## COMMISSION OF THE EUROPEAN COMMUNITIES

**COM(89)** 379 final

Brussels, 27 September 1989

Proposal for a

COUNCIL DECISION

concerning the administration of Bovine Somatotrophin (B.S.T.)

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Report

concerning Bovine Somatotrophin (B.S.T.)

x x x

(presented by the Commission)

#### Explanatory Memorandum

- The report annexed deals with the main considerations that need to be taken into account in connection with the authorization and use of Bovine Somatotrophin (BST). When administered to the lactating cow BST is capable of bringing about a significant increase in milk yield.
- 2. The existing authorization arrangements in relation to BST provide for a national decision-making procedure after the Committee on Veterinary Medicinal Products (CVMP) established under Directive 81/851/EEC has delivered an opinion. The Committee is expected to issue an opinion on two applications in relation to BST within the next six months.
- 3. The conclusion of the report is that it would be inappropriate to decide on the use of BST until all the necessary studies and assessments have been completed. Furthermore a decision on BST should await the putting in place of revised dispositions in relation to veterinary medicinal products and feed additives intended for promotion of yield. Present indications are that, apart from BST, other comparable products applied to livestock may have a significant effect on productivity, with potentially far reaching implications for production and socio/economic structures in agriculture.
- 4. It is, accordingly, proposed to the Council to adopt the annexed proposal with a view to establishing an evaluation period, until 31 December 1990 as regards the administration of BST. There are no implications for the Community budget.

### Draft Proposal for a Council Decision of Concerning the administration of Bovine Somatotrophin (B.S.T.)

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 of the Commission,

Having regard to the opinion of the European Parliament,

Having regard to the opinion of the Economic and Social Committee,

Whereas products arising from milk production have a very important place in the Community; Whereas they are an essential source of income for a part of the agricultural population;

Whereas knowledge acquired gives the possibility for the placing on the market of substances which may have a significant impact on productivity. In milk production;

Whereas despite the work accomplished, in particular the evaluation of Bovine Somatotrophin by the Committee on veterinary Medicinal Products in accordance with Council Directive 81/851/EEC of 28th September 1981 on the approximation of the laws of the Member States relating to veterinary medicinal products<sup>(1)</sup> and Council Directive 87/22/EEC of 22nd December 1986 on the approximation of national measures relating to the placing on the market of high-technology medical products, particularly those derived from biotechnology<sup>(2)</sup>, the various effects of new

(1) O.J. N° L 317 of 06.11.1981, p. 1
(2) O.J. N° L 15 of 12.01.1987, P. 38

substances such as Bovine Somatotrophin are not yet sufficiently clear; in this respect, a necessary period should be forseen for in-depth studies to be made;

Whereas in the absence of a Community decision, the Member States may adopt divergent measures; whereas these divergencies may lead to a distortion of competition between milk producers and to new barriers to intra-Community trade;

Whereas in the view of the preceeding considerations, it is a matter of overriding public interest to provide for a temporary prohibition of administration to dairy cows of the substances in question, until all necessary information is obtained;

Whereas it will be necessary to re-examine the overall situation.

HAS ADOPTED THIS DECISION:

#### Article 1

Notwithstanding the scientific and technical examination of applications in accordance with Community legislation, until 31 December 1990 the administration by any means whatsoever within the Community to dairy cows of Bovine Somatotrophin, shall not be authorized in the Member States.

#### Article 2

in derogation from Article 1, the Member States may authorise the administration to dairy cows of Bovine Somatotrophin for carrying out scientific and technical trials.

#### Article 3

On a proposal from the Commission the Council may, acting by a qualified majority, adopt measures necessary for the implementation of this Decision.

#### Article 4

The Commission shall, before 1 October 1990, submit a report to the Council and to the European Parliament on the development of the situation, accompanied by any necessary proposals. The Council shall decide before 31 December 1990.

#### Article 5

This Decision is addressed to the Member States.

Done at Brussels

By the Council

#### REPORT

from the Commission to the Council

and to Parliament

concerning

Bovine Somatotrophin (B.S.T.)

#### Report from the Commission to the Council

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#### Bovine Somatotrophin (B.S.T.)

#### GENERAL BACKGROUND

- 1. Somatotrophin is a growth hormone, secreted by the pitultary gland. In general the activity of this hormone is species specific, so that for example, Bovine Somatotrophin (BST) from the cow should have no influence on human growth. It has been known since the 1930s that the administration of BST to dairy cattle could increase milk yields. However, since BST could only be extracted as a natural hormone post mortem, the quantities available were too limited and too expensive to permit commercial use.
- 2. Following the development of recombinant DNA biotechnology in the 1970s, it became possible to produce large quantities of somatotrophins at relatively low cost. Apart from use of recombinant BST (rBST) for milk production, for which authorisation is now being sought by the companies concerned, research is being conducted into use of bovine, porcine and ovine somatotrophins for fattening purposes.
- 3. A further factor delaying the commercial exploitation of BST was the need to provide an appropriate sustained release formulation, which would eliminate the need for daily injections. The stage has now been reached where administration at two to four weekly intervals seems to bring about the desired increase in milk yields. Studies have indicated increases of milk yield of upwards of 25% on administration of rBST under controlled conditions. It is

estimated that, given the knowledge and ability required for effective use of the product, yield increases closer to 12% are more likely to be achieved in normal farm conditions.

- 4. The possible use of rBST in milk production has been the subject of widespread public interest. In the Council of Agriculture Ministers several Member States have expressed reservations about its use. mainly in relation to potentially adverse socio/structural consequences and the implications as regards supply and demand for milk and milk products. The matter has been examined extensively bν various Committees in the European Parliament which, on 5 July 1988, adopted a resolution<sup>1</sup> on the effects and risks of using growth hormones and the BST hormone in the dairy and meat industries. The Parliament called on the Commission to examine the consequences of the use of rBST, to consider, inter alia, the necessity for additional criteria, e.g. social and economic factors, in the examination of applications for authorisations and to create a legal framework covering genetically engineered growth accelerators or yleid enhancers. Under existing legislation authorisations are considered on the basis of three criteria viz, safety, quality and efficacy. The BST question was discussed at length at a seminar held in September 1988 under the auspices of the Commission. A wide range of organisations (listed in Annex 1) have been consulted and have had an opportunity to give their views.
- It is clear from the reaction in the Council of Ministers 5. that. while most Member States are very hesitant about authorisation of rBST, there may not be unanimity on the the lssue. Divergent positions of Member States on authorisation carries a serious danger of distortion of competition and trade disputes.

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1 0.J. C 235 (Vol. 31) of 12.9.1988, pp. 41-44.

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#### EXISTING LEGISLATION

- 6. The definition of a medicinal product in Article 1 of Directive 65/65/EEC covers not only products intended to prevent or treat disease but also products which may be administered to humans or animals with a view to modifying physiological functions, such as an increase in milk yield in cattle. BST is therefore regarded as a veterinary medicinal product.
- 7. Directive 81/851/EEC is designed to harmonize the laws of the Member States on the authorization of veterinary medicinal products. The approach to authorisation - a matter for decision by the Member State concerned - is based on three exclusive criteria namely quality, safety and efficacy of the products concerned. The procedure in the case of biotechnology products is somewhat different in that under Directive 87/22/EEC, Member States may not application for authorization for a decide on any veterinary medicinal product derived from blotechnology until the Committee for Veterinary Medicinal Products (CVMP) has given an opinion. Final evaluation of the test results and the decision on authorization remains the responsibility of the Member States.
- 8. As regards other comparable legislation in agriculture, somatotrophin is not subject to Council Directives 1981/602/EEC of 31 July 1981<sup>2</sup>, 85/358/EEC of 16 July 1985<sup>3</sup> and 88/146/EEC of 7 March 1988<sup>4</sup> in relation to prohibition on the use of certain hormones for fattening purposes. It is not affected either by the provisions of Council Directive 70/524/EEC of 23 November 1970 on additives in feedingstuffs.<sup>5</sup> Under this Directive the only substances that may be used as additives in animal

<sup>2 0.</sup>J. L 222 of 7.8.1981, p. 32.

<sup>3 0.</sup>J. L 191 of 23.7.1985, p. 46.

<sup>4 0.</sup>J. L 70 of 16.3.1988, p. 16.

<sup>5 0.</sup>J. L 270 of 14.12.1979, p. 1.

feedingstuffs are those approved <u>by a Community procedure</u> and listed in the Annexes to the Directive. Since no oral preparation is currently available in the case of rBST formulations are administered by injection - the question of authorising rBST as an additive in feedingstuffs has not arisen. It may be noted, however, that several antibiotics and other chemical additives, whose effect is to increase productivity of livestock, are either currently authorised or the subject of applications for authorisation.

Two applications for a marketing authorization for BST were 9. for an opinion to the CVMP 1987. referred l n One application would cover all Member States except Luxembourg and the Netherlands. A second application concerns France and the United Kingdom.

Under existing procedures it is a matter for the applicant to submit the data necessary to prove that the three criteria have been met; applications are assessed by the authorIties and the national bу Committee. The authorities of the States concerned receive a Member complete set of the data submitted by each company, and have the opportunity to submit questions and comment.

The commercial implications of receiving authorisation requires that the regulatory authorities protect the confidentiality of the data submitted. The Commission is obliged also to respect the confidentiality of discussions within the CVMP, a requirement that limits the degree of detail that can be furnished in this report.

10. In its examination of this matter the CVMP has been assisted by an ad-hoc group of experts on biotechnology. It is understood that the assessment process within the Committee may be entering its final phase. Expectations are for an opinion in or about the end of this year. At this stage, therefore, it is only possible to provide an interim review of the authorisation process.

#### EXAMINATION BY COMMITTEE ON VETERINARY MEDICINAL PRODUCTS (CVMP)

11. Following is an indication of progress on the main elements taken into account in the Committee's assessment.

#### a) <u>Safety in the animal</u>

The studies initially submitted by the applicants were considered to be of insufficient duration. Both applicants have been requested to provide substantial additional data covering three lactation perlods; this Involves the monitoring of a wide range of physiological parameters in COW and her progeny to enable a comprehensive the assessment to be made. Among the factors which are being specifically considered under this heading are the potential effects of BST on reproductive performance, on the incidence of mastitis, on bone growth and development in the calf and on the extent and clinical significance of injection site rejections.

#### b) <u>Human safety</u>

It is assumed at present that any residues of BST in milk should not pose a risk to consumer health since the overal! level of BST IS not significantly Increased after administration. destroyed Besides, BST IS during pasteurization, the hormone is broken down completely in the stomach and is not active in man. The applicants have been required to provide scientific data to justify these Since BST operates either directly or via assumptions. stimulation of another hormone (|GF|)the effect as regards other hormone levels has to be considered also.

While BST is designed to increase milk yields, consideration must be given also to residues of BST in meat, in particular to any persistence of residues at the injection site. As with any veterinary medicinal product, the applicant must propose a routine method of analysis of

sufficient sensitivity to detect residues at low levels. Moreover, in addition to studies of the safety of residues, the potential risk of direct human contact with the products must be addressed to ensure the safety of persons using the product on the farm. These elements form part of the assessment by the Committee.

#### c) <u>Quality of synthetic B.S.T.</u>

While BST is a naturally occurring substance, the commercial formulations are complex products requiring advanced technology in manufacture. The applicants have had to provide appropriate guarantees of their ability to produce a consistent, pure and homogenous product on an industrial scale.

#### d) <u>Efficacy of synthetic B.S.T</u>.

While the effect of BST in increasing milk yields is well documented, further information has been requested to justify the proposed dosage levels and the intervals between injections.

#### 12. Resume of examination by CVMP

The various elements involved are still under assessment by scientists from the national regulatory authorities.

The examination process is now entering its final phase; it is expected that an opinion will be delivered by the Committee by the end of the year.

#### OTHER IMPACTS

13. Apart from the examination by the Committtee, some of the elements involved are the subject of other studies being carried out at the request of the Commission eg on quality and composition of the product, and likely consumer and producer attitudes to the use of BST. Other important socio-economic and economic factors eg effects on agricultural production and structures are not at present the subject of in-depth studies.

#### Food Product Quality

- As regards milk quality, apart from the safety of residues, 14. applicants for authorisation must identify the any potential difficulties in the subsequent industrial processing of foodstuffs. In the course of examination by the CVMP, additional information has been required on the effects of the use of BST on protein, fat and vitamin content of milk and on the effects for the manufacture of cheeses and other dairy products.
- An aspect requiring particular attention relates to the 15. somatic cell count (SCC) which is one of the main tests of milk bacteriological quality and is used as an indication Reports from the United States and of mastitis in animals. a recent German study (Heeschen 1988), indicate that BSTapplication leads to an increased number of somatic cells the milk and to Increased pyruvate levels In also. increased SCC levels would have implications as regards the standards laid down in Directive 85/397 as regards intra Community trade in milk for consumption and the price paid to producers for milk for manufacturing. An increase in somatic cells affects the composition of milk eg the lactose/salts ratio, a factor that could influence product quality and yield. A research project is currently underway (funded resources from the milk by co~ responsibility levy) at the Bundesanstalt für Mlichforschung at Kiel to examine these aspects; a report is expected by the end of 1990.
- 16. The standard of farm management is essential if the likely adverse effects of BST on composition are to be mitigated. The availability of good quality feeding and the ability of the cow to consume it in increased amounts is a prerequisite to effective application of rBST. Should

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producers fail to operate an adequate feeding system, the fatty acid composition of milk fat, and in turn butter quality, would be affected.

The impact of BST on milk composition needs to be examined more fully, in relation to, for example, milk concentration, the combination effects of heat treatments and the effects on rennetablility, the effect of increases in the level of whey proteins and consequences for the consumption of ilquid milk. These are questions that need to be addressed by way of further studies.

#### ECONOMIC AND SOCIAL CONSEQUENCES

#### Impact at farm level

17. The consequences have to be considered in the context of the milk quota, established as part of the Community's milk policy, remaining beyond its review date in 1992. At the individual farm level the main consequence of the introduction of rBST in milk production is an increase in the milk yield per cow. The actual level of milk yield increase would be less (probably about 12%) than the 25% recorded in research. since farm management in normal circumstances is likely to be less rigorous than under the conditions highly-controlled of experimental studies. While intake of feed has to increase significantly, perhaps by as much as 10%, to achieve optimum results, BST can lead to an increase in the efficiency of feed conversion to milk by up to 6%. There is a view that on many farms BST may be used as a tactical management tool, for example to increase milk output where production seems likely to fall below quota, or to adjust the seasonality of production or treat individual cows, rather than to as а routine treatment.

While, in the initial period at least, the response to BST by way of increased milk yield at farm level may be below the research levels, it is reasonable to expect a growing increase in yield levels as further research and management are refined to achieve optimum results. It has to be assumed that BST would be made available at a price to permit economic use.

- 18. The Community's milk quota regime is designed to ensure that milk production does not increase beyond a fixed the present tendency for large scale level. Nevertheless, dairy farmers to produce in excess of their individual quotas creates an ongoing risk of higher milk deliveries. BST would add to this risk. Furthermore its use by milk producers to avoid production being under quota would Important "safety valve" from the existing remove an system.
- The general use of BST would likely lead to reduced dairy 19. This would affect the beef sector cow numbers. through an increase. In the short-term, in the number of cows taken out of milk production and sent for slaughter. In the longer-term fewer dairy cows should lead to lower beef production. in the normal course is without BST, heef production from the dairy herd would tend to fall due to the ongoing increase in milk yield as a result of improved feeding and housing techniques and better selection in the The use of BST would accelerate this trend: dairy herd. some studies suggest that the decline in cow numbers would accelerate by some 10 percent.
- 20. Reduction in dairy cow numbers raises the question of the utilisation of the factors of production, i.e. labour and capital, that would be freed at the farm level. Many farmers affected by the milk quota are already starting new enterprises, especially in beef, sheepmeat and cereals. This tendency could grow despite there being few increased outlets for further production; beef and cereals are subject to the stabiliser mechanisms, while sheepmeat has

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been the subject of proposals designed to reduce the guarantee, in view of the sharp rise in FEOGA expenditure in the sector. The development of opportunities for diversification and alternative rural enterprises could be a factor also.

#### Milk Policy Aspects

- 21. In considering this question it is necessary also to bear in mind the agricultural policy pursued in recent years by the Community, notably since 1984. This has involved a programme to control output directly and to encourage farmers to diversify and engage in less intensive forms of production. The policy was developed against a background of sharply increasing production, and mounting surpluses leading to unsustalnable pressures on the Community budget.
- 22. and a satisfactory Despite the quota system market situation. the miik regime costs about 5 000 MECU annually. The quota, central to the Community's policy of containing production and expenditure. is a fragile mechanism whose beneficial effects are at constant risk from surplus production. Deliveries in the 1988/89 season were some 1.8 million tonnes above quota; this has led to requests to the budgetary authority for increased credits for the milk sector this year.

#### Socio-Structural

23. As regards the socio-structural aspects, milk production is central to incomes of smaller producers ie those with less than 10 cows in the Community. While such producers represent some 53% of holdings (1.6 million), only 12% of dairy cows are kept on their holdings. Producers with larger resources are best placed to take advantage of increases in productivity through the use ٥í new producers. Smaller traditionally technologies. less capable of adapting to change and technical advances are slow to benefit, if at all, from such opportunities.

In the case of BST, the management techniques required and the need to provide supplementary high quality feed for cows, would limit any possible advantages in the case of small herds. Besides, there would normally be no incentive to a herdowner with less than a given minimum to use BST. This number (8) of COWS would have implications as regards the regional distribution of BST usage in the Community.

The ability of BST to increase further the economies of 24. scale and profits of larger producers would give them a greater capacity to engage in other forms of production and/or to purchase smaller holdings with milk quotas. 11 is likely also to lead to growing pressures to break the In existing legislation, between the quota and the link, holding - quotas may not be purchased independently of the corresponding holding – as larger producers seek to consolidate their positions and make optimum use of the new technology.

#### 25. Consumer View

No detailed studies have been made, of the likely consumer reaction to meat and dairy products in the event of BST beina authorised. Consumers organisations have warned that this could be very negative. At the meeting of the Veterinary Advisory Committee on 15 March and at the Advisory Committee for milk and milk products on 31 March 1989. BEUC, the umbreila consumer group organization, called for a total ban on BST. The consumer view is that research carried out to date does not demonstrate any advantage for the consumer eg by reducing retail prices for dairy products or by improving the quality of milk and meat products or the health and nutritional standards of 0n the contrary BST is claimed milk. to engender mistrust and suspicion of the quality of meat and of dairy products. Consumers are concerned also at the animal welfare aspects (see par 29).

#### 26. Market Aspects

As regards the market for dairy products, consumption has been increasing steadily in recent years. There is a growing trend away from traditional products such as butter - perceived by some consumers as harmful to health - to cheeses and diversified products. Dairy products face increasing competition from substitute products. Producers, the dairy industry and indeed the Community, through some 400 MECU committed from the coresponsibility funds, have invested heavily in recent years in promoting an image of milk and dairy products as natural, healthy products.

- 27. It would be a serious setback to producers and to the Community's milk policy were present trends In consumption to be reversed as a result of adverse consumer reaction. This points to the need for the most careful evaluation of this aspect. Since existing techniques do permit the ready identification of rBST in dairy not products, the concerns of consumers cannot at present be through labelling. An important research project, met financed by the milk co-responsibility funds, is being carried out at the University of Munich with the object of finding a method to identify rBST in milk: this ls expected to be completed in the second half of 1990.
- 28. It is intended that other studies currently under way at the institute für Wirtshaftsforshung in Munich and at the University of Glessen due to be completed in November 1990 will provide more information on likely consumer reaction. The studies will cover farmer reaction also to use of BST.

#### 29. <u>Animal Weifare</u>

Concern at the animal welfare implications of the use of BST relates to short-term and long-term effects, and administration. As regards the short-term, the concern is that cattle treated with BST could suffer from a greater incidence of metabolic diseases. In relation to the longer term the concern is that the administration of BST over several lactations could result in changes in the calcium/phosphorus balance, leading to musculo-skeletal deformities, and that there could be unforeseen problems for the calves of treated cows. The CVMP is examining these aspects.

The need to administer BST by injection and to restrain animals for the purpose of administration are seen also as undesirable on animal welfare grounds.

#### 30. Other Somatotrophins

While the immediate subject of this report relates to rBST for milk production, somatotrophin has a potential to be an effective commercial growth and carcase enhancer in other livestock. Significant improvements in daily gains and feed conversion efficiency have been recorded in the course of experimental work on cattle, sheep and especially in pigs. While results are more variable than in the case of milk and the techniques involved have not reached the stage of commercialisation — the need for frequent injections is a major drawback — further research and development in these fields may open the way for a substantial increase in productivity and production of livestock products.

#### 31. Views of Pharmaceutical Industry

The pharmaceutical industry would be concerned about possible adverse impact of changes in present authorisation procedures not founded on a sound scientific basis. The industry would be opposed to criteria relating to social and economic factors. The contention is that departures criteria from established by legislation create likelihood uncertainty, and reduce the of research. development, innovation and investment.

The industry supports the authorization of BST which, it claims, will bring economic benefits for industrial supplier, farmer and consumer.

#### Feed Additives

32. Apart from BST, concern has been expressed in the Council of Ministers in relation to the authorisation of growth animal feedingstuffs promoters in (see par 8). This concern relates to Owconsumer protection, market imbalanc and budgetary costs. The Commission has undertaken to present the results of studies in this area with a view to discussion in Council. It is accordingly intended to launch shortly a wide-ranging study of the impact of growth factors in the production of livestock products. This will cover the economic aspects In relation to agricultural productivity, research and consumption; together with the socio-economic elements. The study is expected to be completed by October 1990. Nine growth promoters have been authorised as feed additives under existing legislation and further applications for authorisation are currently being considered; one such application relates to a substance considered capable of increasing milk yields by upwards of 5%. No authorisations for milk production have been given to date.

#### 33. CONCLUSIONS

- (a) The use of recombinant BST (rBST) is capable of significant increase in milk yields. It is likely to be the forerunner of other products capable of bringing about a substantial increase in meat production.
- (b) On the assumption of the Community's milk quota regime continuing beyond 1992, the use of BST should be reflected in a reduction in the number of dairy cows rather than an increase in overall milk production; this is likely to be

accompanied by a release of resources of labour and capital into other sectors of agriculture, greater concentration of milk production in the hands of the larger milk producers and greater pressure on the quota regime.

- (c) Apart from the Member States and the European Parliament which has adopted a resolution on the issue, this is a matter of considerable public interest especially among consumers, producers, industry, animal welfare organisations and scientific interests. While directly opposing positions have been taken up by consumers and the pharmaceutical industry, most other interested parties have taken a more cautious position, advocating further studies and information.
- (d) Apart from the purely scientific aspects, the reservations expressed by the Member States and the position taken up in the Parliament on these issues, as well as the considerable uncertainty in relation to consumer reaction and consequences for the market, requires that the Community's approach to be based on the fullest awareness of all the implications.
- (e) The present authorisation process for use of BST provides for a decision at national level. Other chemical products, administered to livestock by means of an oral preparation for nutritional purposes as additives in feedingstuffs, are subject to a Community authorisation procedure. While several Member States have expressed reservations about use of BST there may not be unanimity on the issue. This could have implications in relation to free movement of products. Examination of the matter by the Committee on Veterinary Medicinal Products (CVMP), conducted on the basis of the "safety", "efficacy" and "quality" of the product is at an advanced stage. It is likely that Member States will be faced with the decision of whether to authorise rBST by the end of this year. Studies under way into other aspects eg milk composition and quality, consumer reaction etc are due to be completed in the second half of 1990.

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- (f) It is clear that a situation in which Member States may take divergent decisions on BST must be avoided: to this end the Commission will present comprehensive proposals to Council by the end of this year. Having regard to the position of Parliament and the general public concern on preparation of the proposals will require these issues. detailed examination of the most appropriate decision making arrangements and structures in connection with authorisation of all productivity enhancing substances in agriculture, whether veterinary medicinal products. including products of blotechnology, or feed additives.
  - It is clear also that sufficient time should be available (g) to assess the results of the current studies, under the aegls of the CVMP and of the Commission. At the same time It is essential to avoid prolonged uncertainty that would Interests of he harmful to the Industry, especially blotechnology, which Important role in the has an Community, not least in the development of agriculture.
- (h) It will be important also to have an exchange of views on the issues raised with any interested third countries, as it is certain that the questions raised are of deep concern and interest not just in the Community but also in the major producer and consumer countries.

#### Recommendations

It is accordingly proposed that the Council adopt a decision to establish an evaluation period up to the end of 1990 on the administration of rBST. This period is considered to be the minimum necessary to assess the results of ongoing studies and complete the new arrangements to be adopted on procedures. The target date for completion of some of the studies will have to be brought forward to enable the Commission to fully review all aspects in twelve months time. This will provide the opportunity interested also to complete the necessary contacts with

third countries. In keeping with the Community's openness on the definitive conclusion on this question, it is not the intention to prohibit imports of BST or of products derived from BST treated animals during the <u>evaluation</u> period. This approach is not considered to place Community milk producers at a competitive disadvantage in practice.

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#### Annex I

consulted a) <u>THE VETERINARY</u> ADVISORY Bodies COMMITTEE representative of Agricultural Producers (COPA), Agricultural Cooperatives (COGECA). Industry, Confederation of the Food and Drink Industries of the EEC (C.I.A.A.). Commerce. Comite Europeen de Llalson des Commerces Agroallmentaires (C.E.L.C.A.A.). Workers, European Trade Union Confederation (E.T.U.C.). Consumers, Bureau Européen Unions des de (B.E.U.C.), European Consommateurs Community of Consumer Cooperatives (E.U.R.O.C.O.O.P.), Confederation des Organisations Familiales de la CE (C.O.F.A.C.E.). Federation of Veterinarians of the European Economic Community (FVE). b) The ADVISORY COMMITTEE ON MILK AND MILK PRODUCTS, (representatives of Producers/Cooperatives, Dairy and Dairy Related Industries, Trade, Workers and Consumers) c) OTHER HEARINGS/ REPRESENTATIVES/OBSERVERS, European Community Dairy Industries (A.S.S.I.L.E.C., A.S.S.I.F.O.N.T.E., A.S.F.A.L.E.C.), European Community Dalry Traders (U.N.E.C.O.L.A.I.T., E.U.C.O.L.A.I.T), Eurogroup for Animal Welfare, European Federation of Animal Health (F.E.D.E.S.A.), Compassion in World Farming (C.I.W.F.), European Farmers Coordination, Deutscher Tierschutzbund. Tierverschunger – Nordrhein-Westphalla E.V., Gen-ethisches Netzwork G.E.N., Evangelisches Bauernwerk in Wurttemberg, Die Verbraucher Initiative, European Campaign Against B.S.T., Working group for Lactical Veterinary Medicine (A.G.K.T.), EC Livestock Trade (U.E.C.B.V.), EC Meat and Meat Processing Industry (C.L.I.T.R.A.V.I.), European Retail Trade Associations (C.L.D., C.E.C.D.), EC Meat Wholesale Trade (A.E.C.G.V.), The London Food Commission.

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