les résidus de SOMATECH ne présentent aucun risque pour la santé des consommateurs de lait ou de viande provenant des animaux traités. Le produit peut être utilisé sans risque et avec un temps d'attente nul pour le lait ou la viande.

   Le comité considère par ailleurs que l'utilisation du SOMATECH ne modifie pas la qualité du lait ou de la viande et ne sera pas préjudiciable à la transformation industrielle du lait en yaourt ou fromages.

5. La majorité des membres du comité estiment que l'administration de SOMATECH à des vaches laitières ne présente pas de risque excessif pour la santé ou le bien-être de l'animal traité.

S'il a été observé pendant les essais cliniques certains effets sur le taux de fécondité des animaux primipares et les intervalles entre vêlages chez les animaux traités au SOMATECH avant la conception, le comité pense que ces inconvénients peuvent être supprimés par des mises en garde appropriées sur l'emballage du produit.

Après une analyse statistique approfondie des données disponibles, le comité conclut qu'il n'existe pas de preuve que l'utilisation de SOMATECH provoque une augmentation de l'incidence des mammites chez les animaux traités en comparaison avec les animaux de contrôle, une fois prise en considération l'augmentation du rendement laitier des animaux traités. Toutefois, le comité juge que les données expérimentales disponibles sur l'incidence des mammites doivent être confirmées par des éléments d'information supplémentaires obtenus dans des conditions réelles d'utilisation après autorisation du produit. Par conséquent, le comité recommande que l'autorisation de mise sur le marché de ce produit ne soit accordée que sous réserve de l'obligation pour l'entreprise concernée de réaliser une étude de pharmacovigilance structurée sur les effets de l'utilisation de ce produit en termes d'incidence des mammites. Le protocole de cette étude devra être présenté au comité pour approbation. Les délégations irlandaise, italienne et britannique estiment cependant qu'il convient de disposer d'informations supplémentaires sur l'incidence des mammites, à partir d'un plus grand nombre d'animaux, avant de donner l'autorisation de mise sur le marché.

Dans sa demande initiale, l'entreprise concernée proposait que le SOMATECH soit administré par injection sous-cutanée au site sous-scapulaire. Après une évaluation de la nature et de l'importance des réactions locales observées au site d'injection, la majorité des membres du comité ont jugé ces réactions inacceptables. Par la suite, cependant, l'entreprise concernée a modifié sa demande en proposant l'administration de SOMATECH uniquement au site sous-caudal (ischiorectal fossa). Les réactions observées à ce nouveau site sont, en nature et en importance, substantiellement réduites; elles se limitent à un léger gonflement passager et rien n'indique que ce gonflement soit source de douleur ou d'inconfort pour l'animal concerné. Toutefois, les délégations allemande, néérlandaise, irlandaise et britannique se demandent si la portée et la nature des études réalisées au site sous-caudal permettent de tirer des conclusions définitives à ce stade. Ces délégations demandent des analyses détaillées du contrôle vétérinaire des études américaines et de la fréquence des examens et l'importance des réactions au site d'injection.

Bien que les niveaux plasmatiques de somatotropine bovine soient réduits après une injection au site sous-caudal, l'augmentation du rendement laitier constatée dans ce cas est équivalente à celle obtenue après injection au site sous-scapulaire. Le comité considère par conséquent que ces deux voies d'administration présentent une efficacité comparable.

Dans ces circonstances, et compte tenu de l'expérience acquise au niveau de l'administration du vaccin contre la fièvre aphteuse au site sous-caudal dans plusieurs Etats membres, la majorité des membres du comité estiment que l'administration du SOMATECH au site sous-caudal est acceptable et ne présente pas de risque excessif pour l'animal concerné.

Les délégations irlandaise, néérlandaise et britannique s'inquiètent néanmoins des conditions d'hygiène au niveau du site sous-caudal à certaines périodes de l'année et de la possibilité que l'injection à ce site induise une infection chez l'animal traité. Elles demandent par conséquent que des données supplémentaires sur l'incidence des infections soient fournies sur la base des protocoles utilisés aux Etats-Unis pour l'exécution d'essais d'injection à ce site et sur la base des procédures d'examen des réactions constatées à ce niveau.

6. Le comité souhaite insister sur le fait que pour être efficace l'utilisation du SOMATECH exige de l'exploitant qu'il maintienne une qualité d'élevage supérieure. C'est pourquoi le comité recommande que le produit ne soit mis à la disposition des éleveurs que sur prescription d'un vétérinaire.

7. Le comité juge important de veiller à ce que les résultats du SOMATECH se trouvent confirmés lors de l'utilisation pratique de ce produit dans des conditions d'élevage. A cet effet, le comité recommande d'imposer à la firme une condition préalable à toute autorisation de mise sur le marché du SOMATECH qui consisterait à recueillir et à évaluer tous les effets secondaires du produit qui ont été signalés comme suspects et à élaborer un rapport annuel de sécurité durant les cinq années suivant l'autorisation, qui s'ajouterait à l'étude spécifique de l'incidence des mammites chez les animaux traités mentionnée plus haut.

8. Le comité demande que soit mis à la disposition de tous les Etats membres et de la Commission tout élément d'information supplémentaire fourni par le demandeur aux Etats membres conformément au point 5 ci-dessus. Après analyse des informations reçues, le comité envisagera l'adoption d'un second avis concernant la demande.

9. Le comité considérera le résumé des caractéristiques du produit recommandé par la firme et la fiche d'information proposée pour le produit lors de sa prochaine réunion.

10. Le comité signale que son avis concerne exclusivement le produit SOMATECH fabriqué par la firme Monsanto. Il ne préjuge en rien de l'évaluation de toute autre demande d'autorisation concernant un produit élaboré à base de somatotropine bovine.

11. Conformément à la directive 87/22/CEE et compte tenu des dispositions de la décision du Conseil 90/218/CEE relative à l'administration de somatotropine bovine, modifiée par la décision du Conseil 90/61/CEE, en particulier son article premier, les Etats membres concernés sont tenus d'informer la Commission, dans un délai de 30 jours, des mesures qu'ils prendront pour donner suite au présent avis.

12. Le comité a l'intention de préparer un rapport détaillé de son évaluation de ce dossier. Entre-temps, copies de cet avis peuvent être fournies aux personnes intéressées.

13. Le comité note qu'en vertu de la législation nationale actuelle en vigueur, les produits contenant la somatotropine bovine ne peuvent pas être autorisés en Belgique.

PARTIE IV

RESOLUTIONS DU PARLEMENT

(voir JO)

PARTIE V

EXTRAIT DE LA COMMUNICATION DE LA COMMISSION AU PARLEMENT ET AU CONSEIL INTITULEE "PROMOUVOIR LES CONDITIONS DE LA COMPETITIVITE DES ACTIVITES INDUSTRIELLES BASEES SUR LA BIOTECHNOLOGIE DANS LA COMMUNAUTE"

INDUSTRIE PHARMACEUTIQUE / BIOTECHNOLOGIE

La BST étant un produit de la biotechnologie moderne, les industries intéressées se préoccupent de la mise en place d'un cadre réglementaire stable pour leurs activités. La Commission a examiné la question dans sa récente Communication au Parlement et au Conseil intitulée "Promouvoir les conditions de la compétitivité des activités industrielles basées sur la biotechnologie dans la Communauté" (SEC (91) 629 final). Ce document précise notamment ce qui suit:

"Les produits issus de la biotechnologie ne nécessiteront pas tous des procédures d'évaluation ou d'agrément spécifiques. Pour l'heure, les produits de la biotechnologie sont, dans leur grande majorité, obtenus à l'aide de méthodes traditionnelles (par exemple, fromages, extraits de malt, bières, levures). En ce qui concerne les produits issus de la nouvelle biotechnologie, dont la production implique des manipulations génétiques, chaque produit devrait être examiné cas par cas et évalué comme il convient.

Les produits nécessitant l'intervention des pouvoirs publics pourront être examinés et agréés conformément au cadre réglementaire applicable à la biotechnologie mis en place par la Communauté. Celui-ci, qui se fonde sur une analyse et une évaluation scientifiques, couvre à la fois la législation horizontale (concernant l'environnement et la protection des travailleurs) et la législation concernant les produits. Cette dernière se fonde sur les critères de sécurité, de qualité et d'efficacité[1)], qui sous-tendent également la décision d'autoriser ou non la mise sur le marché libre. Le cadre horizontal couvre tous les stades du développement pré-industriel et les aspects environnementaux.

L'approche suivie actuellement par la Communauté, qui se fonde sur l'application correcte et rigoureuse des critères de sécurité, de qualité et d'efficacité, ainsi que sur la législation horizontale applicable, garantit la sécurité et les intérêts économiques du consommateur et permet de proteger l'hygiène humaine, animale et végétale et de l'environnement. En outre, pour assurer la protection du consommateur, il convient de tenir compte également de l'incidence sur l'information et le choix du consommateur.

1) Il est à noter que ces trois critères sont considérés aujourd'hui comme étant inclus dans l'impact sur la nature et sur la sécurité de l'environnement.

Le débat qui s'est ouvert récemment a porté essentiellement sur l'introduction, dans l'évaluation des produits issus de la biotechnologie, de contraintes socio-économiques plus larges, en plus des trois critères traditionnels. Le débat se poursuit et les préoccupations exprimées diffèrent : pour certains, le concept comporte une analyse plus large des aspects sanitaires et environnementaux; pour les autres, il doit être centré sur les répercussions sociales et/ou économiques (par exemple, les conséquences pour la production agricole). La Communauté doit avant tout éviter une situation qui susciterait l'incertitude.

En règle générale, les décisions doivent être fondées sur des évaluations objectives utilisant des critères clairement définis. Toute incertitude concernant l'acceptation et l'agrément des produits peut avoir pour effet de détourner l'investissement et de décourager l'innovation et le développement technologique au niveau de l'entreprise. La Communauté doit, d'autre part, donner au public l'assurance que l'industrie est soumise à une réglementation adéquate. Le dynamisme de l'industrie et la confiance du public dépendent de l'aptitude de la Communauté à rassurer les deux parties.

Quand un produit issu de la biotechnologie a fait l'objet d'une analyse, les trois critères traditionnels basés sur une évaluation scientifique s'appliquent. Par leur nature, les aspects socio-économiques doivent être traités selon une méthode différente. Cela ne veut pas dire avoir une autre évaluation systématique en complément des trois critères. La Commission suivra normalement un avis scientifique. Cependant, la Commission se réserve le droit de prendre une position différente à la lumière de ses obligations générales de tenir compte des politiques et des objectifs communautaires. Cela peut, dans des cas exceptionnels, conduire à des besoins d'information supplémentaires. Cela peut également, dans des cas exceptionnels, conduire la Commission à proposer que d'autres politiques soient modifiées à la lumière des développements scientifiques."

COMMISSION
DES
COMMUNAUTES EUROPEENNES

Secrétariat Général

COM(91)522

Bruxelles, le 3 décembre 1991

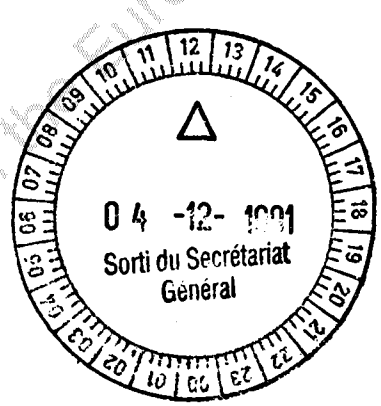
0/91/380

Réunion spéciale des
Chefs de cabinet

TEXTE E

DEUXIEME RAPPORT DE LA COMMISSION AU CONSEIL
ET AU PARLEMENT EUROPEEN EN CE QUI CONCERNE
LE BST - PROPOSITION DE DECISION DU CONSEIL

Communication de M. MAC SHARRY



- Cette question est susceptible d'être inscrite à l'ordre du jour d'une prochaine réunion de la Commission.

Destinataires : Membres de la Commission
MM. LEGRAS, KRENZLER, PERISSICH, DEGIMBE, BRINKHORST, FASELLA, BARLEBO-LARSEN, WILLIAMSON, DEWOST

NOTE DU SECRETARIAT GENERAL 0/380/91

PREPARATION DU DOCUMENT

Direction(s) Générale(s) responsable(s)

VI Agriculture

Service(s) associé(s)

- pour accord -

I	Relations Extérieures	: Consultation en cours
III	Marché Intérieur et Affaires Industrielles	: Consultation en cours
V	Emploi, Relations Industrielles et Affaires Sociales	: Consultation en cours
XI	Environnement, Sécurité Nucléaire et Protection Civile	: Consultation en cours
XII	Science, Recherche et Développement	: Consultation en cours
SPC	Service "Politique des Consommateurs"	: Consultation en cours
SG	Secrétariat Général	: Consultation en cours

- pour avis -

SJ	Service Juridique	: Avis favorable

Langue originale : EN

Communication from Mr Mac Sharry to the Commission

1. Bovine Somatotrophin (BST), is a growth hormone which, in recombinant form, can be administered by injection to lactating cows, in order to bring about a significant increase in milk yields (12% on average).

   BST is likely to be the forerunner of similar biotechnology products developed with a view to increasing meat production.

2. The existing Council Regulation(1) which prohibits the administration of BST to dairy cows, other than for experimental purposes, expires on 31 December 1991. The temporary prohibition was introduced to enable the Commission to bring forward a report on the outcome of studies into certain aspects (animal health, milk quality, economic consequences etc) of the use of BST, and further proposals if necessary in the light of its findings. These are set out in the attached report.

3. In the absence of a further decision by the Council, individual Member States will be free to decide to authorise BST or not. Member States are seriously concerned about approving BST in present circumstances. This could be reflected in divergent decisions at the national level, and general uncertainty. This in turn could have serious implications for intra-Community trade, as well as raising difficulties externally, and should therefore be avoided. The Member States are likely to share this view.

4. Under existing rules, applications for approval of BST, which is classed as a veterinary medicine, are examined under three criteria viz safety, quality and efficacy. This is an essential pre-requisite to a decision to grant approval.

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(1) O.J. No L 37, 09.02.1991, p. 39

The examination has been carried out by the Committee on Veterinary Medicinal Products (CVMP) whose opinion is at Annex III to the report. While the results in relation to "quality" and "efficacy" have not given rise to difficulty, divergent opinions have emerged on the animal health aspects - part of the "safety" criterion - especially as regards the incidence of mastitis and the reactions at the injection site. Concern has been expressed also by the Scientific Veterinary Committee (see par 5.2 of the Report) that insufficient attention is being given to the animal welfare implications. The Committee has called for more comprehensive studies.

As regards human health, while there has been a broad level of agreement on the safety of BST, and the CVMP has indicated that there are no health risks for consumers, doubts have been expressed in the United States as to whether sufficient attention has been given to certain aspects related to immunity.

5. As far as the socio-economic aspects are concerned, the studies suggest that the potential for an increase in Community milk production arising from use of BST would be in the range of 5% to 10% depending on regularity of use. If realised this would require cow numbers to be reduced in a range of 4% to 6% to respect the milk quota. There are varying estimates of the likely drop in consumption of dairy products due to adverse consumer reaction; these range from modest reductions to sharp falls of upwards of 20% in terms of milk equivalent.

6. While the precise extent of consumer reaction is difficult to forecast, the likelihood of a sharp drop in consumption of dairy products can not be ignored. With the growing emphasis on "natural" products, consumer reaction will tend to be unfavourable towards a product that can be associated with a hormone and/or abnormal treatment of animals. There is a

danger also that the situation will be exploited to the advantage of imitation products; the sharp decline in butter consumption, as a result of associating non-milk fat products with good health, illustrates the potential threat to dairy products. Consumers organisations are also opposed to the authorisation of BST.

Community exports could be at a serious disadvantage also on certain third country markets. Major world importers may be unwilling to accept product from sources where BST is allowed or may give preference to other suppliers. The impact of the BSE controversy on the beef market is an unhappy precedent from that point of view. Labelling is not a solution since the recombinant product cannot easily be detected and proper control is not therefore possible.

7. Developments likely to encourage higher agricultural production could be considered inconsistent with the position taken by the Commission on CAP reform. At the general level, this called for a greater emphasis on quality rather than quantity. In the milk sector itself, which has a structural surplus of some 15% and costs almost some 6 billion ECU in support annually, the reform involves promotion of dairy products, reduction in quotas, and removal of incentives to produce in excess of quota.

BST does not improve milk quality. While the milk quota arrangments could normally be expected to establish a ceiling on production, in practice regular use of BST could give rise to i) added pressure for increased quotas and/or resistance to proposed quota cuts and ii) adding to the already serious difficulties in implementing the quota system in certain parts of the Community.

As far as farm structures are concerned, BST is likely to be used systematically only by larger producers whose economic situation could be expected to be improved and consolidated.

The findings suggest however that producers generally are opposed to its authorisation.

8. While the economic factors argue in favour of refusing authorisation for BST, at least for the proposed duration of the milk quota policy ie up to the year 2000, other considerations suggest a more prudent approach.

There is the need to re-assure the biotechnology industry which will be concerned at any action that could be perceived as contrary to progress and innovation, and may argue that the Commission's position is inconsistent its communciation on biotechnology.

While the Commission has indeed indicated in that communication that it would normally follow scientific advice in these matters ie based on the criteria of quality, safety and efficacy, it has pointed out also that it reserved the right to take a different view in the light of other Community policies and objectives. A similar position was taken by the Commission in its proposals(2) for new procedures for authorising medicines, when it was recognised that a veterinary medicinal product may not be authorised if its use would contravene the objectives of the common agricultural policy.

The report shows that, in present circumstances, BST opens up the prospect of potentially damaging repercussions for the markets and for consumer confidence in agricultrual products.

(2) Proposal for a Council Regulation (EEC) laying down Community procedures for authorization and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products (COM (90) 283 Final of 14th November 1990.

Such developments would in turn reflect adversely on the biotechnology industry itself which has an interest also in avoiding precipitous conclusions in this matter.

9. The external aspect must be considered also. Divergent national decisions by Member States are difficult to explain internationally. At Community level an indefinite prohibition on BST could give rise to difficulties with the United States administration. It is notable however that within the US itself, strongly opposing positions have been taken up.

Many third countries, for example the United States, New Zealand, Canada, Austria, Switzerland and the Nordic countries, have a special interest in preserving a balanced market for dairy products and for beef also, and face a similar dilemma in considering BST. None of these countries has authorised BST to date and most have shown a marked reluctance to do so. Before any final Community decision in relation to BST there would be advantage in exploring a common approach with these countries, and also with major importing countries.

10. On a broader front animal welfare questions are now to the forefront of public concern and this will be reflected more and more in consumer attitudes. In agriculture the Community has responded to these developments by adopting several measures designed to protect animals and to ensure fair competition. Apart from the health aspects, the inter-relationship between biotechnology and animal welfare raises important ethical questions which have an important influence on public perceptions. It would be helpful to have an objective and informed view also on these aspects.

11. Having regard to the various considerations outlined above it is proposed that the Commission decides as follows:-

(i) that, against the background of likely divergent views on BST in the Member States, the interests of the single market, and potential difficulties on the external side, authorisation of BST should not be for decision on an individual Member State basis; that the Council be asked therefore to decide on this question on the basis of a proposal from the Commission.

(ii) that having regard to differences of view within the CVMP, and the opinion of the Scientific Veterinary Committee, the animal health/welfare aspects be further clarified. For this purpose additional studies should, if necessary, be arranged by DG VI in cooperation with the CVMP and the Scientific Veterinary Committee.

iii) that, having regard to the potential impact of BST and other biotechnology developments in the animal products sector, the recently constituted group of advisers on the ethical implications of biotechnology be invited to furnish an opinion. This might cover the ethical considerations associated with the administration, by potentially stressful methods, of substances designed to bring about a significant improvement in the productivity of farm animals, where such substances have no therapeutic value and the additional production is surplus to requirements.

iv) that in order to take account of the views of third countries in this matter contacts be taken with the third countries most concerned, that is major world exporters and importers of dairy products, and also

countries pursuing direct production control policies in the milk sector, with a view to exploring a common approach to BST.

v) that the objective should be to prepare a proposal for a final decision on BST by 30 June 1993 with a view to a Council decision within the following 12 months.

vi) that the attached report and proposal be sent to the Council with a view to extending the existing evaluation period up to 30 June 1994. This would enable the further investigations to be carried out and the Council to take a decision within the time scale envisaged.

Projet de proposition

de

DECISION DU CONSEIL

DU

modifiant la décision 90/218/CEE relative à la mise sur le marché et à l'administration de la somatotropine bovine (BST)

LE CONSEIL DES COMMUNAUTES EUROPEENES,

vu le traité institutant la Communauté économique européenne, et notamment son article 43,

vu la proposition de la Commission(1)

vu l'avis du Parlement européen(2)

vu l'avis du comité économique et social(3)

considérant que, dans sa décision 90/218/CEE(4), relative à la mise sur le marché et à l'administration de la somatotropine bovine (BST), modifiée par la décision 91/61/CEE du 4 février 1991, le Conseil a demandé aux Etats membres d'interdire, jusqu'au 31 décembre 1991, l'administration sur leur territoire, par quelque moyen que ce soit, de la somatotropine bovine aux vaches laitières, parce que les effets et les conséquences d'une telle administration n'étaient pas encore suffisamment établis;

considérant que le délai imparti pour étudier ces effets et conséquences s'est avéré trop court; que les recherches mises en oeuvre n'ont abouti que sur les aspects de la qualité et de l'éfficacité du BST; qu'il n'existe, par contre, pas encore de résultats suffisaments précis et réprésentatifs quant aux effets que l'injection du BST pourrait avoir sous l'angle de la santé et du bien-être des animaux; qu'il importe dès lors de continuer de manière approfondie les études afin de disposer d'informations complémentaires tant sur certains aspects de santé et de bien-être des animaux que sur les réactions des consommateurs à l'égard d'utilisation d'une substance destinée à accroître artificiellement la production du lait.

considérant que pour ne pas préjuger du résultat de ces études, il est nécessaire de proroger ultérieurement l'interdiction de mise sur le marché et d'administrer la somatotropine bovine;

A ARRETE LA PRESENTE DECISION :

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(1)
(2)
(3)
(4) JO n° L 116 du 8.5.1990, p. 27

Article premier

La décision 90/218/CEE est modifiée comme suit :

1. L'article 1er est remplacé par le texte suivant :

"Article premier

Nonobstant l'examen scientifique et technique des demandes prescrites par la réglementation communautaire, les Etats membres veillent, jusqu'au 30 juin 1994 à ne pas autoriser la mise sur le marché de la somatotropine bovine et son administration sur leur territoire par quelque moyen que ce soit aux vaches laitières."

2. A l'article 4, les dates du 1er octobre 1991 et du 31 décembre 1991 sont remplacées respectivement par celles du 30 juin 1993 et du 30 juin 1994.

Article 2

Les Etats membres sont destinataires de la présente décision.

Fait à Bruxelles, le

Par le Conseil

COMMISSION
OF THE
EUROPEAN COMMUNITIES

Directorate-General for Agriculture

VI/B/II.2

NOTE/1042

Second Report
from the Commission to the Council
and to the Parliament
concerning
Bovine Somatotropin (B.S.T.)

CONTENTS

Second Report from the Commission
to the Council and to the Parliament concerning
Bovine Somatotrophin (B.S.T.)

INTRODUCTION

1. On 27th September 1989 the Commission presented a report to the Council and to the Parliament concerning the administration of bovine somatotrophin to dairy cows as a productivity aid to milk production(1).

   It proposed the establishment of an evaluation period up to the end of 1990 on the administration of BST in the Community. It also indicated that this period was considered to be the minimum necessary to assess the results of the ongoing studies and develop new arrangements to be adopted on procedures in relation to such products. By its decision 90/218/EEC of 25th April 1990(2) the Council agreed to the request of the Commission and subsequently agreed by its decision of 4th February 1991(3) that an additional time up to 31 December 1991 was necessary to enable the studies under way to be completed and the results to be considered.

2. The present report should be considered together with the first report submitted to the Council in 1989. It may be recalled that two pharmaceutical companies (Monsanto, Eli-Lily) have made applications for marketing of products containing rBST in the Community, whilst others may be interested. To the knowledge of the Commission a number of third countries have authorized the use of BST. These include Mexico, Brazil, U.S.S.R., Czechoslovakia, Bulgaria, South Africa, Namibia and Zimbabwe. On the other hand no authorisation has been given in the United States, Canada, New Zealand, Austria, Switzerland and the Nordic countries.

3. BST is an issue which gives rise to considerable interest among consumer, agricultural and industry interests. In this context concerns have been expressed about the safety to humans, animals and to the environment, the quality of milk, the economic and social consequences in agriculture, the climate for research and development, industrial competitiveness and trade implications.

   This report seeks to address these concerns and to ensure that an overall Community perspective is taken on the problems raised.

(1) [COM (89) 379 final]
(2) O.J. No L 116, 08.05.1990, p. 27
(3) O.J. No L 37, 09.02.1991, P. 39

4. Industries involved in biotechnology are concerned to ensure a stable regulatory framework for their activities. The Commission considered this question in its recent Communication to the Parliament and the Council concerning 'Promoting the competitive environment for the industrial activities based on biotechnology within the Community' [Sec (91) 629 final]. In this it is indicated:

> 'Not all products derived through biotechnological methods will require a specific assessment and/or authorization procedures. Currently the vast majority of biotechnology products are produced through traditional methods (eg. cheeses, malt extracts, beers and yeasts). As far as new biotechnology products are concerned, which involve gene manipulation, each product will have to be considered on a case-by-case basis and assessed as necessary....'
>
> 'The approach now applied by the Community, based upon the correct and thorough application of the criteria of safety, quality and efficacy, in conjunction with relevant horizontal legislation, ensures consumers' safety and economic interests and permits the protection of human, animal and plant health and of the environment. Furthermore, in order to ensure that the consumer protection aspect is covered, the impact on consumers' information and choice needs to be taken into account....'
>
> 'As a rule, decisions have to be based upon objective assessments using clearly identified criteria. Uncertainties about product acceptance and authorization could result in a diversion of investment and could act as a disincentive for innovation and technological development by industry. The Community must however guarantee the public that the industry is properly controlled. The dynamism of the industry and the confidence of public opinion depend on the ability of the Community to reassure both parties.'
>
> 'Where a biotechnological product is assessed, the three traditional criteria, based on scientific evaluation apply. By their nature, socio-economic aspects need to be considered in a different way. It is not the intention to have another systematic assessment in addition to the three criteria. The Commission will normally follow scientific advice. The Commission reserves the right, however, to take a different view in the light of its general obligation to take into account other Community policies and objectives. This might, in exceptional cases, lead to requirements for further information. It might equally, in exceptional cases, lead the Commission to propose that other policies be modified in the light of biotechnological developments.'

Similar considerations arose in connection with the Commission's proposal for a Council Regulation (EEC) laying down Community procedures for the authorization and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products of 14th November 1990 (COM (90) 283 final), where the following consideration was expressed in connection with the authorisation procedures for veterinary medicines:

'Whereas in the interests of public health it is necessary that decisions on the authorization of such medicinal products should be based on the objective scientific criteria of the quality, the safety and the efficacy of the medicinal product concerned to the exclusion of economic or other considerations; whereas, however, Member States should exceptionally be able to prohibit the use on their territory of medicinal products for human use which infringe objectively defined concepts of public order or public morality; whereas moreover a veterinary medicinal product may not be authorized by the Community if its use would contravene the rules and objectives laid down by the Community within the framework of the Common Agricultural Policy.'

5. The European Parliament has also adopted several Resolutions (see Annex IV) dealing directly with this matter. Of particular note are the Resolutions on Biotechnology in the European Farming Industry (16 February 1987) and on Hormones and the BST Hormone in the Dairy and Meat Industry (5 July 1988). The general thrust of the Parliaments approach is that biotechnology products should be directed less to increasing production and yields and more to improving quality and health.

6. In drawing up this report the Commission has made use of a number of studies and analyses: Firstly, within the Committee for Veterinary Medicinal Products (CVMP concertation procedure (Directive 87/22/EEC), see Annex III) the aspects of the safety, quality and efficacy of the products for which authorization for marketing has been requested are examined.

A further five independent studies have been undertaken at the request of the Commission. Four have been carried out in Germany, namely:

a) 'Research to improve the bacteriological characteristics of raw and heat-treated milk (BST-treated cows) - increased number of somatic cells, influence on quality and yield, processibility, mastitis' prepared by Bundesanstalt für Milchforschung, Kiel (1991).

b) 'Research into lactation physiology in dairy cows' by Institut für Physiologie, TU München/Weihenstephan (1991).

c) 'Producers and consumers as factors in increasing disposals of milk and milk products in the Community' by IFO-Institut für Wirtschaftsforschung, München (1991).

d) 'Effects of the use of somatotrophin on consumption of milk products' by Institut für Agrarpolitik, Giessen (1991).

The fifth more general study was: 'Study on the impact on animal husbandry by the use of growth promoters in animal feed and other productivity enhancers' prepared by CEAS Consultants (Wye) Ltd. (1991) (CEAS I).

In addition the Commission has considered the studies 'BST and the consumer: an overview of perception and practices' prepared by CEAS Consultants (Wye) Ltd. (1989) (CEAS II), and 'U.S. Dairy Industry at a Crossroad: Biotechnology and Policy Choices', Congress of the United States, Office of Technology Assessment (Washington D.C., May 1991).

The Commission Services have also undertaken some separate analyses.

SUMMARY AND CONCLUSIONS

6. This report covers both the traditonal aspects about safety, quality and efficacy of recombinant Bovine Somatotrophin (BST) as well as an evaluation of consumer and producer attitudes, repercussions on the agricultural markets, the budgetary consequences and the environment.

7. Safety, quality and efficacy

In terms of safety, quality and efficacy these seem to be satisfactorily addressed in relation to the Monsanto product except for the question of possible increased incidence of mastitis and injection site reactions in dairy cows treated with BST which have not received a satisfactory answer according to experts from five Member States.

As far as quality is concerned the product studied is in accordance with the requirements of the Community Directives. The Committee on Veterinary Medicinal Products (CVMP) which studied the Monsanto product is satisfied that its use does not affect the quality of milk or meat. However, some doubts still exist about the implications of increased somatic cell counts.

In terms of efficacy, it is estimated that milk yield in well managed dairy herds will increase by 12%. However, the increase is likely to be in absolute terms for both medium and already high yielding cows - giving a relatively bigger increase for the medium yielding dairy cows. The increase will vary between 2.5-5.7 kg per day.

Finally, it should be pointed out that so far no comprehensive studies of the welfare of animals treated with rBST have been reported.

8. Consumer and producer surveys

a) The consumer surveys were carried out in four Member States: Germany, France, Italy and the United Kingdom, representing 70% of the Community population.

The surveys indicate sharp reductions in consumption, varying between the Member States and between the different milk products. The lowest figures being for France (butter circa 10%) and the highest figure for Italy (butter circa 26%).

The survey carried out in 1989 (CEAS II) and commissioned by the U.K. National Office of Animal Health shows clearly that:

- The rejection rates of food-production practices involving the use of chemicals are higher than those of any other practices, including those related to animal welfare.

- The rejection rate of the use of BST is the highest recorded.

b) The producer survey carried out in 6 Member States (UK, Germany, France, Netherlands, Denmark and Ireland) representing 52% of producers, 75% of cows and about 80% of milk production, shows strong opposition to the use of BST. This reflects concern about the potential impact on the dairy market. Secondary considerations for producers are the issues on animal health and welfare.

Should BST be approved, many producers indicate an interest in using this new technique.

9. Agricultural markets - Dairy sector

a) Consumption

The effect on agricultural markets will depend heavily on consumer behaviour. If the surveys' estimates of consumer reaction is to be taken as the basis for the assessment, then the market effects could be quite dramatic in terms of excess supply and budgetary consequences.

The milk market continues to experience difficulties in spite of reduction in quotas (the most recent reduction of 2% decided in the price package 1991/92 was not considered sufficient). This led the Commission in the context of its reform proposals to propose reductions in milk quotas by a further net 3% in order to bring the market into balance. In the detailed rules proposed, it also sought to discourage developments eg through equalisation of deliveries for levy purposes, that might lead to production over quota. Any additional decrease in consumption as the result of the introduction of BST would further exacerbate the imbalance on the milk market which has a structural surplus of some 15%.

Different outcomes can be contemplated, ranging from a very sharp consumer reaction, a smaller reaction than predicted by the surveys, or even a situation with only a slight reaction, as one survey predicts. All outcomes predict some decrease in consumption.

Recent market developments in relation to milk substitutes are relevant also in considering authorisation of BST. There has been sharp growth in the substitute milk products sector in recent years, mainly at the expense of butter whose consumption is falling at an annual rate of some 40.000 tonnes. This growth has come about mainly due to consumer reaction to health claims and/or oversimplification of research findings. If BST were to be allowed, it is likely that the image of milk and milk products from the health viewpoint would be severely tarnished since promoters of competing products

could be expected to ruthlessly exploit the use of the BST hormone. In the case where a sharp reduction in consumption is assumed - survey results suggest that this could be as high as 20% - there would have to be a corresponding quota reduction with adverse consequences for the beef sector also and for agriculture generally.

b) Production

BST could be used on a regular basis during a part of the lactation period. Producers might use the drug in the context of acquisition or leasing of milk quota from other producers, or by reducing the number of cows or perhaps in anticipation of shortfalls by other producers which could be compensated through the equalisation arrangements at the level of the dairy.

BST can also be used as a tactical tool to avoid shortfall of a producer's individual reference quantity; in that case the number of cows would remain unchanged.

The significance of regular or tactical use would vary between Member States. The use of BST will depend on 1) the price of BST 2) the price of extra quota 3) the cost of extra fodder and 4) the value of alternative use of land in case of a reduction in cow numbers.

Leaving aside the possible consumer reaction and taking account of present quota levels, a conservative estimate based on the CEAS I study suggests that in the short term, BST would be adminsitered to 20% of all dairy cows in the Community, at some point during their lactation period. In the medium-long term (over 5-10 years) this proportion would rise to 55%.

An important explanation for the relatively limited use of BST is that it is assumed that herds with 15 cows or less would not use BST on a regular basis because of practical (too few cows) and economic constraints. In this respect regular use means systematic use during a part or most of the lactation period - not necessarily during the whole period.

On the basis of an increase in yield of 12%, applied to 55% of the dairy cows concerned and assuming the low yielding cows will not use BST, the potential for extra milk production as a result of the use of BST is in the range of 6% to 10%. However other surveys suggest that in the medium term a figure of 5% is more likely.

'Extra' milk does not necessarily mean an increase in deliveries but represents the share of BST-milk, out of total milk production. This implies, in a quota system, a reduction in the number of dairy cows, an increase of quotas, or exceeding existing quotas.

It is estimated that over the period 1992-1998, the reduction in cow numbers would be in the range of 4% to 6%, additional to the normal decline in dairy cow numbers.

The main benefit for the medium and larger producers, who would find it worthwhile to use BST regularly, would be a reduction in production costs for those reducing cow numbers or increased margins for those who purchase or lease extra quota from other producers. Smaller farmers would not normally use BST.

The quota system in the milk sector should limit the economic incentive for using BST.

However there are two elements that need to be considered. Despite its introduction in 1984 the quota system has not been correctly implemented in some parts of the Community and strenuous efforts will have to be made to bring deliveries within quota. BST would be unhelpful to this effort. In the second place any instrument that increases the quantity of milk in the system creates pressures for extra quota, encourages fraudulent devices to avoid payment of supplementary levy, and destabilises markets.

10. Other agricultural sectors

As far as other agricultural sectors are concerned, the greatest area of concern is the beef sector.

For beef production, reduced numbers of cows implies an increase in slaughterings which could in the short-term worsen the beef market, already well out of balance.

In the medium to long term, the replacement of dairy cows by suckler cows and/or other beef animals would have a negative impact also on the balance in the beef market, though the reduction in the number of calves from dairy herds would be an offsetting factor.

As far as other land uses are concerned, the consequences are not significant.

11. Environment and Structures

Since only the larger dairy herds (more than 15 cows) are likely to use BST on a regular basis, there is likely to be further concentration of milk production in the more intensive producing regions and greater pressure on smaller farms.

This may lead to higher concentration in intensive producing regions and add to local environmental problems. In terms of overall production of animal waste, the consequences of BST introduction would be significant if milk cows were replaced by greater numbers of suckler and/or other beef animals.

12. CAP Reform

In the Commission's Communications on the Development and Future of the Common Agricultural Policy (February and July of 1991) it was concluded that the present structural surpluses had largely arisen because of the direct link between support and quantity produced.

The general thrust of the communication was that the Community should discourage intensification, encourage quality and seek to maintain sufficient number of farmers on the land so as they could fulfill a dual function of producers of food and guardians of the countryside.

In the milk sector, the proposals involve a further reduction of a net 3% in quotas, measures to avoid a quota cut for small producers, and support for promotion in order to redress the decline in consumption of some dairy products eg butter. In the beef sector, the proposals involve price reductions, with increased premiums conditional on fulfilling extensification criteria and subject to a ceiling on eligible numbers. A promotion scheme to encourage greater consumption of beef, which was especially affected by the BSE controversy, was proposed also.

To the extent that BST encourages extra quantity rather than quality it tends to run counter to the objectives of the reform. Authorisation of BST with the accompanying risks to consumption would seem to be inconsistent also with the policies to promote milk products.

At the socio/structural level producers with smaller herds are not likely to benefit from the use of BST for practical and economic reasons. BST is likely also to accelerate the trend towards the reduction in the number of dairy farms and the trend towards fewer but larger herds with bigger concentration in certain regions.

The use of BST, resulting in higher marginal returns will be capitalised in the value of the milk quota making it more difficult for producers not using BST to acquire extra quota.

As far as repercussions on the beef market are concerned replacement of dairy cows with animals for beef production would have a negative effect on market balance. There would be more immediate problems for the market in the event of a sharp up take of BST leading to the slaughter of a significant number of cows.

13. Control and Labelling

Since the use of BST is of public concern it would be necessary to consider controls to check observance of Community regulations.

a) Control of the manufacture and distribution of BST should be no more complex than for other pharmaceutical products. While the nature of the treatment would appear to require limiting administration to professional veterinarians this could be difficult in practice.

b) Checking of residues in both indigenous and imported livestock products cannot be realistically executed within current technology and practice, because of the levels of naturally occuring hormone present in samples.

There is currently no forensic detection method to analyse the use of the rBST hormone in dairy cows. Current methods permit a degree of general monitoring, but this requires taking blood samples in the cow stall. Taking the example of simultaneous recording of growth hormone and the growth factor IGF 1, it appears that an error rate of 20% is to be expected. A possible alternative would be the regular, individual monitoring of milk yield graphs.

Any control measures to be introduced would in practice be limited to the level of the farm, veterinary practice and pharmaceutical distribution channels.

It seems impossible, however, to satisfy consumer demands for an effective labelling system to distinguish milk products obtained by using BST.

It might be possible to consider labelling requirements with a compulsory indication as to whether BST was authorised in the Member State of origin of the product. Such a requirement might be divisive and there would be a strong incentive to circumvent a rule of this type.

Legislative Framework

The present basis for a decision on BST is Council Directive 87/22/EEC which provides for a decision at national level. Given the sensitivity of the BST question it is clear that Member States are likely to face a considerable dilemma in arriving at a decision. It is likely also that divergent decisions would give rise to serious difficulties in intra-Community trade related to the competition aspects. There could be problems also in explaining such decisions at the international level.

In its proposals for new procedures for the authorisation of veterinary medicines the Commission has recognised the drawbacks in a national decision system especially where biotechnology products are concerned. This has led it to propose a centralised Community authorisation procedure in such cases. These proposals are under consideration

by the Council. A Community scheme[1] for the approval of maximum residue levels (MRLs) will enter into force on 1 January 1992. This provides that after that date Member States will not be able to authorise use of products such as BST in the absence of MRLs fixed by the Commission.

External Aspects

Most third countries which have an active interest in control of milk production eg Canada, or in export markets eg New Zealand have not authorised BST. Indeed it is likely that countries with high consumer awareness will be slow to do so. In the United States the Food and Drug Adminsitration has not approved BST. A total Community ban on BST may give rise to difficulties with the United States because of its insistence that products that comply fully with scientific criteria be approved. However BST has been the source of controversy in the United States where State laws have been introduced in Wisconsin and Minnesota (both with significant milk-producing interests) for a moratorium on BST. While these provisions may lapse due to Governor veto - in Wisconsin the Governor has actually vetoed the relevant Bill - it is not to be excluded that any decision to authorise BST will give rise to further controversy in the United States.

All major milk producer and exporting countries have a special interest in maintaining consumption levels and stability in the markets. While the Community has often tended to see these countries in terms of competitors they have a common interest with the Community in ensuring that the BST question is treated in a way such as to avoid prejudicing their essential interests.

The Community is the world's largest dairy exporter - in a typical year it would export the equivalent of 15% of its production with an export value of some 4 billion ECU.

14. Budget

The budgetary implications will depend mainly upon the effects on consumption of the introduction of BST.

In the event of a small drop in consumption the budgetary consequences should be limited to some 250 MECU annually.

Consumer surveys indicate a potential fall of consumption of up to 17 million tonnes for human consumption. In that event total costs would be of some 3.500 MECU annually.

(1) Directive 81/851/EEC as modified by Directive 90/676/EEC, and Commission Regulation 2377/90/EEC (JO L224 of 18th August 1990 p. 1.

A third outcome would be a result between the two extremes, with a drop in consumption of some 9 million tonnes. In that case the total cost would be of some 2.000 MECU annually.

15. Conclusions

a) BST represents an important technological advance which because of the magnitude of the productivity effect, the animal welfare aspects and the potential effects for consumption and the markets, cannot be treated solely as a normal veterinary medicine designed to improve the well being of animals.

b) The Community must, in the first instance, ensure that prior to authorisation products are safe for humans, animals and the environment. In the case of BST, while the criteria of "quality" and "efficacy" appear to have been satisfied certain aspects of "safety" need to be further clarified. The question of increased levels of IGF-1 in milk from BST treated cows in relation to human health has also been raised.

The issue of increased incidence of mastitis and injection site reactions has been the subject of divergent views among the experts. Use of BST may be inconsistent also with the efforts being made by the Community to reduce the somatic cell count in milk for the market.

At a more general level the Scientific Veterinary Committee has expressed doubts about whether considerations of animal welfare have been sufficiently taken into account in the context of BST and has called for further studies.

c) The use of rBST cannot be detected in milk and dairy products in practice. It would be impossible therefore, to ensure respect of labelling rules or other possible arrangements for partial or conditional approval.

d) Consumers' organisations are opposed to the authorisation of BST. Consumer surveys show a negative reaction towards BST which is likely to be reflected in a sharp downturn in consumption of milk products. This would have serious adverse effects on Community agriculture, on the dairy industry in particular, and for the budget also. It could also damage the Community's export performance in milk products and in beef since there may be a reluctance on the part of some third countries to authorise BST and accept products from animals treated with BST.

e) The CAP reform proposals place the emphasis on quality rather than extra quantity of production. They seek to maintain also a socio/economic structure that would allow sufficient numbers of farmers to remain in agriculture

to allow them to fulfil a dual role as producers of quality food and guardians of the countryside. The introduction of BST would appear to be contrary to these objectives.

f) Because of outstanding questions in relation to animal health and welfare, the need for greater clarity on the ethical aspects, and the need to investigate the possibility of a common approach by the principal countries involved in producing, exporting and importing dairy products, it is considered that more time is needed to evaluate all the elements involved. It is considered also that in the interests of the single market, a final decision in relation to the authorisation of BST should continue to be made at the Community level. With this in mind the Commission will aim to present its final conclusions and a proposal to the Council by 30 June 1993. In the meantime it is proposed that the existing evaluation period be extended to 30 June 1994 to enable a decision to be taken within the time scale envisaged.

The draft Council Decision (attached) is proposed accordingly.

ANNEX:

I Study Findings

II Potential budgetary consequences resulting from the use of BST

III Opinion of the Committee for Veterinary Medicinal Products

IV Resolutions of Parliament

V Extract from Commission Communication to Parliament and the Council concerning 'Promoting the competitive environment for the industrial activities based on biotechnology in the Community'

PART I

STUDY FINDINGS

SAFETY, QUALITY AND EFFICACY

The aspects of safety relate to safety for humans, animals and the environment. It also covers food product quality. Quality relates to the chemical characteristics of the products whereas efficacy relates to the product actually achieving what it pretends to do.

1. rBST

Recombinantly derived BST products may have slightly different chemical structures from natural BST produced by the pituary gland, adding a number of additional amino acids. Each product must be considered on its own merits. The additional amino acids that may be produced, however, may not change the active part of the molecule and as such may not change the biological activity of BST in dairy cows or the inactivity of BST in humans.

2. Opinion of the Committee on Veterinary Medicinal Products (CVMP) and other observations

The CVMP has delivered in March 1991 its opinion on the rBST product 'SOMATECH' submitted by Monsanto.

In respect of that product the following statements can be made.

3. Quality of rBST

The product studied can be manufactured to produce a homogeneous stable product, with a shelf life of 18 months, in accordance with the quality requirements laid down by Community directives.

4. Efficacy of rBST

The CVMP 'considers that the manufacturer has demonstrated that SOMATECH is effective in producing a significant increase in milk yields in treated cattle. The extent of this increase in yields depends, amongst other factors, on the breed of animal treated, the individual animal treated, the stage in lactation cycle at which the product is administered and the quality of animal husbandry techniques used, but may be expected to be in the range of 2.5-5.7 kilogrammes per day' in the lactation period.

The US Congress study presents this aspect in a slightly different way stating that 'successful adopters on average would experience a 12 per cent boost in production. However, the increase in output per cow tends to be absolute (in number of pounds) rather than proportional to normal production. Thus approximately the same increase in pounds of milk produced might be expected (in comparably managed herds) from all cows producing 12.000 to 20.000 pounds of milk per year'.

The CEAS I study talks about 'responses of 15-25% as being the most usual. After the initial injection, milk yield increases rapidly and with continued treatment the lactation curve then remains higher and about parallel with that of control animals for the rest of the lactation. There are some records of the gap widening as the slope of lactation decline becomes steeper in the controls than in treated cows'. This last comment reflects the possibility of extended lactation periods as seen in the trials.

Feed intake

The CEAS I study states 'Voluntary feed intake usually increases, but not until 5-10 weeks after the first treatment. When this occurs, it compensates wholly or in part for the earlier negative nutritional balances.' It further states that 'BST treatment does not affect the digestibility of feeds and there is no evidence that it improves the efficiency with which absorbed nutrients are converted into milk or for maintenance of the animal. But because of the raised feed consumption with BST treatment, the proportion of the total feed consumed which is used for body maintenance is lower. Furthermore this maintenance 'overhead' is spread over a greater weight of milk produced. Hence the apparent or gross efficiency which food is converted into milk is improved.'

The US study concludes that 'Obtaining a milk response to BST does not require special diets or unusual feeds ingredients. Substantial milk responses have been observed on diets ranging from pasture to the more typical forage/concentrate diets used in the United States. However, voluntary intake of feed increases in BST-supplemented dairy cows.'

This observation may, however, depend to some extent on how BST would be used - since a catching up use in view of quota shortfall will more likely be obtained with concentrates (CEAS I).

5. Safety

5.1 Human safety

According to the CVMP, the applicant has demonstrated that residues of its product do not present any risk to the health of consumers of meat or milk obtained from treated animals and that the product may safely be accepted for use without any withdrawal period for meat or milk.

There is, however, an outstanding question raised in the US-study about the level of insulin-like growth factor 1 (IGF-1) in milk frm BST-treated dairy cows.

> 'The importance of increased amounts of IGF-1 in milk from BST-treated animals is uncertain. However, the amount of IGF-1 ingested in 1 liter milk approximates the amount of IGF-1 in saliva swallowed daily by adults' (US-study).

5.2 Safety in the animal

The CVMP was unable to reach consensus on the acceptability of the product from the point of view of safety of the treated animals. Although the majority considered the manufacturer had provided sufficient guarantees on this point, five members considered that additional data were required on the incidence of mastitis and the importance of reactions at the injection site and the hygiene of this site before definitive conclusions could be reached. Because of the doubts expressed by certain delegations, the CVMP in its opinion makes the following qualifications (point 6 and 7):

'6. The Committee would emphasise that the successful use of SOMATECH will require the maintenance of high standards of animal husbandry. For this reason the Committee recommends that the product should be used only under veterinary supervision.

7. The Committee considers that it is important to verify that the results described in the application dossier for SOMATECH are confirmed during the practical use of the product in the field. For this reason, the Committee recommends that in addition to the specific study concerning the incidence of mastitis in treated animals referred to above, authorization to place SOMATECH on the market should be subject to a condition requiring the company to collect and evaluate all reported suspected adverse reactions to the product throughout the Community and to prepare an annual safety report for the five years following authorization.' - See Part III of this Annex for the detailed opinion.

The Commission's Scientific Veterinary Committee has also examined this aspect and has given the following opinion.

> "The Committee is concerned that in discussions about the use of products resulting from biotechnology procedures, such as recombinant bovine somatotrophin, insufficient attention is paid to effects on the welfare of the animals treated with the product. Such a new product should not be licensed for general use unless adequate information from scientific studies of the welfare of animals treated with the product has been obtained and considered. Such studies should include measurements of

welfare such as those of disease incidence, physical disorders, injuries, behaviour and physiology. These studies should be carried out over a period of the animal's life at least as long as the longest time that such an animal would be kept on a farm and in a variety of management conditions. Studies in commercial farm conditions should be included.

No comprehensive studies of the welfare of animals treated with recombinant bovine somatotrophin have been reported in the publicly available scientific literature. Work on the effects on the incidence of mastitis and other production-related diseases indicates that some welfare problems may exist but more comprehensive studies are desirable to clarify the extent of the problems."

5.3 Food product quality

The chemical structure and mode of action of each group of growth promoting agents is unique.

a) The Committee for Veterinary Medicinal Products which studied the use of 'Somatech', the Monsanto product, is satisfied that its use does not affect the quality of milk or meat nor will its use adversely affect the industrial processing of such milk into yoghurt or cheeses.

b) However, increased somatic cell counts (SCC) would have implications as regards the standards laid down in Directive 85/397 as regard Community marketing of milk for consumption and the price paid to producers for milk for manufacturing. An increase in somatic cell affects the composition of milk eg the lactose/salts ratio, a factor that could influence product quality and yield.

c) The data acquired from the (Bundesanstalt für Milchforschung, Institut für Hygiene, Leiter: Prof. Dr. W. Heeschen) Study requested by the Commission indicate that for somatic cell counts 'cyclical increases' are dependent on initial cell count. Therefore, a careful assessment of udder health must form part of the recommendations prior to the use of rBST in a dairy herd. In view of the risk of exceeding cytological thresholds, only dairy herds whose cell count does not exceed about 200 000/ml should be treated with rBST. The main reason for this recommendation is the fact that rBST would be given continuously, which does not occur with other treatments in this form using pharmacologically active substances.

5.4 Environmental impact

Environmental effects are important considerations where animal production is concerned. In general, intensive animal husbandry causes some concern in relation to the environment,

largely on account of the problems of disposing of animal manure. However, where productivity enhancing measures have been introduced, in general, there is a reduction in the manure and methane produced per animal. This is normally derived from altering the partitioning of feed between growth (meat production) and energy (maintenance). Hence for some growth promoters the effect is to capture more of the nutrients in the form of meat rather than allowing them to be passed into the environment in the form of nitrogen, phosphorous or methane.

As for growth promoters, the use of BST in milk production may reduce the emissions of copper, nitrogen and phosphorous and methane. However, the spatial distribution of the emission of manure is more likely to influence potential pollution difficulties.

It is envisaged that only larger dairy herds (more than 15 cows) will use BST on a regular basis. This implies a concentration of milk production in some regions with consequences for the environment in those areas as well as environmental changes for the areas where the reduction in dairy production occurs.

In terms of overall production of animal waste, the consequences of BST introduction will be significant as milk cows are replaced by a higher number of suckler and/or other beef animals. However, a negative local environmental effect will result if production becomes more concentrated.

5.5 Genetic selection

The adoption of any new technolgies can influence breeding strategies and if new productivity enhancers were available and widely adopted, the prudent commercial response of the animal breeders would be to adapt their selection strategies to take the availability of these technologies into account.

An important issue is to avoid distortion in comparisons of performance testing of animals sold for breeding. Breeding stock purchasers must be confident that the performance data they use in assessing possible breeding stock are directly comparable. The introduction of BST would create doubts of the certainty in this area unless appropriate measures are taken at Community level.

In addition, the effect of the introduction of BST on the Community gene-pool needs further clarification.

5.6 Animal welfare

Mention of this aspect has already been made in relation to safety in the animal.

In general, issues of animal welfare are prominent in the debate in several parts of the Community and are of growing concern. Whilst animal welfare criteria are difficult to

define in quantitative terms, it is clear that society as a whole is less willing to accept the use of technologies which are difficult to defend on this basis.

Again market factors operate and growing awareness of production methods has led to the market providing premiums for more 'animal-friendly' systems (eg, free range egg and poultry production and less intensive veal production systems). Whether or not less intensive systems are necessarily more animal-friendly remains an area of debate. However, consumer' surveys indicate that the use of rBST would be regarded as changing the quality of milk and destroy its 'natural' product image.

SURVEYS - CONSUMER AND PRODUCER ATTITUDES

6. Introduction

Consumer concerns can be summarized by three categories: price, quality (including safety) and choice. Productivity enhancements may lower price and this is the essential motor for society to seek technological progress in a market economy. Quality is a more complex issue.

The quality of a product can cover many different dimensions including the method (or even perceived method) of production. Quality perceptions are interlinked with price and perceptions of health and safety.

In order to investigate the possible repercussions on the consumption of milk and milk products in the Community in case of the introduction of BST, two surveys have been undertaken by German research institutes.

Despite the uncertainty which is normally experienced with this kind of survey, it can be assumed that the difference between the response to a hypothetical question and the actual behaviour in a real life situation will not be so great as to contradict the results.

The surveys do, indeed, give a clear picture about the attitudes of consumers and producers to the introduction of BST at the existing level of knowledge and information about the subject.

7. Consumer Surveys

a) The language used to disseminate information and educate people is an important factor in determining the level of understanding and attitude to a subject.

In this context it should be pointed out that the IFO study on consumer attitude to BST gives an explanation on BST before asking the key question to respondents.

'Presentation

You surely know that the production of milk in the body of an animal is a decidedly complex biochemical process. Research has succeeded in imitating one of the compounds which is responsible for the control of milk production in the body. The compound in question is the growth hormone BST (not to be mixed up with sexual hormones for the fattening of calves). Extensive experiments have shown that the milk yield can be increased considerably by BST. During the natural process of milk formation small amounts of BST always get into the milk. In the milk of BST-treated cows, this BST-component consists of a mixture of natural and additionally added BST-hormones. In the numerous investigations no hazardous effects for the consumer whatsoever have been ascertained so that there would be no objection against licensing the compound because of health reasons.'

b) This IFO consumer survey was carried out in the four Member States with the highest populations: Germany, France, Italy and the United Kingdom. These four countries account for 71.5% of the total population of the Community of 12. The findings were split up into three categories:

- 'refusal of products produced using BST' (100% level)
- 'greatly reduced consumption' (30%)
- 'somewhat reduced consumption' (10%)

The survey took in a total of seven product groups: drinking milk, milk-based drinks, all cheeses, butter, yoghurts and sour-milk products, cream and cream products and condensed milk.

The survey shows that the reaction, by consumers of milk and milk products, to the use of genetically engineered BST growth hormone in milk production, would imply a reduction in consumption in all four countries. However, there are marked scatters between consumers and the individual products/product groups in the different Member States.

The percentage of consumers who said they would boycott milk products totally was 17% in Italy, 13% in Germany, 12% in the UK and about 8% in France.

c) There was a very high positive response to the question whether products made with milk from farms using BST should be clearly labelled. Over 82% of respondents, as an average over the four countries surveyed, were in favour of such labelling. The rest were either indifferent to or against it. The UK had the largest percentage in favour, 87%, with Italy next with 85%. The figures for Germany and France were around 80% and 77% respectively.

d) On the question of purchasing behaviour, 45% on average in the four countries stated that they would generally prefer products made from milk produced in farms not using BST ("BST-free" milk). This attitude is particularly marked in Italy, with 57%. Consumers in Germany are above the average at 49% while France is just under, at 43%. In contrast, only 29% expressed this intention in the UK.

There is also an appreciable proportion of consumers who would prefer to buy products made with milk from non-BST-using farms, but only if the price for 'BST-free' products were acceptable.

e) The result of the IFO consumer survey indicates a high degree of opposition to allowing BST. If we add together all consumer groups who indicated they would change their consumption patterns if BST were registered by buying somewhat less milk, much less milk or no milk at all, about 65% of respondents in Germany and Italy and about 40% in the UK and France would change their habits.

This consumer survey extrapolated to the Community as a whole, shows that there would be an appreciable reduction in consumption. Taking account only of the 'total boycott' group, the reduction in consumption would amount to some 11 million tonnes of milk which corresponds to 480.000 tonnes of butter and 985.000 tonnes of skimmed milk powder.

If, in addition, account is taken of those consumers who alleged they would reduce their consumption by 30%, the decline in demand would be around 17 million tonnes. This would correspond to 750.000 tonnes of butter and 1,5 Mill tonnes of skimmed milk powder.

A total of 70% of all respondents believe that the use of BST would change the quality of milk products, with the main damage being to the healthy image, the property 'free of additives', naturalness, taste and the levels of nutrients and other components.

As far as the reasons for not buying are concerned, health concerns and the unnaturalness of somatotrophin were by far the most important (53%), followed by inadequate information (14%) and insufficient tests and research (7%).

f) 1989 CEAS Study (II) 'BST and the consumer: an overview of perception and practices'

The study is based on surveys which were carried out only in the United Kingdom and Germany.

It reflects the very limited knowlege of consumers about dairy practices. Nevertheless, it indicated the degree to which consumers would avoid buying milk if they were aware of different production methods used. The proportion of respondents who would avoid buying milk can be summarised as follows:

Production methods used	% respondants who would avoid buying milk
1. normal intensive farming practices e.g. artificial insemination, machine milking	3 - 12
2. practices which impinge on Animal Welfare issues e.g. dry cow therapy, keeping cows in enclosed concrete yards for 5-6 months per year	18 - 26
3. use of chemical additives in feed and hormones to regulate breeding . .	33 - 38
4. use of hormones (BST) to regulate milk yields	45

This clearly shows that BST registered the greatest concern amongst the respondents.

g) Labelling of milk

The 1991 consumer surveys as mentioned indicate strong preferences for labelling if BST is licensed.

The CEAS Study (1989) arrived at the same conclusions saying:

> 'If BST were to be approved for commercial use, the most frequently suggested method of allowing consumers the choice of purchasing milk containing BST or not would be to label milk according to its method of production. Whilst milk suppliers are not currently obliged to provide such label information it appears that a majority of consumers are in favour of milk being so labelled.'

More specifically, this CEAS survey identified that if milk was labelled according to its production techniques, 45 per cent of respondents said that they would avoid milk produced using BST.

Finally the CEAS Study (1989) makes the following recommendation:

'Even if milk does not become labelled according to production technique (the practicalities of implementation, policing and clarity in labelling would be extremely difficult to achieve), there remains a clear need for improving the provision of consumer information relating to BST and the subject of biotechnology.... The information should be presented in a non-technical and neutral manner by trusted sources of information.'

The US Study also addressed this question.

8. Producer survey

a) The producer survey was carried out across six Member States: Germany, France, the United Kingdom, the Netherlands, Denmark and Ireland. These six account for just under 52% of the Community's milk producers and about three-quarters of its dairy cows (EUR 12).

Awareness of Bovine Somatotrophin (BST) varies greatly between the individual Member States but less so between the regions in a single Member State. As could be expected, milk producers with large herds show a greater awareness than those with small herds.

Milk producers were asked about their attitudes to the following aspects of BST:

- should its use be allowed?
- would they use it on their own herds?
- would they use it if there were a difference in price and market between milk produced with and without BST?

b) The most striking result of the survey was the unequivocal rejection of moves to allow use of BST. Only a small minority argued for its registration; the vast majority wanted a ban. This finding even applies in France and Ireland where there is a generally higher acceptance of BST - even in these countries there is only one category of holding in which the percentage 'for a ban' is less than twice the percentage 'for registration'.

Just as striking is the finding that only a minority of producers would use BST immediately if it were to be allowed. Nevertheless, there is also no clear majority (meaning more than 50%, except in the UK) of producers who would definitely do without BST in any case. A similar proportion of producers intend first to wait and see whether their concerns about animal health can be put to rest, whether there are commercial advantages and not least whether there are likey to be adverse effects on the development of the milk and milk-products market, before they decide for or against using BST.

c) The results of the survey reflect the uncertainty about consumer reaction as discussed above. Producers are clearly very concerned about possible negative market repercussions and as such their opposition is not surprising.

Only as a secondary consideration is the question of concern about animal health/welfare.

This is confirmed by the finding of the survey that should BST be allowed, there would be a relatively rapid uptake by milk producers.

9. EFFECT ON THE MILK MARKET

This effect will depend largely on two factors - adoption rates and consumer reaction.

a) As mentioned above, several different scenarios can be envisaged in terms of consumer reaction.

The IFO consumer survey suggests a drop in consumption of 17 to 18 Mill tonnes whereas the CEAS II-study concludes that a lesser reaction should be expected. The US-study operates with two possibilities - a) a 10% drop in consumption on a permanent basis or b) a 10% drop in consumption of a temporary nature. The US-study does not attempt to justify these assumptions, but uses them merely to calculate through the economic and budgetary consequences.

Each 1% drop in milk consumption in the Community represents 46.000 tonnes of butter and 89.000 tonnes of skimmed milk powder. Since outlets outside the Community can hardly be increased without negative budgetary and trade effects, a further reduction in milk quotas would be necessary to match any drop in internal consumption in the Community.

There is, moreover, the aspect of milk substitutes which deserves mentioning in relation to BST.

In the Third Commission report to the Council on "Developments on the Market in Milk Products and Competing Products" (Sec (91) 1297 final) it is concluded that, amongst others, there is:

- greater consumption of cheeses and a stabilization in the consumption of milk and milk products;

- a considerable drop in the household consumption of butter, particularly in Member States where competing products are more developed;

- a considerable increase in sales of mixtures of milk- and non-milk fats;

- continuing consumer confusion due to the names, labelling and positioning in stores of milk products and their competing products.

There has been considerable growth in the substitute milk products sector in recent years, notably in the yellow fats sector and more recently in the cheese sector. This growth has come about mainly due to consumer confusion which has arisen as a result of unsubstantiated health claims and/or oversimplification of research findings, particularly in relation to heart disease and its causative agents. This has lead to the use of some dubious and emotive advertising by the

industry producing milk substitutes'. Were BST to be allowed, it cannot be ruled out that this industry would attempt to even more profit through such advertising.

b) In terms of <u>adoption rates</u> there is considerable uncertainty.

(i) In the US Study a survey of dairy farmers, found that about 50 per cent of respondents would adopt BST within the first year of its commercial availability, and that over 80 per cent would within 3 years. Most analysts, relying heavily on such studies, have tended to assume relatively rapid adoption of BST. However, the use of surveys to indicate prospective adoption rates of a technology that is not yet available is problematic.

This study further says:

> 'Moreover, new dairy technologies, as a general rule, have not tended to be adopted rapidly. For example, despite having been available commercially for over 40 years, artificial insemination technology is used only by 65 to 70 per cent of dairy farmers.'

On this basis the US study makes the following assessment on adoption rates: After 5 years adoption rates would range between 25 and 46 per cent depending on region and, after 10 years, they are forecast to range from 31 to 67 per cent depending on region.

ii) <u>The CEAS-Study</u> (1) makes an analysis taking the milk quota arrangement and the probable price of BST into account.

It concludes that adoption and use of BST will not be extensive in practice.

It also indicates:

> 'The decisions of whether or not to use bST, on which cows and when will be taken by each individual farmer based on his perceptions of the risks and benefits and his attitude to new technology. Each farmer will assess the situation differently but overall adoption might be expected to relate to:
>
> - benefits of BST (reflecting in part the existing profitability of the herd and degree of opportunity to redeploy any resources released);
> - price of BST;
> - management ability;
> - size of herd.
>
> Because of the restrictions in milk production with milk quotas and based on assumption on average yield

increase with BST (12%) and a realistic price for BST the incentive for major use of BST in the Community will be small.

Overall milk production as a result of BST would amount to 1,2% of total production in the short term and 5% in the long term assuming the results for the 5 Member States is representative for EC-12.

The reduction in cow numbers as a result of regular use is estimated to be 0,5% in the short term rising to 3,6% in the medium term.

This would be the result of a combination of regular use through quota transfer from presumably smaller herds to bigger as well as reduced number of cows within a fixed quota and use of BST by smaller dairy farmers to avoid quota shortfall.

It seems that the presence of milk quotas has a significant effect not only by limiting overall production, but because of the capitalization of the value of a milk quota belonging to a farm. The price of quota is an extra cost which any farmer has to pay if he seeks to make a more widespread use of BST.'

These calculations may be conservative.

A different estimate based on the CEAS study figures, implies a different conclusion as far as the increase in milk production is concerned.

According to the CEAS II (1989) study:

- The use of BST will, on average increase yields by 12% and
- 55% of cows will use BST in the medium-long term.

It could therefore be estimated that the increase in milk production could fall somewhere between the following two scenarios:

a) 55% of cows are responsible for 55% of milk production; this would imply an increase of $\frac{55 \times 12}{100} = 6.6\%$

b) because BST usage will be confined to the medium-high yielding cows and these cows already account for approximately 80% of milk production, this would imply an increase of 9.6%

10. <u>Effect on the beef market</u>

The effect on the beef market will also depend on the assumptions made on consumption and adoption rates. If consumption drops

significantly and this results in a decision to adjust milk quotas accordingly, then there will be a slaughtering of dairy cows increasing beef production in the short run.

If, however, no major reduction in consumption is assumed, then the knock-on effect on the beef market will be smaller.

Halving the price of BST would lead to a further decline in the number of dairy cows. This will, however, be distributed over a number of years depending on the rate of uptake of BST.

The reduced number of cows will release land for alternative use either for crop production or more likely for beef production.

Based on past experience with milk quota reductions dairy cow replacement with animals for beef production will occur - in that case total beef production in the long run is expected to increase mainly because of the higher beef yield of non-dairy cows in comparison to dairy cows.

However, it is also possible as some recent experience shows that dairy farmers who reduce their dairy herds replace dairy cows not only with suckler cows but also with other beef animals such as steers or young bulls. In order to maintain their income they are obliged to have a higher number of beef animal replacements than the number of dairy cows removed. In this case the result would be a significant increase in beef production.

11. BST - Effect on Cow Numbers

Year	Production Million tons	NO B.S.T.	Cow Numbers (000s) Uptake of B.S.T.	
			20% short term	55% long term
1991	111.2	23,300	23,300	23,300
1992	111.2	22,950	22,410	22,410
1993	111.2	22,600	22,080	21,900
1994	111.2	22,260	21,760	21,400
1995	111.2	21,930	21,440	20,920
1996	111.2	21,610	21,140	20,460
1997	111.2	21,300	20,840	20,020
1998	111.2	21,000	20,550	19,750

NOTE: These projections are based on production remaining constant, and average milk yields increasing by 75 kg per year exluding the use of BST.

Statistics are for EC-12 including ex-GDR.

PART II

POTENTIAL BUDGETARY CONSEQUENCES RESULTING FROM THE USE OF BST

BUDGETARY CONSEQUENCES RESULTING FROM THE USE OF BST

The adoption and diffusion of BST would have important effects for agricultural markets both at the level of supply and of demand, with corresponding consequences for the Community budget.

The possible annual budgetary consequences are indicated below. The assumptions used are based on present policies and therefore do not take account of the CAP reform proposals recently presented by the Commission.

The supply of agricultural products

The adoption and diffusion of BST will lead to an increase in the average yield of milk from the Community's dairy cow population. Given that overall Community milk production is limited by the quota system, the higher average yield implies a reduction in dairy cow numbers. The following alternative scenarios may be envisaged regarding the diffusion of BST within the dairy cow population :

a) There is a rapid take-up of BST affecting 20% of the dairy herd.

b) In addition to the immediate take-up by 20% of the herd, there is a susequent extension of usage affecting an additional 7% of the herd each year for a further five years so that ultimately BST is used by 55% of the total herd.

On the assumption that the use of BST increases milk yield per cow by 12%, the consequent fall in dairy cow numbers is as follows :

	1000 head
a) Usage by 20% of the herd	- 540
b) Usage by 55% of the herd	- 1 280

- Additional beef cows

  Assuming that 75% of the overall reduction in dairy cows will be converted into beef cows in order to maintain beef production at an unchanged level, there will be additional suckler cows eligible for the Community premium of 40 ECU/head.

  The additional eligible numbers and the resulting budgetary cost is as follows :

  a) 540 000 head x 75% = 405 000 head x 40 ECU/head x 1.145 (DT) = 18.5 Mio ECU (B)

  b) 1 280 000 head x 75% = 960 000 head x 40 ECU/head x 1.145 (DT) = 44.0 Mio ECU (B)

- *Additional beef production (temporary)*

The conversion to beef cows will limit the reduction in overall cow numbers as follows :

Net decrease in cow numbers :
a) 540 000 - 405 000 = 135 000 head
b) 1 280 000 - 960 000 = 320 000 head.

The net decrease in cow numbers will lead to additional beef production resulting from the slaughter of these animals. The quantity of additional meat and the likely consequent budgetary cost (purchase into public intervention) is as follows :

a) 135 000 head x 300 kg/head = 40 500 t x 2 035 ECU/t x 1.145 (DT) = 94.4 Mio ECU (B)
b) 320 000 head x 300 kg/head = 96 000 t x 2 035 ECU/t x 1.145 (DT) = 223.7 Mio ECU (B)

However, this cost is incurred only during the period during which BST is being adopted and is therefore a once-for-all effect, spread over several years in the case of alternative b).

- *Release of land for other agricultural productions*

A further consequence of the net decrease in cow numbers is that land and other resources currently devoted to dairying will be released and made available for the production of other agricultural products. Assuming a dairy cow stocking rate of 1.5 head per hectare, the potential released area may be estimated as follows :

a) 135 000 head x 1.5 head/hectare = 202 500 hectares
b) 320 000 head x 1.5 head/hectare = 480 000 hectares.

Cereals production may represent one of the alternative uses for this land. Based on existing average Community yields of 4.6 tonnes per hectare, the additional cereals production and consequent extra budgetary costs (purchase into public intervention) would be as follows :

a) 202 500 ha x 4.6 t/ha = 930 000 t (rounded) x 128 ECU/t x 1.145 (DT) = 136.3 Mio ECU (B)
b) 480 000 ha x 4.6 t/ha = 2 210 000 t (rounded) x 128 ECU/t x 1.145 (DT) = 323.9 Mio ECU (B)

Demand considerations

The survey on consumer reactions suggests that the use of BST could lead to a decrease in Community consumption of milk and milk products of almost 17 mio tonnes milk equivalent (a fall of nearly 20% on current estimated consumption of about 90 mio tonnes).

If such a decline were to be realized, it would correspond to additional annual production of about 780 000 tonnes of butter and of almost 1.45 million tonnes of skimmed milk powder. The budgetary cost of purchasing these quantities into public intervention would be some 3 200 Mio ECU.

Alternatively, if, as suggested by the US study on BST, the fall in consumption (temporary or permanent) was limited to 10% (- 9 mio tonnes), the budgetary cost of purchasing the corresponding additional quantities of butter and skimmed milk powder into intervention would be about 1 700 Mio ECU.

Conclusion

Based on the possible scenarios outlined above, the introduction of BST could have the following annual budgetary consequences :

1. Demand reduction of approx. 20%

	MioECU(B) (rounded)	
	(a)	(b)
Additional suckler cow premium payments	+ 20	+ 45
Additional cereals production	+ 135	+ 325
Decreased consumption (- 20%) of milk and milk products	+ 3 200	+ 3 200
TOTAL (*)	+ 3 355	+ 3 570

2. Demand reduction of approx. 10%

	MioECU(B) (rounded)	
	(a)	(b)
Additional suckler cow premium payments	+ 20	+ 45
Additional cereals production	+ 135	+ 325
Decreased consumption (- 10%) of milk and milk products	+ 1 700	+ 1 700
TOTAL (*)	+ 1 855	+ 2 070

(*) Excludes additional costs resulting from temporarily higher beef production due to transitional net reduction in cow numbers.

PART III

OPINION OF THE COMMITTEE FOR VETERINARY MEDICINE PRODUCTS

COMMISSION
OF THE EUROPEAN
COMMUNITIES

III/9260/90 final
Brussels, 20 March 1991

Directorate-General
for internal market and industrial affairs

Committee for Veterinary
Medicinal Products

Opinion of the Committee for Veterinary Medicinal Products
on an application for marketing authorization submitted by the
MONSANTO Company for SOMATECH (formerly Sometribove)
recombinant bovine somatotropin

(CVMP Concertation Procedure (Directive 87/22/EEC) Application No 1)

INTRODUCTION

On 24 August 1987, France referred an application for marketing authorization from the Monsanto company to the Committee for Veterinary Medicinal Products for an opinion in accordance with Article 2 of Directive 87/22/EEC in respect of Somatech, recombinant bovine somatotropin intended for administration to dairy cattle at 14 day intervals in order to increase milk yields. The Monsanto company has subsequently submitted applications in respect of the same product to Italy and the United Kingdom.

The application was considered by an ad hoc meeting of the Committee devoted to biotechnology and veterinary medicine on 24-25 November 1987. The Committee noted that there were differences between the documentation submitted to France and the United Kingdom. In accordance with Article 3 of Directive 87/22/EEC, the company was invited to re-submit identical dossiers to the Member States concerned, and further consideration of the application was suspended.

A revised application was accepted by the French authorities on 23 February 1988, and copies of the complete application have subsequently been made available to all Member States and to the Committee.

The amended application was discussed by a second ad hoc meeting on biotechnology and veterinary medicine on 16 June and by the Committee itself on 17 June 1988. The Committee considered that the information provided by the company was not sufficient to determine whether the product satisfied the criteria for authorization laid down by Directives 81/851/EEC and 81/852/EEC on the harmonization of the laws of the Member States relating to veterinary medicinal products. The Committee therefore prepared a comprehensive series of questions which were transmitted to the company immediately after the meeting of 17 June.

In July 1989 the company submitted its initial response, comprising in excess of 22,000 pages of additional data, to all Member States. However, because of difficulties in correlating the data contained in the original submission from the company with the new information contained in its reply, this submission was considered unacceptable for the purposes of assessment by the Committee. A new reply from the company was submitted in December 1989.

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This reply was discussed in detail by the Committee at its meeting of 17-18 May 1990, at which the Committee concluded that several answers from the company, relating to the quality and biotechnological aspects of the product, and to the safety of the product in the target species remained unsatisfactory. The company was informed of these conclusions and agreed to submit further documentation which was circulated to all Member States in two parts, in June and August 1990. On 19 September 1990, representatives of the company were present at a hearing before the Committee, at which, in addition to responding to questions from the Member States, the company confirmed that, subject to further written responses to be provided to certain questions posed at the hearing, all relevant information, whether favourable or unfavourable, relating to the product had been made available to the Committee. The replies to these outstanding questions were circulated to all Member States at the end of October 1990.

Further discussion of the application took place at the CVMP meetings of 26-28 November 1990 and 15-16 January 1991. The Committee adopted the following opinion at its meeting of 19-20 March 1991.

OPINION OF THE COMMITTEE FOR VETERINARY MEDICINAL PRODUCTS IN RESPECT OF SOMATECH

- The majority of the Committee consider that the product SOMATECH satisfies the criteria for authorization laid down in Directives 81/851/EEC and 81/852/EEC.

- The Committee is satisfied that the manufacturer has demonstrated its ability to produce a homogeneous stable product, with a shelf life of 18 months, in accordance with the quality requirements laid down by the Community directives, using a well-controlled biotechnological process. However, the company should provide the Committee with the results of the plasmid DNA assay conducted on the first 20 industrial scale batches produced following authorization.

The Committe considers that the applicant has demonstrated that SOMATECH is effective in producing a significant increase in milk yields in treated cattle. The extent of this increase in yields depends, amongst other factors, on the breed of animal treated, the individual animal treated, the stage in the lactation cycle at which the product is administered and the quality of animal husbandry techniques used, but may be expected to be in the range of 2.7 - 5.7 kilogrammes per day.

The Committee considers that the applicant has demonstrated that residues of SOMATECH do not present any risk to the health of consumers of meat or milk obtained from treated animals. The product may safely be accepted for use without any withdrawal period for meat or milk.

Moreover, the Committee is satisfied that the use of SOMATECH does not affect the quality of milk or meat, nor will its use adversely affect the industrial processing of such milk into yoghurt or cheese.

5. A majority of the Committee consider that the administration of SOMATECH to dairy cattle does not present any undue risk for the health or welfare of the treated animal.

Although some effects on the pregnancy rates of primi parous animals and the calving intervals of animals treated with SOMATECH before conception were observed during clinical trials, the Committee considers that these points can be resolved by appropriate warnings in the packaging of the product.

After a careful statistical analysis of the available data, the Committee has concluded that there is no evidence that the use of SOMATECH results in an increase in the incidence of mastitis in treated animals in comparison with controls, after the increase in milk yield of the treated animals is taken into consideration. However: the Committee considers that the experimental data available on the incidence of mastitis should be confirmed by additional information obtained under practical conditions of use after the authorisation of the product. Therefore the Committee recommends that the granting of marketing authorization for this product should be subject to a requirement for the company to undertake a structured pharmacovigilance study of the effects of the use of the product on the incidence of mastitis. The protocol for this study should be submitted to the Committee for approval. The Irish, Italian and United Kingdom delegations consider however that additional information about the incidence of mastitis should be provided, using a larger number of animals, before authorisation may be granted.

In its original application, the company proposed that SOMATECH should be administered by subcutaneous injection at the shoulder. Following an evaluation of the nature and importance of the local reactions observed at the injection site, the majority of the Committee considered that the reactions were unacceptable. Subsequently, however, the company amended its application to envisage the administration of SOMATECH only at the tailhead (ischiorectal fossa). The nature and importance of the reactions observed at this new site are substantially reduced to a mild, transient swelling and there is no evidence to suggest that this swelling causes any pain or discomfort to the target animal. However, the German, Dutch, Irish and United Kingdom delegations have doubts as to whether the scope and design of the studies of the tailhead site make it possible to reach a definitive conclusion at this stage. These delegations would require detailed analyses of veterinary supervision of the US trials and the frequency of examinations and the extent of any injection site reactions.

Although plasma levels of BST are reduced following injection through the tailhead, use of the product through the tailhead provides an equivalent increase in milk yield to use through the shoulder site and the Committee therefore considers that the two routes have comparable efficacy.

In these circumstances, and having regard to the experience of the use of the tailhead site for the administration of foot and mouth vaccine in several Member States, the majority of the Committee consider that the administration of SOMATECH through the tailhead site is acceptable and does not present an undue risk to the target animal.

The Irish, Dutch and United Kingdom delegations, however, are concerned about the hygiene of the tailhead site at certain times of the year and the possibility that injection through this site could result in the extraneous infection of the treated animal. These delegations therefore require additional information about the incidence of infection on the basis of the protocols used for the conduct of trials through this site in the United States and the procedures used for the examination of reactions at the injection site.

6. The Committee would emphasise that the successful use of SOMATECH will require the maintenance of high standards of animal husbandry. For this reason the Committee recommends that the product should be used only under veterinary supervision.

7. The Committee considers that it is important to verify that the results described in the application dossier for SOMATECH are confirmed during the practical use of the product in the field. For this reason, the Committee recommends that in addition to the specific study concerning the incidence of mastitis in treated animals referred to above, authorization to place SOMATECH on the market should be subject to a condition requiring the company to collect and evaluate all reported suspected adverse reactions to the product throughout the Community and to prepare an annual safety report for the five years following authorization.

8. The Committee requests that copies of any additional data submitted by the applicant to Member States pursuant to point 5 above be made available to all Member States and to the Commission. After evaluation of the information received, the Committee will consider the adoption of a second opinion on the application.

9. The Committee will consider the summary of product characteristics and the data sheet proposed by the firm for the product at its next meeting.

10. The Committee points out that this opinion is exclusively concerned with the product SOMATECH, produced by Monsanto. It in no way prejudices the evaluation of any other application for authorization for a product based on bovine somatotropin.

11. In accordance with Directive 87/22/EEC, and taking into account the provisions of Council Decision 90/218/EEC concerning the administration of bovine somatotropin, as amended by Council Decision 91/61/EEC, in particular Article 1 thereof, the Member States concerned will inform the Commission within 30 days of the action they intend to take on this opinion.

12. The Committee intends to prepare a detailed report of its evaluation of this application. In the meantime copies of this opinion may be made available to interested parties.

13. The Committee notes that, in accordance with national legislation currently in force, products containing BST may not be authorized in Belgium.

PART IV

RESOLUTIONS OF PARLIAMENT

— having regard to the judgments of the Court of Justice of the European Communities of 12 May 1964 (1) and 10 July 1986 (2),

— having regard to Article 68 of the Italian Constitution,

— having regard to Rule 5 of its Rules of Procedure,

— having regard to the report of the Committee on Legal Affairs and Citizens' Rights (Doc. A2-221/86),

1. Hereby decides not to waive Mr Maurizio Valenzi's parliamentary immunity;

2. Instructs its President immediately to forward this decision and the report of its committee to the appropriate authority of the Italian Republic.

(1) CJ CE, 12 May 1964 (*Wagner* v. *Fohrmann and Krier*, Case 101/63/1964/ECR 195).
(2) Judgment in Case 149/85 (*Wybot* v. *Faure*), not yet published in the ECR.

3. Biotechnology in the European farming industry

(a) Doc. A2-159/86

RESOLUTION

on the effects of the use of biotechnology on the European farming industry

The European Parliament,

— having regard to the motion for a resolution tabled on behalf of the Committee on Agriculture, Fisheries and Food by Mr Tolman and Mr Eyraud on the use of agricultural products in biotechnology (Doc. B2-1087/85),

— having regard to the motion for a resolution tabled by Mr F. Pisoni and others on new uses for agricultural products and, in particular, the use of cereals for ethanol production (Doc. B2-1351/85),

— having regard to its resolution of 20 February 1986 on the genetic variety of cultivated plants and trees (1),

— having regard to its resolution of 8 July 1986 on bioethanol (2),

— having regard to the Commission discussion paper entitled: Biotechnology in the Community: stimulating agro-industrial development (COM(86) 221 final),

— having regard to the new Community Framework Programme of technological research and development (COM(86) 129 final),

— having regard to the Commission reports on the Biomolecular Engineering Programme (BEP) and the Commission RAP Biotechnology,

— having regard to the US Congress OTA report on the impact of the new technologies on the structure of American agriculture,

— having regard to the EEC FAST programme: The End of Farm Workers — the new farm workers (XII/108/86),

— having regard to the report by the Committee on Agriculture, Fisheries and Food (Doc. A2-159/86),

(1) OJ No C 68, 24. 3. 1986, p. 119.
(2) OJ No C 227, 8. 9. 1986, p. 30.

A. in view of the extensive efforts and the levels of expenditure brought to bear at Community level for the promotion of biotechnology in order to modernize agriculture and industry,

B. whereas these efforts are necessary so that agriculture and the agro-industrial sector can maintain their position and their competitiveness on the world market,

C. whereas biotechnologies, if used judiciously, can help reduce production costs and open new markets, thus improving the economic situation of farmers,

D. whereas multi-nationals are spending huge sums of money on biotechnology research, and it is important that the Community and national governments invest more in this area to avoid a situation where multinationals might gain a near monopoly of the knowledge available in this new technology,

E. whereas the commercial application of biotechnology may lead to an acceleration of rationalization of production in certain sectors of agriculture but will also lead to the development of new opportunities and new markets for farm products,

F. whereas there will continue to be a reduction in the numbers employed on the land, but new employment openings can be created through the careful application of biotechnology,

G. whereas biotechnology must be directed less towards increasing production capacity and yields than towards improving the quality of agricultural products and opening up new markets for such products, for example in the chemical and pharmaceutical industries, the agro-industry, etc.,

H. whereas the pursuit of such objectives (working to improve quality and seeking new markets) is likely to have a beneficial effect on employment in agriculture, as well as upstream and downstream of that sector,

I. whereas immediate thought must be given both at the Community level and at international level, particularly in the context of the new GATT negotiations, to the effects of production increases to which wrongly or inadequately directed biotechnology could give rise, such as collapsing exchange rates, the destabilization of international trade and the creation of new forms of dependence,

J. whereas traditional intensive agriculture posed many dangers to the environment, but biotechnology could assist in reducing the hazards by increasing the efficiency of nitrogen fixation and resistance to diseases and pests thus helping to reduce inputs of fertilizer, fungicides, insecticides and pesticides; tests and checks should be carried out in order to avoid possible adverse side-effects; likewise it could contribute to the safe disposal of farm wastes by converting animal waste an other organic substances to methane gas to be used as energy on the farm,

K. whereas serious studies must continue into energy production from biomass, in the context of developing the prospects for decentralized coverage of energy needs,

L. whereas genetic variety in crops and livestock has decreased over the centuries, and biotechnology and gene banks can contribute to increasing and conserving genetic variety,

M. whereas the application of biotechnology, like all new technologies, entails certain risks, and therefore it is very important that there should be adequate controls, preferably harmonized on a Community-wide basis,

N. whereas the development of biotechnologies will not necessarily lead to a solution of the problems of famine in the Third World, but may on the contrary widen the gulf between rich and poor, between large-scale farms and subsistence farming, between cash crop production and the supply of basic foostuffs,

O. whereas genetic plasma comes mainly from Third World countries,

1. Feels that, in the present context, biotechnology must promote an agricultural policy geared to quality, with high added value, rather than further increasing yields and quantities produced;

2. Believes that the European Community has a duty to support and encourage biotechnological research aimed at improving alternative forms of production and/or finding new ones;

3. Wishes to maintan family farming as the basis of our agriculture, the main task of which is to provide people with healthy food and to provide the agro-industries with suitable raw material for processing, without damaging the environment;

3.1 A purely biotechnological approach must be rejected and biotechnology must be integrated within already existing technologies by being made part of a wider policy designed to sustain vigorous rural life and a flourishing rural economy;

3.2 In food processing, the primary aim must be to produce food that is safe and nutritious. Genetic engineering is already contributing in this sector particularly in the production of fermented products such as cheese, yoghurts, soured milk drinks, beers, etc. ...;

3.3 The links between agriculture and industry, both upstream and downstream, should be strengthened with the object of supplying the consumer with competitively priced high quality food, while maintaining the viability of as many family farms as possible;

3.4 For our agriculture to stay competitive it will be essential to invest more in the continuous breeding of plants and animals, preferably, though not exclusively in government-controlled research centres;

3.5 Producer, processor and consumer cooperatives should be encouraged, likewise small and medium-sized industries should be encouraged in this sector;

3.6 Farmers should be given appropriate training to enable them to be involved closely in putting biotechnological research and applications to use and assessing their value;

4. Calls for all the ecological consequences to be taken into account in the use and application of biotechnology;

5. Supports the cooperation in the field of breeding between scientists, breeders, working farmers, environmentalists and conservationists designed to preserve a broad genetic potential;

6. Hopes that the guiding principles behind research into the breeding of particular animal species and the cultivation of particular plant varieties will be a concern to enhance qualitative, rather than quantitative performance, and an unfailing respect for the basic natural characteristics of such species and varieties;

7. Believes that successful plant breeding relies on the creation of diversity and this process can be accelerated using biotechnology;

8. Stresses the importance of species and gene conservation and the part played by gene banks and species repositories; considers, however, that the natural inheritance of mankind which these represent must be safeguarded outside any spirit of a desire to secure a commercial monopoly;

9. Calls for gene banks to be made subject to public supervision and the protection of intellectual property by means of adequate patent safeguards;

10. Considers that genetically manipulated organisms may not be introduced into the environment until all the relevant tests and experiments have been approved;

11. Calls on the Commission to propose directives on the basis of OECD recommendations and ensure that European undertakings comply with same both inside and outside the European Community;

12. Is seriously concerned at experiments recently carried out in certain countries; calls on the Commission to make contact with the international organizations concerned with a view to drawing up and ensuring respect for a code of conduct on experiments in the environment;

13. Calls for comprehensive testing of genetically engineered organisms before releasing them in any part of the world. Calls on the Commission to introduce standards for testing;

14. Supports the efforts of Third World countries to use appropriate technology to develop their agriculture and their economies and to reduce their dependence on multi-nationals;

15. Calls for prices for agricultural products to be fixed at a level which will help to give a reasonable income in farming thus helping to safeguard family farming in the Community;

16. Feels, nevertheless, that the prospects for industrial markets for agricultural products must be analyzed, as they represent:

— a further way of disposing of surpluses,

— a far from negligible source of indigenous raw materials for Community industry;

17. Considers it imperative that energy-production resources (bioethanol) be exploited, with all the necessary precautions to protect soil and groundwater;

18. Approves of the fact that the Community has passed legislation banning growth hormones; calls on the Commission to pursue this restrictive policy in respect of all types of hormones, and asks it to make approaches to the international organizations concerned (FAO, WHO, the International Dairy Products Council, etc.) and third countries which produce, use and export hormones, to ensure that a set of overall international rules on the trade in and use of hormones in agriculture and stockbreeding is introduced;

19. Calls on the Commission to produce a forcast, along the lines of the US Congress OTA report, of the likely structural and social consequences of the promotion and application of biotechnology and genetic technology in the European farming industry;

20. Instructs its President to forward this resolution to the Council and the Commission.

(b) Doc. A2-134/86

RESOLUTION

on biotechnology in Europe and the need for an integrated policy

The European Parliament,

— having regard to the communication from the Commission to the Council concerning the review of the multiannual reasearch programme for the EEC in the field of biotechnology (1985-1989) (COM(86) 272 final),

— having regard to the discussion paper of the Commission 'Biotechnology in the Community: Stimulating Agro-Industrial Development' (Com(86) 221 final),

— having regard to the motions for resolutions by Mr Roux and others, on behalf of the ERDA Group, on research in the field of biotechnology (Doc. B2-579/85), by Mr Tolman and Mr Eyraud, on behalf of the Committee on Agriculture, on the use of agricultural products in biotechnology (Doc. B2-1087/85) and by Mr Pearce on developments in the manufacture of hormones (Doc. B2-1162/85),

4. Hormones and the BST hormone in the dairy and meat industry

— Doc. A2-30/88

RESOLUTION

on the effects and risks of using the growth hormones and the BST hormone in the dairy and meat industries

The European Parliament,

— having regard to the motion for a resolution tabled by Mr Glinne and others on the effects and risks of using the BST-type hormone in the dairy industry (Doc. B2-988/86),

— having regard to the motion for a resolution tabled by Mr Graefe zu Baringdorf on the risks associated with the use of genetically engineered growth hormones in stock farming and the effects with regard to

  — natural animal husbandry,

  — the preservation of traditional, environment-related farming,

  — increases in output (surpluses),

  — providing consumers with high-quality, nutritious food,

  — animal feed imports and subsidized food exports between the Community and Third World countries (Doc. B2-767/87),

— having regard to the report of the Committee on Agriculture, Fisheries and Food and the opinions of the Committee on the Environment, Public Health and Consumer Protection and the Committee on Energy, Research and Technology (Doc. A2-30/88),

— having regard to Directive 88/146/EEC prohibiting the use of certain substances having a hormonal action in the following sector,

A. whereas, on 16 February 1987, it adopted a resolution on the effects of the use of biotechnology on the European farming industry (1),

B. whereas, in certain fields, agriculture is already dependent on biotechnologies which undoubtedly can bring about progress in agriculture but cannot, however, all be accepted and used indiscriminately on the pretext that they represent progress,

C. whereas the scientific revolution we are witnessing is taking place in an economic and political climate that is extremely uncertain and hard to gauge,

D. whereas BST is a genetically engineered hormone whose effect is to boost milk and meat production,

E. whereas the quota system is designed to prevent any overall increase in milk production,

F. whereas the current market situation is characterized by agricultural surpluses and escalating storage costs,

G. whereas the use of hormones artificially increases the carcase weight of cattle,

H. whereas the Community has a duty to protect the health and defend the interest of its consumers and farm animals,

I. whereas the introduction of BST would run counter to the policy of extensive farming and might well, because the method of use means it is only suitable for the most efficient producers, create inequalities between individual regions and producers,

(1) OJ No C 76, 23.3.1987, p. 22.

J. whereas quality cirteria rather than considerations of quantity should prevail in determining production techniques, which should also eschew all chemical or artificial processes which might be harmful to the health of consumers or to the quality of the environments,

K. whereas it is dishonest to play on the producer's fear of being excluded from the system as a means of inducing him to use production techniques which have been insufficiently tested and whose harmlessness has not been empirically demonstrated, on either humans or animals over the short or long term,

L. whereas the Council, the Commission and the European Parliament have expressed their determination to join forces with the Member States in combating the traffic in hormones,

M. whereas the pressure being brought to bear by the USA within GATT, with the aim of circumventing the Community directives prohibiting the use of anabolic agents in livestock farming as from 1 January 1988, is fallacious both in legal terms (GATT allows its members freedom to specify production methods) and economic terms (the prohibition is not protectionist as it applies equally to Community and third country producers),

N. whereas it is opposed to all downward harmonization of health and hygiene standards with regard to the production and marketing of foodstuffs at international level,

O. whereas absolute priority must be given to safeguarding health,

P. whereas the future selection of dairy cattle might be distorted because of the undeclared use of BST, with the risk that animals with the best genetic potential may be rejected in favour of mediocre but treated animals,

Q. whereas the Commission is currently reviewing the future of veterinary medicine licensing,

1. Welcomes the decision of the Council of Ministers of Agriculture of 7 March 1988 to re-enact Directive 85/649/EEC prohibiting the use of certain substances having a hormonal action, which had been annulled by the Court of Justice on 23 February 1988 on the grounds of breach of procedure (Directive 88/146/EEC);

2. Is disturbed by the fact that the use of BST is accelerating the growth of intensive livestock farming at a time when production limits have been imposed;

3. Believes it essential for a careful assessment to be made of the economic implications of using products such as BST, which are indirectly linked to, and exert an indirect influence on, agricultural surpluses;

4. Points out that the geographical conditions of certain Community regions are such as to tie farming to the exploitation of the land, with the result that the feeding methods required by the introduction of BST are likely to provoke competition between individual regions and producers;

5. Notes the adoption by the Council of Directive 88/146/EEC prohibiting the use in livestock farming of certain substances having a hormonal action; believes this to be a timely measure, but notes that it does not cover BST and other new hormonal substances;

6. Calls on the Commission to formulate an assessment procedure for veterinary medicines, including hormones, produced by genetic engineering to take into account not only safety, efficacy and quality but also the socio-economic and ecological consequences, the impact on agricultural structures and compatibility with the aims of reducing surpluses and promoting extensive farming;

7. Notes that the studies being conducted by industry and also by universitities and other research organizations include studies of the socio-economic effects of BST; hopes that industry finds it appropriate to distribute widely the results of these studies, in particular to MEPs and the Commission;

8. Draws attention to the fundamental importance of research for the development of the biotechnologies, the basic aim of which must be to improve quality rather than boosting output;

9. Decides that it is now appropriate for Parliament's Office of Technology Assessment to conduct research into the implications of rapidly evolving scientific knowledge in the field of veterinary medicine;

10. Believes that the provisions of Directive 88/146/EEC banning certain substances in the Community must be applied in the same way by producer countries which export their meat products to the Community;

11. Is concerned at the differences that exist between the various national laws regarding hormones, which is creating difficulties in international trade;

12. Calls on the Commission to apply itself without delay to the task of coordinating and analyzing the findings of current experiments concerning the use of BST and not to leave such important work entirely in the hands of the pharmaceutical laboratories;

13. Considers it essential for a programme of exhaustive studies and trials to be instituted, notably with a view to examining the effects of BST on human and animal health;

14. Takes the view that these studies must be linked with a far-reaching information campaign, addressed both to the general public and veterinary surgeons, concerning the nature, location, structure, objectives and results of the studies;

15. Considers that milk from the animal used in the various trials should not be distributed to consumers;

16. Believes that an investigation should be carried out into the cumulative effects of the different hormones;

17. Is of the opinion that where a Member State, as in the case of the UK, allows testing of BST on cattle, neither the milk, nor the meat from BST injected animals, should be used for either human or animal consumption;

18. Considers that, before the use of BST is authorized at Community level, its long-term socio-economic effects, particularly on the smaller farm, should be the subject of a special study, the results of which should be taken into account when the relevant decision is taken;

19. Calls for a system of aid to be introduced to compensate for the loss of income which discontinuing the use of growth hormones would entail, thereby ensuring that proper economic and social provision can be made in the event that the ban on hormones in livestock farming is really applied;

20. Calls on the Commission to oppose any attempt by individual Member States to authorize the use of BST at national level until such time as the conditions for its authorization at Community level have been met;

21. Believes it necessary to bring about complete harmonization with regard to inspections in the Community's slaughterhouses and imports from third countries;

22. Draws attention to the need for consultation with all producer countries in the world;

23. Calls for a tightening of the measures for the detection of fraud and irregularities with a view to preventing the development of a black market (in this field) and for the national administrations to be closely involved in those measures;

24. Emphasizes the importance of setting up appropriate bodies to carry out checks on the premises of livestock breeders; such bodies should have a team of veterinary inspectors whose task would be to fix product quality standards and to penalize any infringement of Community rules;

25. Takes the view that the use of hormones for production purposes should be restricted as far as possible and that where their use is permitted it should be subject to very strict rules; stresses, in this connection, that only persons with training in veterinary medicine should administer therapeutic preparations;

26. Calls on the Commission to create a legal framework in which other genetically engineered growth accelerators or yield enhancers such as PST (porcine growth hormone), etc. are taken into account;

27. Calls for all meat and animal products produced within the EEC and imported from third countries to indicate clearly all treatments used in their production with a view to safeguarding, and giving the consumers, a choice;

28. Calls for the introduction of European quality labels guaranteeing the conditions laid down jointly by representatives of the cattle producers and the consumer associations;

29. Calls on the Commission and the Council to impose identical health standards for meat products imported into the Community;

30. Instructs its President to forward this resolution to the Commission and the Council.

PART V

EXTRACT FROM COMMISSION COMMUNICATION TO PARLIAMENT AND COUNCIL

CONCERNING

PROMOTING THE COMPETITIVE ENVIRONMENT FOR THE INDUSTRIAL

ACTIVITIES BASED ON BIOTECHNOLOGY IN THE COMMUNITY

As B.S.T. is a product of modern biotechnology the industries involved are concerned to ensure a stable regulatory framework for their activities. The Commission considered this question in its recent Communication to the Parliament and the Council concerning 'Promoting the competitive environment for the industrial activities based on biotechnology within the Community' [SEC (91) 629 final]. In this it is indicated:

> 'Not all products derived through biotechnological methods will require a specific assessment and/or authorization procedures. Currently the vast majority of biotechnology products are produced through traditional methods (e.g. cheeses, malt extracts, beers and yeasts). As far as new biotechnology products are concerned, which involve gene manipulation, each product will have to be considered on a case-by-case basis and assessed as necessary.'

Those products which do require governmental activity may be assessed and authorized under the regulatory framework for biotechnology which has been developed by the Community. This regulatory framework, which is based upon scientific analysis and evaluation, covers horizontal (environmental and worker protection) and product legislation. This later is based on the tree criteria of safety, quality and efficacy(2)(2), which are also applied when assessing whether a product can be authorized for distribution on the open market. The horizontal framework ensures that all stages of pre-industrial development and environmental aspects are covered.

The approach now applied by the Community, based upon the correct and thorough application of the criteria of safety, quality and efficacy, in conjunction with relevant horizontal legislation, ensures consumers' safety and economic interests and permits the protection of human,

.../...

(2) It should be noted that these criteria are nowadays considered to include impact on nature and safety for the environment.

animal and plant health and of the environment. Furthermore, in order to ensure that the consumer protection aspect is covered, the impact on consumers' information and choice needs to be taken into account.

Recent debate has focussed on the introduction of broader socio-economic needs in addition to the three traditionsl criteria when assessing biotechnologically derived products. The debate is on-going and the preoccupations involved differ. To some the concept includes a broader analysis of health and environmental aspects, to others it should focus on social and/or economic impacts (for example, consequences on agricultural production). The Community must, above all, avoid a situation creating uncertainty.

As a rule, decisions have to be based upon objective assessments using clearly identified criteria. Uncertainties about product acceptance and authorization could result in a diversion of investment and could act as a disincentive for innovation and technological development by industry. The Community must however guarantee the public that the industry is properly controlled. The dynamism of the industry and the confidence of public opinion depend on the ability of the Community of reassure both parties.

Where a biotechnological product is assessed, the three traditional criteria, based on scientific evaluation apply. By their nature, socio-economic aspects need to be considered in a different way. It is not the intention to have another systematic assessment in addition to the three criteria. The Commission will normally follow scientific advice. The Commission reserves the right, however, to take a different view in the light of its general obligation to take into account other Community policies and objectives. This might, in exceptional cases, lead to requirements for further information. It might equally, in exceptional cases, lead to the Commission to propose that other policies be modified in the light of biotechnological developments.

COMMISSION
DES
COMMUNAUTES EUROPEENNES

Secrétariat Général

COM(91)522/2

Bruxelles, le 6 décembre 1991

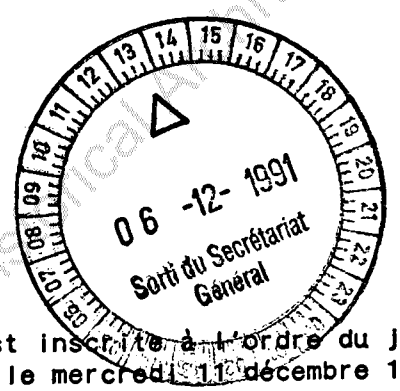
0/91/380

O.J. 1086 - point 11

(Modifications à la proposition de décision du Conseil suite à la réunion spéciale des Chefs de cabinet du 5 décembre 1991)

DEUXIEME RAPPORT DE LA COMMISSION AU CONSEIL ET AU PARLEMENT EUROPEEN EN CE QUI CONCERNE LE BST - PROPOSITION DE DECISION DU CONSEIL

Communication de M. MAC SHARRY



- Cette question est inscrite à l'ordre du jour de la 1086ème réunion de la Commission le mercredi 11 décembre 1991

Destinataires : Membres de la Commission
MM. LEGRAS, KRENZLER, PERISSICH, DEGIMBE, BRINKHORST, FASELLA, BARLEBO-LARSEN, WILLIAMSON, DEWOST

Explanatory Memorandum

Bovine Somatotrophin

1. On 27th September 1989 the Commission presented a report to the Council and to the Parliament concerning the administration of bovine somatotrophin to dairy cows as a productivity aid to milk production[1].

   It proposed the establishment of an evaluation period up to the end of 1990 on the administration of BST in the Community. It also indicated that this period was considered to be the minimum necessary to assess the results of the ongoing studies and develop new arrangements to be adopted on procedures in relation to such products. By its decision 90/218/EEC of 25th April 1990[2] the Council agreed to the request of the Commission and subsequently agreed by its decision of 4th February 1991[3] that an additional time up to 31 December 1991 was necessary to enable the studies under way to be completed and the results to be considered.

2. In the meantime several studies have been made into the various aspects of BST and a further interim report in the matter will be presented to the Council and to the Parliament shortly.

3. The Commission can indicate already that more time will be needed to arrive at definitive conclusions both as regards the scientific and ethical aspects and the implications for Community policies and objectives. Accordingly it is proposed that the Council decide to extend the existing evaluation period up to [30 June 1994]. This will enable the Commission to present its further conclusions accompanied by proposals concerning future arrangements by 30th June 1993 at the latest.

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(1) [COM (89) 379 final]
(2) O.J. No L 116, 08.05.1990, p. 27
(3) O.J. No L 37, 09.02.1991, P. 39

PKa/91/0840 - nt

Projet de proposition

de

DECISION DU CONSEIL

DU

modifiant la décision 90/218/CEE relative à la mise sur le marché et à l'administration de la somatotropine bovine (BST)

LE CONSEIL DES COMMUNAUTES EUROPEENES,

vu le traité institutant la Communauté économique européenne, et notamment son article 43,

vu la proposition de la Commission(1)

vu l'avis du Parlement européen(2)

vu l'avis du comité économique et social(3)

considérant que, dans sa décision 90/218/CEE(4), relative à la mise sur le marché et à l'administration de la somatotropine bovine (BST), modifiée par la décision 91/61/CEE du 4 février 1991, le Conseil a demandé aux Etats membres d'interdire, jusqu'au 31 décembre 1991, l'administration sur leur territoire, par quelque moyen que ce soit, de la somatotropine bovine aux vaches laitières, parce que les effets et les conséquences d'une telle administration n'étaient pas encore suffisamment établis;

considérant que le délai imparti pour étudier ces effets et conséquences s'est avéré trop court; que les recherches mises en oeuvre n'ont abouti que partiellement; qu'il n'existe pas encore de résultats suffisaments réprésentatifs, notamment sous l'angle de la santé et du bien-être des animaux; qu'il importe dès lors de continuer de manière approfondie les études afin de disposer d'informations complémentaires; que ces études doivent porter également sur les réactions des consommateurs à l'égard d'utilisation d'une substance destinée à accroître artificiellement la production du lait; qu'il convient enfin d'approfondir certains aspects de cohérence avec les politiques communautaires.

considérant que pour ne pas préjuger du résultat de ces études, il est nécessaire de proroger ultérieurement l'interdiction de mise sur le marché et d'administrer la somatotropine bovine;

A ARRETE LA PRESENTE DECISION :

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(1)
(2)
(3)
(4) JO n° L 116 du 8.5.1990, p. 27

Article premier

La décision 90/218/CEE est modifiée comme suit :

1. L'article 1er est remplacé par le texte suivant :

"Article premier

Les Etats membres veillent, jusqu'au [30 juin 1994] à ne pas autoriser la mise sur le marché de la somatotropine bovine et son administration sur leur territoire par quelque moyen que ce soit aux vaches laitières."

2. L'article 4 est remplacé par le texte suivant :

"Article 4

Avant le 30 juin 1993 au plus tard, la Commission présente au Parlement européen et au Conseil un rapport sur la situation, assorti de propositions concernant le régime ultérieur."

Article 2

Les Etats membres sont destinataires de la présente décision.

Fait à Bruxelles, le

Par le Conseil

COMMISSION
DES
COMMUNAUTES EUROPEENNES

Secrétariat Général

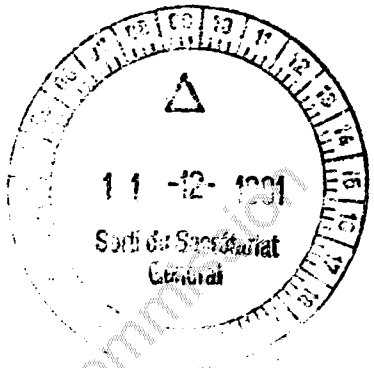
COM(91)522/3

Bruxelles, le 10 décembre 1991

0/91/380

O.J. 1086 - point 11

(Nouvelle version suite à la réunion hebdomadaire des Chefs de Cabinet du 6 décembre 1991)



TEXTE F

PROPOSITION DE DECISION DU CONSEIL CONCERNANT LA BST

Communication de M. MAC SHARRY

- Cette question est inscrite à l'ordre du jour de la 1086ème réunion de la Commission le mercredi 11 décembre 1991

Destinataires : Membres de la Commission
MM. LEGRAS, KRENZLER, PERISSICH, DEGIMBE, BRINKHORST, FASELLA, BARLEBO-LARSEN, WILLIAMSON, DEWOST

Exposé des motifs

Somatotropine bovine

1. Le 27 septembre 1989, la Commission a présenté un rapport au Conseil et au Parlement sur l'administration de la somatotropine bovine aux vaches laitières en vue d'améliorer la productivité du secteur considéré(1).

Il est proposé de fixer une période d'évaluation se terminant fin 1990 et devant permettre d'évaluer l'utilisation de la BST dans la Communauté. Il est également indiqué que cette période représente le délai minimum nécessaire pour apprécier les résultats des études en cours et mettre au point de nouvelles dispositions à adopter quant aux procédures applicables à de tels produits. Par sa décision 90/218/CEE, du 25 avril 1990(2), le Conseil a agréé la demande de la Commission puis, par sa décision du 4 février 1991(3), a accepté un délai supplémentaire, expirant le 31 décembre 1991, nécessaire pour permettre l'achèvement des études en cours et l'examen de leurs résultats.

2. Dans l'intervalle, plusieurs études ont été réalisées sur divers aspects de la BST et un second rapport intérimaire sur le sujet sera présenté au Conseil et au Parlement à bref délai.

3. La Commission est en mesure d'indiquer dès à présent qu'il faudra davangage de temps pour dégager des conclusions définitives. En conséquence, il est proposé que le Conseil décide de prolonger la période d'évaluation actuelle jusqu'au 31 décembre 1993. Ceci permettra à la Commission de présenter ses nouvelles conclusions accompagnées de propositions relatives à des arrangements futurs pour le 30 juin 1993 au plus tard.

4. La présente decision n'a aucune consequence financière.

(1) [COM (89) 379 final]
(2) JO n° L 116 du 8. 5.1990, p. 27.
(3) JO n° L 37 du 9. 2.1991, p. 39.

Projet de proposition

de

DECISION DU CONSEIL

DU

modifiant la décision 90/218/CEE relative à la mise sur le marché et à l'administration de la somatotropine bovine (BST)

LE CONSEIL DES COMMUNAUTES EUROPEENES,

vu le traité institutant la Communauté économique européenne, et notamment son article 43,

vu la proposition de la Commission(1)

vu l'avis du Parlement européen(2)

vu l'avis du comité économique et social(3)

considérant que, dans sa décision 90/218/CEE(4), relative à la mise sur le marché et à l'administration de la somatotropine bovine (BST), modifiée par la décision 91/61/CEE du 4 février 1991, le Conseil a demandé aux Etats membres d'interdire, jusqu'au 31 décembre 1991, l'administration sur leur territoire, par quelque moyen que ce soit, de la somatotropine bovine aux vaches laitières, parce que les effets et les conséquences d'une telle administration n'étaient pas encore suffisamment établis;

considérant que le délai imparti pour étudier ces effets et conséquences s'est avéré trop court; que les recherches mises en oeuvre n'ont abouti que partiellement; qu'il n'existe pas encore de résultats suffisaments réprésentatifs, notamment sous l'angle de la santé et du bien-être des animaux; qu'il importe dès lors de continuer de manière approfondie les études afin de disposer d'informations complémentaires; qu'il convient enfin d'approfondir certains aspects de cohérence avec les politiques communautaires.

considérant que pour ne pas préjuger du résultat de ces études, il est nécessaire de proroger ultérieurement l'interdiction de mise sur le marché et d'administrer la somatotropine bovine;

A ARRETE LA PRESENTE DECISION :

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(1)
(2)
(3)
(4) JO n° L 116 du 8.5.1990, p. 27

Article premier

La décision 90/218/CEE est modifiée comme suit :

1. L'article 1er est remplacé par le texte suivant :

"Article premier

Les Etats membres veillent, jusqu'au 31 decembre 1993 à ne pas autoriser la mise sur le marché de la somatotropine bovine et son administration sur leur territoire par quelque moyen que ce soit aux vaches laitières."

2. L'article 4 est remplacé par le texte suivant :

"Article 4

Avant le 30 juin 1993 au plus tard, la Commission présente au Parlement européen et au Conseil un rapport sur la situation, assorti de propositions concernant le régime ultérieur."

Article 2

Les Etats membres sont destinataires de la présente décision.

Fait à Bruxelles, le

Par le Conseil

COMMISSION
DES
COMMUNAUTES EUROPEENNES

Secrétariat Général

COM(91)522/3

Bruxelles, le 10 décembre 1991

O/91/380

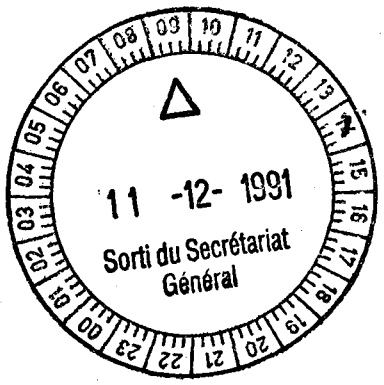
O.J. 1086 - point 11

(Nouvelle version suite à la réunion hebdomadaire des Chefs de Cabinet du 6 décembre 1991)

TEXTE D

PROPOSITION DE DECISION DU CONSEIL CONCERNANT LA BST

Communication de M. MAC SHARRY



- Cette question est inscrite à l'ordre du jour de la 1086ème réunion de la Commission le mercredi 11 décembre 1991

Destinataires : Membres de la Commission
MM. LEGRAS, KRENZLER, PERISSICH, DEGIMBE, BRINKHORST, FASELLA, BARLEBO-LARSEN, WILLIAMSON, DEWOST

Begründung

Rindersomatotropin

1. Am 27. September 1989 hat die Kommission dem Rat und dem Parlament einen Bericht über die Verabreichung von Rindersomatotropin an Milchkühe zur Steigerung der Milchleistung (1) vorgelegt.

Darin war angeregt worden, einen Beurteilungszeitraum (bis Ende 1990) festzulegen, in dem die Verwendung von bST in der Gemeinschaft geprüft werden konnte. Außerdem kam der Bericht zu dem Schluß, daß mindestens soviel Zeit benötigt würde, um die Ergebnisse der laufenden Untersuchungen zu prüfen und neue Vorschriften über die Zulassung solcher Produkte zu entwickeln. Mit der Entscheidung 90/218/EWG vom 25. April 1990 (2) stimmte der Rat dem Vorschlag der Kommission zu und erklärte in der Entscheidung vom 4. Februar 1991 (3), daß eine Fristverlängerung bis zum 31. Dezember 1991 erforderlich sei, um die laufenden Untersuchungen beenden und deren Ergebnisse prüfen zu können.

2. Inzwischen wurden zu verschiedenen Aspekten von bST Untersuchungen angestellt. Ein weiterer Zwischenbericht wird dem Rat und dem Parlament in Kürze zugehen.

3. Die Kommission kann bereits jetzt übersehen, daß mehr Zeit benötigt wird. Aus diesem Grund wird vorgeschlagen, daß der Rat den bestehenden Bewertungszeitraum bis zum 31. Dezember

1993 verlängert. Dies würde es der Kommission ermöglichen, über weitere Schlußfolgerungen zu berichten und entsprechende Vorschläge für eine spätere Regelung bis spätestens 30.Juni 1993 vorzulegen.

4. Diese Entscheidung wird keine finanziellen Auswirkungen haben.

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(1) KOM (89) 379 endg.

(2) ABl. Nr. L 116, 8.5.1990, S. 27

(3) ABl. Nr. L 37, 9.2.1991, S. 39

Kommission der
Europäischen Gemeinschaften

CAB/XV/165/91
PKa/91/0840-nt

Entwurf einer

ENTSCHEIDUNG DES RATES

vom....

zur Änderung der Entscheidung 90/218/EWG über die Verbreichung von Rindersomatotropin (BST)

DER RAT DER EUROPÄISCHEN GEMEINSCHAFTEN --

gestützt auf den Vertrag zur Gründung der Europäischen Wirtschaftgemeinschaft, insbesondere auf Artikel 43,

auf Vorschlag der Kommission (1),
nach Stellungnahme des Europäischen Parlaments (2),
nach Stellungnahme des Wirtschafts- und Sozialausschusses (3),

in Erwägung nachstehender Gründe:

In der Entscheidung 90/218/EWG (4) über die Verabreichung von Rindersomatotropin (BST), geändert durch die Entscheidung 91/61/EWG vom 4. Februar 1991, hatte der Rat die Mitgliedstaaten aufgefordert, bis zum 31. Dezember 1991 jegliche Verabreichung von Rindersomatotropin an Milchkühe in ihrem Hoheitsgebiet zu verbieten, da die Auswirkungen noch nicht hinreichend geklärt waren.

Die ursprünglich vorgesehene Frist, in der diese Auswirkungen untersucht werden sollten, reicht nicht aus; die Forschungsarbeiten sind erst teiweise abgeschlossen; ausreichend repräsentative Ergebnisse, inbesondere über Gesundheit und Wohlbefinden der Tiere, liegen noch nicht vor. Weitere Studien sind erforderlich, um zusätzliche Informationen zu erhalten. Schließlich ist zu untersuchen, inweiweit eine Übereinstimmung mit den gemeinschaftlichen Politiken gesichert ist.

Um den Ergebnissen dieser Studien nicht vorzugreifen, ist das Inverkehrbringen und die Verabreichung von Rindersomatotropin weiterhin zu verbieten --

HAT FOLGENDE ENTSCHEIDUNG ERLASSEN:

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(1)

(2)

(3)

(4) ABl. Nr. L 116 vom 8.5.1990, S. 27.

Artikel 1

Die Entscheidung 90/218/EWG wird wie folgt geändert:

1. Artikel 1 erhält folgende Fassung:

"Artikel 1

Die Mitgliedstaaten sorgen bis zum 31. Dezember 1993 dafür, daß das Inverkehrbringen und jegliche Verabreichung von Rindersomatotropin an Milchkühe innerhalb ihres Hoheitsgebiets nicht zugelassen wird."

2. Artikel 4 erhält folgende Fassung:

"Artikel 4

Die Kommission unterbreitet dem Europäischen Parlament und dem Rat spätestens bis 30. Juni 1993 einen Lagebericht mit Vorschlägen für eine spätere Regelung."

Artikel 2

Diese Entscheidung ist an die Mitgliedstaaten gerichtet.

Geschehen zu Brüssel am

Im Namen des Rates

COMMISSION
DES
COMMUNAUTES EUROPEENNES

Secrétariat Général

COM(91)522/3

Bruxelles, le 10 décembre 1991.

0/91/380

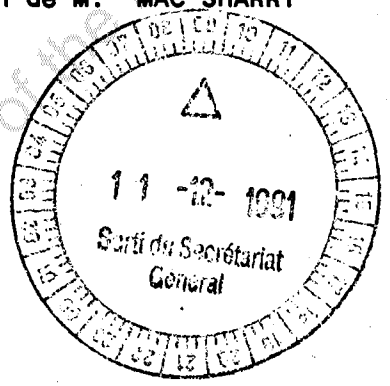
O.J. 1086 - point 11

(Nouvelle version suite à la
réunion hebdomadaire des Chefs
de Cabinet du 6 décembre 1991)

TEXTE E

PROPOSITION DE DECISION DU CONSEIL CONCERNANT LA BST

Communication de M. MAC SHARRY



- Cette question est inscrite à l'ordre du jour de la 1086ème réunion de la Commission le mercredi 11 décembre 1991

Destinataires : Membres de la Commission
MM. LEGRAS, KRENZLER, PERISSICH, DEGIMBE, BRINKHORST, FASELLA, BARLEBO-LARSEN, WILLIAMSON, DEWOST

Explanatory Memorandum

Bovine Somatotrophin

1. On 27th September 1989 the Commission presented a report to the Council and to the Parliament concerning the administration of bovine somatotrophin to dairy cows as a productivity aid to milk production[1].

   It proposed the establishment of an evaluation period up to the end of 1990 on the administration of BST in the Community. It also indicated that this period was considered to be the minimum necessary to assess the results of the ongoing studies and develop new arrangements to be adopted on procedures in relation to such products. By its decision 90/218/EEC of 25th April 1990[2] the Council agreed to the request of the Commission and subsequently agreed by its decision of 4th February 1991[3] that an additional time up to 31 December 1991 was necessary to enable the studies under way to be completed and the results to be considered.

2. In the meantime several studies have been made into the various aspects of BST and a further interim report in the matter will be presented to the Council and to the Parliament shortly.

3. The Commission can indicate already that more time will be needed to arrive at definitive conclusions. Accordingly it is proposed that the Council decide to extend the existing evaluation period up to 31 December 1993. This will enable the Commission to present its further conclusions accompanied by proposals concerning future arrangements by 30th June 1993 at the latest.

4. The Decision would have no financial consequences.

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(1) [COM (89) 379 final]
(2) O.J. No L 116, 08.05.1990, p. 27
(3) O.J. No L 37, 09.02.1991, P. 39

Draft
Proposal for a
COUNCIL DECISION
of .....
amending Decision 90/218/EEC on the placing on the market and administration of Bovine Somatotrophin (BST)

(../.../EEC)

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community, and in particular Article 43 thereof,

Having regard to the proposal from the Commission[1],

Having regard to the opinion of the European Parliament[2],

Having regard to the opinion of the Economic and Social Committee[3],

Whereas by Decision 90/218/EEC of 25 Aprtil 1990 on the placing on the market and administration of bovine somatotrophin[4], as amended by Decision 91/61/EEC of 4 February 1991, the Council called on the Member States to prohibit, until 31 December 1991, the administration of bovine somatotrophin on their territory by any means whatsoever to dairy cows in view of the fact that the consequences of such administration were not yet sufficiently clear;

Whereas the time set for studying the effects and consequences of BST has proved too short; whereas the research initiated has only been partially completed; whereas sufficiently representative results have not yet been obtained, in particular from the point of view of animal health and welfare; whereas in-depth studies should continue in order to secure the additional data needed; whereas, finally, further deliberation is necessary regarding some aspects of consistency with other Community policies;

Whereas, in order not to anticipate the results of these studies, the prohibition regarding the placing on the market and administration of BST should be extended until a later date,

HAS ADOPTED THIS DECISION:

1 OJ No C..
2 OJ No C ..
3 OJ No C..
4 OJ No L 116, 8.5.1990, p.27.

Article 1

Decision 90/218/EEC is amended as follows:

1. Article 1 is replaced by the following:

"Article 1

The Member States shall ensure that, until 31 December 1993, the placing on the market of bovine somatotrophin and its administration on their territory to dairy cows by any means whatsoever will not be authorized."

2. Article 4 is replaced by the following:

"Article 4

The Commission shall, by 30 June 1993 at the latest, present the European Parliament and the Council with a report on the situation together with proposals for future arrangements."

Article 2

This Decision is addressed to the Member States.

Done at ... ,

For the Council
The President

COMMISSION
DES
COMMUNAUTES EUROPEENNES

Bruxelles, le 16 décembre 1991

Secrétariat Général

0/91/380

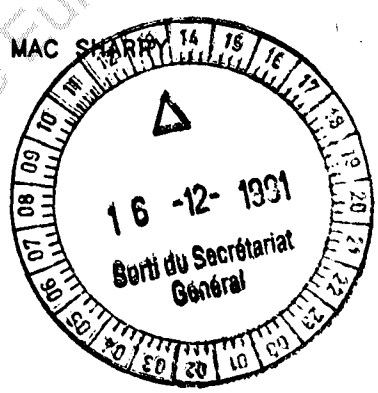
COM(91)522/4

O.J. 1087 - point 15

(Nouvelle version du rapport suite à la réunion spéciale des Chefs de cabinet du 13 décembre 1991. Remplace celle du document COM(91) 522)

2eme RAPPORT DE LA COMMISSION AU CONSEIL ET AU PARLEMENT SUR LA BST

Communication de M. MAC SHARRY



- Cette question est inscrite à l'ordre du jour de la 1087ème réunion de la Commission le mercredi 18 décembre 1991

Destinataires : Membres de la Commission
MM. LEGRAS, KRENZLER, PERISSICH, DEGIMBE, BRINKHORST, FASELLA, BARLEBO-LARSEN, WILLIAMSON, DEWOST

COMMISSION
OF THE
EUROPEAN COMMUNITIES

Directorate-General for Agriculture

VI/B/II.2

NOTE/1042

Second Report
from the Commission to the Council
and to the Parliament
concerning
Bovine Somatotropin (B.S.T.)

CONTENTS

Second Report from the Commission to the Council and to the Parliament concerning Bovine Somatotrophin (B.S.T.)

INTRODUCTION

1. On 27th September 1989 the Commission presented a report to the Council and to the Parliament concerning the administration of bovine somatotrophin to dairy cows as a productivity aid to milk production(1).

   It proposed the establishment of an evaluation period up to the end of 1990 on the administration of BST in the Community. It also indicated that this period was considered to be the minimum necessary to assess the results of the ongoing studies and develop new arrangements to be adopted on procedures in relation to such products. By its decision 90/218/EEC of 25th April 1990(2) the Council agreed to the request of the Commission and subsequently agreed by its decision of 4th February 1991(3) that an additional time up to 31 December 1991 was necessary to enable the studies under way to be completed and the results to be considered.

2. The present report should be considered together with the first report submitted to the Council in 1989. It may be recalled that two pharmaceutical companies (Monsanto, Eli-Lily) have made applications for marketing of products containing rBST in the Community, whilst others may be interested. To the knowledge of the Commission a number of third countries have authorized the use of BST. These include Mexico, Brazil, U.S.S.R., Czechoslovakia, Bulgaria, South Africa, Namibia and Zimbabwe. On the other hand no authorisation has been given in the United States, Canada, New Zealand, Austria, Switzerland and the Nordic countries. (However, the US Food and Drug Administration has ruled that residues of BST do not present a risk for public health and that food from treated animals may therefore be used for human consumption).

3. BST is an issue which gives rise to considerable interest among consumer, agricultural and industry interests. In this context concerns have been expressed about the safety to humans, animals and to the environment, the quality of milk, the economic and social consequences in agriculture, the climate for research and development, industrial competitiveness and trade implications.

   The present report describes the current status of the evaluation of BST. The Commission will present a more detailed report in 1993.

(1) [COM (89) 379 final]
(2) O.J. No L 116, 08.05.1990, p. 27
(3) O.J. No L 37, 09.02.1991, P. 39

4. Industries involved in biotechnology are concerned to ensure a stable regulatory framework for their activities. The Commission considered this question in its recent Communication to the Parliament and the Council concerning 'Promoting the competitive environment for the industrial activities based on biotechnology within the Community' [Sec (91) 629 final]. In this it is indicated:

> 'Not all products derived through biotechnological methods will require a specific assessment and/or authorization procedures. Currently the vast majority of biotechnology products are produced through traditional methods (eg. cheeses, malt extracts, beers and yeasts). As far as new biotechnology products are concerned, which involve gene manipulation, each product will have to be considered on a case-by-case basis and assessed as necessary....'
>
> 'The approach now applied by the Community, based upon the correct and thorough application of the criteria of safety, quality and efficacy, in conjunction with relevant horizontal legislation, ensures consumers' safety and economic interests and permits the protection of human, animal and plant health and of the environment. Furthermore, in order to ensure that the consumer protection aspect is covered, the impact on consumers' information and choice needs to be taken into account....'
>
> 'As a rule, decisions have to be based upon objective assessments using clearly identified criteria. Uncertainties about product acceptance and authorization could result in a diversion of investment and could act as a disincentive for innovation and technological development by industry. The Community must however guarantee the public that the industry is properly controlled. The dynamism of the industry and the confidence of public opinion depend on the ability of the Community to reassure both parties.'
>
> 'Where a biotechnological product is assessed, the three traditional criteria, based on scientific evaluation apply. By their nature, socio-economic aspects need to be considered in a different way. It is not the intention to have another systematic assessment in addition to the three criteria. The Commission will normally follow scientific advice. The Commission reserves the right, however, to take a different view in the light of its general obligation to take into account other Community policies and objectives. This might, in exceptional cases, lead to requirements for further information. It might equally, in exceptional cases, lead the Commission to propose that other policies be modified in the light of biotechnological developments.'

Similar considerations arose in connection with the Commission's proposal for a Council Regulation (EEC) laying down Community procedures for the authorization and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products of 14th November 1990 (COM (90) 283 final), where the following consideration was expressed in connection with the authorisation procedures for veterinary medicines:

'Whereas in the interests of public health it is necessary that decisions on the authorization of such medicinal products should be based on the objective scientific criteria of the quality, the safety and the efficacy of the medicinal product concerned to the exclusion of economic or other considerations; whereas, however, Member States should exceptionally be able to prohibit the use on their territory of medicinal products for human use which infringe objectively defined concepts of public order or public morality; whereas moreover a veterinary medicinal product may not be authorized by the Community if its use would contravene the rules and objectives laid down by the Community within the framework of the Common Agricultural Policy.'

5. The European Parliament has also adopted several Resolutions (see Annex IV) dealing directly with this matter. Of particular note are the Resolutions on Biotechnology in the European Farming Industry (16 February 1987) and on Hormones and the BST Hormone in the Dairy and Meat Industry (5 July 1988). The general thrust of the Parliaments approach is that biotechnology products should be directed less to increasing production and yields and more to improving quality and health.

6. Products containing or consisting of BST are veterinary medicinal products within the meaning of Directive 81/851/EEC on the approximation of the laws of the Member States relating to veterinary medicinal products (4).

As such, they are subject to a system of prior marketing authorization, which is granted by Member States, based on the traditional criteria of quality safety and efficacy.

However, in the case of veterinary medicines derived from biotechnology, the opinion of the Committee for Veterinary Medicinal Products must be obtained, through the special Community concertation procedure established by Directive 87/22/EEC (5), before any final national decision on the authorization of these products can be adopted . The CVMP is composed of the representatives of the regulatory authorities of the 12 Member States and the Commission. Hitherto the CVMP has been requested to give an opinion in respect of two application for authorization submitted by the Monsanto and Eli Lily companies.

Following the entry into force on 1 January 1992 of Regulation (EEC) 2377/90 laying down a Community procedure for the establishment of maximum residue limits of veterinary medicinal products in foodstuffs of animal origin (4), Member States may not authorize veterinary medicinal products containing or consisting of B.S.T. unless the Commission has adopted to include BST in Annex I, Annex II or Annex III of that regulation. Once the Commission has adopted maximum residue limits (MRLs) for a compound, or determined that it is not necessary for the protection of public health to establish MRLs, Member States may not prohibit or impede the free circulation of foodstuffs obtained from treated animals on residue grounds, if the residues fall within the prescribed limits.

The inclusion of BST in one of the Annexes to the Regulation would eliminate difficulties in intra-Community trade relating to the health aspects of BST; However, because the final decision on authorization of products containing BST remains at the national level, divergent national decision could result in difficulties in intra-Community trade in relation to the competition aspects. Moreover, on the eve of the internal market, there would be difficulties in explaining such decisions at international level.

Because of the disadvantages of the current system of national authorizations for veterinary medicinal products, in particular those derived from biotechnology, or intended for use as performance enhancers, on 14 November 1990, the Commission presented a proposal for a Council Regulation laying down Community procedures for the authorization and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products (COM (90) 283 final). This proposal, which would provide for a centralized Community authorization procedure in cases such as BST, is currently under consideration by the Council.

The fourth recital of the proposal describes the Commission's approach in these cases :

"Whereas in the interests of public health it is necessary that decisions on the authorization of such medicinal products should be based on the objective scientific criteria of the quality, the safety and the efficacy of the medicinal product concerned to the exclusion of economic or other considerations ; whereas, however, Member States should exceptionally be able to prohibit the use on their territory of medicinal products for human use which infringe objectively defined concepts of public order or public morality ; whereas, moreover, a veterinary medicinal product may not be authorized by the Community if its use would contravene the rules and objectives laid down by the Community within the framework of the common agricultural policy."

7. In drawing up this report the Commission has made use of a number of studies and analyses: Firstly, within the Committee for Veterinary Medicinal Products (CVMP concertation procedure (Directive 87/22/EEC), see Annex III) the aspects of the safety, quality and efficacy of the products for which authorization for marketing has been requested are examined.

A further five independent studies have been undertaken at the request of the Commission. Four have been carried out in Germany, namely:

a) 'Research to improve the bacteriological characteristics of raw and heat-treated milk (BST-treated cows) - increased number of somatic cells, influence on quality and yield, processibility, mastitis' prepared by Bundesanstalt für Milchforschung, Kiel (1991).

b) 'Research into lactation physiology in dairy cows' by Institut für Physiologie, TU München/Weihenstephan (1991).

c) 'Producers and consumers as factors in increasing disposals of milk and milk products in the Community' by IFO-Institut für Wirtschaftsforschung, München (1991).

d) 'Effects of the use of somatotrophin on consumption of milk products' by Institut für Agrarpolitik, Giessen (1991).

The fifth more general study was: 'Study on the impact on animal husbandry by the use of growth promoters in animal feed and other productivity enhancers' prepared by CEAS Consultants (Wye) Ltd. (1991) (CEAS I).

In addition the Commission has considered the studies 'BST and the consumer: an overview of perception and practices' prepared by CEAS Consultants (Wye) Ltd. (1989) (CEAS II), and 'U.S. Dairy Industry at a Crossroad: Biotechnology and Policy Choices', Congress of the United States, Office of Technology Assessment (Washington D.C., May 1991).

The Commission Services has undertaken analyses of this work.

SUMMARY

8. This report covers both the traditional aspects about safety, quality and efficacy of recombinant Bovine Somatotrophin (BST) as well as an evaluation of consumer and producer attitudes, repercussions on the agricultural markets, the budgetary consequences and the environment.

9. Safety, quality and efficacy

In terms of safety, quality and efficacy these seem to be satisfactorily addressed in relation to the Monsanto product except for the question of possible increased incidence of mastitis and injection site reactions in dairy cows treated with BST which have not received a satisfactory answer according to experts from five Member States.(p.m. Lily)

As far as quality is concerned the product studied is in accordance with the requirements of the Community Directives. The Committee on Veterinary Medicinal Products (CVMP) which studied the Monsanto product is satisfied that its use does not affect the quality of milk or meat. However, some doubts still exist about the possible implications of increased somatic cell counts.

In terms of efficacy, it is estimated that milk yield in well managed dairy herds will increase by 12%. However, the increase is likely to be in absolute terms for both medium and already high yielding cows - giving a relatively bigger increase for the medium yielding dairy cows. The increase will vary between 2.5-5.7 kg per day.

Finally, it should be pointed out that so far no comprehensive studies of the welfare of animals treated with rBST have been reported in public literature. Another application for authorization from the Lily Company is also being studied.

8. Consumer and producer surveys

a) The consumer surveys were carried out in four Member States: Germany, France, Italy and the United Kingdom, representing 70% of the Community population.

The survey shows that the reaction , by consumers of milk and milk products, to the use of genetically engineered B.S.T. growth hormone in milk production, would imply a reduction in consumption in all four countries. However, they are marked scatters between consumers and the individual products/product groups in the different Member States.

The survey carried out in 1989 (CEAS II) and commissioned by the U.K. National Office of Animal Health shows clearly that:

- The rejection rates of food-production practices involving the use of chemicals are higher than those of any other practices, including those related to animal welfare.

- The rejection rate of the use of BST is the highest recorded.

b) The producer survey carried out in 6 Member States (UK, Germany, France, Netherlands, Denmark and Ireland) representing 52% of producers, 75% of cows and about 80% of milk production, shows strong opposition to the use of BST. This reflects concern about the potential impact on the dairy market. Secondary considerations for producers are the issues on animal health and welfare.

Should BST be approved, many producers indicate an interest in using this new technique.

10 Agricultural markets - Dairy sector

a) Consumption

The effect on agricultural markets will depend heavily on consumer behaviour. If the surveys' estimates of consumer reaction is to be taken as the basis for the assessment, then the market effects could be quite dramatic in terms of excess supply and budgetary consequences.

The milk market continues to experience difficulties in spite of reduction in quotas (the most recent reduction of 2% decided in the price package 1991/92 was not considered sufficient). This led the Commission in the context of its reform proposals to propose reductions in milk quotas by a further net 3% in order to bring the market into balance. In the detailed rules proposed, it also sought to discourage developments eg. through equalisation of deliveries for levy purposes, that might lead to production over quota. Any additional decrease in consumption as the result of the introduction of BST would further exacerbate the imbalance on the milk market which has a structural surplus of some 15%.

Different outcomes can be contemplated, ranging from a very sharp consumer reaction, a smaller reaction than predicted by the surveys, or even a situation with only a slight reaction, as one survey predicts. All outcomes predict some decrease in consumption.

Recent market developments in relation to milk substitutes are relevant also in considering authorisation of BST. There has been sharp growth in the substitute milk products sector in recent years, mainly at the expense of butter whose consumption is falling at an annual rate of some 40.000 tons. It is likely that the image of milk and milk products from the health viewpoint would be severely tarnished since promoters of competing products

could be expected to ruthlessly exploit the use of the BST. In the case where a sharp reduction in consumption is assumed - survey results suggest that this could be as high as 20% - there would have to be a corresponding quota reduction with adverse consequences for the beef sector also and for agriculture generally.

b) Production

BST could be used on a regular basis during a part of the lactation period. Producers might use the drug in the context of acquisition or leasing of milk quota from other producers, or by reducing the number of cows or perhaps in anticipation of shortfalls by other producers which could be compensated through the equalisation arrangements at the level of the dairy.

BST can also be used as a tactical tool to avoid shortfall of a producer's individual reference quantity; in that case the number of cows would remain unchanged.

The significance of regular or tactical use would vary between Member States. The use of BST will depend on 1) the price of BST 2) the price of extra quota 3) the cost of extra fodder and 4) the value of alternative use of land in case of a reduction in cow numbers.

Leaving aside the possible consumer reaction and taking account of present quota levels, a conservative estimate based on the CEAS I study suggests that in the short term, BST would be administered to 20% of all dairy cows in the Community, at some point during their lactation period. In the medium-long term (over 5-10 years) this proportion would rise to 55%, according to the Commissions estimate.

An important explanation for the relatively limited use of BST is that it is assumed that herds with 15 cows or less would not use BST on a regular basis because of practical (too few cows) and economic constraints. In this respect regular use means systematic use during a part or most of the lactation period - not necessarily during the whole period.

According to the Commissions estimation the basis of an increase in yield of 12%, applied to 55% of the dairy cows concerned and assuming the low yielding cows will not use BST, the potential for extra milk production as a result of the use of BST is in the range of 6% to 10%. However other surveys suggest that in the medium term a figure of 5% is more likely.

'Extra' milk does not necessarily mean an increase in deliveries but represents the share of BST-milk, out of total milk production. This implies, in a quota system, a reduction in the number of dairy cows, an increase of quotas, or exceeding existing quotas.

The Commission estimates that over the period 1992-1998, the reduction in cow numbers would be in the range of 4% to 6%, additional to the normal decline in dairy cow numbers.

The main benefit for the medium and larger producers, who would find it worthwhile to use BST regularly, would be a reduction in production costs for those reducing cow numbers or increased margins for those who purchase or lease extra quota from other producers. Smaller farmers would not normally use BST.

The quota system in the milk sector should limit the economic incentive for using BST.

However, there are two elements that need to be considered. Strenuous efforts will have to be made to bring deliveries within quota. BST would be unhelpful to this effort. In the second place any instrument that increases the quantity of milk in the system creates pressures for extra quota, encourages fraudulent devices to avoid payment of supplementary levy, and destabilizes markets.

11. Other agricultural sectors

As far as other agricultural sectors are concerned, the greatest area of concern is the beef sector.

For beef production, reduced numbers of cows implies an increase in slaughterings which could in the short-term worsen the beef market, already well out of balance.

In the medium to long term, the replacement of dairy cows by suckler cows and/or other beef animals would have a negative impact also on the balance in the beef market, though the reduction in the number of calves from dairy herds would be an offsetting factor.

As far as other land uses are concerned, the consequences are not significant.

12. Environment and Structures

Since only the larger dairy herds (more than 15 cows) are likely to use BST on a regular basis, there is likely to be further concentration of milk production in the more intensive producing regions and greater pressure on smaller farms.

This may lead to higher concentration in intensive producing regions and add to local environmental problems. In terms of overall production of animal waste, the consequences of BST introduction would be significant if milk cows were replaced by greater numbers of suckler and/or other beef animals.

13. CAP Reform

In the Commission's Communications on the Development and Future of the Common Agricultural Policy (February and July of 1991) it was concluded that the present structural surpluses had largely arisen because of the direct link between support and quantity produced.

The general thrust of the communication was that the Community should discourage intensification, encourage quality and seek to maintain sufficient number of farmers on the land so as they could fulfill a dual function of producers of food and guardians of the countryside.

In the milk sector, the proposals involve a further reduction of a net 3% in quotas, measures to avoid a quota cut for small producers, and support for promotion in order to redress the decline in consumption of some dairy products eg. butter. In the beef sector, the proposals involve price reductions, with increased premiums conditional on fulfilling extensification criteria and subject to a ceiling on eligible numbers. A promotion scheme to encourage greater consumption of beef, which was especially affected by the BSE controversy, was proposed also.

To the extent that BST encourages extra quantity rather than quality it tends to run counter to the objectives of the reform. Authorisation of BST with the accompanying risks to consumption would seem to be inconsistent also with the policies to promote milk products.

At the socio/structural level producers with smaller herds are not likely to benefit from the use of BST for practical and economic reasons. BST is likely also to accelerate the trend towards the reduction in the number of dairy farms and the trend towards fewer but larger herds with bigger concentration in certain regions.

The use of BST, resulting in higher marginal returns will be capitalized in the value of the milk quota making it more difficult for producers not using BST to acquire extra quota.

As far as repercussions on the beef market are concerned replacement of dairy cows with animals for beef production would have a negative effect on market balance. There would be more immediate problems for the market in the event of a sharp up take of BST leading to the slaughter of a significant number of cows.

14. Control and Labelling

Since the use of BST is of public concern it would be necessary to consider controls to check observance of Community regulations.

a) Control of the manufacture and distribution of BST should be no more complex than for other pharmaceutical products. While the nature of the treatment would appear to require limiting administration to professional veterinarians this could be difficult in practice.

b) Checking of residues in both indigenous and imported livestock products cannot be realistically executed within current technology and practice, because of the levels of naturally occuring hormone present in samples.

There is currently no forensic detection method to analyse the use of the rBST hormone in dairy cows. Current methods permit a degree of general monitoring, but this requires taking blood samples in the cow stall. Taking the example of simultaneous recording of growth hormone and the growth factor IGF 1, it appears that an error rate of 20% is to be expected. A possible alternative would be the regular, individual monitoring of milk yield graphs.

Any control measures to be introduced would in practice be limited to the level of the farm, veterinary practice and pharmaceutical distribution channels.

At the present state of knowledge it seems impossible, however, to satisfy consumer demands for an effective labelling system to distinguish milk products obtained by using BST.

15. ETHICS

In its communication to the European Parliament and the Council on promoting the competitive environment for the industrial activities based on biotechnology within the Community of April 1991 (SEC (91) 629 final), the Commission felt it desirable that the Community has an advisory structure on ethics and biotechnology which would be capable of dealing with ethical issues where they arose in the course of Community activities. Following this commitment , a Group of Advisers on the Ethical implications of Biotechnology has been set up by the Commission

In view of concerns expressed on animal health and welfare, the Commission considers that it would be appropriate for the Group to provide an appraisal of the potential ethical impact of the application of growth enhancers in agriculture and fisheries. The Commission will therefore request the Group to deliver an opinion on this matter.

16. External Aspects

The main concern from an external commercial policy point of view, is to ensure that any measure taken by the Community is compatible with our international obligations in general, and with the GATT in particular.

It shall be recalled that the GATT (General Agreement and TBT Code) refers only to the traditional criteria (quality, safety, efficiency).

If a decision on BST affecting trade were taken, the Community would have to notify to the GATT TBT Committee the precise criteria and justifications for the measures concerned. These criteria and justifications should be carefully selected in order to avoid any challenge by third parties.

In addition, the US Authorities expressed concern after the publication of the EC Communication on biotechnology (SEC (91) 629 final) as elements going beyond the three normally admitted criteria for the authorisation of human or veterinary medicines.

The US has already sought to compare the BST case with that of hormones in meat. In the hormones case, the US took unilateral trade measures against the Community which are still in force.

17. Conclusions

a) BST represents an important technological advance which because of the magnitude of the productivity effect, the animal welfare aspects and the potential effects for consumption and the markets, as it is not a therapeutic product it needs special attention.

b)) The Community must, in the first instance, ensure that prior to authorisation products are safe for humans, animals and the environment. In the case of BST, product so far examined, while the criteria of "quality" and "efficacy" appear to have been satisfied certain aspects of "animal safety" need to be further clarified.

The issue of increased incidence of mastitis and injection site reactions has been the subject of divergent views among the experts. Use of BST may be inconsistent also with the efforts being made by the Community to reduce the somatic cell count in milk for the market.

The Scientific Veterinary Committee (SVC) has noted that "... no comprehensive studies of the welfare of animals treated with BST have been reported in the publicly available literature ...." and that adequate information should be available on ".... questions such as disease incidence, physical disorder, injuries, behaviour on physiology....". Information on these topics has been supplied to the CVMP for the two BST products under consideration and the CVMP is of the opinion that these concerns have been adequately met except for two questions - injection site reaction and the incidence of mastitis, which are currently under consideration on the basis of substantial new information.

c) According to the present state of knowledge, the use of rBST cannot be detected in milk and dairy products in practice. It would be difficult therefore, to ensure respect of labelling rules or other possible arrangements for partial or conditional approval.

d) Consumers' organisations are opposed to the authorisation of BST as long as no labelling provisions can be made. Consumer surveys show a negative reaction towards BST which is likely to be reflected in a sharp downturn in consumption of milk products. This would have serious adverse effects on Community agriculture, on the dairy industry in particular, and for the budget also. It could also damage the Community's export performance in milk products and in beef since there may be a reluctance on the part of some third countries to authorise BST and accept products from animals treated with BST.

e) The CAP reform proposals place the emphasis on quality rather than extra quantity of production. They seek to maintain also a socio/economic structure that would allow sufficient numbers of farmers to remain in agriculture to allow them to fulfil a dual role as producers of quality food and guardians of the countryside. (The introduction of BST would appear to be contrary to these objectives.)

f) Because of outstanding questions in relation to animal health and welfare, the need for greater clarity on the ethical aspects, and the need to investigate the possibility of a common approach by the principal countries involved in producing, exporting and importing dairy products, it is considered that more time is needed to evaluate all the elements involved. It is considered also that in the interests of the single market, a final decision in relation to the authorisation of BST should continue to be made at the Community level. With this in mind the Commission will aim to present its final conclusions and a proposal to the Council by 30 June 1993. In the meantime it is proposed that the existing evaluation period be extended to 31 December 1993 to enable a decision to be taken within the time scale envisaged.

Any measures taken should be compatible with international obligations of the Community.

ANNEX:

I Study Findings

II Opinion of the Committee for Veterinary Medicinal Products

III Resolutions of Parliament

IV Extract from Commission Communication to Parliament and the Council concerning 'Promoting the competitive environment for the industrial activities based on biotechnology in the Community'

PART I

STUDY FINDINGS

SAFETY, QUALITY AND EFFICACY

The aspects of safety relate to safety for humans, animals and the environment. It also covers food product quality. Quality relates to the chemical characteristics of the products whereas efficacy relates to the product actually achieving what it pretends to do.

1. BST

Recombinantly derived BST products may have slightly different chemical structures from natural BST produced by the pituary gland, adding a number of additional amino acids. Each product must be considered on its own merits. The additional amino acids that may be produced, however, may not change the active part of the molecule and as such may not change the biological activity of BST in dairy cows or the inactivity of BST in humans.

2. Opinion of the Committee on Veterinary Medicinal Products (CVMP) and other observations

The CVMP has delivered in March 1991 its opinion on the rBST product 'SOMATECH' submitted by Monsanto.

In respect of that product the following statements can be made.

3. Quality of rBST

The product studied can be manufactured to produce a homogeneous stable product, with a shelf life of 18 months, in accordance with the quality requirements laid down by Community directives.

4. Efficacy of rBST

The CVMP 'considers that the manufacturer has demonstrated that SOMATECH is effective in producing a significant increase in milk yields in treated cattle. The extent of this increase in yields depends, amongst other factors, on the breed of animal treated, the individual animal treated, the stage in lactation cycle at which the product is administered and the quality of animal husbandry techniques used, but may be expected to be in the range of 2.5-5.7 kilogrammes per day' in the lactation period.

The US Congress study presents this aspect in a slightly different way stating that 'successful adopters on average would experience a 12 per cent boost in production. However, the increase in output per cow tends to be absolute (in number of pounds) rather than proportional to normal production. Thus approximately the same increase in pounds of milk produced might be expected (in comparably managed herds) from all cows producing 12.000 to 20.000 pounds of milk per year'.

The CEAS I study talks about 'responses of 15-25% as being the most usual. After the initial injection, milk yield increases rapidly and with continued treatment the lactation curve then remains higher and about parallel with that of control animals for the rest of the lactation. There are some records of the gap widening as the slope of lactation decline becomes steeper in the controls than in treated cows'. This last comment reflects the possibility of extended lactation periods as seen in the trials.

Feed intake

The CEAS I study states 'Voluntary feed intake usually increases, but not until 5-10 weeks after the first treatment. When this occurs, it compensates wholly or in part for the earlier negative nutritional balances.' It further states that 'BST treatment does not affect the digestibility of feeds and there is no evidence that it improves the efficiency with which absorbed nutrients are converted into milk or for maintenance of the animal. But because of the raised feed consumption with BST treatment, the proportion of the total feed consumed which is used for body maintenance is lower. Furthermore this maintenance 'overhead' is spread over a greater weight of milk produced. Hence the apparent or gross efficiency which food is converted into milk is improved.'

The US study concludes that 'Obtaining a milk response to BST does not require special diets or unusual feeds ingredients. Substantial milk responses have been observed on diets ranging from pasture to the more typical forage/concentrate diets used in the United States. However, voluntary intake of feed increases in BST-supplemented dairy cows.'

This observation may, however, depend to some extent on how BST would be used - since a catching up use in view of quota shortfall will more likely be obtained with concentrates (CEAS I).

5. Safety

5.1 Human safety

According to the CVMP, the applicant has demonstrated that residues of its product do not present any risk to the health of consumers of meat or milk obtained from treated animals and that the product may safely be accepted for use without any withdrawal period for meat or milk.

(In the literature and in the CEAS I study undertaken for the Commission, some questions are raised about the potential significance, from a safety point of view, of raised levels of insulin-like growth factor 1 (IGF-1) in milk because this hormone is apparently the same as human IGF-1. The CVMP specifically requested both companies to undertake further studies of this question, and concluded that the levels of IGF-1, which remain with the normal pysiological levels in untreated animals, were not a hazard to human health. A similar conclusion was reached by the FDA review of the safety of BST for humans).

5.2 Safety in the animal

The CVMP was unable to reach consensus on the acceptability of the product from the point of view of safety of the treated animals. Although the majority considered the manufacturer had provided sufficient guarantees on this point, five members considered that additional data were required on the incidence of mastitis and the importance of reactions at the injection site and the hygiene of this site before definitive conclusions could be reached. Because of the doubts expressed by certain delegations, the CVMP in its opinion makes the following qualifications (point 6 and 7):

'6. The Committee would emphasize that the successful use of SOMATECH will require the maintenance of high standards of animal husbandry. For this reason the Committee recommends that the product should be used only under veterinary supervision.

7. The Committee considers that it is important to verify that the results described in the application dossier for SOMATECH are confirmed during the practical use of the product in the field. For this reason, the Committee recommends that in addition to the specific study concerning the incidence of mastitis in treated animals referred to above, authorization to place SOMATECH on the market should be subject to a condition requiring the company to collect and evaluate all reported suspected adverse reactions to the product throughout the Community and to prepare an annual safety report for the five years following authorization.' - See Part III of this Annex for the detailed opinion.

The Commission's Scientific Veterinary Committee has also examined this aspect and has given the following opinion.

"The Committee is concerned that in discussions about the use of products resulting from biotechnology procedures, such as recombinant bovine somatotrophin, insufficient attention is paid to effects on the welfare of the animals treated with the product. Such a new product should not be licensed for general use unless adequate information from scientific studies of the welfare of animals treated with the product has been obtained and considered. Such studies should include measurements of welfare such as those of disease incidence, physical disorders, injuries, behaviour and physiology. These studies should be carried out over a period of the animal's life at least as long as the longest time that such an animal would be kept on a farm and in a variety of management conditions. Studies in commercial farm conditions should be included.

No comprehensive studies of the welfare of animals treated with recombinant bovine somatotrophin have been reported in the publicly available scientific literature. Work on the effects on the incidence of mastitis and other production-related diseases indicates that some welfare problems may exist but more comprehensive studies are desirable to clarify the extent of the problems."

5.3 Food product quality

The chemical structure and mode of action of each group of growth promoting agents is unique.

a) The Committee for Veterinary Medicinal Products which studied the use of 'Somatech', the Monsanto product, is satisfied that its use does not affect the quality of milk or meat nor will its use adversely affect the industrial processing of such milk into yoghurt or cheeses.

b) However, increased somatic cell counts (SCC) would have implications as regards the standards laid down in Directive 85/397 as regard Community marketing of milk for consumption and the price paid to producers for milk for manufacturing. An increase in somatic cell affects the composition of milk eg. the lactose/salts ratio, a factor that could influence product quality and yield.

c) The data acquired from the (Bundesanstalt für Milchforschung, Institut für Hygiene, Leiter: Prof. Dr. W. Heeschen) Study requested by the Commission indicate that for somatic cell counts 'cyclical increases' are dependent on initial cell count. Therefore, a careful assessment of udder health must form part of the recommendations prior to the use of rBST in a dairy herd. Existing Community dairy regulations regarding somatic cell counts in milk would indicate that in view of the risk of exceeding cytological thresholds, only dairy herds whose cell count does not exceed about 200 000/ml should be treated with rBST. The main reason for this recommendation is the fact that rBST would be given continuously, which does not occur with other treatments in this form using pharmacologically active substances.

5.4 Environmental impact

Environmental effects are important considerations where animal production is concerned. In general, intensive animal husbandry causes some concern in relation to the environment, largely on account of the problems of disposing of animal manure. However, where productivity enhancing measures have been introduced, in general, there is a reduction in the manure and methane produced per animal. This is normally derived from altering the partitioning of feed between growth (meat production) and energy (maintenance). Hence for some growth promoters the effect is to capture more of the nutrients in the form of meat rather than allowing them to be passed into the environment in the form of nitrogen,

phosphorous or methane.

As for growth promoters, the use of BST in milk production may reduce the emissions of copper, nitrogen and phosphorous and methane. However, the spatial distribution of the emission of manure is more likely to influence potential pollution difficulties.

It is envisaged that only larger dairy herds (more than 15 cows) will use BST on a regular basis. This implies a concentration of milk production in some regions with consequences for the environment in those areas as well as environmental changes for the areas where the reduction in dairy production occurs.

In terms of overall production of animal waste, the consequences of BST introduction will be significant as milk cows are replaced by a higher number of suckler and/or other beef animals. However, a negative local environmental effect will result if production becomes more concentrated.

5.5 Genetic selection

The adoption of any new technologies can influence breeding strategies and if new productivity enhancers were available and widely adopted, the prudent commercial response of the animal breeders would be to adapt their selection strategies to take the availability of these technologies into account.

An important issue is to avoid distortion in comparisons of performance testing of animals sold for breeding. Breeding stock purchasers must be confident that the performance data they use in assessing possible breeding stock are directly comparable. The introduction of BST would create doubts of the certainty in this area unless appropriate measures are taken at Community level.

In addition, the effect of the introduction of BST on the Community gene-pool needs further clarification.

5.6 Animal welfare

Mention of this aspect has already been made in relation to safety in the animal.

In general, issues of animal welfare are prominent in the debate in several parts of the Community and are of growing concern. Whilst animal welfare criteria are difficult to define in quantitative terms, it is clear that society as a whole is less willing to accept the use of technologies which are difficult to defend on this basis.

Again market factors operate and growing awareness of production methods has led to the market providing premiums for more 'animal-friendly' systems (eg., free range egg and poultry production and less intensive veal production systems). Whether or not less intensive systems are necessarily more animal-friendly remains an area of debate.

SURVEYS - CONSUMER AND PRODUCER ATTITUDES

6. Introduction

Consumer concerns can be summarized by three categories: price, quality (including safety) and choice. Productivity enhancements may lower price and this is the essential motor for society to seek technological progress in a market economy. Quality is a more complex issue.

The quality of a product can cover many different dimensions including the method (or even perceived method) of production. Quality perceptions are interlinked with price and perceptions of health and safety.

In order to investigate the possible repercussions on the consumption of milk and milk products in the Community in case of the introduction of BST, two surveys have been undertaken by German research institutes.

Despite the uncertainty which is normally experienced with this kind of survey, it can be assumed that the difference between the response to a hypothetical question and the actual behaviour in a real life situation will not be so great as to contradict the results.

The surveys do, indeed, give a clear picture about the attitudes of consumers and producers to the introduction of BST at the existing level of knowledge and information about the subject.

7. Consumer Surveys

a) The language used to disseminate information and educate people is an important factor in determining the level of understanding and attitude to a subject.

In this context it should be pointed out that the IFO study on consumer attitude to BST gives an explanation on BST before asking the key question to respondents.

'Presentation

You surely know that the production of milk in the body of an animal is a decidedly complex biochemical process. Research has succeeded in imitating one of the compounds which is responsible for the control of milk production in the body. The compound in question is the growth hormone BST (not to be mixed up with sexual hormones for the fattening of calves). Extensive experiments have shown that the milk yield can be increased considerably by BST. During the natural process of milk formation small amounts of BST always get into the milk. In the milk of BST-treated cows, this BST-component consists of a mixture of natural and additionally added BST-hormones. In the numerous investigations no hazardous effects for the consumer whatsoever have been ascertained so that there would be no objection against licensing the compound because of health reasons.'

b) This IFO consumer survey was carried out in the four Member States with the highest populations: Germany, France, Italy and the United Kingdom. These four countries account for 71.5% of the total population of the Community of 12. The findings were split up into three categories:

- 'refusal of products produced using BST' (100% level)
- 'greatly reduced consumption' (30%)
- 'somewhat reduced consumption' (10%)

The survey took in a total of seven product groups: drinking milk, milk-based drinks, all cheeses, butter, yoghurts and sour-milk products, cream and cream products and condensed milk.

The survey shows that the reaction, by consumers of milk and milk products, to the use of genetically engineered BST growth hormone in milk production, would imply a reduction in consumption in all four countries. However, there are marked scatters between consumers and the individual products/product groups in the different Member States.

The percentage of consumers who said they would boycott milk products totally was 17% in Italy, 13% in Germany, 12% in the UK and about 8% in France.

c) There was a very high positive response to the question whether products made with milk from farms using BST should be clearly labelled. Over 82% of respondents, as an average over the four countries surveyed, were in favour of such labelling. The rest were either indifferent to or against it. The UK had the largest percentage in favour, 87%, with Italy next with 85%. The figures for Germany and France were around 80% and 77% respectively.

d) On the question of purchasing behaviour, 45% on average in the four countries stated that they would generally prefer products made from milk produced in farms not using BST ("BST-free" milk). This attitude is particularly marked in Italy, with 57%. Consumers in Germany are above the average at 49% while France is just under, at 43%. In contrast, only 29% expressed this intention in the UK.

There is also an appreciable proportion of consumers who would prefer to buy products made with milk from non-BST-using farms, but only if the price for 'BST-free' products were acceptable.

e) The result of the IFO consumer survey indicates a high degree of opposition to allowing BST. If we add together all consumer groups who indicated they would change their consumption patterns if BST were registered by buying somewhat less milk, much less milk or no milk at all, about 65% of respondents in Germany and Italy and about 40% in the UK and France would change their habits.

This consumer survey extrapolated to the Community as a whole, shows that there would be an appreciable reduction in consumption. Taking account only of the 'total boycott' group, the reduction in consumption would amount to some 11 million tons of milk which corresponds to 480.000 tons of butter and 985.000 tons of skimmed milk powder.

If, in addition, account is taken of those consumers who alleged they would reduce their consumption by 30%, the decline in demand would be around 17 million tons. This would correspond to 750.000 tons of butter and 1,5 Mill tons of skimmed milk powder.

A total of 70% of all respondents believe that the use of BST would change the quality of milk products, with the main damage being to the healthy image, the property 'free of additives', naturalness, taste and the levels of nutrients and other components.

As far as the reasons for not buying are concerned, health concerns and the unnaturalness of somatotrophin were by far the most important (53%), followed by inadequate information (14%) and insufficient tests and research (7%).

f) 1989 CEAS Study (II) 'BST and the consumer: an overview of perception and practices'

The study is based on surveys which were carried out only in the United Kingdom and Germany.

It reflects the very limited knowledge of consumers about dairy practices. Nevertheless, it indicated the degree to which consumers would avoid buying milk if they were aware of different production methods used. The proportion of respondents who would avoid buying milk can be summarised as follows:

Production methods used	% respondants who would avoid buying milk
1. normal intensive farming practices e.g. artificial insemination, machine milking	3 - 12
2. practices which impinge on Animal Welfare issues e.g. dry cow therapy, keeping cows in enclosed concrete yards for 5-6 months per year	18 - 26
3. use of chemical additives in feed and hormones to regulate breeding . .	33 - 38
4. use of hormones (BST) to regulate milk yields	45

This clearly shows that BST registered the greatest concern amongst the respondents.

g) Labelling of milk

The 1991 consumer surveys as mentioned indicate strong preferences for labelling if BST is licensed.

The CEAS Study (1989) arrived at the same conclusions saying:

> 'If BST were to be approved for commercial use, the most frequently suggested method of allowing consumers the choice of purchasing milk containing BST or not would be to label milk according to its method of production. Whilst milk suppliers are not currently obliged to provide such label information it appears that a majority of consumers are in favour of milk being so labelled.'

More specifically, this CEAS survey identified that if milk was labelled according to its production techniques, 45 per cent of respondents said that they would avoid milk produced using BST.

Finally the CEAS Study (1989) makes the following recommendation:

'Even if milk does not become labelled according to production technique (the practicalities of implementation, policing and clarity in labelling would be extremely difficult to achieve), there remains a clear need for improving the provision of consumer information relating to BST and the subject of biotechnology.... The information should be presented in a non-technical and neutral manner by trusted sources of information.'

The US Study also addressed this question.

Finally, Community consumer surveys indicate that the use of rBST would be regarded as changing the quality of milk and destroy its natural product image.

8. Producer survey

a) The producer survey was carried out across six Member States: Germany, France, the United Kingdom, the Netherlands, Denmark and Ireland. These six account for just under 52% of the Community's milk producers and about three-quarters of its dairy cows (EUR 12).

Awareness of Bovine Somatotrophin (BST) varies greatly between the individual Member States but less so between the regions in a single Member State. As could be expected, milk producers with large herds show a greater awareness than those with small herds.

Milk producers were asked about their attitudes to the following aspects of BST:

- should its use be allowed?
- would they use it on their own herds?
- would they use it if there were a difference in price and market between milk produced with and without BST?

b) The most striking result of the survey was the unequivocal rejection of moves to allow use of BST. Only a small minority argued for its registration; the vast majority wanted a ban. This finding even applies in France and Ireland where there is a generally higher acceptance of BST - even in these countries there is only one category of holding in which the percentage 'for a ban' is less than twice the percentage 'for registration'.

Just as striking is the finding that only a minority of producers would use BST immediately if it were to be allowed. Nevertheless, there is also no clear majority (meaning more than 50%, except in the UK) of producers who would definitely do without BST in any case. A similar proportion of producers intend first to wait and see whether their concerns about animal health can be put to rest, whether there are commercial advantages and not least whether there are likely to be adverse effects on the development of the milk and milk-products market, before they decide for or against using BST.

c) The results of the survey reflect the uncertainty about consumer reaction as discussed above. Producers are clearly very concerned about possible negative market repercussions and as such their opposition is not surprising.

Only as a secondary consideration is the question of concern about animal health/welfare.

This is confirmed by the finding of the survey that should BST be allowed, there would be a relatively rapid uptake by milk producers.

9. EFFECT ON THE MILK MARKET

This effect will depend largely on two factors - adoption rates and consumer reaction.

a) As mentioned above, several different scenarios can be envisaged in terms of consumer reaction.

The IFO consumer survey suggests a drop in consumption of 17 to 18 Mill tons whereas the CEAS II-study concludes that a lesser reaction should be expected. The US-study operates with two possibilities - a) a 10% drop in consumption on a permanent basis or b) a 10% drop in consumption of a temporary nature. The US-study does not attempt to justify these assumptions, but uses them merely to calculate through the economic and budgetary consequences.

Each 1% drop in milk consumption in the Community represents 46.000 tons of butter and 89.000 tons of skimmed milk powder. Since outlets outside the Community can hardly be increased without negative budgetary and trade effects, a further reduction in milk quotas would be necessary to match any drop in internal consumption in the Community.

There is, moreover, the aspect of milk substitutes which deserves mentioning in relation to BST.

In the Third Commission report to the Council on "Developments on the Market in Milk Products and Competing Products" (Sec (91) 1297 final) it is concluded that, amongst others, there is:

- greater consumption of cheeses and a stabilization in the consumption of milk and milk products;

- a considerable drop in the household consumption of butter, particularly in Member States where competing products are more developed;

- a considerable increase in sales of mixtures of milk- and non-milk fats;

- continuing consumer confusion due to the names, labelling and positioning in stores of milk products and their competing products.

There has been considerable growth in the substitute milk products sector in recent years, notably in the yellow fats sector and more recently in the cheese sector. This growth has come about mainly due to consumer confusion which has arisen as a result of unsubstantiated health claims and/or oversimplification of research findings, particularly in relation to heart disease and its causative agents. This has lead to the use of some dubious and emotive advertising by the industry producing milk substitutes'. Were BST to be allowed, it cannot be ruled out that this industry would attempt to even more profit through such advertising.

b) In terms of adoption rates there is considerable uncertainty.

(i) In the US Study a survey of dairy farmers, found that about 50 per cent of respondents would adopt BST within the first year of its commercial availability, and that over 80 per cent would within 3 years. Most analysts, relying heavily on such studies, have tended to assume relatively rapid adoption of BST. However, the use of surveys to indicate prospective adoption rates of a technology that is not yet available is problematic.

This study further says:

> 'Moreover, new dairy technologies, as a general rule, have not tended to be adopted rapidly. For example, despite having been available commercially for over 40 years, artificial insemination technology is used only by 65 to 70 per cent of dairy farmers.'

On this basis the US study makes the following assessment on adoption rates: After 5 years adoption rates would range between 25 and 46 per cent depending on region and, after 10 years, they are forecast to range from 31 to 67 per cent depending on region.

ii) The CEAS-Study (1) makes an analysis taking the milk quota arrangement and the probable price of BST into account.

It concludes that adoption and use of BST will not be extensive in practice.

It also indicates:

> 'The decisions of whether or not to use BST, on which cows and when will be taken by each individual farmer based on his perceptions of the risks and benefits and his attitude to new technology. Each farmer will assess the situation differently but overall adoption might be expected to relate to:

- benefits of BST (reflecting in part the existing profitability of the herd and degree of opportunity to redeploy any resources released);
- price of BST;
- management ability;
- size of herd.

Because of the restrictions in milk production with milk quotas and based on assumption on average yield increase with BST (12%) and a realistic price for BST the incentive for major use of BST in the Community will be small.

Overall milk production as a result of BST would amount to 1,2% of total production in the short term and 5% in the long term assuming the results for the 5 Member States is representative for EC-12.

The reduction in cow numbers as a result of regular use is estimated to be 0,5% in the short term rising to 3,6% in the medium term.

This would be the result of a combination of regular use through quota transfer from presumably smaller herds to bigger as well as reduced number of cows within a fixed quota and use of BST by smaller dairy farmers to avoid quota shortfall.

It seems that the presence of milk quotas has a significant effect not only by limiting overall production, but because of the capitalization of the value of a milk quota belonging to a farm. The price of quota is an extra cost which any farmer has to pay if he seeks to make a more widespread use of BST.'

These calculations may be conservative.

A different estimate based on the CEAS study figures, implies a different conclusion as far as the increase in milk production is concerned.

According to the (CEAS II (1989)) study:

- The use of BST will, on average increase yields by 12% and

- 55% of cows will use BST in the medium-long term.

It could therefore be estimated that the increase in milk production could fall somewhere between the following two scenarios:

a) 55% of cows are responsible for 55% of milk production; this would imply an increase of $\frac{55 \times 12}{100} = 6.6\%$

b) because BST usage will be confined to the medium-high yielding cows and these cows already account for approximately 80% of milk production, this would imply an increase of 9.6%

10. Effect on the beef market

The effect on the beef market will also depend on the assumptions made on consumption and adoption rates. If consumption drops significantly and this results in a decision to adjust milk quotas accordingly, then there will be a slaughtering of dairy cows increasing beef production in the short run.

If, however, no major reduction in consumption is assumed, then the knock-on effect on the beef market will be smaller.

Halving the price of BST would lead to a further decline in the number of dairy cows. This will, however, be distributed over a number of years depending on the rate of uptake of BST.

The reduced number of cows will release land for alternative use either for crop production or more likely for beef production.

Based on past experience with milk quota reductions dairy cow replacement with animals for beef production will occur - in that case total beef production in the long run is expected to increase mainly because of the higher beef yield of non-dairy cows in comparison to dairy cows.

However, it is also possible as some recent experience shows that dairy farmers who reduce their dairy herds replace dairy cows not only with suckler cows but also with other beef animals such as steers or young bulls. In order to maintain their income they are obliged to have a higher number of beef animal replacements than the number of dairy cows removed. In this case the result would be a significant increase in beef production.

11. BST - Effect on Cow Numbers

Year	Production Million tons	NO B.S.T.	Cow Numbers (000s) Uptake of B.S.T.	
			20% short term	55% long term
1991	111.2	23,300	23,300	23,300
1992	111.2	22,950	22,410	22,410
1993	111.2	22,600	22,080	21,900
1994	111.2	22,260	21,760	21,400
1995	111.2	21,930	21,440	20,920
1996	111.2	21,610	21,140	20,460
1997	111.2	21,300	20,840	20,020
1998	111.2	21,000	20,550	19,750

NOTE: These projections are based on production remaining constant, and average milk yields increasing by 75 kg per year exluding the use of BST.

Statistics are for EC-12 including ex-GDR.

PART II

OPINION OF THE COMMITTEE FOR VETERINARY MEDICINE PRODUCTS

COMMISSION
OF THE EUROPEAN
COMMUNITIES

III/9260/90 final
Brussels, 20 March 1991

Directorate-General
for internal market and industrial affairs

Committee for Veterinary
Medicinal Products

Opinion of the Committee for Veterinary Medicinal Products
on an application for marketing authorization submitted by the
MONSANTO Company for SOMATECH (formerly Sometribove)
recombinant bovine somatotropin

(CVMP Concertation Procedure (Directive 87/22/EEC) Application No 1)

INTRODUCTION

On 24 August 1987, France referred an application for marketing authorization from the Monsanto company to the Committee for Veterinary Medicinal Products for an opinion in accordance with Article 2 of Directive 87/22/EEC in respect of Somatech, recombinant bovine somatotropin intended for administration to dairy cattle at 14 day intervals in order to increase milk yields. The Monsanto company has subsequently submitted applications in respect of the same product to Italy and the United Kingdom.

The application was considered by an ad hoc meeting of the Committee devoted to biotechnology and veterinary medicine on 24-25 November 1987. The Committee noted that there were differences between the documentation submitted to France and the United Kingdom. In accordance with Article 3 of Directive 87/22/EEC, the company was invited to re-submit identical dossiers to the Member States concerned, and further consideration of the application was suspended.

A revised application was accepted by the French authorities on 23 February 1988, and copies of the complete application have subsequently been made available to all Member States and to the Committee.

The amended application was discussed by a second ad hoc meeting on biotechnology and veterinary medicine on 16 June and by the Committee itself on 17 June 1988. The Committee considered that the information provided by the company was not sufficient to determine whether the product satisfied the criteria for authorization laid down by Directives 81/851/EEC and 81/852/EEC on the harmonization of the laws of the Member States relating to veterinary medicinal products. The Committee therefore prepared a comprehensive series of questions which were transmitted to the company immediately after the meeting of 17 June.

In July 1989 the company submitted its initial response, comprising in excess of 22,000 pages of additional data, to all Member States. However, because of difficulties in correlating the data contained in the original submission from the company with the new information contained in its reply, this submission was considered unacceptable for the purposes of assessment by the Committee. A new reply from the company was submitted in December 1989.

This reply was discussed in detail by the Committee at its meeting of 17-18 May 1990, at which the Committee concluded that several answers from the company, relating to the quality and biotechnological aspects of the product, and to the safety of the product in the target species remained unsatisfactory. The company was informed of these conclusions and agreed to submit further documentation which was circulated to all Member States in two parts, in June and August 1990. On 19 September 1990, representatives of the company were present at a hearing before the Committee, at which, in addition to responding to questions from the Member States, the company confirmed that, subject to further written responses to be provided to certain questions posed at the hearing, all relevant information, whether favourable or unfavourable, relating to the product had been made available to the Committee. The replies to these outstanding questions were circulated to all Member States at the end of October 1990.

Further discussion of the application took place at the CVMP meetings of 26-28 November 1990 and 15-16 January 1991. The Committee adopted the following opinion at its meeting of 19-20 March 1991.

OPINION OF THE COMMITTEE FOR VETERINARY MEDICINAL PRODUCTS IN RESPECT OF SOMATECH

The majority of the Committee consider that the product SOMATECH satisfies the criteria for authorization laid down in Directives 81/851/EEC and 81/852/EEC.

The Committee is satisfied that the manufacturer has demonstrated its ability to produce a homogeneous stable product, with a shelf life of 18 months, in accordance with the quality requirements laid down by the Community directives, using a well-controlled biotechnological process. However, the company should provide the Committee with the results of the plasmid DNA assay conducted on the first 20 industrial scale batches produced following authorization.

The Committe considers that the applicant has demonstrated that SOMATECH is effective in producing a significant increase in milk yields in treated cattle. The extent of this increase in yields depends, amongst other factors, on the breed of animal treated, the individual animal treated, the stage in the lactation cycle at which the product is administered and the quality of animal husbandry techniques used, but may be expected to be in the range of 2.7 - 5.7 kilogrammes per day.

The Committee considers that the applicant has demonstrated that residues of SOMATECH do not present any risk to the health of consumers of meat or milk obtained from treated animals. The product may safely be accepted for use without any withdrawal period for meat or milk.

Moreover, the Committee is satisfied that the use of SOMATECH does not affect the quality of milk or meat, nor will its use adversely affect the industrial processing of such milk into yoghurt or cheeses.

5. A majority of the Committee consider that the administration of SOMATECH to dairy cattle does not present any undue risk for the health or welfare of the treated animal.

Although some effects on the pregnancy rates of primi parous animals and the calving intervals of animals treated with SOMATECH before conception were observed during clinical trials, the Committee considers that these points can be resolved by appropriate warnings in the packaging of the product.

After a careful statistical analysis of the available data, the Committee has concluded that there is no evidence that the use of SOMATECH results in an increase in the incidence of mastitis in treated animals in comparison with controls, after the increase in milk yield of the treated animals is taken into consideration. However, the Committee considers that the experimental data available on the incidence of mastitis should be confirmed by additional information obtained under practical conditions of use after the authorisation of the product. Therefore the Committee recommends that the granting of marketing authorization for this product should be subject to a requirement for the company to undertake a structured pharmacovigilance study of the effects of the use of the product on the incidence of mastitis. The protocol for this study should be submitted to the Committee for approval. The Irish, Italian and United Kingdom delegations consider however that additional information about the incidence of mastitis should be provided, using a larger number of animals, before authorisation may be granted.

In its original application, the company proposed that SOMATECH should be administered by subcutaneous injection at the shoulder. Following an evaluation of the nature and importance of the local reactions observed at the injection site, the majority of the Committee considered that the reactions were unacceptable. Subsequently, however, the company amended its application to envisage the administration of SOMATECH only at the tailhead (ischiorectal fossa). The nature and importance of the reactions observed at this new site are substantially reduced to a mild, transient swelling and there is no evidence to suggest that this swelling causes any pain or discomfort to the target animal. However, the German, Dutch, Irish and United Kingdom delegations have doubts as to whether the scope and design of the studies of the tailhead site make it possible to reach a definitive conclusion at this stage. These delegations would require detailed analyses of veterinary supervision of the US trials and the frequency of examinations and the extent of any injection site reactions.

Although plasma levels of BST are reduced following injection through the tailhead, use of the product through the tailhead provides an equivalent increase in milk yield to use through the shoulder site and the Committee therefore considers that the two routes have comparable efficacy.

In these circumstances, and having regard to the experience of the use of the tailhead site for the administration of foot and mouth vaccine in several Member States, the majority of the Committee consider that the administration of SOMATECH through the tailhead site is acceptable and does not present an undue risk to the target animal.

The Irish, Dutch and United Kingdom delegations, however, are concerned about the hygiene of the tailhead site at certain times of the year and the possibility that injection through this site could result in the extraneous infection of the treated animal. These delegations therefore require additional information about the incidence of infection on the basis of the protocols used for the conduct of trials through this site in the United States and the procedures used for the examination of reactions at the injection site.

6. The Committee would emphasise that the successful use of SOMATECH will require the maintenance of high standards of animal husbandry. For this reason the Committee recommends that the product should be used only under veterinary supervision.

7. The Committee considers that it is important to verify that the results described in the application dossier for SOMATECH are confirmed during the practical use of the product in the field. For this reason, the Committee recommends that in addition to the specific study concerning the incidence of mastitis in treated animals referred to above, authorization to place SOMATECH on the market should be subject to a condition requiring the company to collect and evaluate all reported suspected adverse reactions to the product throughout the Community and to prepare an annual safety report for the five years following authorization.

8. The Committee requests that copies of any additional data submitted by the applicant to Member States pursuant to point 5 above be made available to all Member States and to the Commission. After evaluation of the information received, the Committee will consider the adoption of a second opinion on the application.

9. The Committee will consider the summary of product characteristics and the data sheet proposed by the firm for the product at its next meeting.

10. The Committee points out that this opinion is exclusively concerned with the product SOMATECH, produced by Monsanto. It in no way prejudices the evaluation of any other application for authorization for a product based on bovine somatotropin.

11. In accordance with Directive 87/22/EEC, and taking into account the provisions of Council Decision 90/218/EEC concerning the administration of bovine somatotropin, as amended by Council Decision 91/61/EEC, in particular Article 1 thereof, the Member States concerned will inform the Commission within 30 days of the action they intend to take on this opinion.

12. The Committee intends to prepare a detailed report of its evaluation of this application. In the meantime copies of this opinion may be made available to interested parties.

13. The Committee notes that, in accordance with national legislation currently in force, products containing BST may not be authorized in Belgium.

PART III

RESOLUTIONS OF THE PARLIAMENT

— having regard to the judgments of the Court of Justice of the European Communities of 12 May 1964 (1) and 10 July 1986 (2),

— having regard to Article 68 of the Italian Constitution,

— having regard to Rule 5 of its Rules of Procedure,

— having regard to the report of the Committee on Legal Affairs and Citizens' Rights (Doc. A2-221/86),

1. Hereby decides not to waive Mr Maurizio Valenzi's parliamentary immunity;

2. Instructs its President immediately to forward this decision and the report of its committee to the appropriate authority of the Italian Republic.

(1) CJ CE. 12 May 1964 (*Wagner v. Fohrmann and Krier*. Case 101/63/1964/ECR 195).
(2) Judgment in Case 149/85 (*Wybot v. Faure*), not yet publishedin the ECR.

3. Biotechnology in the European farming industry

(a) Doc. A2-159/86

RESOLUTION

on the effects of the use of biotechnology on the European farming industry

The European Parliament,

— having regard to the motion for a resolution tabled on behalf of the Committee on Agriculture, Fisheries and Food by Mr Tolman and Mr Eyraud on the use of agricultural products in biotechnology (Doc. B2-1087/85),

— having regard to the motion for a resolution tabled by Mr F. Pisoni and others on new uses for agricultural products and, in particular, the use of cereals for ethanol production (Doc. B2-1351/85),

— having regard to its resolution of 20 February 1986 on the genetic variety of cultivated plants and trees (1),

— having regard to its resolution of 8 July 1986 on bioethanol (2),

— having regard to the Commission discussion paper entitled: Biotechnology in the Community: stimulating agro-industrial development (COM(86) 221 final),

— having regard to the new Community Framework Programme of technological research and development (COM(86) 129 final),

— having regard to the Commission reports on the Biomolecular Engineering Programme (BEP) and the Commission RAP Biotechnology,

— having regard to the US Congress OTA report on the impact of the new technologies on the structure of American agriculture,

— having regard to the EEC FAST programme: The End of Farm Workers — the new farm workers (XII/108/86),

— having regard to the report by the Committee on Agriculture, Fisheries and Food (Doc. A2-159/86),

(1) OJ No C 68, 24. 3. 1986, p. 119.
(2) OJ No C 227, 8. 9. 1986, p. 30.

A. in view of the extensive efforts and the levels of expenditure brought to bear at Community level for the promotion of biotechnology in order to modernize agriculture and industry,

B. whereas these efforts are necessary so that agriculture and the agro-industrial sector can maintain their position and their competitiveness on the world market,

C. whereas biotechnologies, if used judiciously, can help reduce production costs and open new markets, thus improving the economic situation of farmers,

D. whereas multi-nationals are spending huge sums of money on biotechnology research, and it is important that the Community and national governments invest more in this area to avoid a situation where multinationals might gain a near monopoly of the knowledge available in this new technology,

E. whereas the commercial application of biotechnology may lead to an acceleration of rationalization of production in certain sectors of agriculture but will also lead to the development of new opportunities and new markets for farm products,

F. whereas there will continue to be a reduction in the numbers employed on the land, but new employment openings can be created through the careful application of biotechnology,

G. whereas biotechnology must be directed less towards increasing production capacity and yields than towards improving the quality of agricultural products and opening up new markets for such products, for example in the chemical and pharmaceutical industries, the agro-industry, etc.,

H. whereas the pursuit of such objectives (working to improve quality and seeking new markets) is likely to have a beneficial effect on employment in agriculture, as well as upstream and downstream of that sector,

I. whereas immediate thought must be given both at the Community level and at international level, particularly in the context of the new GATT negotiations, to the effects of production increases to which wrongly or inadequately directed biotechnology could give rise, such as collapsing exchange rates, the destabilization of international trade and the creation of new forms of dependence,

J. whereas traditional intensive agriculture posed many dangers to the environment, but biotechnology could assist in reducing the hazards by increasing the efficiency of nitrogen fixation and resistance to diseases and pests thus helping to reduce inputs of fertilizer, fungicides, insecticides and pesticides; tests and checks should be carried out in order to avoid possible adverse side-effects; likewise it could contribute to the safe disposal of farm wastes by converting animal waste an other organic substances to methane gas to be used as energy on the farm,

K. whereas serious studies must continue into energy production from biomass, in the context of developing the prospects for decentralized coverage of energy needs,

L. whereas genetic variety in crops and livestock has decreased over the centuries, and biotechnology and gene banks can contribute to increasing and conserving genetic variety,

M. whereas the application of biotechnology, like all new technologies, entails certain risks, and therefore it is very important that there should be adequate controls, preferably harmonized on a Community-wide basis,

N. whereas the development of biotechnologies will not necessarily lead to a solution of the problems of famine in the Third World, but may on the contrary widen the gulf between rich and poor, between large-scale farms and subsistence farming, between cash crop production and the supply of basic foostuffs,

O. whereas genetic plasma comes mainly from Third World countries,

1. Feels that, in the present context, biotechnology must promote an agricultural policy geared to quality, with high added value, rather than further increasing yields and quantities produced;

2. Believes that the European Community has a duty to support and encourage biotechnological research aimed at improving alternative forms of production and/or finding new ones;

3. Wishes to maintan family farming as the basis of our agriculture, the main task of which is to provide people with healthy food and to provide the agro-industries with suitable raw material for processing, without damaging the environment;

3.1 A purely biotechnological approach must be rejected and biotechnology must be integrated within already existing technologies by being made part of a wider policy designed to sustain vigorous rural life and a flourishing rural economy;

3.2 In food processing, the primary aim must be to produce food that is safe and nutritious. Genetic engineering is already contributing in this sector particularly in the production of fermented products such as cheese, yoghurts, soured milk drinks, beers, etc. ...;

3.3 The links between agriculture and industry, both upstream and downstream, should be strengthened with the object of supplying the consumer with competitively priced high quality food, while maintaining the viability of as many family farms as possible;

3.4 For our agriculture to stay competitive it will be essential to invest more in the continuous breeding of plants and animals, preferably, though not exclusively in government-controlled research centres;

3.5 Producer, processor and consumer cooperatives should be encouraged, likewise small and medium-sized industries should be encouraged in this sector;

3.6 Farmers should be given appropriate training to enable them to be involved closely in putting biotechnological research and applications to use and assessing their value;

4. Calls for all the ecological consequences to be taken into account in the use and application of biotechnology;

5. Supports the cooperation in the field of breeding between scientists, breeders, working farmers, environmentalists and conservationists designed to preserve a broad genetic potential;

6. Hopes that the guiding principles behind research into the breeding of particular animal species and the cultivation of particular plant varieties will be a concern to enhance qualitative, rather than quantitative performance, and an unfailing respect for the basic natural characteristics of such species and varieties;

7. Believes that successful plant breeding relies on the creation of diversity and this process can be accelerated using biotechnology;

8. Stresses the importance of species and gene conservation and the part played by gene banks and species repositories; considers, however, that the natural inheritance of mankind which these represent must be safeguarded outside any spirit of a desire to secure a commercial monopoly;

9. Calls for gene banks to be made subject to public supervision and the protection of intellectual property by means of adequate patent safeguards;

10. Considers that genetically manipulated organisms may not be introduced into the environment until all the relevant tests and experiments have been approved;

11. Calls on the Commission to propose directives on the basis of OECD recommendations and ensure that European undertakings comply with same both inside and outside the European Community;

12. Is seriously concerned at experiments recently carried out in certain countries; calls on the Commission to make contact with the international organizations concerned with a view to drawing up and ensuring respect for a code of conduct on experiments in the environment;

13. Calls for comprehensive testing of genetically engineered organisms before releasing them in any part of the world. Calls on the Commission to introduce standards for testing;

14. Supports the efforts of Third World countries to use appropriate technology to develop their agriculture and their economies and to reduce their dependence on multi-nationals;

15. Calls for prices for agricultural products to be fixed at a level which will help to give a reasonable income in farming thus helping to safeguard family farming in the Community;

16. Feels, nevertheless, that the prospects for industrial markets for agricultural products must be analyzed, as they represent:

— a further way of disposing of surpluses,

— a far from negligible source of indigenous raw materials for Community industry;

17. Considers it imperative that energy-production resources (bioethanol) be exploited, with all the necessary precautions to protect soil and groundwater;

18. Approves of the fact that the Community has passed legislation banning growth hormones; calls on the Commission to pursue this restrictive policy in respect of all types of hormones, and asks it to make approaches to the international organizations concerned (FAO, WHO, the International Dairy Products Council, etc.) and third countries which produce, use and export hormones, to ensure that a set of overall international rules on the trade in and use of hormones in agriculture and stockbreeding is introduced;

19. Calls on the Commission to produce a forcast, along the lines of the US Congress OTA report, of the likely structural and social consequences of the promotion and application of biotechnology and genetic technology in the European farming industry;

20. Instructs its President to forward this resolution to the Council and the Commission.

(b) Doc. A2-134/86

RESOLUTION

on biotechnology in Europe and the need for an integrated policy

The European Parliament,

— having regard to the communication from the Commission to the Council concerning the review of the multiannual reasearch programme for the EEC in the field of biotechnology (1985-1989) (COM(86) 272 final),

— having regard to the discussion paper of the Commission 'Biotechnology in the Community: Stimulating Agro-Industrial Development' (Com(86) 221 final),

— having regard to the motions for resolutions by Mr Roux and others, on behalf of the ERDA Group, on research in the field of biotechnology (Doc. B2-579/85), by Mr Tolman and Mr Eyraud, on behalf of the Committee on Agriculture, on the use of agricultural products in biotechnology (Doc. B2-1087/85) and by Mr Pearce on developments in the manufacture of hormones (Doc. B2-1162/85),

4. Hormones and the BST hormone in the dairy and meat industry

— Doc. A2-30/88

RESOLUTION

on the effects and risks of using the growth hormones and the BST hormone in the dairy and meat industries

The European Parliament,

— having regard to the motion for a resolution tabled by Mr Glinne and others on the effects and risks of using the BST-type hormone in the dairy industry (Doc. B2-988/86),

— having regard to the motion for a resolution tabled by Mr Graefe zu Baringdorf on the risks associated with the use of genetically engineered growth hormones in stock farming and the effects with regard to

  — natural animal husbandry,

  — the preservation of traditional, environment-related farming,

  — increases in output (surpluses),

  — providing consumers with high-quality, nutritious food,

  — animal feed imports and subsidized food exports between the Community and Third World countries (Doc. B2-767/87),

— having regard to the report of the Committee on Agriculture, Fisheries and Food and the opinions of the Committee on the Environment, Public Health and Consumer Protection and the Committee on Energy, Research and Technology (Doc. A2-30/88),

— having regard to Directive 88/146/EEC prohibiting the use of certain substances having a hormonal action in the following sector,

A. whereas, on 16 February 1987, it adopted a resolution on the effects of the use of biotechnology on the European farming industry (1),

B. whereas, in certain fields, agriculture is already dependent on biotechnologies which undoubtedly can bring about progress in agriculture but cannot, however, all be accepted and used indiscriminately on the pretext that they represent progress,

C. whereas the scientific revolution we are witnessing is taking place in an economic and political climate that is extremely uncertain and hard to gauge,

D. whereas BST is a genetically engineered hormone whose effect is to boost milk and meat production,

E. whereas the quota system is designed to prevent any overall increase in milk production,

F. whereas the current market situation is characterized by agricultural surpluses and escalating storage costs,

G. whereas the use of hormones artificially increases the carcase weight of cattle,

H. whereas the Community has a duty to protect the health and defend the interest of its consumers and farm animals,

I. whereas the introduction of BST would run counter to the policy of extensive farming and might well, because the method of use means it is only suitable for the most efficient producers, create inequalities between individual regions and producers,

(1) OJ No C 76, 23.3.1987, p. 22.

J. whereas quality criteria rather than considerations of quantity should prevail in determining production techniques, which should also eschew all chemical or artificial processes which might be harmful to the health of consumers or to the quality of the environments,

K. whereas it is dishonest to play on the producer's fear of being excluded from the system as a means of inducing him to use production techniques which have been insufficiently tested and whose harmlessness has not been empirically demonstrated, on either humans or animals over the short or long term,

L. whereas the Council, the Commission and the European Parliament have expressed their determination to join forces with the Member States in combating the traffic in hormones,

M. whereas the pressure being brought to bear by the USA within GATT, with the aim of circumventing the Community directives prohibiting the use of anabolic agents in livestock farming as from 1 January 1988, is fallacious both in legal terms (GATT allows its members freedom to specify production methods) and economic terms (the prohibition is not protectionist as it applies equally to Community and third country producers),

N. whereas it is opposed to all downward harmonization of health and hygiene standards with regard to the production and marketing of foodstuffs at international level,

O. whereas absolute priority must be given to safeguarding health,

P. whereas the future selection of dairy cattle might be distorted because of the undeclared use of BST, with the risk that animals with the best genetic potential may be rejected in favour of mediocre but treated animals,

Q. whereas the Commission is currently reviewing the future of veterinary medicine licensing,

1. Welcomes the decision of the Council of Ministers of Agriculture of 7 March 1988 to re-enact Directive 85/649/EEC prohibiting the use of certain substances having a hormonal action, which had been annulled by the Court of Justice on 23 February 1988 on the grounds of breach of procedure (Directive 88/146/EEC);

2. Is disturbed by the fact that the use of BST is accelerating the growth of intensive livestock farming at a time when production limits have been imposed;

3. Believes it essential for a careful assessment to be made of the economic implications of using products such as BST, which are indirectly linked to, and exert an indirect influence on, agricultural surpluses;

4. Points out that the geographical conditions of certain Community regions are such as to tie farming to the exploitation of the land, with the result that the feeding methods required by the introduction of BST are likely to provoke competition between individual regions and producers;

5. Notes the adoption by the Council of Directive 88/146/EEC prohibiting the use in livestock farming of certain substances having a hormonal action; believes this to be a timely measure, but notes that it does not cover BST and other new hormonal substances;

6. Calls on the Commission to formulate an assessment procedure for veterinary medicines, including hormones, produced by genetic engineering to take into account not only safety, efficacy and quality but also the socio-economic and ecological consequences, the impact on agricultural structures and compatibility with the aims of reducing surpluses and promoting extensive farming;

7. Notes that the studies being conducted by industry and also by universitities and other research organizations include studies of the socio-economic effects of BST; hopes that industry finds it appropriate to distribute widely the results of these studies, in particular to MEPs and the Commission;

8. Draws attention to the fundamental importance of research for the development of the biotechnologies, the basic aim of which must be to improve quality rather than boosting output;

9. Decides that it is now appropriate for Parliament's Office of Technology Assessment to conduct research into the implications of rapidly evolving scientific knowledge in the field of veterinary medicine;

10. Believes that the provisions of Directive 88/146/EEC banning certain substances in the Community must be applied in the same way by producer countries which export their meat products to the Community;

11. Is concerned at the differences that exist between the various national laws regarding hormones, which is creating difficulties in international trade;

12. Calls on the Commission to apply itself without delay to the task of coordinating and analyzing the findings of current experiments concerning the use of BST and not to leave such important work entirely in the hands of the pharmaceutical laboratories;

13. Considers it essential for a programme of exhaustive studies and trials to be instituted, notably with a view to examining the effects of BST on human and animal health;

14. Takes the view that these studies must be linked with a far-reaching information campaign, addressed both to the general public and veterinary surgeons, concerning the nature, location, structure, objectives and results of the studies;

15. Considers that milk from the animal used in the various trials should not be distributed to consumers;

16. Believes that an investigation should be carried out into the cumulative effects of the different hormones;

17. Is of the opinion that where a Member State, as in the case of the UK, allows testing of BST on cattle, neither the milk, nor the meat from BST injected animals, should be used for either human or animal consumption;

18. Considers that, before the use of BST is authorized at Community level, its long-term socio-economic effects, particularly on the smaller farm, should be the subject of a special study, the results of which should be taken into account when the relevant decision is taken;

19. Calls for a system of aid to be introduced to compensate for the loss of income which discontinuing the use of growth hormones would entail, thereby ensuring that proper economic and social provision can be made in the event that the ban on hormones in livestock farming is really applied;

20. Calls on the Commission to oppose any attempt by individual Member States to authorize the use of BST at national level until such time as the conditions for its authorization at Community level have been met;

21. Believes it necessary to bring about complete harmonization with regard to inspections in the Community's slaughterhouses and imports from third countries;

22. Draws attention to the need for consultation with all producer countries in the world;

23. Calls for a tightening of the measures for the detection of fraud and irregularities with a view to preventing the development of a black market (in this field) and for the national administrations to be closely involved in those measures;

24. Emphasizes the importance of setting up appropriate bodies to carry out checks on the premises of livestock breeders; such bodies should have a team of veterinary inspectors whose task would be to fix product quality standards and to penalize any infringement of Community rules;

25. Takes the view that the use of hormones for production purposes should be restricted as far as possible and that where their use is permitted it should be subject to very strict rules; stresses, in this connection, that only persons with training in veterinary medicine should administer therapeutic preparations;

26. Calls on the Commission to create a legal framework in which other genetically engineered growth accelerators or yield enhancers such as PST (porcine growth hormone), etc. are taken into account;

27. Calls for all meat and animal products produced within the EEC and imported from third countries to indicate clearly all treatments used in their production with a view to safeguarding, and giving the consumers, a choice;

28. Calls for the introduction of European quality labels guaranteeing the conditions laid down jointly by representatives of the cattle producers and the consumer associations;

29. Calls on the Commission and the Council to impose identical health standards for meat products imported into the Community;

30. Instructs its President to forward this resolution to the Commission and the Council.

PART IV

EXTRACT FROM COMMISSION COMMUNICATION TO PARLIAMENT AND COUNCIL CONCERNING PROMOTING THE COMPETITIVE ENVIRONMENT FOR THE INDUSTRIAL ACTIVITIES BASED ON BIOTECHNOLOGY IN THE COMMUNITY

As B.S.T. is a product of modern biotechnology the industries involved are concerned to ensure a stable regulatory framework for their activities. The Commission considered this question in its recent Communication to the Parliament and the Council concerning 'Promoting the competitive environment for the industrial activities based on biotechnology within the Community' [SEC (91) 629 final]. In this it is indicated:

> 'Not all products derived through biotechnological methods will require a specific assessment and/or authorization procedures. Currently the vast majority of biotechnology products are produced through traditional methods (e.g. cheeses, malt extracts, beers and yeasts). As far as new biotechnology products are concerned, which involve gene manipulation, each product will have to be considered on a case-by-case basis and assessed as necessary.'

Those products which do require governmental activity may be assessed and authorized under the regulatory framework for biotechnology which has been developed by the Community. This regulatory framework, which is based upon scientific analysis and evaluation, covers horizontal (environmental and worker protection) and product legislation. This later is based on the tree criteria of safety, quality and efficacy(2)(2), which are also applied when assessing whether a product can be authorized for distribution on the open market. The horizontal framework ensures that all stages of pre-industrial development and environmental aspects are covered.

The approach now applied by the Community, based upon the correct and thorough application of the criteria of safety, quality and efficacy, in conjunction with relevant horizontal legislation, ensures consumers' safety and economic interests and permits the protection of human.

.../...

(2) It should be noted that these criteria are nowadays considered to include impact on nature and safety for the environment.

animal and plant health and of the environment. Furthermore, in order to ensure that the consumer protection aspect is covered, the impact on consumers' information and choice needs to be taken into account.

Recent debate has focussed on the introduction of broader socio-economic needs in addition to the three traditionsl criteria when assessing biotechnologically derived products. The debate is on-going and the preoccupations involved differ. To some the concept includes a broader analysis of health and environmental aspects, to others it should focus on social and/or economic impacts (for example, consequences on agricultural production). The Community must, above all, avoid a situation creating uncertainty.

As a rule, decisions have to be based upon objective assessments using clearly identified criteria. Uncertainties about product acceptance and authorization could result in a diversion of investment and could act as a disincentive for innovation and technological development by industry. The Community must however guarantee the public that the industry is properly controlled. The dynamism of the industry and the confidence of public opinion depend on the ability of the Community of reassure both parties.

Where a biotechnological product is assessed, the three traditional criteria, based on scientific evaluation apply. By their nature, socio-economic aspects need to be considered in a different way. It is not the intention to have another systematic assessment in addition to the three criteria. The Commission will normally follow scientific advice. The Commission reserves the right, however, to take a different view in the light of its general obligation to take into account other Community policies and objectives. This might, in exceptional cases, lead to requirements for further information. It might equally, in exceptional cases, lead to the Commission to propose that other policies be modified in the light of biotechnological developments.

The Scientific Veterinary Committee (SVC) has noted that "... no comprehensive studies of the welfare of animals treated with BST have been reported in the publicly available literature ...." and that adequate information should be available on ".... questions such as disease incidence, physical disorder, injuries, behaviour on physiology....". Information on these topics has been supplied to the CVMP for the two BST products under consideration and the CVMP is of the opinion that these concerns have been adequately met except for two questions - injection site reaction and the incidence of mastitis, which are currently under consideration on the basis of substantial new information.

c) According to the present state of knowledge, the use of rBST cannot be detected in milk and dairy products in practice.
Respect of labelling rules or other possible arrangements for partial or conditional approval could not therefore be achieved.

d) Consumers' organisations are opposed to the authorisation of BST as long as no labelling provisions can be made. Consumer surveys show a negative reaction towards BST which is likely to be reflected in a sharp downturn in consumption of milk products. This would have serious adverse effects on Community agriculture, on the dairy industry in particular, and for the budget also. It could also damage the Community's export performance in milk products and in beef since there may be a reluctance on the part of some third countries to authorise BST and accept products from animals treated with BST.

e) The CAP reform proposals place the emphasis on quality rather than extra quantity of production. They seek to maintain also a socio/economic structure that would allow sufficient numbers of farmers to remain in agriculture to allow them to fulfil a dual role as producers of quality food and guardians of the countryside. (The introduction of BST would appear to be contrary to these objectives.)

f) Because of outstanding questions in relation to animal health and welfare, the need for greater clarity on the ethical aspects, and the need to investigate the possibility of a common approach by the principal countries involved in producing, exporting and importing dairy products, it is considered that more time is needed to evaluate all the elements involved. It is considered also that in the interests of the single market, a final decision in relation to the authorisation of BST should continue to be made at the Community level. With this in mind the Commission will aim to present its final conclusions and a proposal to the Council by 30 June 1993. In the meantime it is proposed that the existing evaluation period be extended to 31 December 1993 to enable a decision to be taken within the time scale envisaged.

g) Any measures taken should be compatible with international obligations of the Community.

COMMISSION DES COMMUNAUTES EUROPEENNES

COM(91) 522 final

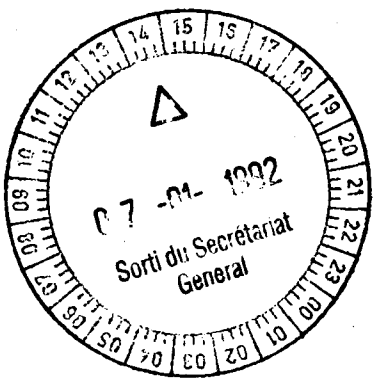
Bruxelles, le 12 décembre 1991

Proposition de

DECISION DU CONSEIL

modifiant la décision 90/218/CEE relative à la mise sur le marché et à l'administration de la somatotropine bovine (BST)

(présentée par la Commission)



Exposé des motifs

Somatotropine bovine

1. Le 27 septembre 1989, la Commission a présenté un rapport au Conseil et au Parlement sur l'administration de la somatotropine bovine aux vaches laitières en vue d'améliorer la productivité du secteur considéré[1].

Il est proposé de fixer une période d'évaluation se terminant fin 1990 et devant permettre d'évaluer l'utilisation de la BST dans la Communauté. Il est également indiqué que cette période représente le délai minimum nécessaire pour apprécier les résultats des études en cours et mettre au point de nouvelles dispositions à adopter quant aux procédures applicables à de tels produits. Par sa décision 90/218/CEE, du 25 avril 1990[2], le Conseil a agréé la demande de la Commission puis, par sa décision du 4 février 1991[3], a accepté un délai supplémentaire, expirant le 31 décembre 1991, nécessaire pour permettre l'achèvement des études en cours et l'examen de leurs résultats.

2. Dans l'intervalle, plusieurs études ont été réalisées sur divers aspects de la BST et un second rapport intérimaire sur le sujet sera présenté au Conseil et au Parlement à bref délai.

3. La Commission est en mesure d'indiquer dès à présent qu'il faudra davangage de temps pour dégager des conclusions définitives. En conséquence, il est proposé que le Conseil décide de prolonger la période d'évaluation actuelle jusqu'au 31 décembre 1993. Ceci permettra à la Commission de présenter ses nouvelles conclusions accompagnées de propositions relatives à des arrangements futurs pour le 30 juin 1993 au plus tard.

4. La présente decision n'a aucune consequence financière.

(1) [COM (89) 379 final]
(2) JO n° L 116 du 8. 5.1990, p. 27.
(3) JO n° L 37 du 9. 2.1991, p. 39.

Proposition de

DECISION DU CONSEIL

modifiant la décision 90/218/CEE relative à la mise sur le marché et à l'administration de la somatotropine bovine (BST)

LE CONSEIL DES COMMUNAUTES EUROPEENES,

vu le traité institutant la Communauté économique européenne, et notamment son article 43,

vu la proposition de la Commission(1)

vu l'avis du Parlement européen(2)

vu l'avis du comité économique et social(3)

considérant que, dans sa décision 90/218/CEE(4), relative à la mise sur le marché et à l'administration de la somatotropine bovine (BST), modifiée par la décision 91/61/CEE du 4 février 1991, le Conseil a demandé aux Etats membres d'interdire, jusqu'au 31 décembre 1991, l'administration sur leur territoire, par quelque moyen que ce soit, de la somatotropine bovine aux vaches laitières, parce que les effets et les conséquences d'une telle administration n'étaient pas encore suffisamment établis;

considérant que le délai imparti pour étudier ces effets et conséquences s'est avéré trop court; que les recherches mises en oeuvre n'ont abouti que partiellement; qu'il n'existe pas encore de résultats suffisaments réprésentatifs, notamment sous l'angle de la santé et du bien-être des animaux; qu'il importe dès lors de continuer de manière approfondie les études afin de disposer d'informations complémentaires; qu'il convient enfin d'approfondir certains aspects de cohérence avec les politiques communautaires.

considérant que pour ne pas préjuger du résultat de ces études, il est nécessaire de proroger ultérieurement l'interdiction de mise sur le marché et d'administrer la somatotropine bovine;

A ARRETE LA PRESENTE DECISION :

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(1)
(2)
(3)
(4) JO n° L 116 du 8.5.1990, p. 27

Article premier

La décision 90/218/CEE est modifiée comme suit :

1. L'article 1er est remplacé par le texte suivant :

"Article premier

Les Etats membres veillent, jusqu'au 31 decembre 1993 à ne pas autoriser la mise sur le marché de la somatotropine bovine et son administration sur leur territoire par quelque moyen que ce soit aux vaches laitières."

2. L'article 4 est remplacé par le texte suivant :

"Article 4

Avant le 30 juin 1993 au plus tard, la Commission présente au Parlement européen et au Conseil un rapport sur la situation, assorti de propositions concernant le régime ultérieur."

Article 2

Les Etats membres sont destinataires de la présente décision.

Fait à Bruxelles, le

Par le Conseil

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DOCUMENTS

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KOMMISSION DER EUROPÄISCHEN GEMEINSCHAFTEN

KOM(91) 522 endg.

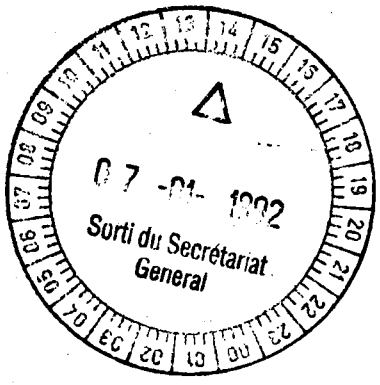
Brüssel, den 12. Dezember 1991

Vorschlag für einen

ENTSCHEIDUNG DES RATES

zur Änderung der Entscheidung 90/218/EWG über die Verbreichung von Rindersomatotropin (BST)

(von der Kommission vorgelegt)



Begründung

Rindersomatotropin

1. Am 27. September 1989 hat die Kommission dem Rat und dem Parlament einen Bericht über die Verabreichung von Rindersomatotropin an Milchkühe zur Steigerung der Milchleistung (1) vorgelegt.

Darin war angeregt worden, einen Beurteilungszeitraum (bis Ende 1990) festzulegen, in dem die Verwendung von bST in der Gemeinschaft geprüft werden konnte. Außerdem kam der Bericht zu dem Schluß, daß mindestens soviel Zeit benötigt würde, um die Ergebnisse der laufenden Untersuchungen zu prüfen und neue Vorschriften über die Zulassung solcher Produkte zu entwickeln. Mit der Entscheidung 90/218/EWG vom 25. April 1990 (2) stimmte der Rat dem Vorschlag der Kommission zu und erklärte in der Entscheidung vom 4. Februar 1991 (3), daß eine Fristverlängerung bis zum 31. Dezember 1991 erforderlich sei, um die laufenden Untersuchungen beenden und deren Ergebnisse prüfen zu können.

2. Inzwischen wurden zu verschiedenen Aspekten von bST Untersuchungen angestellt. Ein weiterer Zwischenbericht wird dem Rat und dem Parlament in Kürze zugehen.

3. Die Kommission kann bereits jetzt übersehen, daß mehr Zeit benötigt wird. Aus diesem Grund wird vorgeschlagen, daß der Rat den bestehenden Bewertungszeitraum bis zum 31. Dezember

1993 verlängert. Dies würde es der Kommission ermöglichen, über weitere Schlußfolgerungen zu berichten und entsprechende Vorschläge für eine spätere Regelung bis spätestens 30.Juni 1993 vorzulegen.

4. Diese Entscheidung wird keine finanziellen Auswirkungen haben.

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(1) KOM (89) 379 endg.

(2) ABl. Nr. L 116, 8.5.1990, S. 27

(3) ABl. Nr. L 37, 9.2.1991, S. 39

Vorschlag für einen

ENTSCHEIDUNG DES RATES

zur Änderung der Entscheidung 90/218/EWG über die Verbreichung von Rindersomatotropin (BST)

DER RAT DER EUROPÄISCHEN GEMEINSCHAFTEN --

gestützt auf den Vertrag zur Gründung der Europäischen Wirtschaftgemeinschaft, insbesondere auf Artikel 43,

auf Vorschlag der Kommission (1),
nach Stellungnahme des Europäischen Parlaments (2),
nach Stellungnahme des Wirtschafts- und Sozialausschusses (3),

in Erwägung nachstehender Gründe:

In der Entscheidung 90/218/EWG (4) über die Verabreichung von Rindersomatotropin (BST), geändert durch die Entscheidung 91/61/EWG vom 4. Februar 1991, hatte der Rat die Mitgliedstaaten aufgefordert, bis zum 31. Dezember 1991 jegliche Verabreichung von Rindersomatotropin an Milchkühe in ihrem Hoheitsgebiet zu verbieten, da die Auswirkungen noch nicht hinreichend geklärt waren.

Die ursprünglich vorgesehene Frist, in der diese Auswirkungen untersucht werden sollten, reicht nicht aus; die Forschungsarbeiten sind erst teiweise abgeschlossen; ausreichend repräsentative Ergebnisse, inbesondere über Gesundheit und Wohlbefinden der Tiere, liegen noch nicht vor. Weitere Studien sind erforderlich, um zusätzliche Informationen zu erhalten. Schließlich ist zu untersuchen, inweiweit eine Übereinstimmung mit den gemeinschaftlichen Politiken gesichert ist.

Um den Ergebnissen dieser Studien nicht vorzugreifen, ist das Inverkehrbringen und die Verabreichung von Rindersomatotropin weiterhin zu verbieten --

HAT FOLGENDE ENTSCHEIDUNG ERLASSEN:

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(1)

(2)

(3)

(4) ABl. Nr. L 116 vom 8.5.1990, S. 27.

Artikel 1

Die Entscheidung 90/218/EWG wird wie folgt geändert:

1. Artikel 1 erhält folgende Fassung:

"Artikel 1

Die Mitgliedstaaten sorgen bis zum 31. Dezember 1993 dafür, daß das Inverkehrbringen und jegliche Verabreichung von Rindersomatotropin an Milchkühe innerhalb ihres Hoheitsgebiets nicht zugelassen wird."

2. Artikel 4 erhält folgende Fassung:

"Artikel 4

Die Kommission unterbreitet dem Europäischen Parlament und dem Rat spätestens bis 30. Juni 1993 einen Lagebericht mit Vorschlägen für eine spätere Regelung."

Artikel 2

Diese Entscheidung ist an die Mitgliedstaaten gerichtet.

Geschehen zu Brüssel am

Im Namen des Rates

ISSN 0254-1467

KOM(91) 522 endg.

DOKUMENTE

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L-2985 Luxemburg

COMMISSIONE DELLE COMUNITA EUROPEE

COM(91) 522 def.
Bruxelles.10 gennaio 1992

Proposta di

DECISIONE DEL CONSIGLIO

che modifica la decisione 90/218/CEE relativa all'immissione sul mercato e all'impiego della somatotropina bovina (BST)

(presentata dalla Commissione)

Relazione

Somatotropina bovina

1. Il 27 settembre 1989, la Commissione aveva sottoposto al Consiglio e al Parlamento una relazione sulla somministrazione della somatotropina bovina alle vacche da latte, al fine di migliorarne la produttività (1).

   Tale documento proponeva che l'impiego della BST nella Comunità venisse tenuto sotto esame sino alla fine del 1990, precisando che questo periodo di valutazione costituiva il minimo necessario per giudicare i risultati degli studi in corso e per mettere a punto le nuove disposizioni che dovevano essere adottate circa le procedure da applicare al prodotto in parola. Con decisione 90/218/CEE del 25 aprile 1990 (2) il Consiglio ha accolto la richiesta della Commissione, indi, con decisione 91/61/CEE del 4 febbraio 1991 (3), ha accettato di prorogare al 31 dicembre 1991 il termine stabilito, per dare la possibilità di ultimare gli studi in corso e di analizzarne i risultati.

2. Nell'intervallo, sono stati realizzati diversi studi su vari aspetti della BST, e fra breve verrà presentata al Consiglio e al Parlamento una seconda relazione interlocutoria in materia.

3. La Commissione può comunicare sin da ora che non sarà possibile trarre conclusioni definitive entro la scadenza fissata e, pertanto, propone che il Consiglio decida di prolungare l'attuale periodo di valutazione fino al 31 dicembre 1993. Ciò consentirà alla Commissione stessa di presentare, per il 30 giugno 1993 al più tardi, nuove conclusioni corredate di proposte sul regime da applicare in futuro.

4. L'acclusa decisione non ha alcuna incidenza finanziaria.

(1) [COM(89)379 def.]
(2) GU n. L 116 dell'8.5.1990, pag. 27.
(3) GU n. L 37 del 9.2.1991, pag. 39.

proposta

di

DECISIONE DEL CONSIGLIO

del ....

che modifica la decisione 90/218/CEE relativa all'immissione sul mercato e all'impiego della somatotropina bovina (BST)

IL CONSIGLIO DELLE COMUNITÀ EUROPEE,

visto il trattato che istituisce la Comunità economica europea, in particolare l'articolo 43,

vista la proposta della Commissione (1),

visto il parere del Parlamento europeo (2),

visto il parere del Comitato economico e sociale (3),

considerando che il Consiglio, con decisione 90/218/CEE del 25 aprile 1990 (4), modificata dalla decisione 91/61/CEE (5), ha invitato gli Stati membri a vietare nel proprio territorio, fino al 31 dicembre 1991, la somministrazione tramite qualsiasi mezzo di somatotropina bovina alle vacche da latte, non essendo ancora sufficientemente chiariti gli effetti di tale sostanza e le conseguenze della sua somministrazione;

considerando che il periodo accordato per lo studio di tali effetti e conseguenze si è rivelato troppo breve; che le ricerche avviate hanno dato soltanto risultati parziali; che non si è ancora pervenuti a risultati sufficientemente rappresentativi, segnatamente sul piano della salute e del benessere degli animali; che occorre pertanto proseguire e intensificare gli studi, per ottenere informazioni supplementari; che è pure opportuno approfondire, sotto determinati aspetti, il problema della coerenza fra le politiche comunitarie;

considerando che, per non anticipare i risultati di tali studi, è necessario prorogare ulteriormente il divieto d'immissione sul mercato e di somministrazione della somatotropina bovina,

HA ADOTTATO LA PRESENTE DECISIONE:

(1) GU n. C
(2) GU n. C
(3) GU n. C
(4) GU n. L 116 dell'8.5.1990, pag. 27
(5) GU n. L 37 del 9.2.1991, pag. 39

Articolo 1

La decisione 90/218/CEE è modificata come segue:

1. Il testo dell'articolo 1 è sostituito dal testo seguente:

"Articolo 1

Gli Stati membri prendono le opportune disposizioni affinché l'immissione sul mercato della somatotropina bovina e la sua somministrazione alle vacche da latte tramite qualsiasi mezzo non siano autorizzate nel loro territorio fino al 31 dicembre 1993."

2. Il testo dell'articolo 4 è sostituito dal testo seguente:

"Articolo 4

Entro il 30 giugno 1993, la Commissione presenta al Parlamento europeo e al Consiglio una relazione sulla situazione, corredata di proposte quanto al regime da applicare in futuro."

Articolo 2

Gli Stati membri sono destinatari della presente decisione.

Fatto a Bruxelles, addì

Per il Consiglio

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COM(91) 522 def.

DOCUMENTI

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COMMISSIE VAN DE EUROPESE GEMEENSCHAPPEN

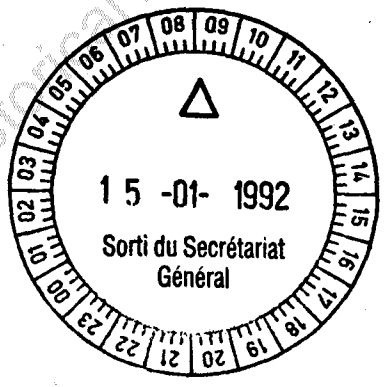
COM(91) 522 def.
Brussel.10 januari 1992

Voorstel voor een

BESCHIKKING VAN DE RAAD

tot wijziging van Beschikking 90/218/EEG met betrekking tot het op de markt brengen en de toediening van bovine somatotropine (BST)

(door de Commissie ingediend)



Toelichting

Boviene somatotropine

1. Op 27 september 1989 heeft de Commissie bij de Raad en het Europese Parlement een verslag ingediend over de toediening van boviene somatotropine aan melkkoeien met het oog op de verbetering van de produktiviteit van de betrokken sector[1].

   Daarin werd voorgesteld om een evaluatieperiode vast te stellen die eind 1990 zou aflopen en op basis waarvan een oordeel zou kunnen worden geformuleerd over het gebruik van BST in de Gemeenschap. Het verdiendde aanbeveling deze periode te laten overeenkomen met de minimumtermijn die nodig was om de resultaten van het lopende onderzoek te beoordelen en nieuwe bepalingen uit te werken met betrekking tot de voor die produkten geldende procedures. Bij Beschikking 90/218/EEG van 25 april 1990[2] heeft de Raad ingestemd met het verzoek van de Commissie, en vervolgens bij beschikking van 4 februari 1991[3] ook met een aanvullende termijn, die afloopt op 31 december 1991; deze aanvullende termijn was nodig om het lopende onderzoek te kunnen beëindigen en de resultaten daarvan te evalueren.

2. Ondertussen zijn vele studies verricht over diverse aspecten van BST en een tweede tussentijds verslag ter zake zal worden ingediend bij de Raad en bij het Parlement.

3. De Commissie kan nu reeds mededelen dat meer tijd nodig is om definitieve conclusies te kunnen trekken. Derhalve wordt aan de Raad voorgesteld de huidige evaluatieperiode te verlengen tot en met 31 december 1993. De Commissie zal dan uiterlijk op 30 juni 1993 nieuwe conclusies kunnen indienen, vergezeld van voorstellen voor de te nemen maatregelen.

4. Deze beschikking heeft geen financiële consequenties.

(1) COM(89)379 def.
(2) PB nr. L 116 van 8.5.1990, blz. 27.
(3) PB nr. L 37 van 9.2.1991, blz. 39.

voorstel
voor een
BESCHIKKING VAN DE RAAD
van
tot wijziging van Beschikking 90/218/EEG met betrekking tot het op de markt brengen en de toediening van bovlene somatotropine (BST)

DE RAAD VAN DE EUROPESE GEMEENSCHAPPEN,

Gelet op het Verdrag tot oprichting van de Europese Economische Gemeenschap, inzonderheid op artikel 43,

Gezien het voorstel van de Commissie[1],

Gezien het advies van het Europese Parlement[2],

Gezien het advies van het Economisch en Sociaal Comité[3],

Overwegende dat de Raad, bij Beschikking 90/218/EEG met betrekking tot het op de markt brengen en de toediening van bovlene somatotropine (BST)[4], gewijzigd bij Beschikking 91/61/EEG van 4 februari 1991[5], de Lid-Staten heeft verzocht om tot en met 31 december 1991 niet toe te staan dat op hun grondgebied, op welke manier ook, bovlene somatotropine aan melkkoeien wordt toegediend, omdat de effecten en gevolgen van die toediening nog niet voldoende duidelijk waren;

Overwegende dat de voor het onderzoek naar deze effecten en gevolgen vastgestelde termijn te kort is gebleken; dat de lopende onderzoeken nog maar gedeeltelijk zijn afgerond; dat nog geen voldoend representatieve resultaten beschikbaar zijn, met name wat de gezondheid en het welzijn van de dieren betreft; dat derhalve verder grondig onderzoek vereist is om over aanvullende gegevens te kunnen beschikken; dat bepaalde aspecten betreffende de samenhang met het communautaire beleid nog verder moeten worden onderzocht;

Overwegende dat, ten einde niet op de resultaten van dat onderzoek vooruit te lopen, het verbod betreffende het op de markt brengen en toedienen van bovlene somatotropine moet worden verlengd,

HEEFT DE VOLGENDE BESCHIKKING VASTGESTELD :

(1)
(2)
(3)
(4) PB nr. L 116 van 8.5.1990, blz. 27.
(5) PB nr. L 37 van 9.2.1991, blz. 39.

Artikel 1

Beschikking 90/218/EEG wordt als volgt gewijzigd :

1. Artikel 1 wordt gelezen :

"Artikel 1

De Lid-Staten zien erop toe dat tot en met 31 december 1993 niet wordt toegestaan dat op hun grondgebied bovlene somatotropine op de markt wordt gebracht en op welke manier dan ook aan melkkoeien wordt toegediend."

2. Artikel 4 wordt gelezen :

"Artikel 4

Vóór 30 juni 1993 dient de Commissie bij het Europese Parlement en de Raad een verslag in over de situatie, vergezeld van voorstellen betreffende de latere regeling."

Artikel 2

Deze beschikking is gericht tot de Lid-Staten.

Gedaan te Brussel, Voor de Raad

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COMMISSION OF THE EUROPEAN COMMUNITIES

COM(91)522 final

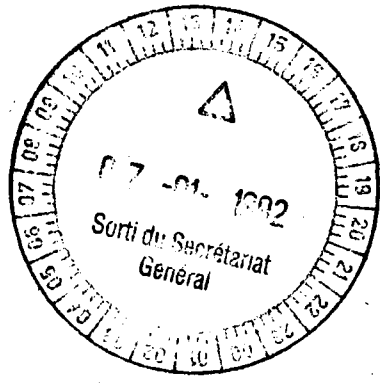
Brussels, 12 December 1991

Proposal for a

COUNCIL DECISION

amending Decision 90/218/EEC on the placing on the market and administration of Bovine Somatotrophin (BST)

(presented by the Commission)



Explanatory Memorandum

Bovine Somatotrophin

1. On 27th September 1989 the Commission presented a report to the Council and to the Parliament concerning the administration of bovine somatotrophin to dairy cows as a productivity aid to milk production[1].

   It proposed the establishment of an evaluation period up to the end of 1990 on the administration of BST in the Community. It also indicated that this period was considered to be the minimum necessary to assess the results of the ongoing studies and develop new arrangements to be adopted on procedures in relation to such products. By its decision 90/218/EEC of 25th April 1990[2] the Council agreed to the request of the Commission and subsequently agreed by its decision of 4th February 1991[3] that an additional time up to 31 December 1991 was necessary to enable the studies under way to be completed and the results to be considered.

2. In the meantime several studies have been made into the various aspects of BST and a further interim report in the matter will be presented to the Council and to the Parliament shortly.

3. The Commission can indicate already that more time will be needed to arrive at definitive conclusions. Accordingly it is proposed that the Council decide to extend the existing evaluation period up to 31 December 1993. This will enable the Commission to present its further conclusions accompanied by proposals concerning future arrangements by 30th June 1993 at the latest.

4. The Decision would have no financial consequences.

(1) [COM (89) 379 final]
(2) O.J. No L 116, 08.05.1990, p. 27
(3) O.J. No L 37, 09.02.1991, P. 39

Proposal for a
COUNCIL DECISION

amending Decision 90/218/EEC on the placing on the market and administration of Bovine Somatotrophin (BST)

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community, and in particular Article 43 thereof,

Having regard to the proposal from the Commission[1],

Having regard to the opinion of the European Parliament[2],

Having regard to the opinion of the Economic and Social Committee[3],

Whereas by Decision 90/218/EEC of 25 Aprtil 1990 on the placing on the market and administration of bovine somatotrophin[4], as amended by Decision 91/61/EEC of 4 February 1991, the Council called on the Member States to prohibit, until 31 December 1991, the administration of bovine somatotrophin on their territory by any means whatsoever to dairy cows in view of the fact that the consequences of such administration were not yet sufficiently clear;

Whereas the time set for studying the effects and consequences of BST has proved too short; whereas the research initiated has only been partially completed; whereas sufficiently representative results have not yet been obtained, in particular from the point of view of animal health and welfare; whereas in-depth studies should continue in order to secure the additional data needed; whereas, finally, further deliberation is necessary regarding some aspects of consistency with other Community policies;

Whereas, in order not to anticipate the results of these studies, the prohibition regarding the placing on the market and administration of BST should be extended until a later date,

HAS ADOPTED THIS DECISION:

1 OJ No C..
2 OJ No C ..
3 OJ No C..
4 OJ No L 116, 8.5.1990, p.27.

Article 1

Decision 90/218/EEC is amended as follows:

1. Article 1 is replaced by the following:

"Article 1

The Member States shall ensure that, until 31 December 1993, the placing on the market of bovine somatotrophin and its administration on their territory to dairy cows by any means whatsoever will not be authorized."

2. Article 4 is replaced by the following:

"Article 4

The Commission shall, by 30 June 1993 at the latest, present the European Parliament and the Council with a report on the situation together with proposals for future arrangements."

Article 2

This Decision is addressed to the Member States.

Done at ... ,

For the Council
The President

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DOCUMENTS

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KOMMISSIONEN FOR DE EUROPÆISKE FÆLLESSKABER

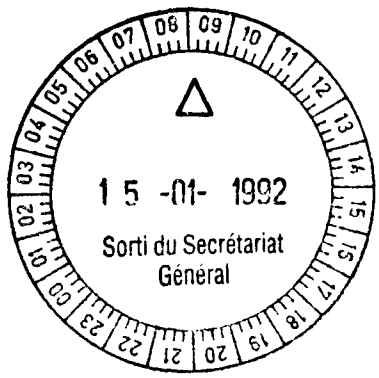
KOM(91) 522 endelig udg.
Bruxelles den 10. januar 1992

Forslag til

RÅDETS AFGØRELSE

om ændring af beslutning 90/218/EØF
om markedsføring og indgift af bovin somatotropin (BST)

(forelagt af Kommissionen)



BEGRUNDELSE

BOVIN SOMATOTROPIN (BST)

1. Kommissionen forelagde den 27. september 1989 Rådet og Parlamentet en rapport om indgift af bovin somatotropin i malkekøer med henblik på at forbedre sektorens produktivitet[1].

   Det blev foreslået at fastsætte en evalueringsperiode indtil udgangen af 1990, som skulle gøre det muligt at bedømme anvendelsen af BST i Fællesskabet. Det blev endvidere angivet, at denne periode ville være den mindste frist, der var nødvendig for at kunne bedømme resultaterne af de igangværende undersøgelser og udarbejde de nye bestemmelser, der skulle vedtages med hensyn til de procedurer, som skulle gælde for sådanne stoffer. Rådet tilsluttede sig ved sin beslutning 90/218/EØF af 25. april 1990[2] Kommissionens anmodning og accepterede derefter ved sin beslutning 91/61/EØF af 4. februar 1991[3] en yderligere frist indtil den 31. december 1991, som var nødvendig for at gennemføre de løbende undersøgelser og gennemgå resultaterne heraf.

2. I mellemtiden er der blevet gennemført flere undersøgelser af forskellige aspekter af BST, og endnu en foreløbig rapport herom vil blive forelagt Rådet og Parlamentet snarligt.

3. Kommissionen kan allerede nu udtale, at der kræves mere tid for at nå frem til endelige konklusioner. Følgelig foreslås det, at Rådet beslutter at forlænge den nuværende evalueringsperiode indtil den 31. december 1993. Det vil gøre det muligt for Kommissionen at forelægge sine nye konklusioner ledsaget af forslag om de fremtidige ordninger senest den 30. juni 1993.

4. Den foreslåede beslutning har ingen finansielle følger.

1) [KOM (89) 379 endelig udg.]
2) EFT nr. L 116 af 08.05.1990, s. 27.
3) EFT nr. L 37 af 09.02.1991, s. 39.

forslag til

RÅDETS BESLUTNING

af

om ændring af beslutning 90/218/EØF
om markedsføring og indgift af bovin somatotropin (BST)

RÅDET FOR DE EUROPÆISKE FÆLLESSKABER HAR -

under henvisning til Traktaten om Oprettelse af Det Europæiske Økonomiske Fællesskab, særlig artikel 43,

under henvisning til forslag fra Kommissionen[1],

under henvisning til udtalelse fra Europa-Parlamentet[2],

under henvisning til udtalelse fra Det Økonomiske og Sociale Udvalg[3], og

ud fra følgende betragtninger:

Ved beslutning 90/218/EØF af 25. april 1990 om markedsføring og indgift af bovin somatotropin (BST)[4], ændret ved beslutning 891/61/EØF[5], pålagde Rådet medlemsstaterne indtil den 31. december 1991 at forbyde, at malkekøer på deres område på nogen måde blev indgivet bovin somatotropin, eftersom virkningerne og følgerne af sådan indgift endnu ikke var tilstrækkeligt klarlagt;

den frist, der var sat til undersøgelse af sådanne virkninger og følger, har vist sig for kort; de igangsatte undersøgelser er kun delvis tilendebragt; der foreligger endnu ikke tilstrækkeligt repræsentative resultater, navnlig ikke med hensyn til dyrs sundhed og velfærd; det er derfor vigtigt at videreføre tilbundsgående undersøgelser, så der kan blive flere oplysninger til rådighed; på nogle punkter må sammenhængen med EF-politikkerne uddybes;

for ikke at foregribe resultatet af disse undersøgelser er det nødvendigt yderligere at forlænge forbuddet mod markedsføring og indgift af bovin somatotropin -

VEDTAGET FØLGENDE BESLUTNING:

1) EFT nr.
2) EFT nr.
3) EFT nr.
4) EFT nr. L 116 af 08.05.1990, s. 27.
5) EFT nr. L 37 af 09.02.1991, s. 39.

Artikel 1

I beslutning 90/218/EØF foretages følgende ændringer:

1. Artikel 1 affattes således:

"Artikel 1

Medlemsstaterne påser, at det indtil den 31. december 1993 ikke på deres område tillades at markedsføre bovin somatotropin eller på nogen måde at indgive malkekøer dette stof."

2. Artikel 4 affattes således:

"Artikel 4

Inden den 30. juni 1993 forelægger Kommissionen Europa-Parlamentet og Rådet en rapport om situationen ledsaget af forslag til den fremtidige ordning."

Artikel 2

Denne beslutning er rettet til medlemsstaterne.

Udfærdiget i Bruxelles, den

På Rådets vegne

ISSN 0254-1459

KOM(91) 522 endelig udg.

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KOM(91) 522 τελικό

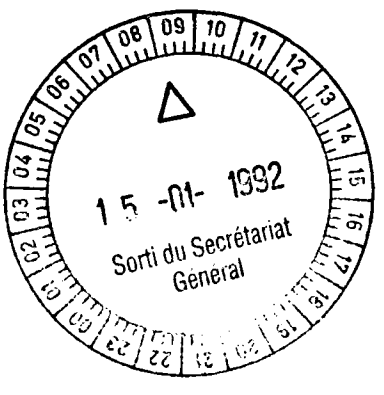
Βρυξέλλες, 10 Ιανουαρίου 1992

Πρόταση

ΑΠΟΦΑΣΗΣ ΤΟΥ ΣΥΜΒΟΥΛΙΟΥ

για την τροποποίηση της απόφασης 90/218/ΕΟΚ σχετικά με τη διάθεση στην αγορά και τη χρήση της σωματοτροπίνης βοοειδών (BST)

(υποβληθείσα από την Επιτροπή)



Αιτιολογική έκθεση

Σωματοτροπίνη των βοοειδών

1. Στις 27 Σεπτεμβρίου 1989, η Επιτροπή υπέβαλε έκθεση στο Συμβούλιο και το Κοινοβούλιο σχετικά με την χορήγηση της σωματοτροπίνης των βοοειδών στις αγελάδες γαλακτοπαραγωγής με σκοπό τη βελτίωση της παραγωγικότητας του εν λόγω τομέα(1).

Προτάθηκε να καθορισθεί μία περίοδος αξιολόγησης, η οποία θα έληγε τέλος 1990 και η οποία θα έπρεπε να επιτρέψει την εκτίμηση της χρησιμοποίησης σωματοτροπίνης βοοειδών στην Κοινότητα. Είναι επίσης σκόπιμο η περίοδος αυτή να αποτελέσει την ελάχιστη αναγκαία προθεσμία για την αξιολόγηση των αποτελεσμάτων των μελετών που βρίσκονται σε στάδιο εκτέλεσης για να θεσπιστούν οι νέες διατάξεις που θα εκδοθούν όσον αφορά τις διαδικασίες που εφαρμόζονται σε τέτοιου είδους προϊόντα. Με την απόφαση του 90/218/ΕΟΚ της 25ης Απριλίου 1990(2) το Συμβούλιο αποδέχθηκε το αίτημα της Επιτροπής, και στη συνέχεια, με την απόφασή του της 4ης Φεβρουαρίου 1991(3), ενέκρινε τη χορήγηση επιπλέον προθεσμίας, η οποία εκπνέει στις 31 Δεκεμβρίου 1991, για να καταστεί δυνατή η ολοκλήρωση των υπό εκτέλεση μελετών και η εξέταση των αποτελεσμάτων τους.

2. Στο ενδιάμεσο χρονικό διάστημα πραγματοποιήθηκαν περισσότερες μελέτες σχετικά με διάφορα θέματα που αφορούν την σωματοτροπίνη των βοοειδών (BST)· σύντομα δε θα υποβληθεί μία δεύτερη ενδιάμεση έκθεση σχετικά με αυτό το θέμα στο Συμβούλιο και το Κοινοβούλιο.

3. Η Επιτροπή είναι σε θέση να επισημάνει ήδη από τώρα ότι θα χρειαστεί επιπλέον χρόνος για να συναφθούν οριστικά συμπεράσματα. Κατά συνέπεια, προτείνεται να αποφασίσει το Συμβούλιο την παράταση της παρούσας περιόδου αξιολόγησης μέχρι τις 31 Δεκεμβρίου 1993. Η παράταση αυτή θα επιτρέψει στην Επιτροπή να υποβάλει νέα συμπεράσματα συνοδευόμενα από προτάσεις σχετικά με τους μελλοντικούς διακανονισμούς το αργότερο έως τις 30 Ιουνίου 1993.

4. Η παρούσα απόφαση δεν συνεπάγεται καμμία δημοσιονομική συνέπεια.

(1) (COM(89) 379 τελικό)
(2) ΕΕ αριθ. L 116 της 8.5.1990, σ.27.
(3) ΕΕ αριθ. L 37 της 9.2.1991, σ.39.

Σχέδιο πρότασης
ΑΠΟΦΑΣΗ ΤΟΥ ΣΥΜΒΟΥΛΙΟΥ
της

για την τροποποίηση της απόφασης 90/218/ΕΟΚ σχετικά με τη διάθεση στην αγορά και τη χρήση της σωματοτροπίνης βοοειδών (BST)

ΤΟ ΣΥΜΒΟΥΛΙΟ ΤΩΝ ΕΥΡΩΠΑΪΚΩΝ ΚΟΙΝΟΤΗΤΩΝ,

Έχοντας υπόψη:

τη συνθήκη για την ίδρυση της Ευρωπαϊκής Οικονομικής Κοινότητας, και ιδίως το άρθρο 43,

την πρόταση της Επιτροπής[1],

τη γνώμη του Ευρωπαϊκού Κοινοβουλίου[2],

τη γνώμη της Οικονομικής και Κοινωνικής Επιτροπής[3],

Εκτιμώντας:

ότι στην απόφαση 90/218/ΕΟΚ[4], σχετικά με τη διάθεση στην αγορά και τη χρήση της σωματοτροπίνης βοοειδών (BST), η οποία τροποποιήθηκε με την απόφαση 91/61/ΕΟΚ της 4ης Φεβρουαρίου 1991, το Συμβούλιο ζήτησε από τα κράτη μέλη να απαγορεύσουν, μέχρι τις 31 Δεκεμβρίου 1991, τη χορήγηση στην επικράτεια τους, υπό οιαδήποτε μορφή, της σωματοτροπίνης βοοειδών στις αγελάδες γαλακτοπαραγωγής, δεδομένου ότι οι συνέπειες και οι επιπτώσεις της χορήγησης αυτής δεν ήταν ακόμη αρκετά γνωστές,

ότι η προθεσμία που είχε ταχθεί για την μελέτη των εν λόγω συνεπειών και επιπτώσεων αποδείχθηκε πολύ μικρή· ότι οι έρευνες που πραγματοποιήθηκαν έχουν ολοκληρωθεί εν μέρει μόνο· ότι δεν υπάρχουν ακόμη επαρκώς αντιπροσωπευτικά αποτελέσματα, κυρίως από την άποψη της υγείας και των καλών συνθηκών διαβίωσης των ζώων· ότι πρέπει επομένως να συνεχιστούν με εμπεριστατωμένο τρόπο οι μελέτες, προκειμένου να παρασχεθούν συμπληρωματικές πληροφορίες· ότι πρέπει τέλος να μελετηθούν σε βάθος ορισμένες πτυχές του θέματος που αφορούν τη συνοχή με τις κοινοτικές πολιτικές,

ότι για να μην προδικασθεί το αποτέλεσμα των μελετών αυτών, είναι αναγκαίο να παραταθεί εκ των υστέρων η απαγόρευση της διάθεσης στην αγορά και της χορήγησης σωματοτροπίνης βοοειδών,

ΕΞΕΔΩΣΕ ΤΗΝ ΠΑΡΟΥΣΑ ΑΠΟΦΑΣΗ:

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(1)
(2)
(3)
(4) ΕΕ αριθ. L 116 της 8.5.1990, σ.27

Άρθρο 1

Η απόφαση 90/218/ΕΟΚ τροποποιείται ως εξής:

1. Το άρθρο 1 αντικαθίσταται από το ακόλουθο κείμενο:

"Άρθρο 1

Τα κράτη μέλη μεριμνούν ώστε να μην επιτρέπουν, μέχρι τις 31 Δεκεμβρίου 1993, στην επικράτεια τους τη διάθεση στην αγορά και τη χορήγηση σωματοτροπίνης βοοειδών στις αγελάδες γαλακτοπαραγωγής υπό οιαδήποτε μορφή."

2. Το άρθρο 4 αντικαθίσταται από το ακόλουθο κείμενο:

"Άρθρο 4

Η Επιτροπή υποβάλλει πριν από τις 30 Ιουνίου 1993 το αργότερο έκθεση στο Ευρωπαϊκό Κοινοβούλιο και το Συμβούλιο σχετικά με την εξέλιξη της κατάστασης, συνοδευόμενη από προτάσεις σχετικά με το μεταγενέστερο καθεστώς."

Άρθρο 2

Η παρούσα απόφαση απευθύνεται στα κράτη μέλη.

Βρυξέλλες,

Για το Συμβούλιο

ISSN 0254-1483

COM(91) 522 τελικό

ΕΓΓΡΑΦΑ

GR **03**

Αριθ. καταλόγου : CB-CO-91-601-GR-C

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Υπηρεσία Επισήμων Εκδόσεων των Ευρωπαϊκών Κοινοτήτων
L-2985 Luxembourg

COMISION DE LAS COMUNIDADES EUROPEAS

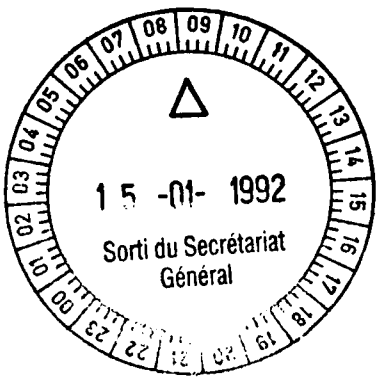
COM(91) 522 final
Bruselas. 10 de enero de 1992

Propuesta de

DECISION DEL CONSEJO

por la que se modifica la Decisión 90/218/CEE sobre la comercialización y administración de la somatotropina bovina (BST)

(presentada por la Comisión)



Exposición de motivos

Somatotropina bovina

1. El 27 de septiembre de 1989, la Comisión presentó un informe al Consejo y al Parlamento sobre la administración de la somatotropina bovina a las vacas lecheras a fin de mejorar la productividad del sector de los productos lácteos(1).

Se propuso que se fijara un periodo hasta finales de 1990 que permitiese evaluar la utilización de la BST en la Comunidad, precisándose que dicho periodo constituía el plazo mínimo necesario para apreciar los resultados de los estudios en curso y elaborar las nuevas disposiciones que deban adoptarse respecto a los procedimientos aplicables a tales productos. El Consejo, mediante sus Decisiones 90/218/CEE, de 25 de abril de 1990(2) y 4 de febrero de 1991(3), aceptó, respectivamente, la solicitud de la Comisión y la ampliación del plazo que permita la finalización de los estudios en curso y el examen de sus resultados hasta el 31 de diciembre de 1991.

2. En ese intervalo, se realizaron varios estudios sobre diversos aspectos de la BST y, en breve, será presentado al Consejo y al Parlamento un segundo informe interino sobre el particular.

3. Desde este momento, la Comisión puede asegurar que hará falta más tiempo para sacar las conclusiones definitivas y, por consiguiente, se propone al Consejo que decida la prolongación del periodo de evaluación actual hasta el 31 de diciembre de 1993. De este modo, la Comisión podrá presentar sus nuevas conclusiones, para el 30 de junio de 1993, acompañadas de las propuestas relativas a las futuras adaptaciones.

4. La presente Decisión no tiene ninguna consecuencia financiera.

(1) [COM (89) 379 final].
(2) DO no L 116 de 8.5.1990, p. 27.
(3) DO no L 37 de 9.2.1991, p. 39.

Proyecto de propuesta

de

DECISIÓN DEL CONSEJO

de

por la que se modifica la Decisión 90/218/CEE sobre la comercialización y administración de la somatotropina bovina (BST)

EL CONSEJO DE LAS COMUNIDADES EUROPEAS,

Visto el Tratado constitutivo de la Comunidad Económica Europea, y, en particular, su artículo 43,

Vista la propuesta de la Comisión(1),

Visto el dictamen del Parlamento Europeo(2),

Visto el dictamen del Comité Económico y Social(3),

Considerando que, en su Decisión 90/218/CEE(4), sobre la comercialización y administración de somatotropina bovina (BST), modificada por la Decisión 91/61/CEE, de 4 de febrero de 1991, el Consejo pidió a los Estados miembros que prohibiesen, hasta el 31 de diciembre de 1991, la administración en su territorio, en cualquiera de sus formas, de somatotropina bovina a las vacas lecheras, dado que todavía no se conocen suficientemente los efectos y las consecuencias de dicha administración;

Considerando que el plazo otorgado para estudiar esos efectos y consecuencias resulta demasiado breve; que las investigaciones que se están realizando no han llegado a su fase final; que todavía no existen resultados que sean suficientemente representativos, especialmente, en lo relativo a la salud y el bienestar de los animales; que, por consiguiente, es importante que se continúe profundizando en los estudios para poder disponer de informaciones complementarias; que, finalmente, es oportuno que se analicen determinados aspectos de la coherencia con las políticas comunitarias;

Considerando que, con objeto de no prejuzgar el resultado de tales estudios, es preciso que se prolongue la prohibición de comercializar y administrar la somatotropina bovina.

HA ADOPTADO LA PRESENTE DECISIÓN:

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(1)
(2)
(3)
(4) DO nº L 116 de 8.5.1990, p. 27.

Artículo 1

La Decisión 90/218/CEE queda modificada como sigue:

1. Se substituye el texto del artículo 1 por el siguiente:

"Artículo 1

Los Estados miembros velarán por que, hasta el 31 de diciembre de 1993, no se autorice en su territorio la comercialización de la somatotropina bovina ni su administración, en ninguna de sus formas, a las vacas lecheras."

2. El texto del artículo 4 se sustituye por el siguiente:

"Artículo 4

Antes del 30 de junio de 1993, la Comisión presentará al Parlamento Europeo y al Consejo un informe sobre la situación, acompañado de propuestas sobre el régimen ulterior."

Artículo 2

Los destinatarios de la presente Decisión son los Estados miembros.

Hecho en Bruselas, el

Por el Consejo

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COMISSÃO DAS COMUNIDADES EUROPEIAS

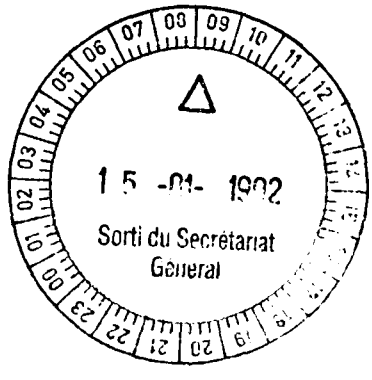
COM(91) 522 final
Bruxelas. 10 de Janeiro de 1992

Proposta de

DECISÃO DO CONSELHO

que altera a Decisão 90/218/CEE relativa à colocação no mercado e à administração da somatotrofina bovina (BST)

(apresentada pela Comissão)



Exposição dos motivos

Somatotrofina bovina

1. Em 27 de Setembro de 1989, a Comissão apresentou ao Conselho e ao Parlamento um relatório sobre a administração da somatotrofina bovina às vacas leiteiras com o objectivo de melhorar a produtividade do sector em causa[1].

Foi proposta a fixação de um período de avaliação com termo no final de 1990 e que deverá permitir avaliar a utilização da BST na Comunidade. Foi igualmente indicado que tal período representa o tempo mínimo necessário para apreciar os resultados dos estudos em curso e apurar novas disposições a adoptar quanto aos processos aplicáveis a tais produtos. Pela sua Decisão 90/218/CEE, de 25 de Abril de 1990[2], o Conselho aprovou o pedido da Comissão, tendo, pela sua decisão de 4 de Fevereiro de 1991[3], aceitado um prazo suplementar, com termo em 31 de Dezembro de 1991, necessário para permitir a conclusão dos estudos em curso e o exame dos seus resultados.

2. Foram, entretanto, realizados vários estudos de diversos aspectos da BST, devendo um segundo relatório provisório sobre o assunto ser brevemente apresentado ao Conselho e ao Parlamento.

3. A Comissão pode desde já indicar que será necessário mais tempo para chegar a conclusões definitivas. Assim, é proposto que o Conselho decida prorrogar o período de avaliação actual até 31 de Dezembro de 1993. Tal permitirá à Comissão apresentar as suas novas conclusões, acompanhadas de propostas relativas a futuras medidas, até 30 de Junho de 1993, o mais tardar.

4. A presente decisão não tem nenhumas incidências financeiras.

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(1) [COM (89) 379 final]
(2) JO nº L 116 de 8.5.1990, p. 27.
(3) JO nº L 37 de 9.2.1991, p. 39.

Projecto de proposta

de

DECISÃO DO CONSELHO

DE

que altera a Decisão 90/218/CEE relativa à colocação no mercado e à administração da somatotrofina bovina (BST)

O CONSELHO DAS COMUNIDADES EUROPEIAS,

Tendo em conta o Tratado que institui a Comunidade Económica Europeia e, nomeadamente, o seu artigo 43º,

Tendo em conta a proposta da Comissão(1),

Tendo em conta o parecer do Parlamento Europeu(2),

Tendo em conta o parecer do Comité Económico e Social(3),

Considerando que, pela sua Decisão 90/218/CEE, relativa à colocação no mercado e à administração da somatotrofina bovina (BST)(4), com a última redacção que lhe foi dada pela Decisão 91/61/CEE, de 4 de Fevereiro de 1991, o Conselho pediu aos Estados-membros que proibissem, até 31 de Dezembro de 1991, a administração no seu território, seja por que meio for, da somatotrofina bovina às vacas leiteiras, dado que os efeitos e as consequências de tal administração não estavam ainda devidamente estudados;

Considerando que se verificou que o prazo previsto para estudar tais efeitos e consequências era demasiadamente curto; que os estudos realizados apenas proporcionaram resultados parciais; que não existem ainda resultados suficientemente representativos, nomeadamente do ponto de vista da saúde e do bem-estar dos animais; que é, pois, necessário continuar e aprofundar os estudos para poder dispor de informações complementares; que é, ainda, conveniente aprofundar certos aspectos de coerência com as políticas comunitárias;

Considerando que, para não tirar conclusões precipitadas do resultado de tais estudos, é necessário prorrogar a proibição de colocação no mercado e administração da somatotrofina bovina,

ADOPTOU A PRESENTE DECISÃO:

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(1)
(2)
(3)
(4) JO nº L 116 de 8.5.1990, p. 27.

Artigo 1o

A Decisão 90/218/CEE é alterada do seguinte modo:

1. O artigo 1o passa a ter a seguinte redacção:

"Artigo 1o

Os Estados-membros velarão, até 31 de Dezembro de 1983, por que não seja autorizada nem a colocação no mercado de somatotrofina bovina, nem a sua administração nos seus territórios, seja por que meio for, às vacas leiteiras.".

2. O artigo 4o passa a ter a seguinte redacção:

"Artigo 4o

Antes de 30 de Junho de 1993, o mais tardar, a Comissão apresentará ao Parlamento Europeu e ao Conselho um relatório da situação, acompanhado de propostas relativas ao regime a adoptar posteriormente.".

Artigo 2o

Os Estados-membros são destinatários da presente decisão.

Feito em Bruxelas, em

Pelo Conselho

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