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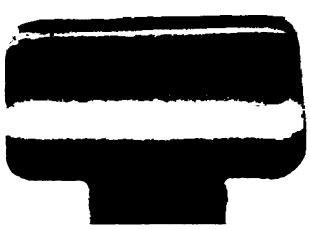
IICA

CONSULTATION ON THE USE OF HORMONAL SUBSTANCES IN ANIMALS: ECONOMIC AND TECHNICAL IMPLICATIONS

FINAL REPORT AND DOCUMENTS PRESENTED

Montevideo, Uruguay
December 11-12, 1986

PROGRAM V: ANIMAL HEALTH AND PLANT PROTECTION



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FINAL REPORT

The opening session began at 9:15 a.m. on December 11, 1986, in the conference hall of the 19 de Junio Branch of the Bank of the Republic of Uruguay. Acting as master of ceremony Dr. José Puignau, of the Ministry of Livestock, Agriculture and Fisheries of the Republic of Uruguay, introduced the Honorary Board, composed of the following persons: Eng. Pedro Bonino Garmendia, Minister of Livestock, Agriculture and Fisheries of Uruguay; Mr. Pedro Olmos, Assistant Director General of the Ministry of Livestock, Agriculture and Fisheries of Uruguay; Dr. Robert Joseph, Assistant Director General of Agriculture of Haiti; Dr. Roberto Caffarena, Director of Animal Industry of the Ministry of Livestock, Agriculture and Fisheries of Uruguay; Dr. Harry Mussman, Director of IICA Program V; Mr. José Barrios Acuna, Deputy Director of IICA-Uruguay. Dr. Puignau apologized to the audience for the audio system difficulties, due to problems related to the general strike called in Uruguay. He asked the participants to join in singing the National Anthem of the Republic of Uruguay.

Thereupon, the program began with a speech by Mr. José Barrios Acuna, Deputy Director of the IICA Office in Uruguay, who welcomed the participants on behalf of the Institute and indicated the importance, within the scope of the medium-term program, of meetings of this type, which contribute to sound decisions and scientific arguments. He expressed his hope that it would be useful for all the participants.

Following, Dr. Harry Mussman welcomed the participants on behalf of IICA's Program for Animal Health and Plant Protection, which he directs.

He indicated that, in view of the action taken by the EEC, IICA had sought a method whereby all concerned could have the opportunity to express their opinions in support of the countries in the Area. He thanked four pharmaceutical companies for their significant support to this forum.

The Minister of Livestock, Agriculture and Fisheries, Mr. Pedro Bonino Garmendia, took the floor to welcome those present and to congratulate IICA for taking responsibility for this meeting on a subject which is so current and important, particularly for meat-exporting countries like Uruguay. He indicated that international meat trade is in the area of 3 million tons, and that it is important to ensure serious study of the problems involved in providing consumers with a safe, quality product. He wished the participants a pleasant stay in Uruguay. The meeting was thus officially opened.

The official program began with item 1 on the Agenda, with Dr. Harry Mussman presenting the EEC directives on the use of hormonal products in animals and restrictions on imports of such animals and products, effective as

of 1988. A translation of the July and December 1985 and September 1986 directives was distributed. Dr. Mussman began his presentation by mentioning IICA's objectives at this meeting, clarifying that the Institute's intention is to maintain a neutral position and to simply provide a forum for all points of view and promote a better understanding among all parties. IICA hopes that at the meeting it will be possible to: 1) express all technical, social, political and economic points of view; 2) obtain conclusions and recommendations which would serve as guidelines for the hemisphere; 3) define subsequent actions and establish an executive body, which could be a committee or IICA, itself, directly.

In relation to the first point, he indicated that he did not feel it was necessary to present the EEC directives in detail, since, in his view, the participants at the meeting would not have attended if they were not familiar with those directives. He mentioned the existence of restrictive directives on this subject since 1964, followed by others in 1972, 1981, 1984 and finally in 1985, with a total ban on all hormonal products as of January 1987 for EEC member countries and 1988 for non-member countries seeking to sell to the EEC. The argument used in support of these measures is that they are geared to avoiding distorsions in the levels of concentration of residues in meat consumed by the European public and to promoting consumption. They permit hormones only for supervised therapeutical use, requiring tests to ensure a 99.9% confidence level indicating non-presence of residues of more than one percent in these animals upon entering the slaughterhouse. Technically, it is very difficult for the countries themselves to comply with this determination, as it was in the United States, when it faced the problem of public demand for stricter control of the use of diethylstilbestrol.

Finally, he recommended that the 1985 directives be read carefully and that solutions be sought, so that the countries may form a united front.

Item 2.

"Market Analysis of the Meat Market in selected countries in the American Hemisphere and the European Economic Community" was presented by Dr. Andrés Troncoso Vilas, from IICA-Uruguay.

In his first chapter on the international economic situation and the beef sector, Dr. Troncoso Vilas pointed out that even though there was a moderate growth trend in the world economy for the fourth consecutive year, several countries had to face heavy foreign debt and had difficulties in maintaining significant economic growth rates. He mentioned that in Latin America in 1986 it is probable that the current account deficit will increase sharply for the second consecutive year reaching 11 billion dollars.

As to the beef sector, in general the price depression continued and trade in terms of value decreased. In Europe, the EEC maintained the policy of increasing consumption and decreasing the number of animals to be slaughtered. Ministers of Agriculture of the EEC adopted some measures to restructure the beef sector. They decided to reduce dairy stock by 3% in the next 3 years.

In North America, meat production increased, with a larger number of high-weight animals slaughtered and lower per capita beef consumption, but even so imports increased by 13%.

In South America, in most of the meat-producing countries of the region, producers were forced to sell their cattle. This caused an increase in the number of slaughtered animals as well as an increase in the trend to lower domestic prices and increase consumption.

In his second chapter, Dr. Troncoso Vilas made an analysis of the meat market by country. He stated that in the United States there has been a considerable decrease in the number of fattening cattle (-3.9%) and an increase of dairy cows (3.5%). He forecasted a decrease in the general domestic consumption of meat for 1986. Imports increased by 13% and exports were relatively stable.

In Canada, the trend is to reduce herds. Beef consumption seems to continue decreasing. Imports decreased, while exports, after a 11.4% increase in 1985, also decreased by 10% in 1986.

In Argentina, herd reduction is also underway. The free market price of meat produced an important increase in domestic consumption (6%) in 1986 and exports increased by 4% in 1985.

In Brazil, cattlemen were forced to sell their animals due to economic and weather conditions, even though domestic consumption is one of the lowest in South America. Imports and exports increased, favoured by the economic situation of the country.

In Uruguay, the process to reduce stocks has apparently ended. Like Argentina, it had to face a lower demand for exports (3.5%) and more intense competition in some of its traditional markets. Its domestic market increased, despite the rise in prices. It is forecasted that exports will be strongly reduced in 1986, together with a 12% reduction in production and an increase in domestic consumption.

The EEC faces a decrease in the number of animals for production, particularly dairy cows. Domestic consumption increased by 1.7% in 1985; imports increased by 3.1% and exports by 5.6%.

Finally Australia and New Zealand had a considerable increase in exports mainly to the United States and Japan.

Item 3.

The presentation by Dr. Guy C. Maghuin-Rogister, of the Veterinary School of Brussels, on "Practical Considerations in Detection of Anabolic Residues", began with a review of the classification of anabolics generally as estrogenic and non-estrogenic.

There are three classes of estrogenic anabolics:

- natural estrogens (17B estradiol)
- phytoestrogens (zeranol)
- synthetic estrogens (DES)

The non-estrogenic products are divided into two groups, androgens and progestagens, with each group containing natural and artificial hormones. He added that of the non-estrogenic products, several are used illegally by producers in Europe.

To illustrate his presentation on the possibilities of the European countries to determine the presence of anabolic residues, Dr. Maghuin-Rogister described the methods used in a study of residues in animals treated with natural hormones (implants containing progesterone/estradiol and estradiol/testosterone) and artificial hormones (estradiol/trenbolone and zeranol/trenbolone). He concluded that radioinmunoassay/methods (RIA) cannot distinguish between animals treated and not treated with estradiol, progesterone or testosterone, in muscle tissue. Thus, examination of carcasses of animals devoid of their liver and kidneys is useless for controlling compliance with EEC requirements prohibiting use of anabolics.

In the case of trenbolone, he concluded that it is almost impossible to distinguish between treated and untreated animals in analyses of muscle tissue, given the low level of residues and the great variability of their concentration.

Zeranol residues in concentrations of 0.5 ppb in the liver, make detection in treated animals almost impossible.

Considering these facts, he indicated that carcass control, without viscera (kidneys and liver) does not permit detection of hormones or of xenobiotic agents.

He concluded by adding that the results obtained through RIA techniques should be confirmed by other physical-chemical methods, such as thin layer chromatography and gas chromatography. These methods are highly expensive and not all EEC laboratories have the infrastructure and technology to implement their use.

His presentation was followed by a question and answer session on the subject, during which clarifications were made on the doses used in the experiments, time prior to slaughter, and costs. Dr. Maurice Morisette indicated that in Canada the studies, with a 95% certainty level, involved a cost of one million dollars for bovines and 1.5 million dollars for other species. The representative of the Livestock Association mentioned that in Brazil cost analyses indicated that it would be possible only to test for DES and that other testing would have to be performed in the importing countries. Dr. Bouffault mentioned that in the EEC no solution has been found for the problem of testing operations, either for internal control of illegal use or for exports. Dr. Rogister added that he is only familiar with the data for Belgium, but that it is known that Ireland, the United Kingdom, Holland and Germany have implemented RIA testing; France, however, is using older methods,

and other countries, such as Italy, Spain, Portugal and Greece, have little experience in this area. In addition, to make RIA testing uniform, monoclonal antibodies from the same source would be required, in sufficient quantity. In view of this situation, it will be difficult to comply with Directive 86/7254/1, which provides for implementation of the laboratory techniques by 1987 and 1988.

Item 4.

Item 4, "Present and Future of Hormone Products for Growth", was presented by three lecturers. The first presentation was made by Dr. Steve Dean of Syntex Agrobusiness Inc., on the economic benefits derived from the use of hormone products. He mentioned that the efficacy and safety of these products have been fully proven and recognized by official agencies including those under the EEC. The return on same is over 10:1 and direct benefits are the higher growth rate (10 to 20%) or early weight gain; higher efficiency in converting food to meat, with grains or pastures; and better quality meat because of its lower fat content and more uniform carcasses. He mentioned that exogenous hormones replace the action of natural hormones in castrated animals producing better growth without the handling problems involved in using intact animals.

He added that animals in countries such as Ireland and the United Kingdom are fattened by natural pasturing, where implants are used with good results, without problems. On the other hand, where animals are fattened with grain, anabolics are also used, especially those prohibited.

He continued by adding that the so-called mountain of meat reaches a stock of 700.000 tons, which is equivalent to 2.5 kgs per capita in the EEC. This is an exagerated amount. He pointed out that it is very common to confuse production and productivity and that the EEC problem lies more in the dairy and beef cattle quota rather than in the technical field. These products greatly benefit countries which need to export. To sum up, he considered that hormonal products benefit both producers and consumers since they decrease costs, increase quality, and therefore they should be not disregarded.

Next, Dr. Jean Claude Bouffault of Hoescht-Roussel spoke on the safety of anabolics. He showed slides of their chemical formulas and of natural hormones, how they are metabolized and eliminated by the body and the results of tests for carcinogenecity, mutagenesis and others. He concluded that these are efficient and safe substances, since they are not basically different from natural hormones in their formula, metabolism and elimination. This has been tested in France in a specialized laboratory in Rhesus monkeys as an experimental model, given their greater similarity with man. Then he showed a table of hormonal content in different foodstuffs such as oil, eggs, beer, meat from animals not treated with anabolics and other foods normally consumed, which show higher levels than animals treated with anabolics. He concluded that experience showed that countries which prohibited their use faced problems such as difficulty in control, creation of a black market with impure and dangerous products, lack of respect to professional veterinarians and failure to discard implanted carcass parts.

To end this session, Dr. Martin K. Terry of International Minerals and Chemicals spoke on the scientific and political considerations. He also dealt with the subject of the future of anabolics.

He said that animal production industry was bearing consequences of being too efficient, since it had created an excess production of meat. As a result, economic barriers without technical bases have appeared, threatening, furthermore, to destroy the technological basis supported by that industry. He added that so-called naturalist groups, ignoring the rural environment, had taken the side of defending public health from these dangers. They united with EEC politicians, giving them a solution to a socio-economic problem. This brought about restrictions on the use of products, without objective evidence since 1981. In that year, a technical committee was created, directed by Dr. Lamming, to study the problem. This Committee asked for more data to xenobiotic producers to clarify the situation.

This doubt was taken as evidence of a potential risk and in 1985, which was one of the critical peaks in meat production, they decided unilaterally to prohibit its use, disregarding the final decision of the technical committee, which was suspended and cancelled.

Thus, a technical twist was given to the problem of market saturation, whose real origin was the policy of price subsidies.

The United Kingdom questioned the legality of the procedure before the European Court and the final decision will be rendered next year. He mentioned that it was important to consider whether in 1985 anabolic agents were in fact the guilty ones, and to ask where the guilt will lie in 1986 and 1987; perhaps it will be antibiotics of something else this time around. The argument used is that these products are not natural; however, he questioned what a natural product is, given that there is not clear criteria, since agriculture from its beginning, has been a manipulation by man of his environment.

He asked whether countries following these directives were not financing EEC subsidy policies, since they would have to guarantee that animals had not been treated with anabolic agents and this implies a high-cost and complex system whose implementation is still not clear. This shows that the policy to be followed by the EEC will reflect subjective appraisal, making imports depend on other interests deriving from the political situation.

To conclude, he mentioned the situation was serious because it set a precedent where politicians could decide as technicians, though not qualified to do so, thereby discouraging scientific progress and promoting a 19th-century agriculture.

Next, there was a series of questions to the three lecturers where different points of view and proposals were discussed such as postponing the prohibition date for a year, the possibility that other products might be prohibited by the EEC, and the fact that the most important point is to inform consumers and give them the option to choose. The real dangers for the Latin American consumers are D.E.S. smuggling, the objectivity of production laboratories, and other technical doubts which Dr. Mussman pointed out might be clarified later.

Item 5.

Presentation by Dr. Lester Crawford on "Action Plan of the Codex Alimentarius Committee on Residues of Veterinary Drugs in Food".

Dr. Crawford defined the activities of the WHO-FAO Codex Alimentarius, broken down as:

1. Activities focused on animal disease prevention and/or therapy and on improvement of production (such as growth factors). This international committee is of upmost importance for the countries which are not in a position to regulate drug use by helping them to identify the minimum requirements to allow for marketing of these products.

2. Veterinary drug residue safety evaluation including establishment of maximum residue limits and definition of analytical methods criteria, which can be conducted through the mechanisms stipulated by the Codex.

3. Dissemination of information which is vitally important to provide for an exchange on the veterinary products statutes, tolerance levels, analytical methods for residues, adverse reactions, and data on residues. Countries having less developed veterinary product control systems would be the first beneficiaries of such an exchange.

He went on to say that the absence of controls on the use of antimicrobial agents represents an enormous risk for public health. Furthermore, countries not having a veterinary product control system are at a trade disadvantage, since great importance is given to residues in international trade of foodstuffs of animal origin.

He indicated that in July 1985 a new Committee on veterinary product residues in foods was created with the purpose of:

- determining priorities in terms of veterinary drug residues in foods;
- recommending maximum residue levels;
- developing necessary codes of practice;
- developing criteria for methods of analysis used to monitor veterinary product residues in foods.

This committee will work in close cooperation with other Codex committees such as those on food additives, analysis and sampling methods, and food hygiene.

He clarified that in evaluation of veterinary product residue safety in foods, one of the important tasks of the new committee will be to establish procedures for selection of methods of analysis and of sampling.

He said that this committee had met for the first time during the last week of October 1986, when it discussed, among other subjects, the criteria to be used for accepting a new veterinary product on the market.

The list of priority veterinary products is headed by chloramfenicol, followed by anabolics (estradiol, progesterone, testosterone, trenbolone and zeranol), sulfonamides, nitrofurans, nitroimidazoles, quinoalines, trypanocides.

He said that in the summer of 1987 there will be a meeting of the food additives committee, to discuss and evaluate these products.

Dr. Crawford concluded his presentation by emphasizing the necessity of an international organization providing the basis for appropriate control of veterinary products and their residues in foods.

Item 6.

Item 6 was discussed by Dr. Emilio Gimeno, President of the OIE, with a presentation on the OIE activities in the field of veterinary pharmaceuticals. He initiated his presentation making a brief overview of the OIE, mentioning that it is an inter-governmental agency since the representatives to it are the animal health authorities in the countries. Among its activities in this area the OIE organized an International Symposium to disseminate technical information on anabolics in 1983. During 1985 and 1986 a survey was held among 48 countries out of which 40 have Toxicology Centers while 23 have Centers for Toxicological Accidents.

The survey also showed that the problem has been divided into two groups: developed countries -in which it is necessary to harmonize criteria and coordinate activities through the creation of world reference centers-, and developing countries where there is absence of information, laboratory infraestructure, control or registration. As a result of this survey, during 1986, the Third International Technical Consultation on Veterinary Pharmaceutical Registration was held at OIE headquarters, with the purpose of dealing with items such as: organized cooperation on consultation on veterinary pharmaceutical registration; organization of an information network on harmful effects; and information and control of pharmaceuticals and toxicological accidents.

The participants to the event resolved to prepare a document to guide countries on registration standards, systems for control and approval of drugs; to designate pharmacological reference centers; and to select technical information on pharmacological registration.

He went on drawing an analogy on products concentration levels in tissues, pondering on how far can we get. He mentioned that there is a difference between the hormonal effects and the level of intake and that the toxicological tests for carcinogenesis, mutagenesis, allergenic effects, and effects on the SNC, are very complex and difficult to conduct. He added that during the XIX century the world witnessed a revolution in the field of chemical synthesis bringing about large benefits to medicine, concluding that according to the various levels, any pharmaceutical may be dangerous, hence the need for control and evaluation. This should be in the hands of the experts because should there be any gap in this process then politicians may take decisions that could lead into chaos.

Immediately after, Dr. Mussman closed the days's session, informing the participants that next day's session will be called to order at 8:30 a.m.

On December 12 the session was opened and presentations were made by the various countries. First, Dr. Iván Barreto, Director of the Division for Veterinary Products Control of the Ministry of Agriculture, introduced the Brazilian delegation. He congratulated IICA for the organization of this meeting which provided the possibility of expressing their points of view. He pointed out that directives published in 1964 and 1969 control the use of hormone substances, prohibiting their use as growth promotants and authorizing their use for therapeutical purposes.

In Brazil, zeranol was registered in 1976. Its license expired at the beginning of 1986 following a suggestion by a technical committee. The Ministry of Agriculture authorized the use of natural steroids and anabolics, while prohibiting D.E.S., subject to the presentation of field studies showing statistically significant results and other safety measures. However, due to the communiqué from the Ministry of Foreign Affairs and from the Meat Exporters Association regarding the EEC resolution, a technical committee was created including all parties and international advisors. The committee came to the conclusion that these products, when used correctly, did not present any risks for health but, since some results still had to be published and Codex meetings yet had to be held, the original decision was revoked, until the results and conclusions of the international community were issued.

He expressed that at present in Brazil only D.E.S. levels are systematically controlled using gas chromatography. However, the necessary equipment and trained personnel in radioimmunoassay are available to start working when necessary. In Brazil, some 700 samples are taken at an approximate cost of 150 dollars per sample. As in all developing countries, there are problems in financing this testing. Therefore the EEC, the United States and other importing countries must reach an agreement on such important topics as hormones laboratory methods and sampling (minimal registration requirements, etc.).

He concluded that developed countries should give their technical-scientific support to developing countries for information on the benefits of those products which, under veterinary control, present no danger for consumers.

Dr. Roberto Caffarena, Director of Animal Industry of the Ministry of Agriculture of Uruguay, pointed out that in this country the use of hormone products to promote growth has been prohibited since 1962. These products are only permitted for therapeutical use. He added that in 1983 a D.E.S. sampling program was started under which kidney of animals from slaughterhouses are analyzed with the help of the "Miguel C. Rubino Institute". He concluded that since its beginning until 1986, some 221 analysis from 7993 animals have been made and no violations of standards have been found.

Next, Dr. Evencio Arvelo, Delegate of Venezuela, reported on the present situation regarding the use of hormones and anabolics in his country. He gave some figures on the number of slaughtered animals for consumption in different places, with a total of 1.6 million yearly. Some 70% are treated with anabolics and hormones. He mentioned products registered in Venezuela. Lately, given the economic situation of the country, there has been excessive consumption of illegal products, such as D.E.S., due to the fact that these products are cheaper. He concluded by thanking IICA for the opportunity to be informed and to work towards creation of common criteria.

Dr. Maurice Morisette, Delegate of Canada, informed that his country regulates all veterinary products. In order to be authorized, the efficiency and harmlessness of a product must be proven; such is the case of anabolics which are authorized in Canada at present. The Canadian Food and Drug Administration can prohibit any product whenever there is evidence of lack of safety in the use of such product.

He added that Agriculture/Canada has a program to monitor residues where approximately 700 tissue samples are analyzed annually, apart from tests carried out on imported meat (including zeranol and D.E.S.).

He indicated that no hormone residues have been found in Canadian meat so far.

The Delegate of Mexico, Dr. Jorge Ymay Seeman, informed the meeting on the system used in Mexico to register and control veterinary products supported by the Law on Plant and Animal Health.

In 1984, the program to control toxic, biological and polluted residues was implemented. Its objective is to guarantee that meat products are free from harmful substances and to offer products which meet international requirements for meat exporting.

Dr. Ymay presented the economic aspects related to the use of hormones. He pointed out that anabolics, especially in implants, are an efficient way of increasing productivity and provide help to attack factors which negatively affect animal production. He calculated that if an implant represents an additional gain of 10 kg of meat, this means some 35 million kg additionally produced at national level.

He concluded that the harmlessness, safety for public health and high efficiency in improving productivity of anabolics have been proven. Therefore, their prohibition by the EEC and the restrictions on trade involving animals and products treated with these substances would cause serious non-tariff trade problems.

Dr. Marvin Norcross, of the Unites States Food and Drug Administration (FDA), reminded the participants that prior to the EEC Directive of December 1985, exhaustive discussions had taken place in the scientific world on safety implications for public health of anabolic residues in beef.

The United States position is that these products do not entail any danger when used in accordance with the pertinent instructions.

He mentioned the case of D.E.S., permitted in 1962 (D.E.S. Proviso 1962) with limitations on residues in tissues. The use of D.E.S. was prohibited in 1979 and the prohibition of estradiol, progesterone and testosterone was proposed. Studies undertaken on these products determined that residues of these products in beef were minimal.

Mean daily production of estradiol, progesterone and testosterone in humans (children, representing the most sensitive sector of the population) was compared to the amount of residues contained in 500 g of beef.

Given that the amount of residues in beef according to the hormone is from 15.000 to several million times less than the amount produced daily by humans, it is difficult to imagine any pathological consequences of the use of anabolics. Dr. Norcross reminded the participants that no physiological changes are to be expected if there is no increase over 1% of the daily hormone production in humans.

In the case of synthetic hormones, the situation is rather more complex since there is no common denominator for production in humans that would permit the evaluation of risks. He then referred to toxicological tests to assess product safety. Mutagenesis tests are carried out to determine whether the products are genetoxic or not. Should the product have genetoxic effects then it should be tested for carcinogenic effects.

In conclusion, for natural hormones, the FDA permits residues that increase up to 1% the daily production of hormones in the most sensitive sector of the population (children) for synthetic hormones, studies are carried out in primates to demonstrate the harmlessness of the product (genetoxicological and toxicological effects).

Trenbalone is a synthetic hormone not yet accepted by the FDA, but that will be accepted soon, since it meets all requirements for efficiency and safety.

The prohibition of hormonal products by the EEC will not affect the regulations of the FDA. In the United States there are no limits as to the quantity of marketed products, provided they meet the requirements of safety and efficiency. He added that it may take many years to withdraw an approved product from the market.

Dr. Robert Joseph of Haiti, after some considerations on residues found according to their form of administration, emphasized the importance of anabolics for the improvement of animal productivity and the danger of prohibited products, such as D.E.S., sold in the black market.

Dr. Joseph suggested taking the following measures:

- to postpone implementation of the EEC directive for a period of 5 years.

- to completely eliminate marketing of anabolics whose residues are recognized as toxic in meat.

- to regulate the processing and distribution of these products and to make their use restrictive only to veterinarians.

- to ensure education of producers and consumer activists.

Dr. Horacio Meyer, of Argentina, reminded the participants that 70 to 90% of the economic system of the countries in the River Plate Basin is contingent upon the trade of their agricultural products. These countries are affected by the protectionist policies of both the EEC and the United States.

Four years ago, Argentina created a national program on residues, through which it can meet the requirements of importing countries.

To determine its position concerning the EEC directive, Argentina must meet with the other River Plate Basin countries, through the competent organization (CINVECC). It adheres to the position taken by Uruguay. Argentina is now committed to continue exporting and to expand the market.

The situation should be further analyzed with the River Plate Basin countries and at international meetings with representation of more countries and of the EEC.

Dr. Robert Biddle, of Australia, indicated that his country exports approximately 50% of its beef production and a significant proportion of its mutton production to markets located around the world, including the United States and EEC countries. In order to maintain this market access, Australia has in place national government controls over the registration of agricultural chemicals and veterinary drugs and their importation, and operates a national residue monitoring scheme to ensure that these agents are used in strict compliance with labelled directions. In order to be registered, agricultural and veterinary chemicals must be shown to be safe, efficacious and to be needed for agricultural and animal production purposes.

Dr. Biddle indicated that a number of hormonal growth promotant agents are currently registered in Australia, including zeranol (3 million implants per year for use in steers) and natural hormone preparations based on oestradiol-17-B (for use in steers and heifers). The natural hormone testosterone also is widely used in Australia to prevent a condition (balanoposthitis or "pizzle-rot") of whethers grazing certain types of improved pastures. Whethers affected by "pizzle-rot" are more prone to blow-fly strike (cutaneous myiasis) and unless receiving testosterone prophylaxis would unnecessarily suffer. The use of testosterone in Australia is thus required for both animal health and welfare purposes. Such use would be banned by the EEC Directive.

Dr. Biddle indicated that the Australian preferred option for reacting to the proposed EEC ban on hormonal agents and related residue monitoring requirements was to attempt to have the European Commission recognize the "equivalency" of existing Australian controls, including its national residue monitoring

program. To this end, Australia was co-operating with similarly affected exporting countries and continuing dialogue with EEC officials, with a view to obtaining interpretations/clarification of their Directives in this area.

Dr. Reuten Katain, Representative of Israel, asked for the floor and expressed his thanks for the invitation to attend the meeting and congratulated IICA on its initiative. He indicated that such products have been used in Israel since 1967, under strict supervision of veterinarians. Imported products are random sampled, as are other substances such as pesticides. He concluded by saying that he would like to see a world reference center under the initiative of CODEX and the OIE, and offered his country's full support for such an effort.

Dr. Jany Luz Cabreira, President of the Association of Veterinarians of Sao Paulo, Brazil, described the position adopted by his organization, explaining that the application and use of veterinary products was the responsibility of the veterinarian and, therefore, veterinarians merited the respect of the EEC in regulations covering the exercise of the profession in each country. He added that the EEC should not intervene in the exercise of the profession of veterinarians.

The Argentine Chamber of Veterinary Products (CAPROVE) presented a document expressing its opinion and asket that it be included in the Final Report, incorporating the following points.

In Argentina bovine protein production is and will be based on extensive pasturing (fiber). The transformation of fat into meat is not considered due to economic reasons. Livestock raising extends into non-arable land. Given the excellent genetic level and good health of Argentine stock, the efficient way to improve nitrogen utilization is through anabolics. Their use, considering the scientific data available, is apparently safe and efficient. Thus the Chamber favors livestock economy in relation to better biological efficiency in the fiber-ruminant ratio.

Mr. William McMillan, of the United States Department of Agriculture (USDA), a former Marketing and Inspection Assistant who collaborated in the formulation of the official United States position, stated that the United States Secretary of Agriculture was in Europe discussing the matter of the EEC directive, and that various mechanisms have been used to arrive at a definition on the EEC's imposition of norms which the EEC itself can hardly comply with.

Dr. Gimeno commented that there is a practical fact, beyond all the other aspects of the directive, which is the sampling standard indicating that 0.15 percent of bovines under two years of age will be sampled for each product. In countries like Brazil, Argentina, Uruguay and the United States, this means approximately 20 to 30 thousand head, with an extremely high cost, given all the techniques involved. He suggested that the form of implementation of this provision should be discussed with the Europeans.

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Dr. Mussman took the floor and pointed out that he had not prepared previous recommendations, out of respect for the participants, which would hinder the possibility of an agile system, without lengthy discussions and problems. He suggested that a vote be taken and the results recorded on a blackboard, to establish the opinions of the group. He asked for suggestions as to what should be included in the conclusions and recommendations of the meeting.

After various opinions were presented by Argentina, Canada and the OIE, it was clarified that the participants at the meeting are not sufficiently empowered to adopt resolutions on behalf of their countries, but that it is in fact necessary to arrive at some general conclusions and recommendations of the meeting.

Dr. Mussman suggested formation of a petit committee, composed of one representative per country, to prepare resolutions which can be presented to all participants for discussion and approval.

The committee was formed as follows:

Dr. Harry Mussman of IICA	Chairman
Dr. Germán Gómez of IICA	Secretary
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Following presentation of the position of Argentina and Uruguay, who do not adhere to the recommendations submitted by the working group, Dr. Germán Gómez read the recommendations of the Working Group, which were submitted to the Plenary Session for discussion. The recommendations included in the Annex were approved.

Thereupon Dr. Mussman closed the meeting, emphasizing the fact that anabolics, from the technical point of view, are looked upon as highly efficient and safe for public health. He indicated that this should be taken into account in analyzing the attitude to be assumed regarding the EEC Directive, which is not supported by scientific arguments.

Dr. Mussman concluded by thanking the representatives of the countries, institutions and international organizations for their active participation in the discussions, as well as the Minister of Livestock, Agriculture and Fisheries of Uruguay, the support personnel and the people of Uruguay for their warm hospitality.

NOTE

The official delegations from Argentina and Uruguay do not support the recommendations and/or conclusions of the Advisory Meeting on the use of hormonal substances in animals, given that they feel it is appropriate to further study the subject at future regional and/or international meetings at which there should be adequate representation.

RECOMMENDATION No. 1

CONSIDERING:

The activities of the OIE for international cooperation on registration of veterinary drugs and the need of official national agencies to ratify and coordinate standards for approval, control and analysis systems, regulations for use of certain drugs, such as anabolics, some antibiotics and other products recently taken into consideration specifically by EEC Directive 86/469 of 9/16/1986;

The lack of coordination among the countries regarding the criteria for approval and registration of drugs, which creates serious difficulties in international trade of animal products;

The advisory group of the countries brought together by IICA in Montevideo on December 11 and 12, 1986;

RECOMMENDS:

1. Organization through the OIE, in coordination with other international organizations, such as CODEX ALIMENTARIUS, WHO, FAO and IICA of an international meeting at the world level, including participation of those persons directly responsible for official veterinary services handling registration and approval of drugs.

2. Such meeting should specifically address:

   a. Coordination of regulations on anabolics, antibiotics and other drugs of special interest, taken into consideration in EEC Directive 86/469 of 9/16/1986.

   b. Establishment and classification of scientific criteria for the selection of techniques for toxicological evaluation of such drugs, including:

      - Acute and chronic toxicology.
      - Mutagenecity, carcinogenecity and teratogenecity.
      - Scientifically recognized levels of ADI and LMR.
      - Other significant non-desirable effects on public health.

3. The promotion of on-going activities for coordination among the countries and international agencies, such as CODEX ALIMENTARIUS, OIE, WHO, FAO and IICA, interested in the regulation and control of veterinary drugs, in support of official entities responsible for such activities.

RECOMMENDATION No. 2

CONSIDERING:

The activities of the Codex Alimentarius for international cooperation on the registration of veterinary drugs and the need of official national agencies to ratify and coordinate standards for approval, control and analysis systems, regulations for use of certain drugs, such as anabolics, some antibiotics and other products recently taken into consideration specifically by EEC Directive 86/469 of 9/16/1986;

The lack of coordination among the countries regarding the criteria for approval and registration of drugs, which creates serious difficulties in international trade of animal products;

The advisory group of the countries brought together by IICA in Montevideo on December 11 and 12, 1986;

RECOMMENDS:

1. Organization through the Codex Alimentarius in coordination with other international organizations, such as OIE, WHO, FAO and IICA, of an international meeting at the world level, including participation of those persons directly responsible for official veterinary services handling the registration and approval of drugs.

2. Such meeting should address:

   a. The criteria and techniques available relating to the establishment of appropriate studies to determine the safety of anabolic agents and other drugs of special interest.

   b. The scientific information currently available addressing the safety of anabolic agents and other drugs.

   c. The recommendation of Acceptable Daily Intakes (ADI) and Maximum Residue Levels (MRL) for anabolic agents and other drugs.

   d. The review of analytical methods for anabolic agents.

   e. Other related areas of concern associated with the use of anabolic agents.

RECOMMENDATION No. 3

CONSIDERING:

That the EEC Directive 85/649 does not reflect scientific evidence currently available and that two international scientific organizations have indicated they are planning activities in 1987 to further evaluate veterinary drugs including anabolic hormones;

That OIE member countries have been requested to call a meeting of government officials responsible for veterinary drug regulation and control;

That the Codex Committee on Residues on Veterinary Drugs in Foods will receive and act on a report of the JEFCA, which will include safety considerations on anabolic substances used in animals;

RECOMMENDS:

1. That the EEC defer the matter of the said directive so that it may be considered in depth and that the two organizations closely follow up these evaluations in order to answer any questions still pending regarding the safety of these products.

2. That the EEC fully take into consideration the results and conclusions of these international bodies.

RECOMMENDATION No. 4

CONSIDERING:

That anabolics used in animal production with positive results in increasing animal weight;

That their use has permitted improvement of the economic situation of producers using them;

That, taking into consideration that appropriate studies have not yet been made to analyze the economic impact of the use of hormones and anabolics on animal production;

RECOMMENDS:

1. That IICA be requested to support studies to measure the economic impact of the use of anabolics on cattle farms.

2. That countries be encouraged to implement systems which allow for permanent maintainance of information on the economic effects of the use of anabolics.

RECOMMENDATION No. 5

CONSIDERING:

That the use of anabolic hormone products requires appropriate handling in order to avoid harmful consequences for public health;

That appropriate control by veterinary professionals must be provided for such use;

RECOMMENDS:

That the countries be asked to eliminate marketing of the anabolic agents used for fattening cattle, such as D.E.S. and its derivatives, the residues of which have been found to be toxic (carcinogenic) and to restric their use only for therapeutical purposes or according to local pharmacological regulations in each country.

RECOMMENDATION No. 6

CONSIDERING:

That the final goal of cattle-breeding is to make available to the population high-quality animal protein in sufficient amounts for their nutrition;

That there is not sufficient and appropriate information on the use and effects of anabolics readily available to producers and consumers of products of animal origin;

RECOMMENDS:

1. That governments involved implement communication campaigns addressed to producers and consumers on the use of anabolics and their consequences.

2. That companies responsible for the processing of these compounds and their respective users be urged to participate actively in communication campaigns organized by the governments of the countries.

REUNION DE CONSULTA SOBRE USO EN ANIMALES DE SUSTANCIAS HORMONALES: IMPLICACIONES ECONOMICAS Y TECNICAS

CONSULTATION ON THE USE OF HORMONAL SUBSTANCES IN ANIMALS: ECONOMIC AND TECHNICAL IMPLICATIONS

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ANALYSIS OF THE MEAT MARKET IN SELECTED COUNTRIES IN THE AMERICAN HEMISPHERE AND THE EUROPEAN ECONOMIC COMMUNITY

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I. INTERNATIONAL SITUATION OF THE ECONOMY AND OF THE BEEF SECTOR*

THE ECONOMY

In 1986 the world economy indicated a moderate growth trend, for the fourth consecutive year since the 1980-82 recession. In various countries the effort to reduce inflation was successful, investments increased and employment figures rose, while in others unemployment levels remained high and various developing countries faced numerous adjustments problems.

Although the recent drops in oil prices, real interest rates and inflation have provided a considerable stimulus to the industrialized and the developing countries, several of the latter, with significant foreing debt, particularly the oil-exporters, are having difficulty in maintaining significant economic growth rate. Therefore, world economic recovery remains weak and uneven.

Table 1. Real Growth of GDP 1965-86

Countries	1965/73 average	1973/80 average	1981	1982	1983	1984	1985
	(annual percentage variation)						
Developing countries	6.6	5.4	3.5	2.0	2.0	5.4	4.4
Low income countries	5.6	4.7	5.0	5.3	7.8	9.4	7.8
Africa	3.9	2.7	1.7	0.7	0.2	0.7	2.1
Asia	5.9	5.0	5.4	5.8	8.6	10.2	8.3
Middle income oil exporters	7.1	5.8	4.4	1.0	-1.9	2.5	2.5
Middle income oil importers	7.0	5.5	2.1	0.8	0.8	4.1	3.0
High income oil exporters	9.2	7.7	1.6	-1.7	-7.1	1.3	-5.0
Industrialized economies	4.7	2.8	1.9	-0.6	2.3	4.6	2.8

Source: World Bank - World Development Report 1986.

In 1985 economic growth in the OECD region decreased to 2.8% from the decade record of 4.6% for the previous year (Table 1). Inflation rates slowed to 4.8% with even better results being obtained in countries like the Federal Republic of Germany and the United States. Outside the region, Argentina achieved significant results in its battle with inflation, reducing it from three to two digits. In the OECD region, unemployment fell slightly to 8.3% of the workforce; unemployment increased in Europe, while it decreased in Japan, with an already low rate by internation standards, and the United States.

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* Based on the World Development Report 1986 - World Bank, Latin American Economic Panorama 1986 - ECLA, and Situation and Perspectives of International Meat Markets, 1986 - IMC/GATT.

Table 2. Growth of Exports from Developing Countries, 1965-85

Product/Country	1965/73 average	1973/80 average	1981	1982	1983	1984	1985
By Product:	(percentage variation in annual volume)						
Industrialized Products	11.6	13.8	8.6	0.1	10.0	16.6	3.3
Food	3.3	3.9	9.7	-2.3	-1.1	7.6	3.9
Agriculture Non-food	3.1	1.1	2.5	-1.6	1.5	1.0	4.5
Metals and Minerals	4.8	7.0	-2.6	-2.8	0.5	3.4	4.8
Fuels	4.0	-0.8	-9.2	0.6	2.3	7.1	-1.4
By Country:							
Africa	4.6	1.3	-4.5	-9.3	-0.2	4.9	2.0
Asia	0.6	6.8	9.1	6.3	7.2	6.6	3.8
Middle income nations							
Oil exporters	4.3	0.0	-7.2	-1.9	3.6	8.6	-0.8
Oil imports	7.1	9.0	7.4	-0.4	5.0	12.8	3.7
All developing countries	5.0	4.6	2.1	-0.5	4.7	10.7	2.3

Source: World Bank. World Development Report. 1986.

In 1984, oil-importing developing countries were correct in expecting growth recovery and less problems with their foreign debt. The volume of international trade had increased by 9%, and the exports of developing nations had increased by 10.7%, having benefitted from improvements in the terms of trade (Table 2). For several of them, their additional income from exports and the rescheduling of their foreign debt, permitted the first increases in per capita income and in imports, since 1980.

However, in 1985 the previous years expectations were diminished. The slower growth of the industrialized nations and of international trade limited the growth rate for developing country exports and their prices fell (Table 3).

The differences in the effects by the group in interest rates and the fall of oil prices will be even greater in the balance of payments. The net direct result of these changes for Latin America as a whole will be negative: in 1986 the region will lose more foreign exchange because of the decrease in its net oil exports than it will save, because of the lower interest payments. Given this situation, it is likely that the current account deficit will increase sharply for the second consecutive year, to a figure around the 11 billion dollars.

This increased negative balance will originate, however, in the radical reverse that will take place in the oil-exporting countries. These countries, after obtaining a surplus of 2.1 billion dollars in 1985, will face a substantial deficit in 1986, as the result of a contraction of approximately 30% in the value of exports.

Table 3. Change in Export Prices and in Terms of Trade, 1965-85

Country	1965-73 average	1973-80 average	1981	1982	1983	1984	1985
Change in prices		(annual percentage variation)					
Developing countries							
Food	5.0	9.6	-8.2	-8.8	5.6	2.0	-8.1
Agricultural products	4.2	10.5	-14.4	-8.6	5.7	-2.0	-10.0
Metals and Minerals	2.4	4.8	-7.6	-8.5	-0.1	-1.7	-4.9
Fuels	7.9	27.2	12.5	-3.2	-12.4	-2.1	-2.5
Manufactures	7.2	8.1	0.2	-3.2	-2.5	-1.9	1.3
Industrial countries							
Manufactures	5.4	11.0	0.5	-1.4	-2.6	-1.8	1.3
Changes in Terms of Trade							
Low income countries							
Africa	0.1	-1.8	-11.8	-0.9	4.8	5.0	-5.6
Asia	3.2	-2.4	1.1	1.2	-1.2	1.5	-1.9
Middle income countries							
Oil-exporters	-0.4	8.5	5.4	0.2	-7.7	0.3	-2.9
Oil-importers	0.0	-3.0	-4.4	-0.6	2.3	0.1	-0.1
All developing countries	0.8	1.5	-1.0	-0.1	-1.3	0.4	-1.1

Source: World Bank. World Development Report 1986.

The Beef Sector

In 1985, the main characteristics of the beef sector were an overall increase in production, consumption and the volumen of trade. However, the sector was affected by the abundant availabilities of meat of all types, whose production was promoted by the low prices of forage grains and a continuing weakness in the demand of some of the chief importers, such as the Middle East, Egypt, the USSR and even some Asian countries. Thus, the general depression of beef prices continued and, presumably, trade dropped in terms of value.

In Europe, the situation of the European Community continued imposing significant repercussions on world beef trade. In spite of the drop in slaughtering especially of dairy cows and calves, the increased weight of slaughtered cattle kept production from decreasing by more than 1.6%. While consumption did in fact increase (2.7%), the EEC self-sufficiency ratio continued high, but with a falling tred (106 in 1985, compared to 110 in 1984). At year end, intervention stock totalled 737.000 tons and private stock totalled 135.000 tons. In these circumstances, internal EEC prices continued far lower than intervention prices, and beef and veal exports (excluding live cattle) increased (5.6%). Nevertheless, beef and veal imports also increased (3.1%).

In the European Economic Community, in spite of the falling but still significant slaughtering levels, production has continued high as a result of the increase in carcass weights. At their April meetings, the Ministers of Agriculture of the EEC postponed possible measures for beef sector restructuring until the end of the year. However, they decided that in the next three years dairy quotas would be reduced by 3%.

In North America, the abundant supply of meat of all types and the drop in the economic growth rate were the chief factors affecting the sector. In the United States, beef production increased, due to the extraordinary slaughter weights, resulting from the decision to postpone sales, with the exceptation that fattened stock prices would go up and due to the low prices of ofrage grains. Per capita beef consumption dropped in the United States and in Canada, nevertheless, United States imports increased significantly (13%).

In the United States, fattened stock prices have maintained their low level and, given the continued abundant availability of meat of all types and the decreased demand, prices are even lower than for the previous year. In April, in view of the announcement of the planned elimination of 1.6 million dairy cows, as the result of the program for purchase of hears, prices dropped again (10% less than the previous year). However, it is possible that this drop may be only temporary, and prices are expected to recover somewhat. The United States' chief suppliers, who benefitted from a favorable United States dollar exchange rate, have faced decreases in income since the April announcement. Their situation has further worsened due to the depreciation of the United States dollar.

In Canada, the Canadian Cattlemen's Association rejected an agreement under which Canada would import 10.668 tons of beef and veal from the Community over three years and requested that its plea for application of countervailing duties be maintained. Beef exports increased in 1985, to a total of 117.100 tons of which 68.600 were frozen meat and 45.300 fresh and chilled meat, primarily to the United States.

In South America, the most important factor in 1985 was the low level of beef prices, on domestic as well as international markets. In the majority of the region's main producing countries, producers were forced to sell their cattle, which resulted in an increase in slaughtering, an accentuation of the depressive trend in domestic prices and an increase in consumption. Argentine exports increased somewhat with respect to their historical low in 1984. Brazil reduced exports and significantly increased imports to meet growing domestic demand.

In Argentina, authorities decided at the beginning of the year to suspend maximum prices (fixed the preceding year) for slaughtered beef stock and to raise maximum wholesale and retail beef prices. During the first quarter of the year, Argentine beef and veal exports decreased by approximately 1.000 tons.

In Oceania, beef and veal production increased as a result of the rise in prices to producers and a greater import demand from its major market, the United States.

In the Far East, the imports of Japan and other countries in the region continued to increase, while the Republic of Korea, with abundant supplies of beef and pork, imported insignificant quantities of beef.

In the Middle East, the continuing decrease in oil income continued to be the chief cause of the decrease in demand for beef and veal, while the USSR, which produced a greater volumen, imported less than the previous year. In this area, we should note that the Soviet Union signed an agreement with the EEC for the import of 175.000 tons of beef and veal at low prices, part of which will be delivered this year.

Table 4. Beef and Veal Trade for Selected Countries 1984-1986.

A. EXPORTS (thousands of carcass weight equivalent)

	1984	1985	% AX 1985/84	Forecast 1986	% AX 1986/85
Argentina	250	260	4.0	270	3.8
Australia	617	707	14.6	723	2.3
Brazil	479	485	1.3	300	-38.1
Canada	105	117	11.4	105	-10.3
EEC	694	733	5.6	725 1/	-1.1
New Zealand	284	362	27.5	385	6.4
United States	151	151	0.0	172	13.9
Uruguay	148	139	-3.5	139	0.0
Others 2/	236	250	5.9	226	-9.6
TOTAL	2.960	3.204	8.2	3.126	2.4

B. IMPORTS

	1984	1985	% AX 1985/84	Forecast 1986	% AX 1986/85
Brazil	37	70	89.1	300	328.5
Canada	117	116	-0.6	107	-7.7
EEC	383	395	3.1	380 1/	-3.8
Japan	222	226	1.8	235	4.0
United States	838	948	13.1	973	2.6
USSR	541 3/	510	-5.7	450	-11.8
Eastern Europe 3/	59	37	-37.3	35	-5.4
Africa 4/	380	387	1.8	390	0.8
Asian countries 4/	80	60	-25.0	63	5.0
Middle East 4/	365	370	1.4	377	1.9
TOTAL	3.022	3.119	3.2	3.110	-0.3

Source: International Meat Council.

1/ The twelve countries of the EEC.
2/ Includes the other exporting countries participating in the Beef Agreement. IMC Secretariat estimates.
3/ Source: U. S. Department of Agriculture (USDA), Dairy, Livestock and Poultry, World Livestock and Poultry Situation, September 1985.
4/ IMC Secretariat estimates.

II. ANALYSIS BY COUNTRY 1/

The United States

In 1986 the cattle herd totalled 105.468.000 head, some 3.9% lower than in 1985. This was the lowest figure since 1963 and the fourth consecutive reduction in the number of cattle in almost all cattle categories, except for dairy cows which increased (3.5%). This has been caused by the prolonged lack of profitability of fattened cattle, the financial crisis of the agricultural sector and the low consumer demand.

In 1985, cattle slaughter was lower (2.9%) but, due to the increased weight of carcasses during almost all the year, beef production increased by 0.2% reaching 10.95 million tons. Estimates for 1986 show a decrease (3.7%) in beef and veal production to 10.548.000 tons, or even more, as a result of the program for the purchase of dairy cattle herds which provides for the elimination of 1.550.400 cows, heifers and calves.

The beef stock should increase by 3.0% but due to the lower weight of carcasses, beef and veal production during 1986 will be lower than in 1985.

Data for 1985 show that beef consumption totalled 11.812.000 tons, an increase of 1.9% in relation to the previous year. Per capita consumption increased (0.8%) hitting 49.9 kg. A reduction of 3.8% in the total consumption of beef and veal is estimated for 1986.

In 1985, prices for cattle were low but there will be a moderate increase during 1986, as production levels decrease.

In 1985, beef imports increased (13.1%) totalling 948.000 tons, most of which came from Australia. A new increase (2.5%) is forecasted for 1986, reaching 973.000 tons, mainly due to the decrease in national production. Nevertheless, the level of activation will not increase and therefore quotas are unlikely.

Beef exports in 1985 were relatively stable reaching 151.000 tons. Japan bought around 70% of all beef exports. In 1986, exports could reach 171.910 tons or even more because the government must buy 180.000 tons of meat to counterbalance the impact on the domestic market of the increase in cattle slaughter; 90.000 tons out of this figure will be exported and 20.000 tons will be sent to the Department of Defense and military units in Europe.

1/ Based on reports from the International Meat Council within the framework of the General Agreement on Tariffs and Trade.

Statistical Synthesis (USA)

Categories	1984	1985	1985/84 % AX	1986 Prelim	1985/85 % AX
No. of bovines 1/	113.700	109.749	-3.8	105.468	-3.9
Beef and veal: 2/					
Production	10.928	10.955	0.2	10.548	-3.7
Consumption	11.597	11.812	1.9	11.359	-3.8
Imports	838	948	13.1	973	2.6
Exports	151	151	0.0	172	27.4

1/ Thousands of head.
2/ Thousands of tons.

Canada

The 1986 Canadian livestock census indicated continuation of the herd elimination process. Herds totalled 10.590.700 head, reflecting a reduction of 3.5% in comparison to the previous year and 25.8% in relation to the most recent maximum recorded in 1975.

This trend is the result of depressed prices, mainly for fattened stock and perspectives for recovery do not seem good, given that forecasts indicate continued herd reduction through mid 1987.

The total number of cattle slaughtered rose (0.8%) to 4.301.300 head in 1985, with an increase (3.9%) in the number of calves and heifers slaughtered. Average carcass weights also increased (3.1%). During the first quarter of 1986 inspected slaughtering decreased (-1.7%) and forecasts indicate a total slaughter of 4.175.000 head (-2.9%), which represents a first step toward herd rebuilding.

In 1985 production increased (3.9%) due to the increase in slaughtering and in dressed weights, hitting a figure of 1.035.100 tons. In 1986, beef production is expected to decrease (-1.7%) to 1.019.000 tons, with another increase in dressed weight.

In 1985 total beef consumption decreased slightly (-0.8%) to 1.030.800 tons, the lowest level recorded since the beginning of the decade. Additional reductions (-1.3%) are forecasted for 1986, as well as in 1987. The major reason seems to be the low growth of income, which in 1985 was less than that of beef retail prices.

In 1985 beef and veal imports totalled 115.900 tons, a small decrease (0.6%) in comparison to the previous year. There was an increase in frozen beef and veal imports from Australia and New Zealand. The 1985 quota level was set at 75.951 tons, but in reality a total of 82.000 tons of beef were imported. A reduction (7.7%) of total imports is expected for 1986, to a figure of 107.000

tons. As yet, no restrictions have been placed on the quota in 1986. At the end of 1985 recourse was made to the Meat Import Law, but it was subsequently declared suspended, and last year Canada imported 56.000 head of cattle from the United States.

Beef exports increased (11.4%) in 1985, to a total of 117.100 tons of which 68.600 were frozen meat and 45.300 fresh and chilled meat, primarily to the United States. Projections for 1986 indicate a decrease (-10.6%). In addition, 235.000 head of cattle were exported to the United States and for 1986 the forecast indicates 200.000 head to be exported.

Statistical Synthesis (Canada)

Categories	1984	1985	1985/84 % AX	1986 Prelim	1986/85 % AX
No. of bovines 1/	11.360	10.980	-3.4	10.591	-3.5
Beef and veal: 2/					
Production	997	1.035	3.9	1.019	-1.7
Consumption	1.039	1.031	-0.8	1.017	-1.3
Imports	117	116	-0.6	107	-7.7
Exports	105	117	11.4	105	-10.6

1/ Thousands of head.
2/ Thousands of tons.

Argentine

In June 1985, the cattle herd in Argentine was 54 million head, some 1.1% lower than the previous year reflecting an early end to herd rebuilding efforts. Besides, serious floods at the end of the year caused very big losses. It is possible that the 1986 cattle census may show a reduction (-2.8%) to a total of 52.5 million head approximately.

The difficult economic situation forced producers to sell their cattle and slaughter of grown and young increased (11.4%) to a total of 13.7 million head. The killing of a significant number of cows and the reduction (3.8%) of the average weight of head had a moderate impact on the increase of the total production of beef and veal which was 2.74 million tons. It is estimated that for 1986 total slaughter will be similar to the previous year and the same tendency is seen for the proportion of heifers and steers slaughtered. Consequently, slaughter weights were low, some 1% lower than the previous year.

Real prices for cattle increased since last February due to the fact that Argentine authorities put a stop to maximum prices for slaughtered cattle but until mid May this measure was not enough to stop the decrease in the number of head.

It is estimated that total consumption for 1985 was 2.48 million tons (82 kg per capita). There was a 7.5% increase due to relatively low prices, a governmental policy to freeze prices, the increase in the domestic supply and the low levels of exports. In 1986, despite the rise in prices, per capita consumption continued increasing (6%) in relation to the previous year, up to a total of 86 kg. The reason for this seems to be that the prices for other foods increased even more.

In 1985, beef and veal exports increased (4%) to a total of 260.000 tons. The main markets for fresh, chilled and frozen beef were the EEC (46%), Israel (16%) and Angola (11%). As regards canned and cooked beef and veal, the United States imported 68% of all exports and the EEC some 16%. Argentine had to face a lower demand from its traditional markets and the big quantities available for export in the EEC continue affecting its exports; especially on markets such as Iran, Iraq and Egypt. Estimates for 1986 show a moderate increase (3.8%) in the level of exports totalling 270.000 tons. The main markets were the same as in 1986.

Statistical Synthesis (Argentine)

Categories	1984	1985	1985/84 % AX	1986 Prelim	1986/85 % AX
No. of bovines 1/	54.600	54.000	-1.1	52.500	-2.8
Beef and veal: 2/					
Production	2.558	2.740	7.1	2.700	-1.5
Consumption	2.308	2.480	7.5	2.430	-2.0
Exports	250	260	4.0	270	3.8

1/ Thousands of head.
2/ Thousands of tons.

Brazil

In Brazil, the cattle herd was estimated at 136.641.000 head in 1985 with an increase of 2.9% in relation to the previous year.

It is estimated that 10.1 million head of grown and young animals were slaughtered that year. There was a considerable increase in the slaughtering in the first half of the year and strong reductions in the second half.

Production totalled 2.1 million tons with an increase (1.3%) limited by a severe drought in the Center-South States which killed a significant number of cattle. Slaughtering is estimated to be reduced in 1986 to a total of 10 million head.

Prices to producers fell around 40% in the first half of 1985. Producers had to face economic as well as weather difficulties and they were forced to sell a bigger number of cattle to cope with the increase in costs and inflation. Nevertheless, in the second half the data on limited beef stock in the public sector together with a reduced supply of fattened stock favored a strong speculation on the market and nominal prices rose almost by 200%. However, they fell by 12% in real terms.

In recent years, beef consumption in Brazil has gone from 14.0 to 16.3 kg/per capita, still one of the lowest figures for South America. Among the factors considered to favor beef consumption are the rise in salaries for some economic sectors, the policy for a price control in force, as from 1986, and the increase in poultry and pork prices.

Until June 1985, beef imports totalled 12.800 tons. In the second half year, the Brazilian government authorized the import from Uruguay of 50.000 tons of beef for processing and 15.000 tons for the domestic market. Due to the broadening of the domestic market and to Brazilian efforts to increase exports, some 290.000 tons will have entered the country in 1986 (an increase of 314.3%) from the EEC, the United States and Uruguay.

In 1985, Brazil exported 485.000 tons of beef, a record figure for exports which kept the country in the third place among world exporters for such product, after the EEC and Australia. The increasing trend in average prices for exports of fresh, chilled and frozen meat to Iraq, the United Kingdom and the Federal Republic of Germany stimulated frozen boneless beef exports which totalled around 31% of all exports. Canned beef exports were 55% of all exports and the best markets were the United Kingdom and the United States.

The result obtained by Brazil in its export activity was favored by the daily "mini-devaluation" policy of the cruzeiro, by sanitary conditions of exported products, as well as by delivery dates which have improved considerably in recent years and by beef imports for processing and re-exporting, all of which has proved important from the financial point of view. In 1986 this situation is changing due to the "Economic Stabilization Program" which together with the freezing of prices and a considerable redistribution of income has greatly stimulated the domestic market.

Statistical Synthesis (Brazil)

Categories	1984	1985	1985/84 % AX	1986 Prelim	1986/85 % AX
No. of bovines 1/	132.801	136.641	2.9	140.740	3.0
Beef and veal: 2/					
Production	2.092	2.120	1.3	2.100	-0.9
Consumption	1.860	1.731	-6.9	2.000	15.5
Imports	37	70	89.2	290	314.3
Exports	479	485	1.3	300	-38.1

1/ Thousands of head.
2/ Thousands of tons.

Colombia

The cattle herd of Colombia has changed little from one year to the other in the recent past. In 1985 there were 24 million animals which meant a decrease (-1.9%) in relation to the previous year. The majority of the cattle was for meat production.

In 1985, 3.216.000 head were slaughtered. Some 1.902.000 were adult male animals. There were no calves. The majority was slaughtered for domestic consumption.

Beef production increased to 619.500 tons in 1985 which means a 3.5% increase in relation to the previous year but a decrease (5%) in comparison to 1981.

Consumption which had also reached a record figure in 1981 totalled 616.300 tons in 1985. This means an approximate increase of 3.9% in relation to 1984 but a decrease (2.1%) in comparison to the year of maximum consumption. Within this same period, per capita consumption decreased from 24.0 to 19.7 kg due to the general economic situation and to the increase in retail prices.

Colombia is a traditional exporter of fresh, chilled and frozen meat especially. In 1985, exports reached 3.200 tons which means a sharp fall (39.0%) in relation to the previous year. This fall can be due, at least partially, to the increasing competition of world markets and the very low prices of some markets. The majority of Colombian beef exports (mainly fresh and chilled) were to Venezuela.

Statistical Synthesis (Colombia)

Categories	1984	1985	1985/84 % AX	1986 Prelim	1986/85 % AX
No. of bovines 1/	24.476	24.000	-1.9	--	--
Beef and veal: 2/					
Production	598.6	619.5	3.5	633.4	2.2
Consumption	593.3	616.3	3.9	630.1	2.2
Exports	5.2	3.2	-39.0	10.0	212.5

1/ Thousand of head.
2/ Thousand of tons.

Uruguay

In accordance with the figures given by the 1985 census, cattle increased (1.5%) totalling 9.222.000 head in Uruguay. Apparently, the process of killing herds finished, and although the number of beef cows increased by 1.7% and of calves by 14.3%, the number of dairy cows continued decreasing, though at a lower pace in relation to the previous year. In 1986, practically all categories of cattle increased.

Cattle slaughtered totalled 1.315.000 head in 1985 which means some 12.5% less than the previous year and clearly shows the end of the killing period. This was due mainly to a decrease (-26.2%) in the slaughtering of female animals. Estimates show that the level of slaughtering will continue to decrease in 1986 to 1.308.000 animals approximately.

In the first half of 1985, beef and veal production decreased (13.2%) due to the decrease in slaughtering. However, partly due to the sales agreements entered into with Brazil (65.000 tons), production increased in the second half up to 319.000 tons, some 3% higher than the previous year.

In real terms, retail prices for beef increased (2.2%) in the first half of 1985, whereas the poultry price, which represents some 6% of the total meat consumption, decreased (-9.0%).

Despite the rise in prices, estimates showed that beef consumption in 1985 would increase to 184.000 tons, that is 61 kg/per capita stimulated by a higher production in the second half of the year and salary increases in the last months. Estimates for 1986 indicate an intensification of the impact of salary increases together with a new increase in consumption as a result of a considerable fall of exports, despite the estimate of a decrease (-12.0%) in production.

In 1985, beef and veal exports totalled 139.000 tons according to projections lower (-3.5%) than in the previous year. The strong increase of exports to Brazil in the second half avoided a sharper decrease. Frozen meat exports (86% of the total) fell to 44.000 tons between January and June 1985 which means almost 50% less than the previous year.

Like Argentine, Uruguay had to face a lower demand for exports which coincided with a more intense competition in some of its traditional markets. In 1985, there were no exports to Egypt, an important market for Uruguay and which had purchased an average of 28.000 tons annually in the last five years. Uruguay could not win any call for bids; in most cases they were won by the EEC with lower prices.

The government has recently fixed the following aims for the beef sector: a seven-year program to eradicate foot and mouth disease in cooperation with Brazil and Argentine; to establish stock regulations to satisfy the domestic market, a gradual increase of canned meat exports over a three-year period until reaching a level of 50% of total exports to markets free of foot and mouth disease.

Statistical Synthesis (Uruguay)

Categories	1984	1985	1985/84 % AX	1986 Prelim	1986/85 % AX
No. of bovines 1/	9.805	9.222	1.5	9.561	3.7
Beef and veal: 2/					
Production	310	319	2.9	280	-12.2
Consumption	177	184	4.0	190	3.2
Exports	148	139	-3.6	139	0.0

1/ Thousand of head.
2/ Thousand of tons.

European Economic Community

According to the figures taken from the EEC beef cattle census, there was a decrease (-1.2%) in a total number of 78.766.000 animals in 1985. As in the previous year, the highest decrease was shown in the number of dairy cows (-2.8%) which was counterbalanced by an increase in the number of beef cows.

The slaughter of grown and young animals which totalled 29.27 million head decreased. Some 7.05 million were calves (-3.5%) and 11.222.000 were female bovines (-5.5%). The slaughtering of 11 million head of malecattle was higher (1.7%) than the estimate. In the first months of 1986, the number of cattle slaughtered was also important, but taking into consideration the twelve months

of the year, the Community forecasts another decrease in the total slaughtering, since a strong decrease in the number of cows slaughtered is expected. Partly as a consequence of the low prices of forage grains, slaughter weights increase more and more and in terms of beef and veal production, they counterbalance the fewer number of slaughtered animals.

The 1985 production was 7.377.000 tons approximately and there was a decrease (-1.6%). The fewer number of slaughtered cows allow a forecast of decrease (-2.8%) in the EEC production for 1986.

By the end of 1985 the intervention stock was 737.000 tons and private stock was 135.000 tons. The sale of 175.000 tons to the Soviet Union together with 50.000 tons to Rumania and Brazil seem to show that the stock in the public sector is decreasing in relation to the previous year, despite bigger intervention sales.

Better economic conditions and relatively stable real prices in 1985 increased consumption (2.7%) which reached 25.6 kg per capita and a total of 6.985.000 tons. In spite of the fact that beef consumption varies considerably from one country to the other in the EEC, a new increase can be estimated for 1986, although it will be a moderate one due to a large supply of poultry and pork (which represented 46% of the total meat consumption of the EEC in 1985), favored by the low prices of forage grains.

Beef and veal imports (excluding live cattle) reached 395.000 tons in 1985 and increased (3.1%) in relation to the previous year. Preferential quotas did not vary much in 1985 but were modified as follows: in 1986 the offset quota for beef for processing was reduced from 50.000 to 25.000 tons and the quota for young male animals was reduced from 190.000 to 175.000 head; the quota of high quality cuts increased by 6.000 tons to counterbalance the reduction in the offset quota for beef for processing.

In 1985 beef and veal exports reached 733.000 tons (excluding live cattle), an increase (5.6%) in relation to the previous year. The biggest part of beef and veal exports of the EEC were to the North of Africa, especially to Egypt and the USSR. At the beginning of 1986, the EEC entered into an agreement with Rumania to export 50.000 tons of beef and veal at relatively low prices. The last estimate available shows a decrease (-1.1%) of beef and veal exports in 1986.

The opening up of the Community from 10 to 12 countries at the beginning of 1986 brought about an increase in the number of cattle, as well as in slaughter levels, production and total beef consumption. Nevertheless, there was a reduction in the average per capita consumption.

Statistical Synthesis (EEC)

Categories	1984	1985	1985/84 % AX	1986 Prelim		1986/85 % AX	
No. of bovines 1/	78.766	77.582	-1.5		(83.500)		(7.6)
Beef and veal:							
Production	7.499	7.377	-1.6	7.193	(7.720)	-2.5	(4.6)
Imports 2/	383	395	3.1	380	(380)	-3.8	(-3.8)
Consumption	6.800	6.985	2.7	7.033	(7.600)	0.7	(8.8)
Exports 2/	694	733	5.6	725	(725)	-1.1	(-1.1)
Cattle on the hoff:							
Imports	428	490	14.5	460	(460)	-6.1	(-6.1)
Exports	367	275	-25.1	285	(285)	3.6	(3.6)

1/ Thousands of head at December 1st.
2/ Including processed veal and beef.

Note: The figures in parentheses refer to the 12 countries of the EEC.

The Soviet Union

In 1986, grown and young animals on state and collective farms totalled 120.7 million head which means a decrease of 0.1% in relation to 1985.

This decrease was due to a high slaughtering level in 1985, especially in the first half as a result of an insufficient supply of fooder.

According to official Soviet figures, total meat production increased marginally in 1985 to 17.1 million tons (0.6%). It is calculated that 6.89 million tons were beef which means an increase (2.9%) in relation to 1985. Meat production continued increasing at the beginning of 1986, as a consequence of good weather and better feed supply than the previous year.

There is some information on the fact that Soviet authorities have increased subsidies in the production price of meat, with a view to increasing during 1986-1990 period, the average level reached between 1981 and 1986. Provided weather conditions and feed supply continue to be good, beef production in 1986 could be either equal to or even higher than in 1985.

The Soviet Union imported some 551.600 tons of frozen meat and some 139.700 tons of canned meat in 1984 according to national statistics. It is estimated that 50-60% of the total meat imports were beef, that is between 345.650 and 417.780 tons in product weight. According to the United States Department of Agriculture, 1985 imports decrease somewhat, due to the higher level of domestic production and a new decrease is forecasted for 1986 because of the same reason. In 1985, the main suppliers were the EEC, Eastern European countries and Finland.

Statistical Synthesis (Soviet Union)

Categories	1984	1985	1985/84 % AX	1986 Prelim	1986/85 % AX
No. of bovines 1/	119.558	120.800	1.0	120.700	-0.1
Beef and veal: 2/					
Production	6.696	6.890	2.9	7.100 3/	3.1
Consumption 4/	7.240	7.410	2.4	7.500	1.9
Exports 5/	541	510	-5.7	450	-11.8

1/ Thousands of head.
2/ Thousands of tons.
3/ IMC Secretariat estimates.
4/ IMC Secretariat estimates based on national statistics and on United States Department of Agriculture estimates.
5/ United States Department of Agriculture estimates.

Australia

After eight years of herd reduction, the 1986 bovine census indicates a second year of expansion, with a total of 23.234.000 head, but with moderate growth (2.0%) in comparison to 1985, due to the price increase and improved weather conditions.

The 1985 slaughter totalled 7.146.200 head of cattle, with an increase (6.2%) in the slaughter of adult cattle and a decrease (-2.4%) in the slaughter of calves. A slowing of slaughtering is forecasted for 1986, due to the rebuilding of herds.

In 1985, beef and veal production increased (7.3%) to 1.338.000 tons. For 1986, projections indicate a decrease in the growth rate of production, due to the increased percentage of cows and heifers slaughtered and the decrease in average carcass weights, resulting in a final figure of 1.360.300 tons.

Consumption of red meat increased to 83 kg per capita in 1985, 2.4% over the figures for the previous year. Beef and veal consumption was 642.000 tons, 0.5% over the previous year (40.8 kg per capita). The moderate increase in beef consumption in comparison to the significant increase in production is explained by the increased in exports.

In 1985, beef exports increased (14.6%), reaching a total of 707.000 tons, stimulated also by the depreciation of the Australian dollar. Almost 60% of the total beef exports (274.000 tons) was sent to the United States, an increase of 21.2% over the previous year. In australian dollars exporters received an average of 248 cents per kilo, i.e., 17% more than in 1984.

Projections for 1986 indicate a slight increase (0.6%) in consumption and a rise (2.3%) in the total volumen of exports, with there being a certain growth in exports to the United States, Japan, and Taiwan, and a slight decrease in exports to Canada and the countries of Southeast Asia.

Statistical Synthesis (Australia)

Categories	1984	1985	1985/84 % AX	1986 Prelim	1986/85 % AX
No. of bovines 1/	22.161	22.784	2.8	23.234	2.0
Beef and veal: 2/					
Production	1.248	1.338	7.3	1.360	1.6
Consumption	638	641	0.5	645	0.6
Exports	617	707	14.6	723	2.3

1/ Thousands of head.
2/ Thousands of tons.

New Zealand

1986 will be the third year of cattle herd rebuilding in New Zealand, where the total number of grown and young head is expected to reach 8.000.000 or 1.0% over the previous year.

It is estimated that the slaughter of grown and young cattle subject to inspection will increase significantly (14.4%) in 1986, compared to 1985, to a total of 3.086.000 head.

Consequently, beef and veal production is expected to increase significantly (17.7%) to a total of 533.000 tons.

On the other hand, there has been a decrease in list prices for beef, which fell approximately 20% as a result of the appreciation of the New Zealand dollar.

Consumption of beef and veal has decreased consistently, due to substitution by poultry and pork at cheaper prices. It is expected that in 1986 beef consumption will stabilize at around 120.000 tons.

An increase in exports of some 23.000 tons is expected in 1986, for a total of approximately 385.000 tons primarily as the result of the projected increase in imports by New Zealand's main market, the United States, and its other two major markets, Canada and Japan.

In addition, it should be noted that in 1985 the sheep herd recorded a reduction (-1.7%) and it is expected to continue decreasing in 1986, to a figure of 66.5 million head (-2.9%). This reflects a change in the relative rentability between ovine and bovine meat. In comparison to the 1984-85 season, list prices for lamb showed an average decrease of 32% while mutton prices fell 46%.

Statistical Synthesis (New Zealand)

Categories	1984	1985	1985/84 % AX	1986 Prelim	1986/85 % AX
No. of bovines 1/	7.776	7.920	1.9	8.000	1.0
Beef and veal: 2/					
Production	460	453	-1.5	533	17.7
Consumption	128	118	-7.8	120	1.7
Exports	284	362	27.4	385	6.3

1/ Thousands of head.
2/ Thousands of tons.

ANNEX: BASIC STATISTICS

Total number of head of beef cattle
Total number of slaughtered animals
Total beef and veal production
Beef stock
Beef consumption
Fresh beef imports
Beef imports
Fresh beef exports
Beef exports
Beef prices: Prices to producers
Beef prices: Export price

Table 5. Total number of head of beef cattle (thousands of head)

Country	1982	1983	1984	1985	% AX 1985/84	Prelim 1986
Argentina	52.500	53.900	54.600	54.000	-1.1	53.500
	20.300	20.800	21.000	20.800	-1.0	20.600
Australia	24.553	22.478	22.161	22.738	2.6	23.300
	10.166	9.303	9.265	9.465	2.2	--
Austria[1/]	2.546	2.633	--	--	--	--
	1.379	1.474	--	--	--	--
Brazil	125.188	128.952	132.801	136.641	2.9	140.740
	56.278	57.854	59.474	61.139	2.8	62.851
Canada	12.088	11.618	11.360	10.965	-3.5	10.540
	5.231	5.823	4.967	4.782	-3.7	4.624
Colombia	24.499	24.275	24.476	24.000	-1.9	--
	--	--	--	--	--	--
EEC	78.791	79.443	78.486	77.700	-1.0	--
	31.351	31.669	31.084	--	--	--
Egypt[3/]	4.187	--	--	--	--	--
	--	--	--	--	--	--
Finland	1.633	1.588	1.592	1.557	-2.2	1.530
	683	658	651	639	-1.8	629
Hungary	1.945	1.922	1.907	1.901	-0.3	1.909
	759	751	735	725	-1.4	--
Japan	4.485	4.590	4.682	4.698	0.3	4.712[2/]
	2.104	2.140	2.152	2.128	-1.1	--
New Zealand[4/]	7.912	7.631	7.776	7.940	2.1	8.050
	3.740	3.797	--	--	--	--
Norway	1.008	975	964	973	0.9	--
	384	381	382	376	-1.6	--
Poland	11.912	11.269	11.197	11.055	-1.3	11.400
	5.835	5.776	5.759	5.528	-4.0	5.760
Rumania	6.303	6.246	7.039	--	--	--
	3.090	3.031	3.095	--	--	--
South Africa	8.445	8.204	7.923	7.830	-1.0	7.945
	4.066	3.973	3.944	--	--	--
Sweden	1.938	1.902	1.878	1.845	-1.8	1.796
	731	724	717	703	-2.0	678
Switzerland	1.945	1.933	1.943	1.926	-0.9	1.920
	1.001	1.001	1.000	974	-2.6	994
Tunisia	578	606	615	637	3.6	661
	382	413	424	438	3.3	467
United States	124.140	123.540	113.700	109.800	-3.4	107.000
	49.970	49.600	48.603	46.212	-4.9	--
Uruguay	11.237	9.704	9.085	9.222	1.5	9.561
	4.091	3.554	3.507	3.566	1.7	3.735
Yugoslavia	5.464	5.351	5.341	5.199	-2.7	--
	3.079	3.050	3.005	2.997	-0.3	--

Source: International Meat Council.

1/ Including beef steers.
2/ International Meat Council Secretariat estimates.
3/ Including buffaloes.
4/ Campaign ended 09.30.

Table 6. Total number of slaughtered animals (thousands of head)

Country	1982	1983	1984	1985	% AX 1985/84	Prelim 1986
Argentina	11.300	10.400	11.200	13.800	23.2	13.000
	1.100	800	1.100	--	--	--
Australia	7.795	6.633	5.482	5.787	5.6	5.850
	1.669	1.470	1.168	1.150	-1.5	1.180
Austria	560	563	--	--	--	--
	196	181	--	--	--	--
Brazil	11.566	11.432	10.042	7.191	-28.4	11.000
	93	92	53	27	-49.1	--
Canada	3.808	3.710	3.641	3.473	-4.6	3.369
	621	649	631	670	6.2	650
Colombia	3.337	3.029	3.198	3.216	0.6	3.562
	--	--	--	--	--	--
EEC	20.389	20.930	22.683	21.900	-3.5	23.050
	6.676	6.858	7.306	6.900	-5.6	7.300
Egypt 2/	1.842	--	--	--	--	--
	--	--	--	--	--	--
Finland	555	551	569	--	--	--
	93	65	602	--	--	--
Hungary	427	463	406	355	-12.6	--
	3	3	4	4	0.0	--
Japan	1.355	1.388	1.492	--	--	--
	44	45	44	--	--	--
New Zealand	2.256	2.111	1.891	1.997	5.6	2.097
	1.004	896	817	834	0.2	875
Norway	359	335	311	316	1.6	308
	55	62	57	54	-5.3	46
Poland	3.120	3.008	3.134	--	--	--
	1.654	1.611	1.520	--	--	--
Rumania	1.238	--	1.416	--	--	--
	--	--	--	--	--	--
South Africa	2.215	2.215	2.358	2.340	-0.8	2.298
	95	99	102	100	-2.0	98
Sweden	607	603	577	586	1.6	567
	111	114	123	134	8.9	143
Switzerland	460	436	469	--	--	--
	367	341	346	--	--	--
Tunisia	232	244	221	110	--	230
	--	--	--	--	--	--
United States 1/	38.864	39.725	40.874	39.232	-4.0	36.682
	3.021	3.076	3.292	3.230	-1.9	2.885
Uruguay	2.019	2.057	1.418	1.230	-13.3	1.222
	200	171	85	85	0.0	86
Yugoslavia	1.397	1.444	1.540	--	--	--
	1.053	840	862	--	--	--

Source: International Meet Council.

1/ Commercial slaughter representing 99% average of total slaughter.
2/ Including buffaloes.

Table 7. Total Beef and Veal Production (thousands of head)

Country	1982	1983	1984	1985	% AX 1985/84	Prelim 1986
Argentina	2.426	2.294	2.428	2.580	6.3	2.530
	125	90	130	180	38.5	150
Australia	1.621	1.360	1.209	1.270	1.8	1.297
	57	52	38	--	--	43
Austria	184	188	--	--	--	--
	16	16	--	--	--	--
Brazil 1/	2.385	2.359	2.153	2.200	2.2	2.300
	--	--	--	--	--	--
Canada	991	945	953	991	4.0	961
	40	42	45	44	-2.2	43
Colombia	613	564	599	620	3.5	633
	--	--	--	--	--	--
EEC	5.895	6.116	6.630	6.415	-3.2	7.100
	761	800	869	835	-3.9	--
Egypt 2/	239	--	--	--	--	--
	--	--	--	--	--	--
Finland	115	118	123	127	3.3	126
	1.4	0.9	0.9	1	11.1	1
Hungary	124	138	130	54	0.4	--
	0.1	0.1	0.2	--	--	--
Japan	479	492	533	555	3.7	565
	2	2	2	--	--	--
New Zealand	509	475	445	514	11.7	521
	21	18	14	--	--	--
Norway	77	72	67	70	4.5	71
	2.8	2.4	2.2	2	4.5	2
Poland	583	559	604	663	2.0	--
	56	51	46	--	--	--
Rumania	196	--	234	--	--	--
	--	--	--	--	--	--
South Africa	609	628	657	675	2.7	692
	3.9	4.4	4.7	5	6.4	94
Sweden	151	151	144	145	0.7	143
	9	9	11	11	0.0	13
Switzerland	122	117	128	131	2.3	130
	38	36	37	40	8.1	39
Tunisia	29	27	29	32	10.3	35
	--	--	--	--	--	--
United States	10.223	10.543	10.622	10.647	0.2	9.888
	203	206	217	213	-1.8	184
Uruguay	407	427	301	319	2.9	280
	--	15	7	--	--	--
Yugoslavia	362	357	371	--	--	--
	--	--	--	--	--	--

Source: International Meat Council.

1/ Total beef and veal production together.
2/ Including buffalo meat.

Table 8. Beef Stock (thousands of metric tons, dressed)

Country	1982	1983	1984	1985	% AX 1985/84	Prelim 1986
Argentina 1/	66.0	55.0	10.0 4/	--	--	--
Australia	32.7	28.0	24.4	--	--	--
Austria	4.0	4.0	--	--	--	--
Brazil 2/	204.0	160.0	20.0	15.0	-25.0	50.0
Canada	20.2	17.3	22.3	19.7	-11.7	18.8
EEC 3/	255.0	432.0	810.0	782.0	-3.5	652.0 5/
Finland	7.6	5.7	5.1	--	--	--
Hungary	1.4	1.3	4.3	8.0	+86.0	--
New Zealand	50.1	39.5	47.0	44.5	-5.3	44.5
Norway	6.2	6.2	3.5	--	--	--
South Africa	4.5	15.0	35.1	5.0	-85.8	3.0
Sweden	6.0	9.0	14.0	12.0	-14.3	10.0
Switzerland	3.1	0.5	8.3	4.0	-51.8	3.0
Tunisia	1.8	2.6	2.0	1.5	-25.0	1.2
United States	115.6	136.5	168.0	139.0	-17.3	139.0
Uruguay	26.0	21.0	10.0	10.0	0.0	--

Source: International Meat Council.

1/ Most of the stock is the deboned meat and figures refer only to the stock kept in meat-packing plants authorized for export.
2/ Stock up to January 1°.
3/ Including intervention and private stock.
4/ January-June.
5/ EEC - 12 countries since 1986.

Table 9. Beef consumption (thousands of metric tons, dressed and kg per capita)

Country	1982	1983	1984	1985	% AX 1985/84	Prelim 1986
Argentina	2.031	1.975	2.338	2.500	6.9	2.330
	70.0	67.0	77.0	82.0	6.5	75.0
Australia	750	651	638	600	-6.0	614
	49.4	42.3	41.0	38.3	-6.6	38.6
Austria	184	174.5	--	--	--	--
	24.5	23.1	--	--	--	--
Brazil	2.043	2.000	1.860	1.917	3.1	1.959
	16.3	15.5	14.0	14.4	2.9	14.7
Canada	1.039	1.039	1.010	1.021	1.1	990
	42.1	41.7	40.1	40.0	-0.2	38.8
Colombia	595	551	593	676	3.9	630
	21.9	19.2	20.7	--	--	--
EEC	6.600	6.620	6.800	6.950	2.2	7.000
	24.3	24.4	25.0	25.5	2.0	25.5
Finland	106	104	106	102	3.8	102
	22.0	21.4	21.7	21.0	-3.2	21
Hungary	99	89	74	70.0	-5.4	--
	9.3	8.3	7.0	7.4	5.7	--
Japan	671	706	757	590 2/	4.3 2/	816 2/
	5.6	5.9	6.3	6.5 2/	3.2	6.7 2/
New Zealand 1/	155	142	136	118	-13.2	119
	43.0	42.1	39.5	35.9	-9.1	35.7
Norway	76	69	72	74	2.8	75
	18.7	16.7	17.3	17.9	3.5	18.3
Poland	519	580	585	585	0.0	--
	14.4	15.8	15.8	15.8	0.0	--
Rumania	--	--	--	--	--	--
	--	--	--	--	--	--
South Africa	663	664	682	721	5.6	734
	21.3	20.8	20.8	21.4	2.9-	21.1
Sweden	141	141	132	137	3.8	140
	16.9	16.9	15.8	16.4	3.8	16.8
Switzerland	176	169	173	181	4.6	179
	26.8	25.7	26.3	27.5	4.6	27.2
Tunisia	50	53	59	59	0.0	60
	6.8	7.6	8.4	8.3	-1.2	8.1
United States	11.182	11.492	11.597	11.690	0.8	10.882
	48.2	49.1	49.5	49.4	-0.2	45.6
Uruguay	230	215	177	184	4.0	190
	78.0	72.0	59.0	51.1 2/	-13.4 2/	51.7
Yugoslavia	332	325	337	--	--	--
	15.2	14.8	14.7	--	--	--

Source: International Meat Council.

1/ Campaing ended 09.30.81.
2/ International Meat Council Secretariat estimates.

Table 10. Imports of Fresh, Chilled and/or Frozen Beef (dressed weight equivalent in thousands of metric tons)

Country	1982	1983	1984	1985	% AX 1985/84	Prelim 1986
Australia	3.2	3.4	3.9	--	--	--
Austria	9.0	5.0	3.1 1/	--	--	--
Brazil	21.0	25.4	36.9	11.6	-68.6	--
Bulgaria	0.2	0.1	0.1	--	--	--
Canada	77.4	79.6	106.4	106.0	-0.4	112.0 2/
EEC	236.0	240.0	213.0	215.0	0.9	220.0 3/
Egypt 2/	97.0	77.6	--	--	--	--
Finland	1.0	--	--	--	--	--
Hungary	14.3	11.2	7.2	0.1 1/	-97.8 1/	--
Japan	175.0	196.0	207.0	220.0 4/	6.3	236.0 4/
Noruega	1.1	1.3	1.7	1.0	-41.2	1.0
Poland	6.3	1.5	14.4	3.8	-73.6	1.5
Rumania	17.1	--	--	--	--	--
South Africa	19.6	23.0	25.1	23.5	-6.4	22.5
Sweden	6.2	7.2	5.1	6.0	17.6	6.0
Switzerland	9.2	11.5	10.6	8.5	-19.8	9.3
Tunisia	4.7	11.4	15.2	14.6	-3.9	11.7
United States	817.4	884.3 2/	838.0 1/	885.0 2/	5.6	902.0 2/
Yugoslavia	30.2	42.3	24.0	5.2 1/	--	--

Source: International Meat Council.

1/ January/June.
2/ Total imports. Broken-down data not available.
3/ EEC - 12 countries since 1986.
4/ Secretariat estimates.

Table 11. Imports of Beef other than Fresh, Chilled and/or Frozen (canned, cooked, etc.) (dressed weight equivalent in thousands of metric tons)

Country	1982	1983	1984	1985	% AX 1985/84	Prelim 1986
Australia 1/	0.4	0.6	0.6	--	--	--
Brazil	--	--	--	--	0.0	--
Bulgaria	0.1	0.1	0.1	--	--	--
Canada	10.8	12.1	9.9	6.0	-39.4	--
EEC	138.0	144.0	147.0	145.0	-1.4	150.0 2/
Hungary	0.1	1.0	0.1	--	--	--
Japan	15.0	15.0	15.0	15.0	0.0	15.0
Poland	0.7	0.5	0.2	0.1	-50.0	--
Sweden	0.4	0.4	0.3	0.5	66.6	0.5
Switzerland	2.1	2.9	3.1	1.5	-35.5	2.7
United States	87.8	--	--	--	--	--
Uruguay	8.0	8.0	2.0	8.0	300.0	0.0

Source: International Meat Council.

1/ Including cooked and corned beef and canned kidneys and fillets.
2/ EEC - 12 countries since 1986.

Table 12. Exports of Fresh, Chilled and/or Frozen Beef (dressed weight equivalent in thousands of metric tons)

Country	1982	1983	1984	1985	% AX 1985/84	Prelim 1986
Argentina	359.0	262.0	125.0	-52.3	119.0	200
Australia	898.0	726.0	575.0	-20.8	650.0	680
Austria	23.0	28.0	20.0 1/	53.8	--	--
Brazil	124.6	159.9	153.3	-4.1	450.0 3/	400 3/
Bulgaria	10.6	12.5	12.5	0.0	6.0 5/	7
Canada	79.5	79.0	101.9	29.0	112.0	78
Colombia	18.2	12.6	5.2	-58.4	3.2	10
EEC	355.0	462.0	650.0	40.7	640.0	610 4/
Finland	7.0	14.0	14.0	-0.7	14.0	20 3/
Hungary	48.0	44.0	50.0	14.1	19.0 1/-3/	--
New Zealand 2/	357.0	368.0	284.0	-22.8	362.0	402
Norway	5.0	7.2	2.0	-72.2	17.0 3/	--
Poland	3.8	6.6	5.8	-12.1	8.7	9
Rumania	12.4	--	38.6 3/	--	--	--
South Africa	--	1.3	1.9	46.2	32.0	5
Sweden	33.6	22.9	22.6	-1.3	23.5	27
Switzerland	0.8	0.7	0.0	-100.0	1.5 3/	1 3/
United States	107.9	106.0	152.0 3/	21.6 3/	158.0	172 3/
Uruguay	161.0	222.0	131.0	-41.0	139.0 3/	90 3/
Yugoslavia	43.8	36.8	42.0	14.1	34.8 1/	--

Source: International Meat Council.

1/ January/June.
2/ Campaing ended 09.30. Product weight.
3/ EEC - 12 countries since 1986.
4/ IMC Secretariat estimates.

Table 13. Exports of Beef other than Fresh, Chilled and/or Frozen (canned cooked, etc.) (dressed weight equivalent in thousands of metric tons)

Country	1982	1983	1984	1985	% AX 1985/84	Prelim 1986
Argentina	163.0	153.0	125.0	141.0	12.8	150.0
Australia	24.0	31.0	42.0	40.0	-4.8	40.0
Brazil	237.2	303.6	325.4	--	--	--
Canada	2.4	2.3	1.9	2.0	5.3	2.0
EEC	38.0	38.0	44.0	50.0	13.6	50.0 1/
Finland	1.0	3.0	5.0	8.0	60.0	--
Hungary	6.4	4.1	6.3	--	--	--
Norway	1.1	0.1	0.1	--	--	--
Poland	3.1	4.9	5.7	5.5	-3.5	6.0
Rumania	4.9	--	--	--	--	--
Sweden	0.8	0.7	1.1	2.5	127.3	1.5
Switzerland	0.5	0.4	0.4	--	--	--
United States	13.0	19.0	--	--	--	--
Uruguay	8.0	10.0	13.0	--	--	--
Yugoslavia	4.5	4.6	2.2	2.2	0.0	--

Source: International Meat Council.

1/ EEC - 12 countries since 1986.

Table 14. Beef Prices: Average Price Paid to Producers and Average Retail Beef Price (in parentheses) (thousands of head)

Country	1982	1983	1984	1985	% AX 1985/84
Argentina (pesos/100 kg)	15.399	72/	43	1453/	5513/
	(48.575)	(19)2/	(120)	(450)3/	6193/
Australia (aus.cents./kg)	115	150	167	1725/	35/
	(633)	(738)	(765)	(788)3/	53/
Austria (aust.sch./kg)	2.434	2.553	--	(--)	--
	(14.100)	(14.810)	(--)	(--)	(--)
Brazil (cruz./100 kg)	1.227	1.532	1.667	1.1596/	--
	(2.940)	(3.360)	(3.228)	(3.190)6/	--
Canada (can.dol./100 kg)	119	121	127	1293/	-0.33/
	(852)	(872)	(975)	(1.012)3/	(6.4)3/
Colombia (col. pesos/100 kg)	--	--	--	--	--
	(22.695)	(28.945)	(--)	(--)	(--)
EEC (ECU/100 kg)	160	161	156	158	1.3
	(--)	(--)	(--)	(--)	(--)
Egypt (piasters/100 kg)	--	--	--	--	--
	(309)	(415)	(--)	(--)	(--)
Finland (Fin.markkas/100 kg)	1.984	2.130	2.317	2.4393/	6.23/
	3.307	(3.310)	(4.049)	(4.305)3/	(8.3)
Hungary (forint/100 kg)	43	44	46	463/	0.03/
	(62)	(62)	(78)	(78)3/	(.0)3/
Japan (yen/100 kg)	46.800	46.300	44.000	45.3003/	3.73/
	(342.000)	(351.000)	357.000	(348.350)3/	(-1.3)3/
New Zealand1/	125	136	148	--	--
(NZ.Dol/100 kg)	(416)	(458)	(500)	(--)	(--)
Norway (Nor Krones/100 kg)	2.273	2.744	2.972	3.1113/	9.53/
	(5.590)	(6.509)	(7.283)	(--)	(--)
Poland (Zlotys/100 kg)	8.973	10.030	11.570	--	--
	(25.000)	(25.000)	(30.000)	(34.000)3/	(13.3)3/
South Africa (Rand/100 kg)	211	215	227	2453/	14.03/
	(530)	(546)	(583)	(628)3/	(6.1)3/
Sweden (Swe.Kronas/100 kg)	1.908	1.974	2.027	1.9323/	-6.43/
	(5.920)	(6.737)	(8.267)	(8.524)4/	(3.8)4/
Switzerland	547	565	576	5603/	-2.43/
(Swyss.francs/100 kg)	(1.722)	(1.766)	(1.846)	(1.841)3/	(1.0)3/
Tunisia (Tun.din/100 kg)	155	190	210	240	14.3
	(180)	(220)	(250)	(320)	(28.0)
United States	140	138	144	1286/	-11.56/
(US dol./100 kg)	(534)	(525)	(528)	(517)6/	(-2.7)6/
Uruguay (Pesos/100 kg)	1.031	2.166	4.781	7.0883/	52.03/
	(1.901)	(2.778)	5.552	(7.632)3/	(73.1)3/
Yugoslavia (Yug.din/100 kg)	114.500	168.700	232.770	346.7474/	52.84/
	(152.000)	(243.000)	(322.000)	(483.000)	(54.3)4/

Source: International Meat Council.

1/ Campaign ended 09.30.
2/ Argentine New Peso since 1983.
3/ January-June.
4/ January-September.
5/ Forecast.
6/ January-August.

Table 15. Beef Prices: Average or Representative Exports Price (FOB); Average or Representative Import Prices (CIF) (in parentheses) (US Dollars/100 kgs)

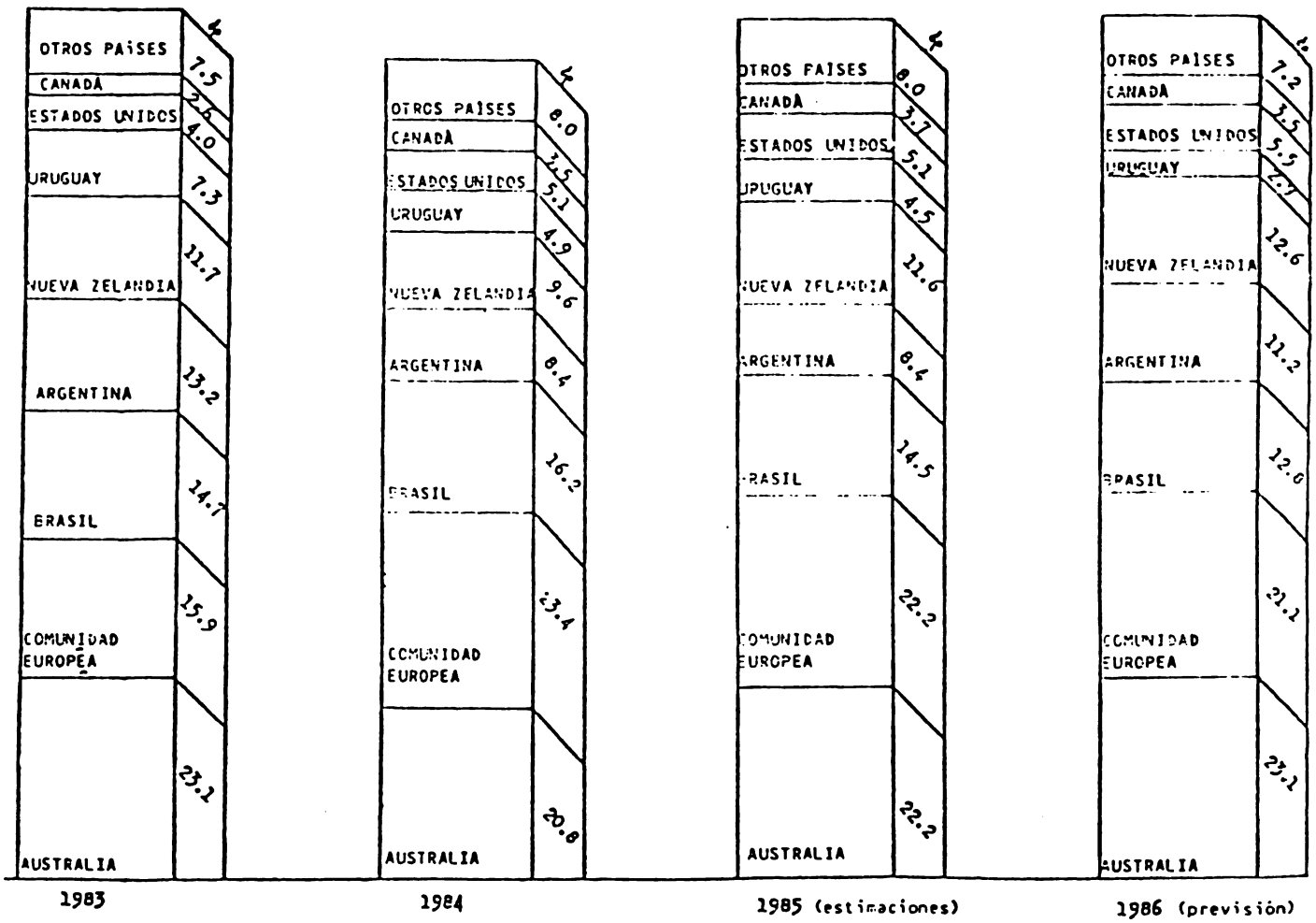
Country	1982	1983	1984	1985	% AX 1985/84
Argentina	139	131	127	74 1/	-41.8 1/
Australia					
(Aus.cents/kg)	138	188	222	174 1/	-19.2 1/
	251	(265)	(261)	(218) 1/	(-16.6) 1/
Austria					
(Sch/100 kg)	4.583	4.307	--	--	--
	(5.146)	(5.196)	(--)	(--)	(--)
Brazil	201	173	171 1/	--	--
	(105)	(80)	(53) 1/	(--)	(--)
Canada	208	188	188	183 3/	-5.4 3/
	(216)	(230)	(229)	(221) 3/	(-7.2) 3/
Colombia	2.111	2.242	--	--	--
EEC (ECU/tons)	1.400	1.400	1.417	1.303	-8.0
	(--)	(--)	(--)	(--)	(--)
Hungary	168	159	107	90 1/	-18.6 1/
	(121)	(105)	(74)	(--)	(--)
Japan	(322)	(325)	(315)	(319) 1/	(0.8) 1/
Norway	541	361	372	575 1/	--
	(292)	(264)	(287)	(287) 1/	(--)
Poland	187	155	134	103 1/	-29.0 1/
	(93)	(98)	(84)	(-)	(-)
Sweden	148	196	161	146 1/	-10.5 1/
	(489)	(394)	365	(366) 2/	(0.3) 2/
Switzerland	(620)	(616)	(580.0)	(897) 3/	(41.3) 3/
Tunisia	(187)	(157)	(165)	(172)	(4.2)
United States	--	--	--	--	--
	(--)	(--)	(--)	(--)	(--)
Uruguay	143	122	109	108	--

Source: International Meat Council.

1/ January-June.
2/ January-September.
3/ April-June.

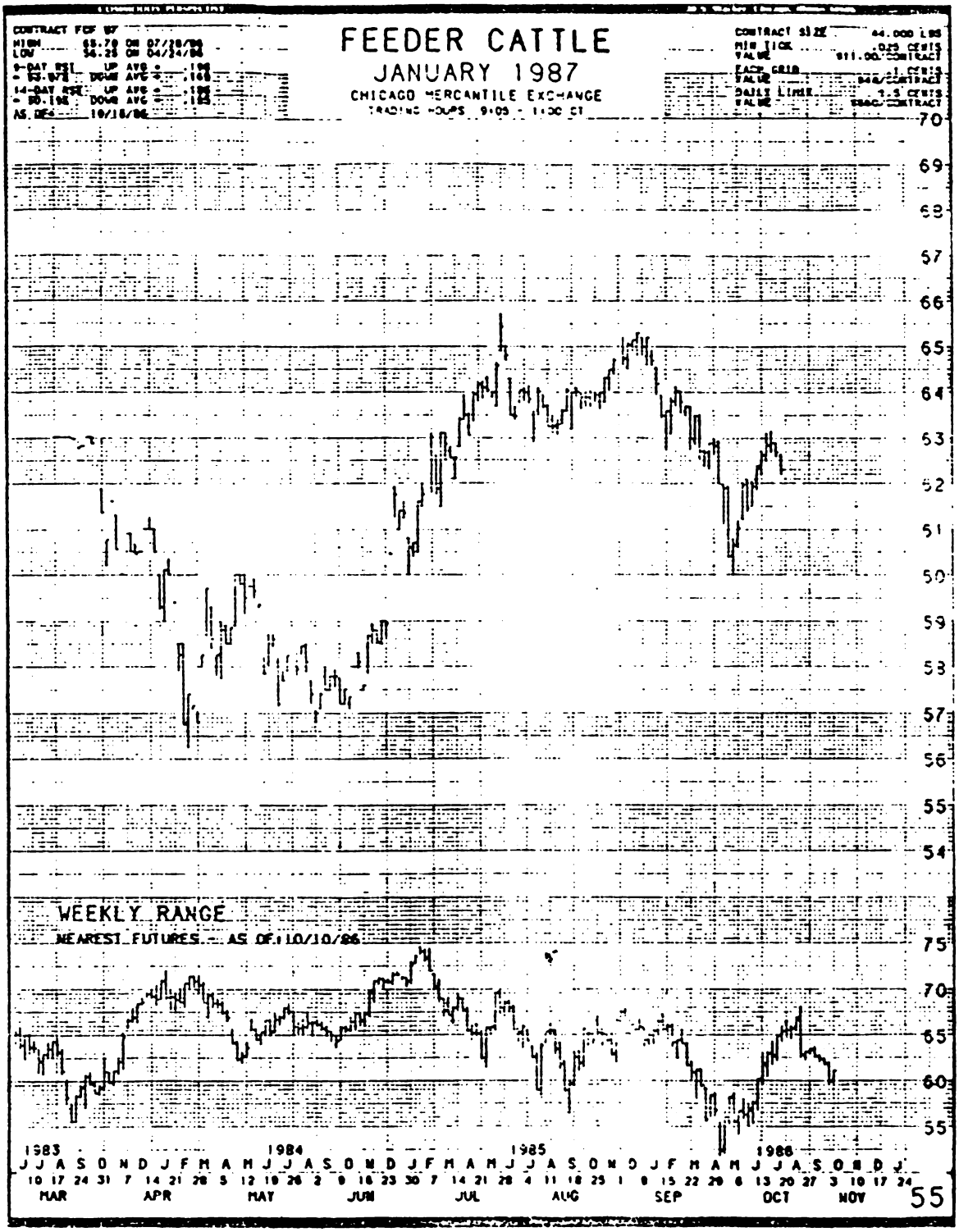
EXPORTACIONES DE CARNE DE BOVINO

Proporciones respectivas del mercado



NOTAS: Estos porcentajes son los correspondientes a la carne de bovino fresca, refrigerada, congelada, cocida, envasada o preparada de otra forma. Queda excluido el ganado vivo en su equivalente de peso en canal.

Quedan comprendidos todos los paises partes en el Acuerdo de la Carne de Bovino, que realizan del 90 al 95 por ciento de las exportaciones mundiales. Queda excluido el comercio interno de la Comunidad Europea.


FEEDER CATTLE
JANUARY 1987
CHICAGO MERCANTILE EXCHANGE
WEEKLY RANGE
NEAREST FUTURES -- AS OF 10/10/86
1983
1984
1985
1986
MAR
APR
MAY
JUN
JUL
AUG
SEP
OCT
NOV
70
69
68
67
66
65
64
63
62
61
60
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58
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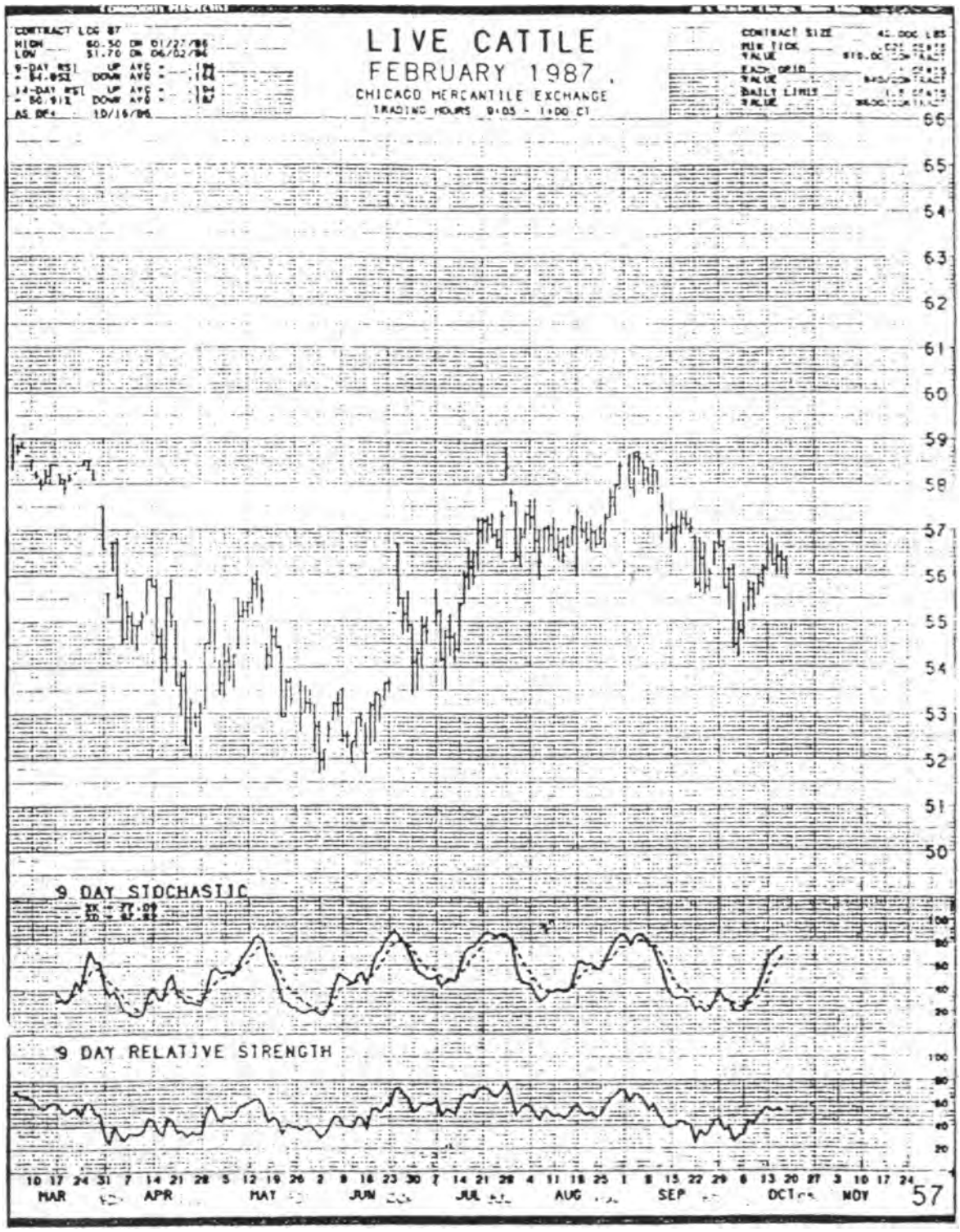
75
70
65
60
55


LIVE CATTLE
FEBRUARY 1987
CHICAGO MERCANTILE EXCHANGE
TRADING HOURS 9:05 - 1:00 CT
9 DAY STOCHASTIC
9 DAY RELATIVE STRENGTH
MAR
APR
MAY
JUN
JUL
AUG
SEP
OCT
NOV

DETECTION OF ANABOLIC RESIDUES: PRACTICAL CONSIDERATIONS

Guy C. Maghuin-Rogister

DETECTION OF ANABOLIC RESIDUES: PRACTICAL CONSIDERATIONS

Guy C. Maghuin-Rogister*

First of all, formula to remind you the kind of substances we are talking about. Generally, anabolics can be classified as estrogenic or non estrogenic hormones. Among the estrogens, three classes:

- natural estrogens: only 17 B oestradiol is used in anabolic treatment
- "phytoestrogens": zeranol is a derivative of a mycotoxin zearalenone
- completely synthetic estrogens: the too famous family of diethylstilbestrol (DES).

For the non estrogenic substances, there are two groups: androgens and progestagens and both groups contain natural and artificial hormones. In the androgen group, of course testosterone is the natural hormone which is used as an anabolic. As artificial androgens, a lot of testosterone analogs have been proposed: but certainly the more potent and the less toxic synthetic androgen is trenbolone acetate.

On the black market in Europe, nandrolone (nortestosterone) and methyltestosterone are often found.

Progestagens are represented by the natural hormone progesterone and by artificial progestagens such as medroxy-progesterone acetate that is largely used illegally by the farmers.

The subject of my today's presentation is to evaluate the potential of the European countries to determine the presence of anabolic residues in animal tissues resulting from non allowed treatments.

I plan to illustrate my purpose by describing the results of several hundred analyses performed on tissues collected from veal calves.

We studied tissues from animals treated with natural hormones containing implants such as Implix BM that contains estradiol and progesterone and Implix BF which contains estradiol and testosterone.

Other veal calves were treated with implants containing artificial hormones: Revalor that contains estradiol and trenbolone acetate and Forplix that contains zeranol and trenbolone acetate.

Residues were measured in several tissues: muscle, liver, kidney, and fat using specific radioimmunoassays for 17 B estradiol, 17 alpha estradiol, one the main metabolites of estradiol in the bovine species also estrone another metabolite.

* Brussels, Belgium.

Testosterone, progesterone

A radioimmunoassay specific for B-trenbolone and another that is specific for alpha-trenbolone. Finally we used for the measurement of zeranol a less specific assay, the anti-zeranol antibody prepared in our lab cross-reacts with the main metabolite zearalanone and the mycotoxin zearalenone.

The slide shows you the results obtained on a large number of control and treated animals in what concerns 17-B-estradiol. Mean levels are very low in the various tissues in the range of 10 to 100 ppb. For the clarity of the slide, standard deviations of the mean are omitted but generally the standard deviations calculated from our measurements were almost as large as the mean value itself. Taking this remark into account, it is not possible to distinguish a treated veal calf from a control animal on the basis of 17-B-estradiol levels in muscle, liver, kidney or fat, hormone levels being too variable among the treated animals and also in the control veal calves.

We measured also 17 alpha estradiol, this metabolite was found in high concentrations in liver. Again, the alpha estradiol contents in liver are not statistically different from that of untreated animals.

The next slide shows the other metabolite of estradiol: estrone. It is easier to distinguish control from estradiol-treated animals but it is only possible in liver and the variability among treated animals was also very high. Thus it could be difficult to distinguish them from untreated veal calves.

For progesterone, it is completely impossible to distinguish treated from control animals. The results for testosterone are paradoxical. As animals treated with testosterone containing implants showed lower levels in kidney and fat. The paradoxical observation can be explained by reference to the feedback regulation of testosterone production by gonads. Testosterone treated animals secreting less luteinizing hormone.

Differences in testosterone contents of kidney and fat were not observed in females. Thus, this is only in male veal calves that a low testosterone content in kidney and fat could be used to identify treated animals.

In what concerns natural hormones, we can thus conclude that veal calves treated with estradiol, progesterone or testosterone cannot be distinguished from untreated animals by hormone assay in muscle. Consequently examination of hormone levels in nude carcasses devoid of their liver and kidneys is useless for controlling their conformity to the EEC directive.

Such a control is possible in farms or in slaughterhouses on excretats: urine, feces and bile, or on typical organs (kidney, liver) for certain hormones or metabolites.

And now what about artificial xenobiotic anabolic hormones: animals treated with trenbolone containing implants show very low levels of residues in their muscles, kidneys, and fat. It is in the liver only that higher residue concentrations can be found.

Just a remark about the white blocks: of course tissues from untreated animals cannot contain trenbolone residues. These white blocks on the slide represent the mean of blanck values determined by B-trenbolone radioimmunoassay in tissues from control animals. We shall see later that the blanck values must be taken into account in the interpretation of the results.

The same is true for the main metabolite of trenbolone acetate in the bovine species: alpha-trenbolone that is mainly located in liver. Again, it is only by analyzing the liver that distinction between treated and untreated animals could be done.

The following slide shows the evolution with time of trenbolone residues in muscle of young bulls treated at day 0 with Torelor (an implant containing 300 mg of trenbolone acetate). The study was performed on 47 bulls residue levels in meat were low: under 0.1 ppb. The hormone content was highly variable among the animals, this is shown by the hached area which symbolises one standard deviation above the mean (n = 3 to 4). In this assay our limit of detection was 10 pg/g.

In conclusion, for trenbolone it is almost impossible to identify individual treated animals by analyzing their muscle due to the low levels of residues and the high variability of their concentrations among the animals.

For zeranol, the situation is almost the same as that of trenbolone, the residue contents of liver is even lower than for trenbolone, of the order of 1/2 ppb.

A statistical certainty of 95% for identification of treated animals cannot be reached due to high individual variations.

This experiment was performed on twins. You see that it is impossible to pick up the treated animal by muscle, kidney or fat contents in zeranol and very difficult by examination of liver. Control in urine is much more efficient.

As for natural hormones, identification of treated animals by assays of the xenobiotic hormone itself or a typical metabolite can only be performed by analyzing liver or better fluids such as urine, bile or feces.

Theoretically, for xenobiotics, the detection of the presence of residues would be sufficient to prove the use of anabolics. But in practice, this distinction will be very difficult for several reasons that will be discussed in the last part of my presentation.

Let us now consider the signification of the results obtained by radioimmunoassay of anabolic hormones and their interpretation to declare if the sample has been really taken from an animal treated with anabolics.

First, a distinction must be done between analytical limit of detection symbolized on the scheme by the letters N or I and tolerance limit T (or limit of decision to declare the sample positive). According to a working document of EEC:

N represents detection limit according to definition:

a. It is the smallest signal or its concentration equivalent from which it is possible with 95% statistical certainty to deduce the presence of the analyte. It must be calculated by adding to the mean of control samples 3 times the standard deviation. According to this definition, the risk of false positive is 5%.

I represents detection limit according to definition:

b. It is the smallest concentration which, if it is actually present, leads with at least 95% statistical certainty to its qualitative detection. It must be calculated by adding to the mean of control sample 6 times the standard deviation. Using this criterium, the risk of false negative will be 5%.

B represents the mean of all analyses of control tissues. Their number must be high enough to define an experimental mean closest as possible of the true value. In the EEC working document this number is 500 (per hormone or metabolite, per tissue and per animal species).

Q is the quantification limit that must be defined for allowed natural or xenobiotic hormones and their metabolites.

It is the smallest signal or its concentration equivalent above which a quantitative determination of the analyte is possible.

T would be the tolerance value or the limit of decision. Taking these requirements into account, I consider that the control of nude carcasses devoid of their liver and kidneys is presently impossible from hormone level determination even for xenobiotic anabolic agents. Furthermore, RIA results must be confirmed by a physico-chemical method, so far generally using GC-MS or chromatographic method like TLC.

Until now, these methods used as routine methods have limit of detection above that of RIA. Consequently, the limit of decision to declare a positive sample will be largely higher than residue levels actually observed in animals treated using good practice.

Finally, only a limited number of anabolic agents will be monitored. Indeed screening methods for controlling a large number of samples must be cheap and easy to perform. Presently, only immunoassays could be used for this purpose but their relative strict specificity will limit the number of detectable hormones.

Numerous substances, and among them some could form harmfull residues in meat, will escape to the control.

ECONOMIC BENEFITS

Dr. Steve Dean T.

ECONOMIC BENEFITS

Dr. Steve Dean T.

I am here today as a representative of Syntex Animal Health to discuss with you the economic benefits of using growth promoting hormone implants. These anabolic implants have been successfully used in beef production systems for over 30 years throughout the world. The efficacy of these implants and their safety has been proven and re-proven in hundreds of studies and these facts have been accepted by many regulatory bodies throughout the world. Indeed even the European Community do not dispute the safety and efficacy of the growth promoting implants. The benefit to the beef producer is readily appreciated but these implants also have direct benefits to the meat trade and the consumer. I hope in the next fifteen minutes to be able to clarify these benefits and to highlight some of the facts and reasoning behind them. As I have said the benefits to the beef producer are clear - in terms of return on investment, growth promoting implants surpass all other animal health or productivity agents used in animal production. They have repeatedly been shown to have a return on investment of greater than 10 to 1 or in excess of 100% and furthermore this is achieved in a time span that would make the banker envious indeed. The direct benefits to the producer or farmer are simply divided into 3 categories.

Firstly and probably most obviously, implants increase the rate of growth. This is usually expressed as an average daily gain and the improvement in this rate of growth allows animals to achieve a market weight at an earlier age or alternatively a higher weight if cattle are fed for a specific period of time.

Secondly, implants improve the conversion of feed into meat, in other words they increase feed efficiency. Thus, less feed is required to produce a given amount of weight gain. Furthermore, this enhancement of feed efficiency can be obtained in both grain fed and pasture reared cattle.

And thirdly, implants produce a higher quality of carcass which is directly related to the increase in lean tissue or protein deposition and a decrease in fat. Higher quality carcasses have a greater value since this leaner beef is the type of meat the consumer is demanding. A further related point is the uniformity of carcasses achieved with implants, and uniformity of product is a very desirable asset.

Let us look in a little more detail at these three benefits of using hormonal implants. As I have said, implants increase the growth rate and this rate of gain can be increased by between 10 and 20 percent when comparing implanted and non-implanted animals. Furthermore, this increase in growth rate can be sustained throughout the life of the animal. Of course, it is important that this increase rate of gain is achieved through the greater deposition of protein (or meat) as this eventually yields saleable product. By utilizing this increase in daily gain the farmer can either choose to rear cattle over a fixed period of time, and therefore achieve greater weights or he can choose to

market cattle to a given market weight and achieve this in a shorter time. By the first method the farmer achieves greater return on his cattle because they are heavier when marketed and by the second method the farmer produces a market weight of cattle more efficiently.

In terms of improvements in feed efficiency the utilization of plant protein and its conversion to animal protein is enhanced by up to 12%. Thus yielding significant savings in feed costs and this applies to either grain fed or pasture grazing cattle. Furthermore we know that this improvement in feed utilization is complementary to the use of other growth promoters administered in feed. The cost effective use of animal food is essential to the production of quality beef at prices attractice to the world's consumers, remember feed is the most significant cost on farm.

In terms of carcass composition we have said that implanted cattle convert consumed feedstuffs into more lean tissue and less fat. This slide clearly shows this effect in both steers and heifers. Note particularly the decrease in the percentage of fat in both heifers and steers when implanted and compared to unimplanted controls. Furthermore, and possibly more importantly from the meat trade, consumers viewpoint the content of lean tissue within the carcass is increased, thus improving the quality of the carcass and the content of saleable product. In short, implanted cattle weight well and pay better.

The improvement in carcass composition is reflected in this slide which clearly shows that in the unimplanted animal protein deposition tends to level out as weight gain increased and conversely fat deposition increases rapidly. The use of implants improves the rate of deposition of protein and reduces the rate of deposition of fat. Clearly then this is a major benefit to the meat trade and the consumer because it improves the quantity of saleable meat in the implanted animal. For the consumer conscious of the quantity of fat consumed, the use of implanted beef could have significant health implications. The benefit of the anabolic steroids in producing leaner beef is a benefit that is only just being understood by the meat trade in the United Kingdom and as yet has not been fully appreciated by the consumers. The effect of using implants is to improve protein retention and to increase protein deposition, as muscle, by almost 6% in terms of carcasses. As I said, the significance of this to the meat trade in the United Kingdom is only just becoming realized expand on consumer slides and the legislation which prevents access to this improvement will have serious financial consequences for the European meat trade in the future. Misunderstanding of the basic concept underlying the application of exogenous hormones in beef production is one of the problems we have experienced in Europe. It is therefore pertinent to take a small amount of time to explain this concept. The use of exogenous hormones in beef production is based on a theory of supplementation or replacement of the naturally occurring hormones produced hormone production by the animals body acts in various ways to influence nutrient utilization and tissue development. The end result is growth. The use of exogenous hormones supplied in continuous and minute amounts mimic the actions of the natural secretions and when supplied in optimum amounts, as in the implant system, these exogenous hormones can enhance growth beyond that experienced in untreated animals and this can be achieved without detrimental side-effects. This slide therefore shows the potential use of exogenous hormones in the various classes of cattle. The use of products in

the bull calf and the female beef animal are designed to replace the hormone that this type of animal is not producing. In the case of the castrated bull, or steer, we use a combination of products in an attempt to replace those natural hormones which have been removed by the act of castration.

A high proportion of the world's beef production comes from castrated animals and by and large this means steer production. Castration as a technique is essential to eliminate the undesirable behavioural characteristics exhibited by entire males and thereby allowing easier management in confined intensive beef systems and their more extensive grazing counterparts. However steers do not grow as well as bulls. Of course, intact male animals are particularly dangerous to human beings and a higher incidence of injuries are reported in those countries where intensive bull beef systems predominate.

Clearly the countries which depend heavily upon steer beef production will also rely heavily upon growth promoting implants to achieve an efficient beef industry. This slide illustrates the methods of beef production within Europe. You will note that the countries which rely on more traditional grazing methods of rearing beef are also those countries which are more concerned regarding the future use of implants. Interestingly the veal industry in all countries throughout Europe depend heavily upon implantation to maintain an economic and efficient business.

Whilst discussing Europe, much has been said about the mountain of beef, 700.000 tonnes, 2 1/2 kg/head, and some would believe that this is a result of over production as a direct result of the application of growth promoting agents. In effect the surplus exists due to artificial economic incentives to farmers to produce beef in excess of demand. Those who would propose that the elimination of growth promoters would reduce this surplus are confusing production with productivity. Productivity implies the most efficient use of resources, implants, by reducing the days to market and conserving the foodstuffs consumed by cattle enhance productivity. European bureaucrats also chose to ignore the effect of the milk quotas levied throughout Europe and the subsequent effect of culling dairy cows on the "mountain of beef". In terms of production there are many countries in the world where there is a real shortage of animal protein. In these countries real increases in production as a result of increased productivity are essential and I would again emphazise that nothing in modern agriculture can surpass the gains derived from growth promoting implants. Where agricultural commodities are a vital element of export economics, implanted beef can supply more saleable beef at a more competitive price.

In summary, anabolic implants benefit the entire meat industry and the consuming public and serve to optimize the traditional economic inputs of land, labour and capital. They benefit producers by producing lower costs and higher incomes, the meat processors benefit through higher quality and more saleable meat and consumers benefit through obtaining more nutritions, I say, more healthy beef without increased prices. In short, implants increase the income of farmers without increasing costs to the consumer. With the proven track record of anabolic hormones in the fields of safety, efficacy and their positive effects on economy, the world simply cannot afford to ignore technology that yields such tremendous benefits.

USE OF ANABOLICS: SAFETY ISSUES

Dr. J. C. Bouffault

USE OF ANABOLICS: SAFETY ISSUES

Dr. J. C. Bouffault*

For the last 25 years, anabolics have been the subject of a very important controversy, centered on the safety aspects of these drugs, in which emotion and reason have often been on opposite sides. It is tempting to refer to it as a "soap opera".

During the first ten years, it was the triumph of the irrational.

Italians, because of their inclination to the "macho" image, became worried about the possibility of losing their virility, and rapidly passed a law banning all uses of hormones in animals, even though Italy is a major meat-importing country.

A chain reaction thus started and similar laws were passed by the main exporting countries of South America, Australia, New Zealand and so on.

At about the same time, France, often considered the home of fine food, discovered that large-scale veal production could be obtained by feeding calves with skim milk from the EEC "milk mountain". Despite the fact that anabolics such as those used in calves are only responsible for improving the nitrogen balance and protein content, some are hormones and hormones in general are blamed for increasing the water content of meat.

In a further step, news from the United States regarding the DES scandal -the appearance of vaginal cancer in daughters of mothers who had been treated with huge amounts of DES in order to prevent abortion- reached Europe.

After this short summary, I must become serious and more scientific.

All this is paradoxical, because anabolics are the safest products we can imagine, even less toxic than vitamins. For example, vitamin A and vitamin D can produce irreversible lesions in the liver (vitamin A) and in the skeleton (vitamin D), while the effects of hormones are always reversible.

SAFETY ISSUES

Anabolics are defined as substances which enhance protein synthesis and therefore meat production. On the animal production level, their effectiveness is not questioned. Difficulties involving problems of safety only concern the possible carcinogenicity of residues in the meat of treated animals.

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The object of this paper is to discuss this important aspect. We shall deal with the following specific questions:

1. nature and metabolism of anabolics,
2. carcinogenicity and risks of residues of steroid hormones,
3. carcinogenicity and risks of residues of xenobiotics,
4. concluding remarks.

I. NATURE AND METABOLISM OF ANABOLICS

Anabolics may be natural or xenobiotics.

1.1 Natural anabolics: steroid hormones (Tables 1 and 1')

There are three kinds of natural, endogenously produced hormones: estrogens, progestogens and androgens. Examples of these are 17-B estradiol, progesterone and testosterone, respectively. All of these are steroidal in structure. These substances are naturally synthesized by humans and animals in their gonads, cortico-adrenal tissue, and in the placenta of gestating females. In the course of meat production, the endogenous production of these hormones may be supplemented by the exogenous administration of one or more of the same hormones.

1.2 Xenobiotics

Historically, several different synthetic anabolics have been used in meat production. The main ones are trenbolone acetate (TBA), zeranol and various stilbenes, including diethylstilbestrol (DES).

- TBA (Table 2) is a synthetic steroid which, in structure, is very similar to testosterone. Like the latter, it has androgenic properties and is rapidly and efficiently converted, particularly in cattle, to more or less hormonally inactive metabolites.

- Zeranol (Table 3) is derived from zearalenone, which is produced naturally by a mold. It has weak estrogenic activity and is non-steroidal in structure.

- The stilbenes, such as DES, are non-steroid synthetic molecules endowed with powerful estrogenic properties. They are very poorly metabolized in the liver, and are found at low but nonetheless active doses in the edible products of treated animals (Table 4).

II. CARCINOGENICITY RISKS OF RESIDUES OF STEROID HORMONES

2.1 General considerations (Table 5)

There is abundant evidence that change in hormonal status may be associated with enhanced or reduced risks of development for various kinds of neoplasms.

Most cancerologists consider that, where cancer risk is enhanced as a result of exposure to a hormone in hormonally effective doses, the mode of action is epigenetic rather than genotoxic.

Whereas it is prudent to assume that there is not threshold for genotoxic carcinogenic mechanisms, it is widely believed that thresholds probably do exist in the case of epigenetic carcinogenic mechanisms, especially with hormones.

In the case of hormonally-mediated carcinogenesis, therefore, it is reasonable to assume that there is no risk from exposure to levels of a hormone which are below the threshold for hormonal activity by the administered substance or its metabolites.

2.2 Natural anabolics

2.2.1 Natural food sources

Estradiol, progesterone and testosterone are necessary to the sexual physiology and anabolism of humans and animals. They are normally biosynthesized and are present in tissue. Thus, they are normal constituents of any food product of animal origin. The levels found in untreated animals show wide variation, and depend on the species, sex and physiological status of the animal. For instance, an adult bovine male synthesizes 40-50 mg of testosterone per day, while a cow at the end of gestation synthesizes several hundred milligrams of estrogen per day. Thus, the highest levels of androgen are found in bull meat and offals (0.6 - 3.0 ppb) and those of estrogen in the meat of gestating females (0.5 - 2.0 ppb). These hormones are also found in milk at concentrations which depend on the physiological condition of the animal (for example: 0.3 - 3.0 ppb in cow's milk during the first few days of lactation).

2.2.2 Metabolism

In humans and animals, natural anabolics are rapidly metabolized, mainly in the liver. This metabolism leads to derivatives with low biological activity which are excreted in the bile and urine in the form of conjugates (glucuronides and sulfoconjugates). Such biotransformation explains why they are almost totally ineffective by the oral route.

2.2.3 Residues of endogenous hormones

Since endogenous production of natural anabolics exists in all animals (Table 6), it should be emphasized that hormones which are produced endogenously and those which are administered are chemically identical. Residues of estrogen, progesterone and testosterone arising endogenously in animals are qualitatively indistinguishable from those resulting from the use of these compounds as anabolics (Table 6). Quantitatively, in practice, there is no difference between treated and untreated animals if the conditions for use are adhered to. Indeed, residues observed in calves treated with estradiol implants (20 mg) 50 days before slaughter (estrogen = 0.1 ppb) are markedly less than those normally found in adult males or females and in gestating females.

In summary, and taking into account the preceding data, it would appear that residues of natural hormones, which are nearly inactive when given orally, are toxicologically negligible. In fact, they do not change the general levels of hormones found in untreated animals. However, they cannot in any case increase hormone concentrations at the level of the receptor sites of target cells. Moreover, their low bioavailability and the existence of hepatic and placental barriers are a guarantee of their harmlessness, even to the fetus. Consequently, from a scientific point of view, there are no toxicological contraindications to the use of natural hormones (estradiol, progesterone and testosterone) under normal animal production conditions, i.e., implantation of properly dosed pellets in those parts of the animal which are eliminated at slaughter (the ear, for example).

III. CARCINOGENICITY AND RISKS OF RESIDUES OF XENOBIOTICS (Table 7)

3.1 General considerations

From the point of view of carcinogenicity, theoretically, these compounds, when tested in long-term toxicity studies, exhibited a tumorogenic (carcinogenic) potential (IARC-Monographes, 1979). In listing these compounds as carcinogens, no distinction is made as to whether they are basically carcinogenic in activity, or whether, alternatively, they are promoters or stimulators of tissue growth only in a hormonal way. To answer this question, it is necessary to demonstrate that xenobiotics are not genotoxic. This can be established through the application of a battery of *in vitro* mutagenicity tests. If these tests prove negative for genotoxicity, animal testing should follow. In this case, experiments must be managed so as to determine, on different animal species (rodents, pigs, monkeys) a hormonal no-observed-effect level. Actually, it is better to use an experimental animal that is quite near the human on

the phylogenetic scale for these determinations. Thus, it has been shown that the female rhesus monkey is a good model. The following remarks from Farber et al illustrate this:

"The pattern of plasma progesterone, the time course of circulating estrogens and serum gonadotropins throughout the menstrual cycle of the rhesus monkey closely resemble, both qualitatively and quantitatively, the pattern in the human female. Moreover, the negative feedback control of LH secretion by estrogens is a finely tuned system. Moreover, there are certain antigenic similarities between the chorionic and pituitary gonadotropins of the rhesus monkey, the baboon and women. In the rhesus monkeys, baboons and women, independence of corpus luteum function from a uterine factor has been convincingly demonstrated. The corpus luteum function during pregnancy is similar and, while in rodents and rabbits maintenance of pregnancy requires functioning ovaries, in women and nonhuman primates the placenta takes over the hormonal control of pregnancy very early. From a descriptive standpoint, the menstrual cycle of the rhesus monkey and the human female are remarkably similar. The rhesus monkey seems to be a most appropriate animal model for the evaluation of the safety of potential tissue residues of exogenous anabolic agents."

When we have the information concerning the absence of genotoxicity and the no-hormonal-effect level in the experimental animal, we can calculate an ADI by applying a safety factor (100) and, from this, ADI tolerances. If the tolerances are higher than the levels of residues observed in meat and treated animals, we can assume that the consumption of these products by consumers is acceptable.

3.2 Trenbolone acetate

This anabolic product can be used as an example of how the ADI tolerance calculation can be applied. Information concerning TBA is given in Tables 8 and 9.

In Table 9, the no-hormonal-effect for pigs was chosen because no-hormonal-effect in this species was lower than that observed in rhesus monkeys. Even in this case, it was clear that the levels of residues were always below the toxicological tolerance levels.

Therefore the depletion curves show that a "no withdrawal time" is justified.

IV. CONCLUDING REMARKS

4.1 Levels of residues

- Steroid hormones: The levels of residues in meat of treated animals are really not different from the levels of residues in non-treated animals.

Finally, the overall problem of the occurrence of tissue concentrations of endogenous sex hormones must be seen in relation to the production of these hormones in the human himself. If the quantities of hormones ingested from food products are compared to those produced daily in humans, it becomes apparent that the latter can in no way disturb the endocrine cycle. The example of estrogens, which are sex hormones normally biosynthesized in low quantities, clearly illustrates this aspect of the problem (Table 10).

- Xenobiotics: The situation is the same. Levels of residues are always very low and below the toxicological tolerances. Finally, for trenbolone, for example, if we compare the quantities which are likely to be found in ingested food to those of testosterone, which is biosynthesized on a daily basis by humans, it can be observed that these levels cannot in any way disturb the endocrine cycle (Table 11).

4.2 Risks of total ban (Table 12)

- In fact, it appears that the only site of the body with substantial residue concentration is the site of implantation or injection. Quoting Hoffmann we can say, "While the legalized use of anabolic sex hormones requires their application at a site which is automatically discarded at slaughter (s.c. at the ear), illegal treatments are usually given by deep i.m. injections, often using excessive dosages. The fact that DES residues could be found in hormonally active concentrations in baby food in various countries most likely can only be attributed to the fact that one (or several) injection sites containing massive amounts of the drug contaminated a whole batch of production (Karg and Vogt, 1981). It is interesting to note that those observations were limited to countries having imposed a total ban on the use of anabolic sex hormones for fattening purposes. This situation (Table 13) is self-explanatory and demonstrates that a considerably greater risk to public health is associated with the illegal use -as a result of a total ban- than the controlled legalized use of certain compounds.

In conclusion, it is evident that, with the exception of DES and other stilbenes, the danger of food products containing residues of anabolics has been overestimated, especially from the point of view of carcinogenicity.

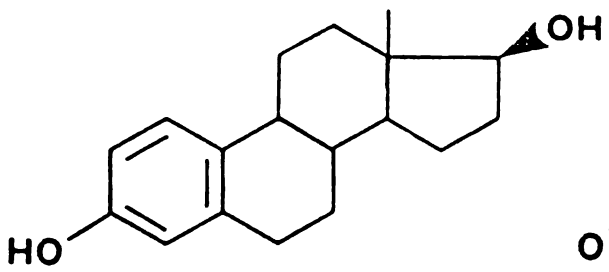
It is clear that the protection of consumers in regard to anabolics must be based mainly on the correct definition of the criteria involved, more specifically, the dosage and the site of implantation. A total ban on these products will lead to a black market, with serious implications for public health.

It is very important to consider the huge estrogen or androgen levels to be found in daily food (cabbage, peas, wheat germ, soya been or olive oil, milk, eggs, and others) versus the VERY MINUTE HORMONAL IMPACT OF MEAT (Table 14).

Table 1

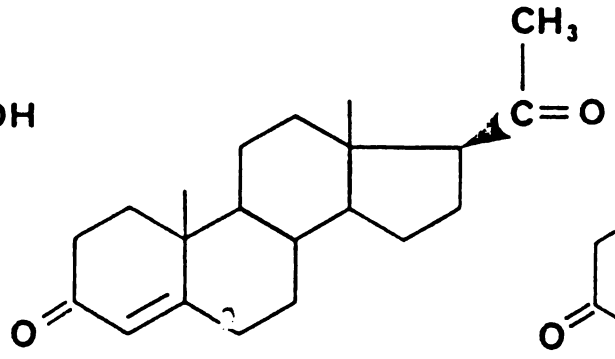
ENDOGENOUS ANABOLIC AGENTS

Steroid hormones



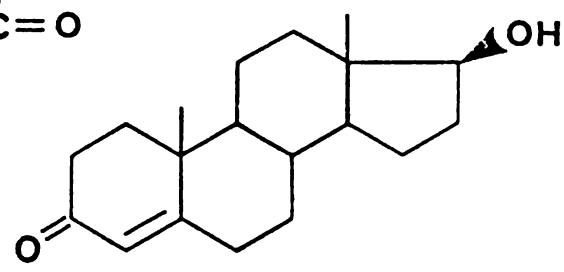
17-β OESTRADIOL

oestrogen



PROGESTERONE

gestagen



TESTOSTERONE

androgen

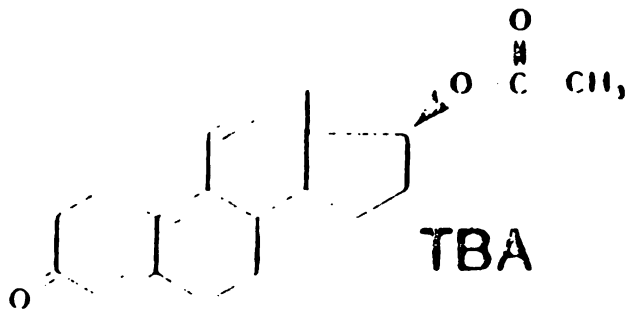
Table 1'

GENERAL METABOLISM OF ENDOGENOUS ANABOLIC AGENTS

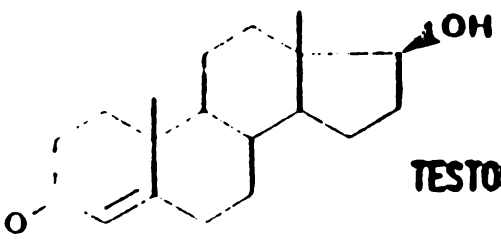
Biosynthesis	IN GONADS,PLACENTA AND CORTICO ADRENAL GLAND CHOLESTEROL → 5-PREGNENOLONE → HORMONE
Blood transport	Aspecific Specific PROTEIN + HORMONE ⇢ PROTEIN/HORMONE ↓ ACTIVITY
Biotransformations	IN THE LIVER PHASE I . OXYDATIONS AND/OR REDUCTIONS PHASE II . CONJUGATIONS
Elimination	CONJUGATED → BILE AND URINE FREE → FECES
Half-life	SHORT

Table 2

TRENBOLONE ACETATE



TBA



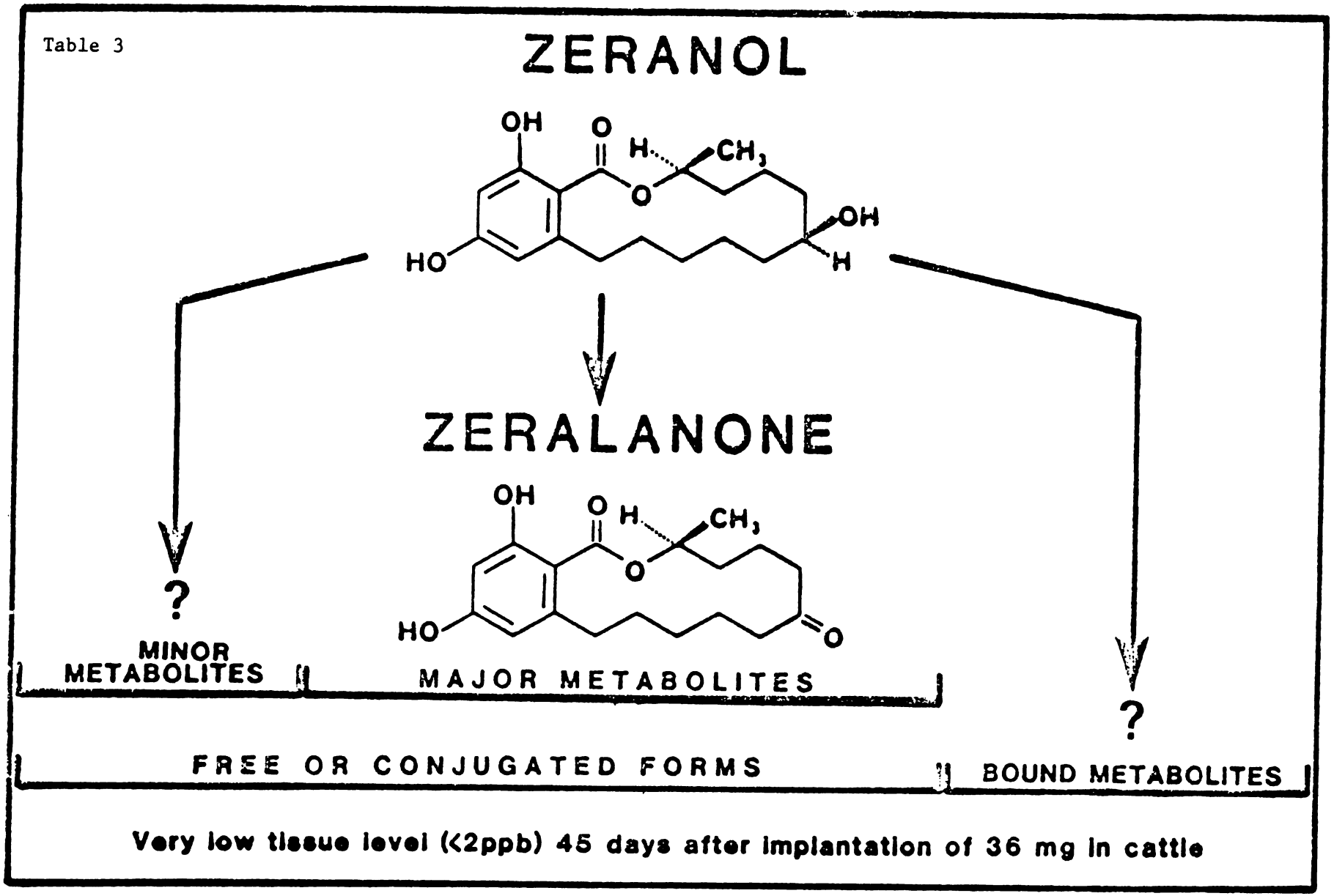
TESTOSTERONE

EFFICIENTLY METABOLIZED AFTER ORAL ADMINISTRATION

TBA ⟶ 17β TB OH ⟶ 17α TB OH

60 DAYS AFTER IMPLANTATION OF STANDARD PELLET IN BASE OF EAR : RESIDUES IN MEAT < 1 PPB

Table 3



Very low tissue level (<2ppb) 45 days after implantation of 36 mg in cattle

Table 4

DES

(Aschbacher, 1976)

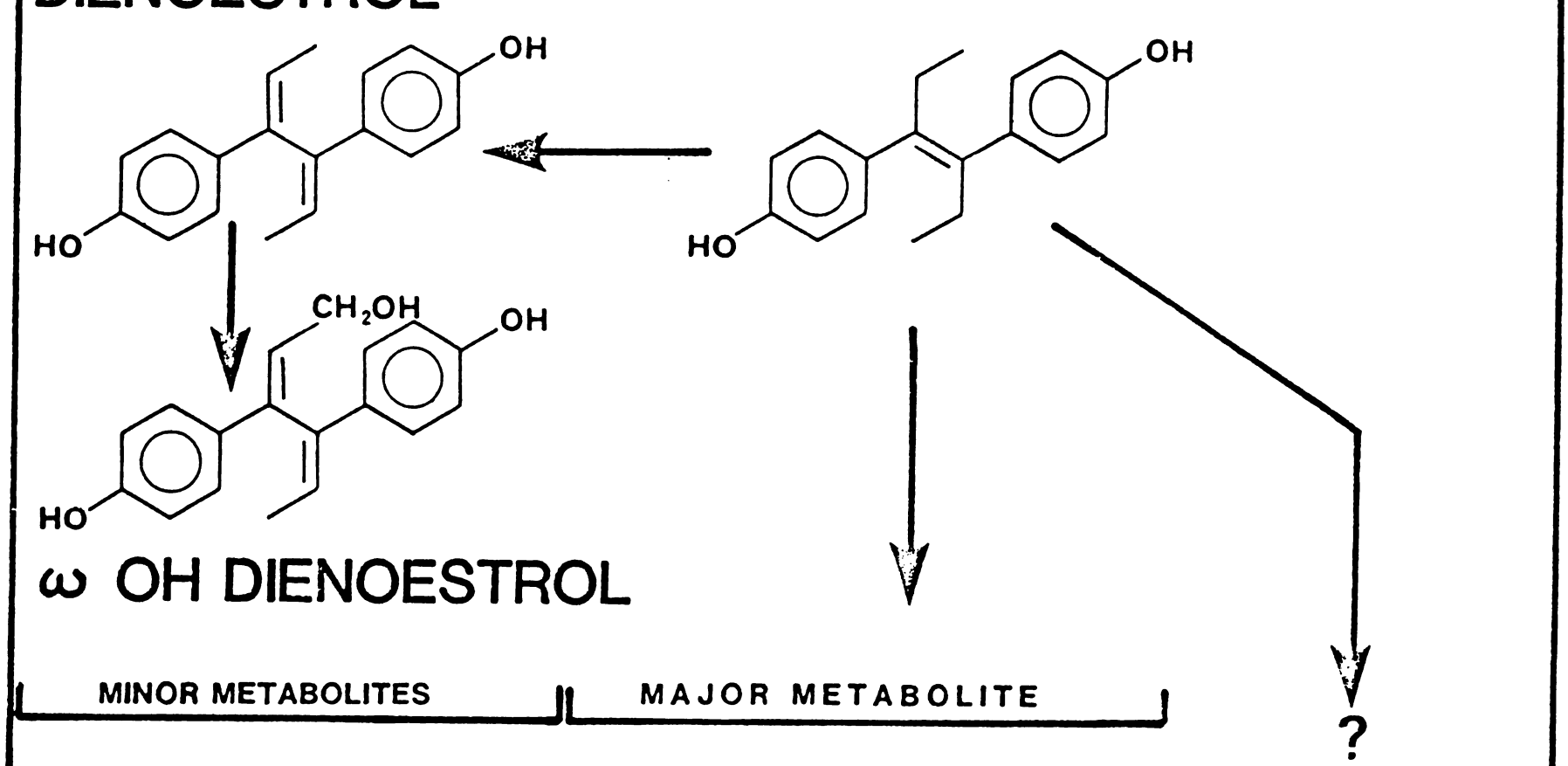


Table 5

CARCINOGENIC MECHANISM

NOT INITIATING AGENTS : not carcinogenic per se

- Not mutagenic
- Unable to bind to D.N.A.

PROMOTING AGENTS :

- Increase the frequency of cell replication in target tissues (X of errors in D.N.A.)
- Modify the host and/or the target tissues

THEIR ACTION APPEARS TO BE REVERSIBLE AND THRESHOLDABLE

Table 6

RESIDUES OF STEROID HORMONES

Qualitatively : endogenous hormones

Quantitatively : in the range of "normal values"

Residues have no toxicological significance

NO CHANGE IN THE NORMAL RISKS

Table 7

XENOBIOTICS RESIDUES

1 - Eventual carcinogenicity

- no carcinogens per se = no genotoxic { mutagenic effects / affinity for D. N. A.
- carcinogenicity related to the hormonal effect = threshold

2 - Toxicological significance

- no hormonal effect level in animal
- A. D. I. & toxicological tolerances

Table 8

TRENBOLONE ACETATE

CARCINOGENICITY

- NO MUTAGENIC : IN VITRO AND IN VIVO
- VERY LOW BINDING TO D.N.A. # TESTOSTERONE
- LONG TERM TOXICITY : MICE : HIGH DOSIS ⟶ LIVER TUMORS
  RAT : NO EFFECT

PROMOTOR BY HORMONAL EFFECT : W.H.O. AND F.A.O. (J.E.C.F.A. APRIL 1983)
F.D.A. (JULY 1983)

Table 9

SAFETY EVALUATION T.B.A.

-CARCINOGENICITY : PROMOTOR AGENT BY HORM. ACT.

-N.H.E.L. (PIG) : βTB-OH = 10/UG/KG

αTB-OH = 360/UG/KG

-A.D.I. : βTB-OH = $\frac{10}{100}$ = 0.10/UG/KG

αTB-OH = $\frac{360}{100}$ = 3.60/UG/KG

-TOLERANCE LEVELS: βTB-OH = $\frac{0.10 \times 70 \text{ KG}}{0.5 \text{ KG}}$ = 14 PPB

αTB-OH = $\frac{3.6 \times 70 \text{ KG}}{0.5 \text{ KG}}$ = 500 PPB

-RESIDUES LEVELS : βTB-OH IN MUSCLE : 0.1 PPB

αTB-OH IN LIVER & KIDNEY : 3 PPB.

AT 15, 30 AND 45 D

WITHDRAWL PERIOD IS NOT NECESSARY.

ENDOGENOUS OESTROGENS

DAILY PRODUCTIONS

INGESTION LEVELS

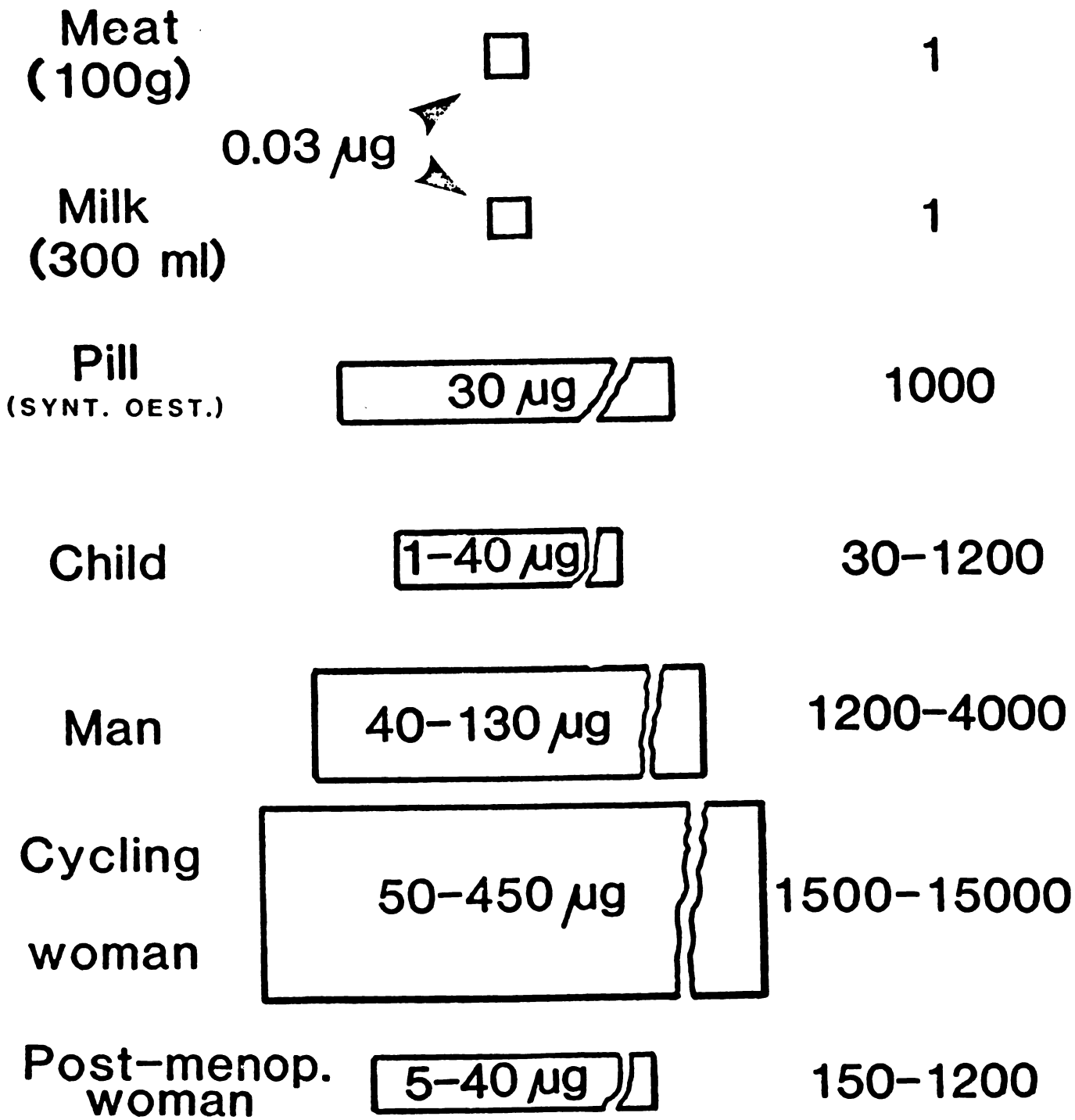
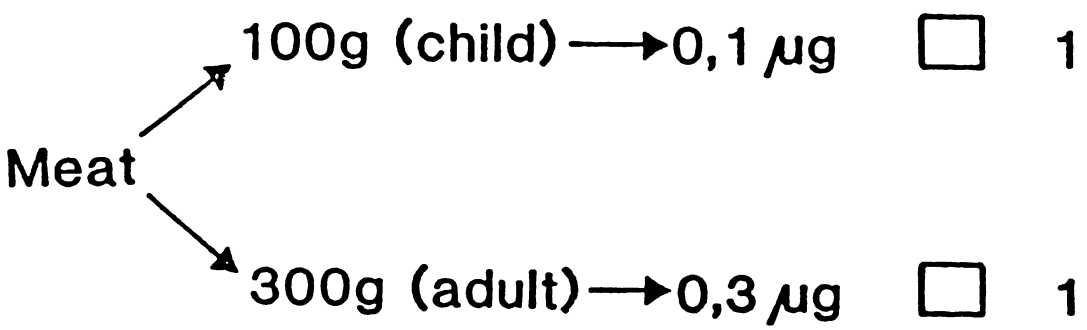


Table 11

TESTOSTERONE - TRENBOLONE

Daily productions/Ingestion levels

Residual levels ≤ 1ppb equivalent of βTB



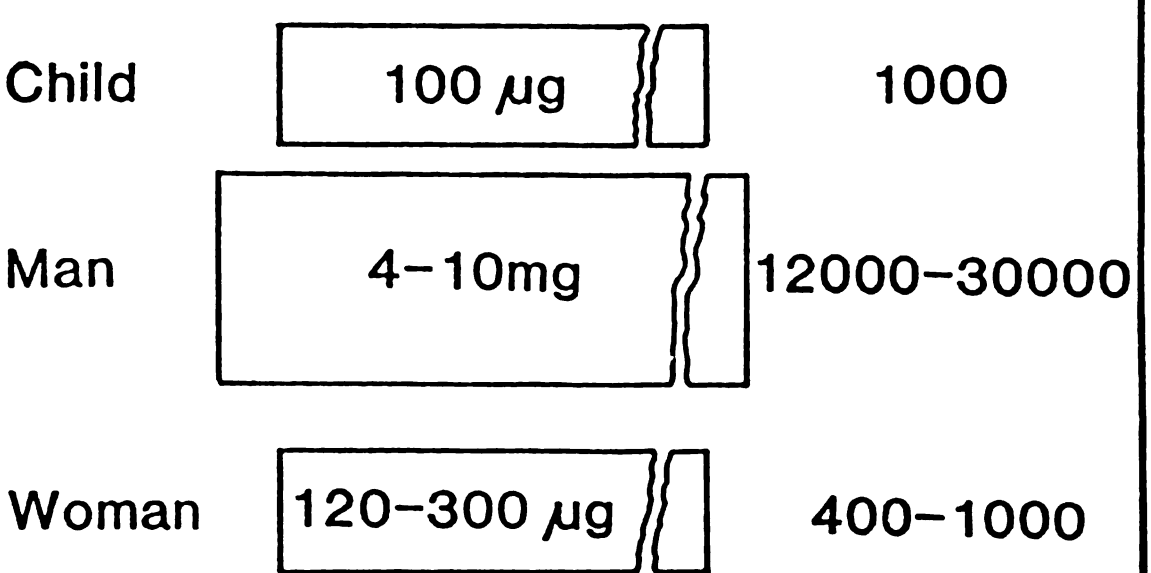


Table 12

Residues after i.m. 150 mg D.E.S.-prop. crist. susp. (ppb) (KARG)		
Tissues	W. Period 23 d	84 d
Liver	2.3	0.24
Kidney	1.5	0.17
Muscle	0.12-0.21	0.05
Muscle (i. s.)	$0.2\text{-}10^5$	0.1-1500

Table 13

TOTAL BAN
– Controls = very difficult
– Black market = true danger - Many active substances - Absence of purity - No respect of good veterinary practices - No elimination at injection site

(A) FEMALE HORMONE (OESTROGENS):

Oestrogen intakes from a variety of food sources are given below:

Food		Weight of Typical Portion (grams)	Oestrogen Intake (ng)	Reference
Unimplanted Steer Meat	(a)	500	6.1	(6)
Oestradiol Implanted Steer Meat	(a)	500	11.4	(6)
Zeranol Implanted Steer Meat	(b)	500	7*	(10)
Cow Meat	(ac)	500	75(7.2-540)*	(2)
Hen's Egg		50-60	1,750*	(3)
Cabbage		100	2,400*	(1)
Peas		100	400*	(1)
Wheat Germ		10	200*	(4)
Soya Bean Oil		10ml	20,000*	(4)
Milk		500ml	75*	(5)

(B) MALE HORMONE (ANDROGENS):

Food		Weight of Typical Portion (grams)	Androgen Intake (ng)	Reference
Unimplanted Bull Meat	(ab)	500	1,560	(7)
Steer or Female Implanted with Trenbolone	(a)	500	135-150	(8 & 9)
Heifer Implanted with Testosterone	(a)	500	35	(9)

(a) Assuming 25% fat, 75% muscle
(b) Muscle tissue only
(c) Oestrone only
(d) Testosterone only
ng Nanogram = 1 billionth of a gram
* Oestradiol equivalents

SCIENCE VS POLITICS IN VET DRUG REGULATION

Dr. Martin Terry, DVM, PhD

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We live in a time in which we in the animal production industry are obliged to consume the bitter fruit of our efforts over the past generation. As producers of wholesome food, we have done our job too well, and the resulting surpluses of beef in major world markets add fuel to the fires of economic protectionism, promoting the erection of international trade barriers -both tariff and non-tariff. The current tendency toward the imposition of non-tariff trade barriers -with the trappings of technical veterinary regulations but with no valid technical basis- hinging on the prohibition of the use of veterinary drugs in food animal production, threatens to destroy the technological base that supports the beef industry. In addition to the purely economic problem of overproduction, we are currently witnessing a sociological blooming of neo-romanticist nostalgia for the "natural", particularly in relation to food production. Such popular notions, nourished by the economic affluence made possible by modern agricultural technology, are finding expression with increasing frequency in legislation that rejects or cripples that technology. Nowhere is this irony more apparent than in the European Economic Community (EEC), and nowhere is it seen so clearly as in the EEC's handling of the issue of the use of anabolic agents in animal production.

In the years 1977-1980 two events occurred in Italy which -albeit unjustifiably- cast a stigma on the use of anabolic agents in beef production: First, in 1977-1979 an "epidemic" of abnormal breast development in children of both sexes was reported (1). Second, in 1980 a number of samples of baby food were found to contain residues of diethylstilbestrol (2). It should be emphasized that no causal relationship between these two events was ever established; indeed, most of the children involved in the "epidemic" were too old to be consuming baby food, and the DES residues were discovered a year after the "epidemic" had ended. That, however, did not inhibit the popular press from assuming and insinuating the existence of a causal relationship. Armed with sensational journalistic documentation of what was perceived to be a hazard to the public health, European consumer activist groups immediately pounced on the issue as political manna from heaven, and called for a total ban on the use of anabolic agents in animal production in the EEC. The Commission of the EC, quick to respond to pressure from the consumerist lobby, issued a proposal (3) for a Directive that would have banned all anabolic agents without considering any objective evidence.

In that instance, reason prevailed in the Council of Ministers, and in July 1981 a compromise was agreed in the form of an interim Directive (4), whereby the stilbenes (DES and its congeners) were banned, along with the thyrostatics (such as thiouracil). However, estradiol, progesterone, testosterone, trenbolone and zeranol were permitted to remain on the market as anabolic implants in those EEC Member States in which they were already authorized. In order to prepare a "report on... scientific developments" as required by the Directive, the EC Commission appointed an ad hoc committee of scientific experts to evaluate the data on the toxicology and residues of each

of these compounds to determine whether or not they could be used in animal production without hazard to the public health. This committee, which called itself the Scientific Group on Anabolic Agents in Animal Production, was convened in 1981 under the chairmanship of Professor G. E. Lamming of the University of Nottingham. The consumer activist groups were not at all pleased with this turn of events, as anything short of a complete ban was a priori unacceptable to them. Uninterested in scientific evidence or rational debate, the consumerists claimed that the Council of Ministers had reneged on its commitment to a total ban. They continued their lobbying in Brussels in a lower key, waiting for another opportunity.

By September of 1982, the "Lamming Committee" (as the Scientific Group came to be known) had completed its first report, which was widely leaked but not actually made public until mid-1984. The gist of the report was that, when used correctly, the endogenously occurring hormones estradiol, progesterone and testosterone represented no hazard to the public health. For the two non-endogenously occurring or "xenobiotic" compounds, trenbolone acetate and zeranol, the Committee reported that further data of specific types were required in order for the Committee to complete its evaluation of their safety for use in animal production.

In response to the 1982 Lamming Committee report, the manufacturers of the xenobiotic anabolic agents immediately set about generating the data requested. The required studies, conducted by independent contract laboratories, were completed and the data were submitted to the EC Commission in January 1984. But even as the reconvened Lamming Committee was evaluating the 1984 data, the EC Commission was busily drafting proposed legislation based on the then obsolete 1982 Lamming report. The proposal for a Directive (5), issued by the Commission in June 1984, proposed to approve the three endogenously occurring compounds and to ban the two xenobiotic compounds "as long as it (had) not been shown that they (were) without danger". The latter language referred to the state of affairs when the 1982 Lamming report was written; the Commission conveniently neglected to acknowledge that the data which had been "missing" in 1982 were no longer missing in 1984.

While the Lamming Committee continued to deliberate during 1984 and 1985, the Commission's proposal for a Directive proceeded through the normal EEC channels of consultation (see Fig. 1). The Economic and Social Committee issued its opinion that definitive legislation on anabolics should not be drafted "until the Commission (could) consider fully the scientific evidence for which it originally called" (i.e., until the results of the Lamming Committee deliberations were available) (6). Meanwhile, the European Parliament began to consider the Commission's proposal, amidst intense lobbying on the part of the pharmaceutical industry on the one hand and the consumer activist groups on the other.

It so happened that in this same period of time (1984-85) the EEC was experiencing one of its cyclical peaks in beef production (7) (see Fig. 2). This record level of production was augmented and prolonged by an 8% cut in EEC milk production quotas in mid-1984, which resulted in a kill-off of a corresponding percentage of the EEC dairy herd. The introduction of this extra cull cow beef into an already oversupplied market contributed to a surplus of EEC beef which exceeded 700.000 tons by late 1985.

This "beef mountain", paid for by the EC Commission at "intervention" (i.e. subsidized) prices and kept in storage (for lack of a market outlet) at taxpayers' expense, attracted the attention of the same consumer activist groups that were pushing for a ban on anabolic agents in animal production. Having hitherto failed to produce any convincing evidence for any adverse effects of anabolics on the public health or on meat quality, the consumerists now turned to the beef mountain as the basis for an effective economic argument for a ban. The logic was simple.

Why should the EEC continue to permit the use of substances that increased beef production in the face of the major economic and political problem of overproduction of beef?

This argument was particularly appealing to politicians, as it suggested a facile pseudo-solution to a complex problem. It was far easier to place the blame for the beef surplus on the use of hormones in cattle production than to place the blame where it belonged: on the EEC system of intervention payments that encouraged maximal levels of beef production and insulated producers from the harsh realities of world market conditions. It did not matter to the consumerists or to the politicians they lobbied, that the beef mountain was partly attributable to a peak in the normal cycle of beef production and partly attributable to the Common Agricultural Policy. Nor did it matter that the major economic effects of the use of anabolics in animal production were to increase efficiency and reduce costs of production, rather than merely to increase total production. What did matter was that the prohibition of the use of anabolic hormones as a means of reducing the beef mountain provided Members of the European Parliament with a powerful, emotive issue with great political potential and negligible political cost.

The European Parliament issued its opinion on the Commission's proposal for a Directive in October 1985 (8). In essence it called upon the Commission to amend its proposal to that of a total ban on all anabolics, citing "scientific information... far from complete" (in reference to the unfinished work of the Lamming Committee) as well as "overproduction of meat... in the European Community" as justifications for the proposed ban.

The Commission swiftly obliged. The Lamming Committee was scheduled to meet on 30 October, purportedly to agree on a draft report which would have given a favorable view of all five anabolics under consideration on the basis of their harmlessness to the public health. Four days prior to 30 October, Professor Lamming and the members of his committee were abruptly informed by the Commission that their scheduled meeting was cancelled and the committee was suspended. Then, lo and behold, on precisely 30 October the Commission made known its new proposal to ban the use of all anabolics (9). Now it was clear that the Commission was not merely ignoring scientific evidence that it found politically inconvenient -it was actively suppressing such evidence.

Equally clear was the fact that science had been overtaken and overwhelmed by politics. The attempt to solve a political problem by technical analysis had failed, largely because the results of the technical analysis (viz., the revised Lamming Committee report) had not become available, in a politically usable form, in time.

The Council of Agriculture Ministers wrestled with the Commission's new proposal until late December 1985, when it voted Directive 85/649/EEC (10), which banned the use of any substance having an "oestrogenic, androgenic or gestagenic action" for growth promotion in food animals in the EEC, as well as prohibiting the trading of meat from animals treated with such substances, effective 1 January 1988.

In March 1986 the United Kingdom, which had voted against the Directive in the Council of Ministers, challenged the legality of the Directive on procedural grounds in the European Court of Justice (11). This case is expected to be adjudicated in 1987.

Where then does that leave EEC policy on livestock production in general? One likely outcome is that, due to natural processes that result in the cyclical fluctuation of beef production, the magnitude of the beef mountain will diminish and the Euro-politicians will claim that they solved the problem of overproduction by banning hormones. In that case, the anabolics would be lost to the EEC, but other types of safe and efficacious drugs could continue to be used to enhance the efficiency of animal production.

But let's assume that the problem of overproduction does not go away spontaneously. What happens then? In the case of the anabolics we have a clear example of the kind of Luddite thinking that prevails in EEC politics: Rather than abolishing the subsidies that encourage overproduction (which would be politically very expensive), one simply prohibits the use of technological inputs that enhance production efficiency, and any increases in production costs that accompany the loss of efficiency are silently and painlessly passed along to the consumer. In 1985 the target of such policy was anabolics. What will it be this year?

Antibiotics as growth promoters are likely candidates for prohibition, particularly in view of the sensationalism that has surrounded the scientific debate over the hypothesis -which was tested and found to be invalid by United States regulatory authorities, but which is still very much alive in Europe- that the use of low-level antibiotics in animal feed could lead to widespread antibiotic resistance in human pathogens. (Unsubstantiated claims of danger to the public health are clearly helpful to the European consumer lobby in persuading the European Parliament to call for a ban.)

Coccidiostats, wormers and pesticides could likewise be targeted, as their prohibition would surely serve as an effective means of curbing production.

The extension of this sort of thinking to its ultimate conclusion would leave the EEC beef producer with essentially 19th-Century production technology. And, indeed, such low-input to no-input agricultural production systems are being aggressively advocated by young urban politicians (typified by members of the German Green Party) who did not experience the deprivations of the War and who have no direct knowledge of agriculture. To such individuals, the banning of modern chemical and veterinary inputs to production serves a double purpose, as it simultaneously reduces the beef mountain and creates the aesthetically pleasing illusion of "natural" animal production.

This notion of the "natural" as a desideratum in animal husbandry demands consideration. It was a recurring theme in the consumerist campaign to ban the anabolics. Ken Collins, rapporteur for the European Parliament Committee on the Environment, Public Health and Consumer Protection (which drafted what turned out to be the decisive resolution to ban all hormones), was paraphrased as saying: "The objection is to the use of hormones to promote unnatural (emphasis mine) rapid growth" (12). The notion of the "natural" is likewise in vogue as a positive attribute in the marketing of all sorts of consumer products, and particularly food products. Thus it would behoove us to understand this apparently vital concept: What intelligible criteria define the "natural"?

Judging from the way in which the words "natural" and "unnatural" are used in the context of animal production (as in the statement of Ken Collins, vide supra), one must conclude that "unnatural" connotes some involvement of human artifice in the manipulation of or interference in biclogical processes, while "natural" connotes the absence thereof. If that be the case, then what is blatantly apparent is that there is absolutely nothing "natural" about agriculture. Indeed, since prehistoric times the very essence of agriculture has been the manipulation of the life processes of other species, utilizing every available artifice for the purpose of increasing the production of human food.

Thus agriculture is totally "unnatural", and it is sheer capriciousness to claim that one kind of human interference in the life of food animals is any more or less "natural" than another. For instance, we routinely interfere with practically every facet of an animal's life by manipulating the animal's genome through genetic selection. Is that interference more "natural" than manipulating the animal's physiology through the implantation of an anabolic agent? I submit that neither procedure is "natural" but that both constitute valuable components of modern animal production.

If we were to delete all the "unnatural" components of animal production (which would have to include every aspect of improved nutrition, hygiene, techniques to enhance reproductive performance, immunization, treatment of disease, and control of parasites, as well as the use of growth promotants to enhance productivity), we would be left with poorly adapted animals suffering from nutritional deficiencies, riddled with parasites and disease, and of such low productivity as to be of little value for the production of human food. Such a situation is a far cry from the idylic green pastures filled with happy, healthy cattle, as envisioned by the Greens who rail against the use of modern technological inputs in animal production. But in the urban environment in which the Greens live, the cherished ideal of "natural" animal production is never confronted with the realities of animal production which render that ideal absurd.

Notwithstanding the thrust of the preceding paragraphs, there would be no objection to the Europeans' satisfying their desire to decrease production by dismantling existing technology, plus indulging their fantasies about "natural" agriculture, if it were merely an internal matter. But what effects do such policies have on the rest of the world? Are non-EEC countries expected to conform to -and indeed to finance- such EEC policies?

Judging from the case of the anabolics, it would appear that the answer is affirmative. The 1985 Directive requires that any meat exported from "third countries" to the EEC come from animals that have never been treated with the banned hormones. Of particular interest is that the focus of this requirement is not on anabolic residues in meat -the levels of which could be quantitatively determined and objectively verified by chemical analysis- but rather on treatment (at any time, in any moment and with any dose) of the beef animal. That is to say, what is being prohibited by the Directive is the act of treatment of an animal with an anabolic. Thus, third countries seeking to export beef to the EEC, will be required to provide "guarantees" that such acts of anabolic treatment did not occur in relation to the cattle whose meat is being exported to the EEC. The exact nature of these "guarantees" has not yet been revealed by the EC Commission, but the operational difficulty of guaranteeing the non-treatment of animals is abundantly obvious. It is a foregone conclusion that a costly system of residue monitoring will be required of any country seeking to export beef to the EEC regardless of whether that country authorizes the use of legitimate anabolic products (as the EEC is well aware that indiscriminate prohibitions stimulate black-market distribution and use of the banned products or alternative products such as DES, and the residues of such illegal products must be monitored and controlled). But even though tissues residue analysis may be capable of detecting concentrations of anabolic residues in the part-per-trillion range, it is totally inadequate for demonstrating that a given animal was not treated with an anabolic agent at some time in its life.

Indeed, the fact that there is no objective means of verifying that a given animal was never treated with an anabolic, constitutes a major flaw in the Directive, rendering the ban essentially unenforceable.

So we have in the EEC hormone ban a legal instrument which presumes to reduce domestic beef production and to impose a non-tariff trade barrier designed to exclude imports of foreign beef. It is difficult for third countries to decide at this time whether the EEC market is worth pursuing or not, as we do not yet know how high the cost of compliance will be.

A reasonable working assumption, however, is as follows: The hormone Directive offers so many technical opportunities for the EEC to stop the importation of meat from third countries, that compliance by third countries will be judged subjectively, depending on the size of EEC stockpiles of intervention beef and possibly on the linkage of beef imports to other economic or political issues. I.e., the enforcement of the hormone ban is likely to be inconsistent, depending on the direction and force of the political and economic winds of the moment. Experience with previous EEC Directives that erected non-tariff trade barriers, would suggest that third countries will be given as much flexibility as they each demand in bilateral negotiations. The United States, for example, has still not complied with the Third Country Red Meat Directive which was enacted by the EEC in 1972. As with that Directive, it may likewise turn out for the hormone Directive that extended negotiations are far more cost-effective than compliance.

The success of failure of EEC efforts to secure compliance with the hormone ban will surely depend on whether or not affected third countries are willing to take a united stand to oppose the application of the ban to third countries as a non-tariff trade barrier. There should be opportunities in the GATT discussions for such a confrontation.

Perhaps the single most disturbing aspect of the ECC hormone ban is that it sets a precedent for the regulation of the use of veterinary drugs by politicians, thereby removing the responsibility for such regulation from the technically competent authorities who are qualified for such work. As soon as one begins to regulate veterinary products on the basis of their political acceptability rather than on the basis of their safety and efficacy, there is a real danger that the politicians will be unable to exercise either judgement or restraint. The banning of every product that is considered "unnatural", for example, is not an unthinkable scenario in the current EEC political climate.

And not only is such witch-hunting unfortunate in terms of the immediate loss of the benefits derived from the banned products: it is ultimately disastrous when one considers the consequences of decisions taken by the affected pharmaceutical companies, to cancel research programs on animal health products, for example, or to drop plans to build manufacturing facilities in Europe because of uncertainty about the legality of selling legitimate animal health products in the EEC market in the future.

Finally, when agriculture is hobbled for lack of technological inputs, when industry pulls out and seeks less perilous environments, depriving the society of investment and employment, and when the only veterinary products available are those supplied by the black market, with the attendant <u>real</u> risks to human health (as opposed to journalistically <u>conjured</u> risks), then the EEC will have arrived at its destination: the 19th Century.

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11. Brown, G.; 1986: Britain Takes EEC to Court. The Daily Telegraph; March 11th, 1986; p. 2.

12. European Parliament, The Week, 7-11 October 1985, pp. 24-25.

Figure 1 : E E C M A C H I N E R Y

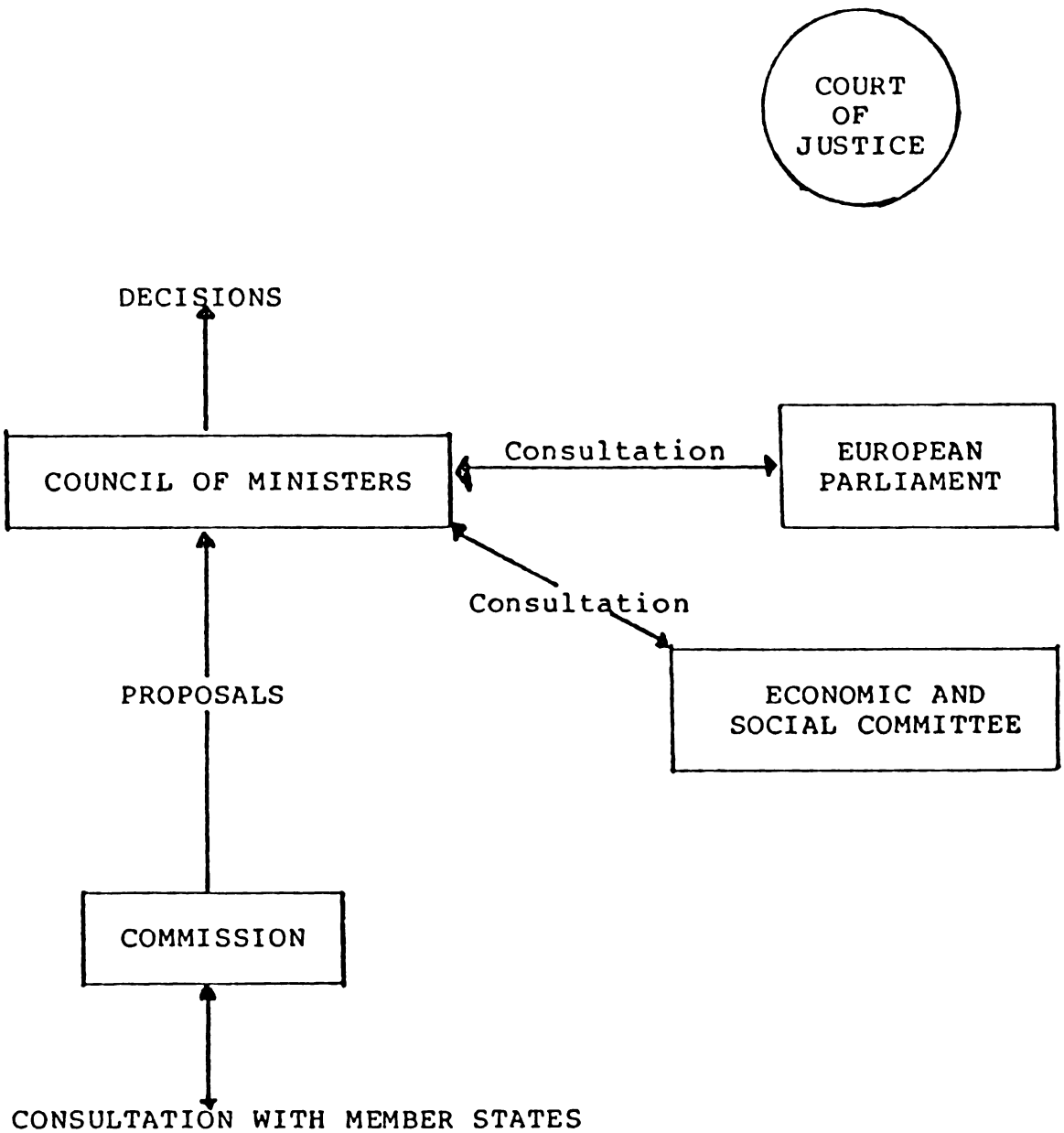
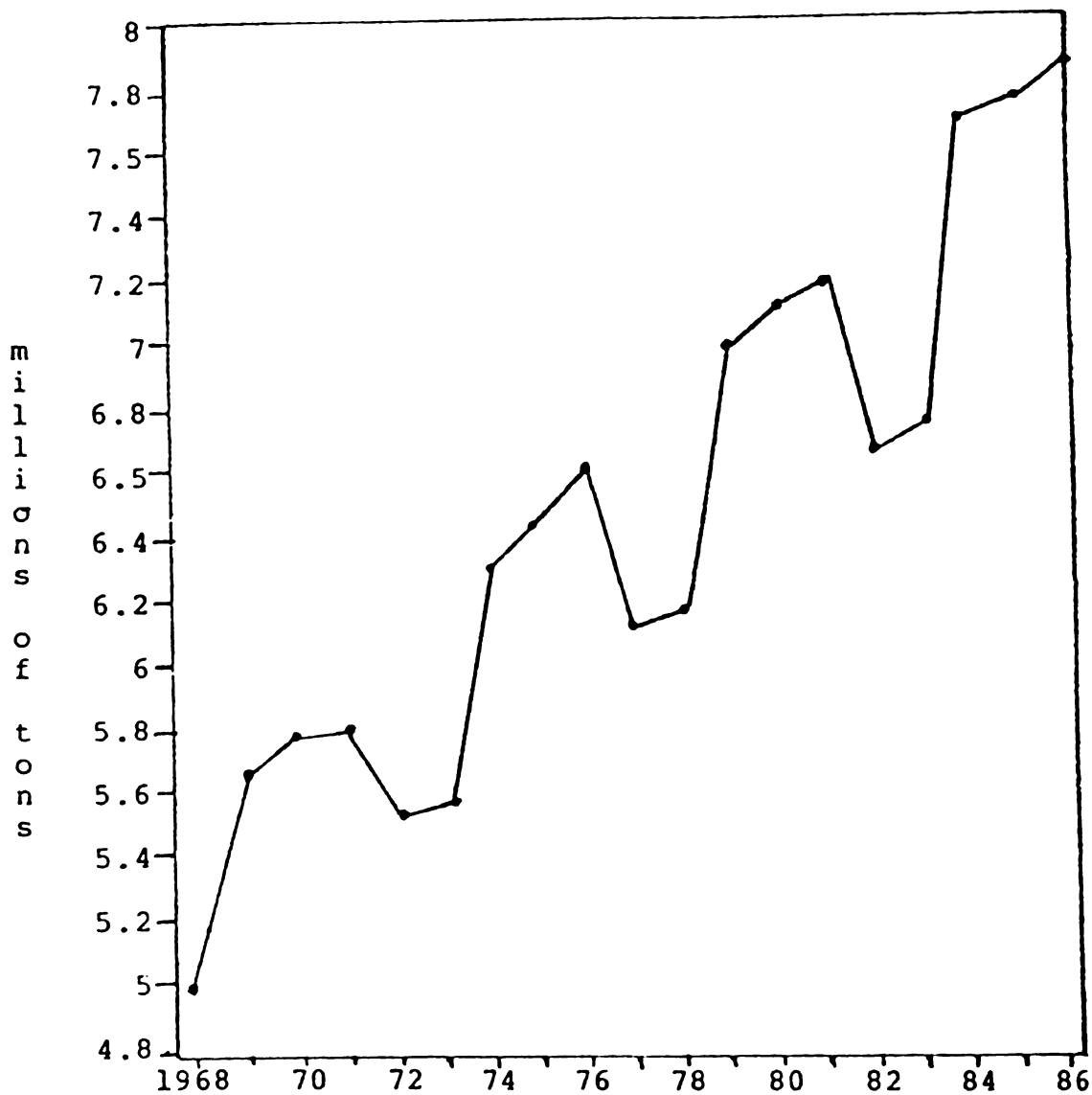


Figure 2 : EEC BEEF PRODUCTION CYCLES



(Adapted from Cordier et al., 1986)

THE WHO-FAO CODEX ALIMENTARIUS COMMITTEE ON VETERINARY DRUG RESIDUES IN FOOD

Lester M. Crawford, DVM

THE WHO-FAO CODEX ALIMENTARIUS COMMITTEE ON VETERINARY DRUG RESIDUES IN FOOD

Lester M. Crawford, DVM*

I am honored to be here this afternoon and to participate in this most important congress. I congratulate you on the program. The other papers to be presented are in every sense representative of the special problems that confront livestock agriculture today. My purpose is to discuss the newly formed WHO-FAO** Codex Alimentarius Commission on Veterinary Drug in Foods (CCVDR).

The World Health Organization's Veterinary Public Health Unit has elaborated a veterinary drug program which describes the current situation in the context of the envisioned activities of CCVDR. Meaningful international activities pertaining to veterinary drugs can be divided into three major categories:

1. Activities focusing on the prevention and/or therapy of animal diseases as well as on increasing production (e.g. growth promotion, enhancement of milk secretion). Such activities are equally important from the viewpoint of animal health and animal production as well as of public health, particularly as numerous animal diseases, e.g., zoonoses, might endanger human health directly or via food of animal origin.

   In order to fulfill the intended purpose of their use, veterinary drugs must meet certain requirements regarding their quality, efficacy and safety. With this aim in mind, numerous countries introduced pertinent regulations.

   To develop and maintain a well function regulatory system is a difficult endeavor requiring substantial expertise and financial resources. Hence, many countries are not in the position to regulate veterinary drugs. In such countries neither public health nor animal production are adequately served. An international organization, such as WHO is in a unique position to help in closing this important gap by identifying <u>minimal requirements</u> veterinary drugs have to fulfill before they can be admitted to the market.

   In addition, compiling a list of <u>essential veterinary drugs</u> along with the elaboration of <u>codes of practice</u> to facilitate the proper use of drugs (achieving optimal efficacy with lowest possible risks) could assist developing countries in starting their own program on animal drug regulation.

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* Associate Administrator, Food Safety and Inspection Service, USDA, Washington, D. C., USA.

** WHO is the World Health Organization headquartered in Geneva, Zwitzerland, FAO is the Food and Agriculture Organization in Rome, Italy. Both are units of the United Nations.

2. Safety

Unlike in human medicine, veterinary drugs, notably those used in food-producing animals, must be safe not only to the target species, i.e., the patient, but also to the consumers of food originating from the treated animals. To achieve this important objective, during the premarket approval of animal drugs, a careful safety evaluation of their residues in edible products of animals must be performed.

The safety evaluation of veterinary drug residues share many features with the evaluation of other chemicals, such as food additives and residues of pesticides. In these latter fields, through its role in the joint expert committee on food additives (JECFA) and the joint meeting on pesticide residues (JMPR), WHO accumulated during the past decades a plethora of information and gained invaluable experience. Thus, in future activities aiming at the evaluation of veterinary drug residues WHO could draw on this experience. Recognizing that veterinary drugs have a number of peculiarities not shared by any other type of chemicals, the joint FAO/WHO Expert Consultation on Residues of Veterinary Drugs in Foods (Food and Nutrition Paper 32, Rome, 1985) recommended that the question of the safety evaluation of animal drug residues should be dealt with by special mechanisms. Several of the pertinent issues, e.g., setting maximal residue limits and priorities as well as determining criteria for analytical methods can be resolved by established codex mechanisms. One important aspect of the recommendations mentioned above, the development of codes of practice, will however require an entirely new orientation and a considerable input from the veterinary profession.

From the public health viewpoint the effectiveness of other measures, i.e., the elimination and/or the reduction of the residue burden for the consumers of food of animal origin will largely depend upon how well veterinarians in the field and the animal care-takers themselves will comply with label instructions. The role of carefully developed codes of practice can in this respect hardly be overestimated. This is particularly true for countries lacking a system of premarket clearance.

3. Dissemination of information

As already referred to, veterinary drugs are in many countries not subject to licensing or registration procedures. In numerous others, merely a premarket notification of the competent authorities is required. Few countries actually authorize the sale and use of veterinary drugs based on a thorough review of data submitted to appropriate agencies by the drug sponsors. Regardless of the category to which a given country may belong, an exchange of information on the status of drugs, tolerance levels and analytical methods for residues, adverse reactions, and residue reporting data are of great importance. Obviously, countries with the least developed regulatory system would be the greatest beneficiaries of such exchange.

This regulatory heterogeneity results in major differences in the public health relevance of the use of veterinary drugs. The uncontrolled use of potent antimicrobial agents (e.g., antibiotics, sulfonamides, nitrofurans,

nitroimidazoles) may increase the prevalence of plasmid coded resistance among enteropathogenic microorganisms in the intestinal flora of animals with the consequent spread of zoonoses to other animals and man. Moreover, the lack of regulatory restraints such as prohibitions, withdrawal times, and other restrictions of use, which may expose consumers to high levels of drug residues some of which are carcinogenic, mutagenic, teratogenic, neurotoxic, or allergenic.

In addition to this public health threat within their own boundaries, countries without regulatory control of veterinary drugs have to endure commercial disadvantages as well, since the significance of residues in international trade in food of animal origin is rapidly increasing.

Quite obviously, an adequate exchange of information among countries on questions pertaining to the safe use of animal drugs resulting in a reduced residue for the population would be of benefit to all nations.

The development of international activities pertaining to veterinary drugs is long overdue. In such activities, veterinary public health specialists have a clear role to play, but can accomplish little without the active and constructive support of animal agriculture.

In July of 1985, the Codex Alimentarius Commission responded to worldwide interest and concern by unanimously voting to establish a new Committee on Residues of Veterinary Drugs in Food. Dr. Gerald B. Guest is the United States Delegate and Dr. Arpad Somogyi is the FRG Delegate. The United States was chosen to act as host country and Dr. Lester M. Crawford of the United States Department of Agriculture was appointed Chairman of the Committee. The Committee was given the following mandate:

- to determine priorities for the consideration of residues of veterinary drugs in foods;

- to recommend maximum residue levels;

- to develop necessary codes of practice;

- to develop criteria for analytical methods used for the control of veterinary drug residues in food.

There are several existing codex committees that we will, of course, need to work closely with: the Committee on Food Additives, the Committee on Methods of Analysis and Sampling, and the Food Hygiene Committee. It is possible that the Chairman of these committees may attend our sessions and I may attend their committee meetings. Certainly we will stay well informed of each other's activities.

At each of our committee meetings, we will establish a list of several drugs for priority review. These will be referred to a small group of scientific experts which will develop the recommended residue levels. Then the

recommendations will be considered by the Veterinary Drug Residue Committee, since that committee is the plenary body and has broader international representation. In my role, I will attend meetings of both the Veterinary Drugs Committee and the Expert Committee.

For the time being, we will use the Expert Committee which is already serving the Food Additives Committee. We recommend a separate Committee of Experts to serve the Veterinary Drug Committee in subsequent years.

Safety evaluations

The safety evaluation of veterinary drug residues share many features with the evaluation of other chemicals, such as food additives and residues of pesticides, and we can certainly build on the ongoing work in these areas. However, veterinary drugs do have certain unique qualities. Thus the safety evaluation of drug residues will require mechanisms different from those already in use. One of the important tasks of the new committee will be to establish procedures for the selection of analytical methods and sampling for control of veterinary residues.

Those who are establishing the committee recognize that the best way to prevent harmful residues is to require an "absence" of drug residues in food. However, the expert consultation studying the need for the committee noted that this requirement for zero residues in many countries has become more and more difficult to support scientifically. Increasingly sensitive analytical methods have revealed minute residues in food that was believed to be "free" of residues. Thus the consultation, as well as other bodies studying the problem, recommended that the concept of "acceptable daily intake" or ADI be applied in this area.

Codes of practice

Since most countries are already using the same veterinary drugs, a listing of those which are essential, along with stated codes of practice for their use, would be useful and desirable. The Committee will be looking into the feasibility of establishing such codes since this would help achieve optimal efficacy with lowest possible risks.

This is an area where the uniqueness of veterinary drugs in the food safety arena comes into play. Veterinarians and animal scientists must be sure to follow approved methods carefully to ensure the well-being of the animal receiving the drug, as well as to the consumer of the meat, milk, or eggs. These codes of practice would have the greatest impact in countries that lack a system of premarket clearance for the drugs.

The First Meeting

The First Meeting of CC/RVDF took place the last week of October (1986). Forty countries and ten international organizations were represented. The main business before the 175 delegates was the establishment of a list of animal drugs for priority review. In addition operating procedures for the Committee, including priority review criteria were determined.

In order to be placed on the CC/RVDF's priority list for the development of an acceptable residue level, the candidate veterinary drug, when used in accordance with good veterinary practices should meet some, but not necessarily all, of the following criteria:

1. the drug results in residues in the food commodity;

2. the drug or its residues are a matter of public health concern;

3. the residues of the drug affect international trade to a significant degree;

4. the residues of the drugs are creating or have a potential to create commercial problems;

5. the drug is available for use as a commercial product.

In addition,

a. There must be a firm indication that relevant data will be made available for evaluation.

b. CC/RVDF should take into account any work on residues of the drug undertaken or completed by other codex committees.

The priority list includes the following substances:

1. Chloramphenicol

2. Anabolic agents (estradiol, progesterone, testosterone, trenbolone, and zeranol)

3. Sulfonamides

4. Nitrofurans

5. Nitroimidazoles

6. Quinoxaline-DI-N-Oxides

7. Trypanocides

A specific session of the joint expert Committee on Food Additives will be held in the summer of 1987 to evaluate these compounds. Experts for the Committee are being chosen on the grounds of their specific expertise in veterinary pharmacology. This group of experts will provide recommendations

for acceptable residue levels of the priority review drugs. CC/RVDF will consider those recommendations at its next meeting which is tentatively scheduled for November, 1987.

Additionally, CC/RVDF agreed it was necessary to elaborate a definition of "good practices for the use of veterinary drugs". One of the member delegations was appointed to prepare, in conjunction with WHO, a first draft of such a definition. The proposed definition will be considered at the next CC/RVDF meeting.

An Ad Hoc working group on methods of analysis and sampling was established. That group will elaborate and recommend to the plenary session at the next CC/RVDF meetings methods of analysis and sampling, as appropriate.

CC/RVDF also considered the need for and feasibility of elaborating codes of practice for certain aspects of the use of veterinary drugs. After some discussion, one of the member delegations was appointed to prepare a first draft for consideration by the committee at its next session.

In other business, a survey of member governments will be conducted to evaluate the drug residue monitoring activities of member countries. A number of other pertinent issues were surfaced which will be placed on the agenda of the next meeting scheduled for Washington, D. C., in November, 1987 (tentative).

Conclusion

It is obvious that the new committee has its work cut out for it. But it is critical that an international body begin to look into veterinary drug use on a regular basis. There is great expertise around the world and it is to everyone's advantage for us to work together to review veterinary drug use, set guidelines for appropriate use, and establish appropriate limits on residues in food. It will not only be a boon to those countries that already have sound regulatory systems, but it will be of tremendous value for those developing nations which are unable to set up adequate control mechanisms.

OIE ACTIVITIES IN THE FIELD OF VETERINARY PHARMACEUTICALS

Emilio J. Gimeno

OIE ACTIVITIES IN THE FIELD OF VETERINARY PHARMACEUTICALS

Emilio J. Gimeno*

PAST ACTIVITIES

1. Symposium

In February 1983, the OIE held a symposium on anabolics in animal production. This symposium revealed that veterinary services in the countries need to receive up to date information on the registration, control, approval and use of drugs for use in animals.

2. Survey

As a result, the OIE held a survey from 1985 to 1986 to identify the duties presently assigned to veterinary services in the field of toxicology and pharmacology, and the means available to these services.

OIE headquarters received completed questionnaires from 48 countries (see list in Appendix 1).

The replies can be found summarized in Appendix 2. They showed that in general, veterinary services are active in this field, but to varying degrees.

Their activities cover two areas:

- epidemiological surveillance of the environment to detect cases of acute intoxication of animals, and overseeing products of animal origin destined for human consumption to ensure that they are not contaminated;
- registration and control of veterinary pharmaceuticals.

a. Analysis of replies

i. Official centers of veterinary toxicology and pharmacology

Forty of the 48 responding countries have one or more official centers of toxicological and pharmacological control for animal health. Some of these centers report directly to the veterinary services. Others operate under other directorates of the ministries of agriculture or under the ministries of health, with some operating out of universities.

* President of the Committee of the International Office of Epizootics (OIE).

ii. Major activities of the veterinary toxicology and pharmacology centers

The activities directed by one or more of these centers in each country fall into four categories:

- Pharmacological control
- Pesticide research
- Environmental pollution
- Residues in food

The centers in 29 countries are involved in all these areas. Three conduct activities in only two areas, and three more, in only one. Centers in the ten remaining countries carry out none of these functions. However, some have adopted regulations for registration of veterinary pharmaceuticals.

iii. Toxicological accidents

Toxicological accidents appear to be a source of general concern, but at present, only 23 countries have systems for detection and reporting of these accidents. Veterinary services generally recognize the importance of acute accidents, but often lack the facilities for identifying them.

The inadequacy of facilities and resources is even more pronounced for chronic toxicology, which requires the use of extremely complex techniques.

b. Conclusions

The OIE survey showed that veterinary services in most of the countries participate in the registration, authorization and control of veterinary pharmaceuticals.

Most of the countries that responded to the survey have their own toxicological and pharmacological centers, but there appears to be no coordination or communication among countries for improving information on standards and regulations for veterinary pharmaceuticals and on prevention of toxicological accidents. Most of the countries lack means for detection, reporting and control of these accidents.

Developed countries and developing countries alike need to understand and harmonize the different methods for toxicological control and standardization of pharmaceuticals. Rapid dissemination of information is particularly important for developing countries, whose limited resources do not allow them to carry out certain pharmacological controls or to perform lengthy, complex toxicological research.

The OIE, as an agency for cooperating with the government veterinary services in improving or establishing systems for the prevention and surveillance of accidents caused by veterinary pharmaceuticals, with the cooperation of other international organizations.

PRESENT ACTIVITIES

The results of this survey were presented to the Fifty-Fourth General Session of the Committee in May 1986. The Committee adopted General Resolution No. 11, to set up a working group that would organize a program, working in conjunction with the organizing committee of the third "International Technical Consultation on Veterinary Pharmaceutical Registration" (ITCVPR), scheduled to take place the following June 10 to 13 at OIE headquarters in Paris, in order to discuss the following technical subjects.

1. Organization of ongoing cooperation between OIE and the International Technical Consultation on Veterinary Pharmaceutical Registration, and if necessary, with other groups of veterinary administrators responsible for pharmaceutical legislation.

2. Organization by OIE of an information network on secondary or harmful effects of veterinary pharmaceuticals.

3. Preparation of a program of OIE activities, expanded to include information on control of veterinary pharmaceuticals and on toxicological accidents.

The Technical Group of the Third Consultation, during its sessions, approved the establishment of a system for ongoing, permanent cooperation in the OIE. This system would operate as a permanent secretariat to coordinate the working group, which is made up of administrators responsible for legislation covering veterinary drugs in the various countries.

As a result of these actions, in October of this year we met with Dr. Boisseau (France), the present coordinator of the technical consultative group, Dr. Arpad Somogyi (Federal Republic of Germany), and Dr. Louis Blajan (Director General of the OIE). The author presided over the committee. During these meetings, it was agreed to prepare the following course of action immediately:

1. Draft a document to guide countries by providing a technical model establishing registration standards, control systems, and approval mechanisms of drugs for veterinary use. This document should include such issues as effectiveness (clinical pharmacology), safety (toxicity, mutagenesis and carcinogenesis), and quality control (analysis and determination of pharmacological quality).

2. Advise the OIE Committee to designate pharmacological reference centers, in certain parts of the world, that could provide advisory services in technical areas and, through the OIE, disseminate information on drug control to the countries.

3. Select reliable information on the registration of drugs and review technical information that is accesible and useful for pharmacological registration.

CONCLUSIONS

The OIE is extremely interested in promoting exchange of technical information on pharmacology among the countries and finding mechanisms of coordination for harmonizing criteria and, as much as possible, unifying drug registration systems.

The OIE therefore would like to take active part in coordinating activities with other international organizations such as WHO, FAO, CODEX ALIMENTARIUS, and now IICA, with which a cooperation agreement has been in existence since 1981. Under this agreement, future courses of action can be taken to improve coordination among countries in an area of great importance: registration and control of drugs used in animals.

APPENDIX 1

LIST OF COUNTRIES THAT RESPONDED TO THE OIE QUESTIONNAIRE

Argentina
Australia
Austria
Bulgaria
Cameroon
Canada
Chile
Colombia
Cyprus
Denmark
Ecuador
Finland
France
Greece
Hungary
Indonesia
Israel
Italy
Jordan
Kenya
Korea
Lesotho
Luxemburg
Madagascar
Malawi
Malaysia
Mali
Netherlands
New Zealand
Norway
Pakistan
Peru
Romania
South Africa
Spain
Swaziland
Sweden
Switzerland
Taiwan R.O.C.
Thailand
Turkey
Uganda
United Arab Emirates
United Kingdom
United States of America
Vanuatu
Zambia
Zimbabwe

TABLE 2

	LUXEMBOURG	ARAB EMIRATES	NEW ZEALAND	DENMARK	AUSTRALIA	UNITED STATES	CANADA	UNITED KINGDOM	LESOTHO	NETHERLANDS	AUSTRIA	CYPRUS
1. Official Toxic. Center	-	-	5	3	6	1	3	3	1	3	3	3
2. Activity												
2.1 Acute toxicity	-	-	+	+	+	+	+	-	+	+	+	-
2.2 Toxicol. res.	-	-	4	4	4	4	4	4	3	4	4	4
. pharm. control	-	-	+	+	+	+	+	+	-	+	+	-
. pestic. ident.	-	-	+	+	+	+	+	+	+	+	+	-
. environ. polut.	-	-	+	+	+	+	+	+	+	+	+	-
. food residues	-	-	+	+	+	+	+	+	+	+	+	-
3. Tox. accidents	-	+	+	+	±	+	+	+	-	+	+	+
Reporting syster		-	+	±	±	-	-	+	+	+Ph	+	+
4. Entity responsib. for pharmaceut.	-	+	+	+	+	+	+	+	-	+	+	+
legal recog.	-	+	+	-	+	+	+	+	-	+	+	+
pharmacological regist. proced.	-	+	+	-	±	+	+	+	-	-	+	-
CONTROLS: PHARMACEUTICALS												
.physical-chemic.	-	-	+	-	-	+	+	+	-	+	+	+
. pharmacological	-	-	+	-	-	+	-	+	-	+	+	-
. biological (7)	-	-	7/7	-	-	7/7	2/7	7/7	-	7/7	7/7	-
AVERAGE TIME FOR REGISTRATION	-	3m	6m	1y	4-6m	1.5y	4m	3-6m	-		2y	3-12m
5. Scientific consultations Groups or Individuals	-	-	4	-	2	4	9	+	-	1	1	1
5.2 Information	0	2	4	0	4	4	4	3	1	4	3	1
Tox. accidents	-	+	+	-	-+	+	+	+	-	+	+	-
New pharmaceutic.	-	-	+	-	+	+	+	+	-	+	+	-
Food resid. res.	-	-	+	-	+	+	+	+	-	+	+	-
Analytical methd.	-	-	+	-	+	+	+	-	-	+	+	-

A = Accidents Ph = Pharmaceuticals If = Information provided by manufactur.
m = months y = year d = day NG = not given

APPENDIX 2

	SWEDEN	TURKEY	FINLAND	ROMANIA	SOUTH AFRICA	ZAMBIA	HUNGARY	KOREA	SWAZILAND	PAKISTAN	NORWAY	MADAGASCAR
1. Official Toxic. Center	2	3	1	3	3	?	3	1	-	2	2	-
2. Activity												
2.1 Acute toxicity	+	+	-	+	+	+?	+	+	-	+	+	-
2.2 Toxicol. res.	4	2	-	4	4	1	4	4	-	4	4	-
. pharm. control	+	+	-	+	+	+?	+	+	-	+	+	-
. pestic. ident.	+	+	-	+	+	-	+	+	-	+	+	-
. environ. polut.	+	-	-	+	+	-	+	+	-	+	+	-
. food residues	+	-	-	+	+	-	+	+	-	+	+	-
3. Tox. accidents Reporting system	+ -	+ +	± -	-? +	+ -A +Ph	+ -	+ +A -Ph	+ +	- +A -Ph	- -	+ -	- -
4. Entity responsib. for pharmaceut.	+	+	+	+	+	-	+	+	-	+	+	-
legal recog.	+	-	+	+	+	-	+	+	-	+	+	-
pharmacological regist. proced.	±?	-	+	+	+	-	-	+	-	+	-	-
CONTROLS: PHARMACEUTICALS												
.physical-chemic.	+	-	+	-	-	+	+	+	-	+	+	-
. pharmacological	+	-	+	-	-	+	-	+	-	+	+	-
. biological (7)	2/7	7/7	7/7	7/7	7/7	4/7	7/7	2/7	-	-	-If	-
AVERAGE TIME FOR REGISTRATION Register	2y -	1y	20-30 m	3y 10y	6m	-	1-3y 6-8y	6m	-	4-6m	1-2y	-
5. Scientific consultations Groups or Individuals	-	1	-	3	2	-	3	1	-	2		-
5.2 Information	0	4	4	4	2	0	4	4	1	2	4	0
Tox. accidents	-	+	+	+	+	?	+	+	+	+	+	-
New pharmaceutic.	-	+	+	+	+	-	+	+	-	+	+	-
Food resid. res.	-	+	+	+	-	-	+	+	-	-	+	-
Analytical methd.	-	+	+	+	-	-	+	+	-	-	+	-

A = Accidents Ph = Pharmaceuticals If = Information provided by manufactur.
m = months y = year d = day NG = not given

APPENDIX 2

	TAIWAN	MALAWI	JORDAN	GREECE	VANUATU	ZIMBABWE	FRANCE	MALI	ECUADOR	MALAYSIA	ISRAEL	CANADA
1. Official Toxic. Center	1	1	-	3	-	2	13	1	1	-	1	4
2. Activity												
2.1 Acute toxicity	+	-	-	+	-	+	+	-	+	-	+	-
2.2 Toxicol. res.	4	1	-	4	-	3	4	-	1	-	4	4
. pharm. control	+	-	-	+	-	-	+	-	-	-	+	+
. pestic. ident.	+	+	-	+	-	+	+	-	+	-	+	+
. environ. polut.	+	-	-	+	-	+	+	-	-	-	+	+
. food residues	+	-	-	+	-	+	+	-	-	-	+	+
3. Tox. accidents Reporting system	+ +	+ +	- -	+ -	- -	+ +A -Ph	+ -	-	+ -	± -	+ +A -Ph	+ +A +Ph
4. Entity responsib. for pharmaceut.	+	+	+	+	+	+	+	-	+	+	+	+
legal recog.	+	-	+	+	-	+	+	-	+	+	-	+
pharmacological regist. proced.	+	-	-	+	-	+	-	-	-	-	+	+
CONTROLS: PHARMACEUTICALS						(±)						
.physical-chemic.	+	-	-	+	-	-	+	-	+	-	-	+
. pharmacological	-	-	-	+	-	-	+	-	+	-	+	+
. biological (7)	2/7	-	-	2/7	-	-	1/7		+?	-	2/7	7/7
AVERAGE TIME FOR REGISTRATION Register	1-1.5 y	- NG	3-6m	4m	-	6m 2y	1y	-	3m	-	3-6m	1.5y
5. Scientific consultations Groups or Individuals	-	-	-	3	-	-	+	-		-	2	1
5.2 Information	4	1	1	4	0	2	2	0	4	1	4	1
Tox. accidents	+	+	+	+	-	+	+	-	+	+	+	+
New pharmaceutic.	+	-	-	+	-	+	+	-	+	-	+	-
Food resid. res.	+	-	-	+	-	-	+	-	+	-	+	-
Analytical methd.	+	-	-	+	-	-	+	-	+	-	+	-

A = Accidents Ph = Pharmaceuticals If = Information provided by manufactur.
m = months y = year d = day NG = not given

APPENDIX 2

	SWITZERLAND	CAMEROON	PERU	INDONESIA	ITALY	CHILE	ARGENTINA	THAILAND	KENYA	SPAIN	UGANDA	BULGARIA
1. Official Toxic. Center	1	-	2	2	1+	3	1	1	4	3	2	2
2. Activity												
2.1 Acute toxicity	-	-	+	+	+	-	-	+	+	+	+	+
2.2 Toxicol. res.	4	0	4	4	4	4	3	2	4	1	2	4
. pharm. control	+	-	+	+	+	+	+	-	+	+	+	+
. pestic. ident.	+	-	+	+	+	+	+	+	+	-	+	+
. environ. polut.	+	-	+	+	+	+	-	-	+	-	-	+
. food residues	+	-	+	+	+	+	+	+	+	-	-	+
3. Tox. accidents	-	+	-	+	+	-	-	-	+		+	-
Reporting system		-	-	+A +Ph	-	-	+	-	-		+	-
4. Entity responsib. for pharmaceut.	+	-	+	+	+	+	+	-	+	+	+	+
legal recog.	+	-	+	+	+	+	+	-	+	+	+	+
pharmacological regist. proced.	+	-	-	+	-	-	-	-	+	-	+	-
CONTROLS: PHARMACEUTICALS												
.physical-chemic.	?	-	+	+	+	+	+	-	-	+	-	+
. pharmacological	?	-	+	-	+	+	-	-	-	-	-	+
. biological (7)	?	-	1/7	4/7	7/7	0-1/7	1/7	0/7	0/7	3/7	4/7	7/7
AVERAGE TIME FOR REGISTRATION Register	1y	-	45d	3m	6m 12m	3m	6m		-	4-6m	12m	1-2y
5. Scientific consultations Groups or Individuals	+	+	-	+	+	+	-	+3	3+	+2	+(7)	+1
5.2 Information	4	0	4	4	4	0	3	4	0	4	4	1
Tox. accidents	+	-	+	+	+	-	-	+	?	+	+	-
New pharmaceutic.	+	-	+	+	+	-	+	+	?	+	+	+
Food resid. res.	+	-	+	+	+	-	+	+	?	+	+	-
Analytical methd.	+	-	+	+	+	-	+	+	?	+	+	-

A = Accidents Ph = Pharmaceuticals If = Information provided by manufactur.
m = months y = year d = day NG = not given

THE IMPORTANCE, USE AND REGULATION OF HORMONE PRODUCTS FOR ANIMAL USE

Dr. Oscar Alejandro Bruni

THE IMPORTANCE, USE AND REGULATION OF HORMONE PRODUCTS FOR ANIMAL USE

Dr. Oscar Alejandro Bruni*

The issues which cause the greatest concern with regard to the use of anabolics in stockraising are those which have to do with their marketing and use. Once a drug has been authorized and the conditions for its sale have been established, it is the veterinarian who bears the main responsibility for its use. The veterinarian has a twofold responsibility, inasmuch as, on the one hand, he is concerned with the animals' health and, on the other hand, unlike the physician, he also engages in practices which are not directly related to disease and health. He also treats animals for other purposes, such as synchronizing the estrus and the stimulus in connection with the economics of raising stock for food. It is well known that stockraisers have a great economic interest in obtaining maximum profit from their production and they sometimes put pressure on veterinarians to prescribe drugs which may not always be strictly necessary. Whether for this reason or for others, in countries where stockraising is important, a high percentage of animals are exposed to chemical substances, at different periods of time, and often throughout a major part of their life span (as in the case of the coccidiostatics) or immediately preceding feeding or slaughtering. Anabolics are a special category within this spectrum of chemicals. It is important, however, to destroy the myth, which is prevalent in many countries, that all anabolics are harmful to human health. Thus, endogenous anabolics, or natural hormones, such as estradiol 17-B, progesterone and testosterone, when implanted in animals, entail no risk to human health.

Although some countries have enacted legislation aimed at controlling animal waste, and certain international organizations have considered this problem, the issue of testing for the presence of residues has not yet been settled scientifically nor accepted internationally. Thanks to the technological advances of recent years, it is now possible to detect traces of anabolics in meat and viscera down to one part per trillion. This amazing development throws new light on our knowledge of anabolics and enables us to make a distinction between those which may be harmful to human health and those which are harmless.

As regards the use of hormone products in the Latin American countries, these may be divided into three groups, as follows:

1. Countries which regulate the use of hormone products in livestock production.

2. Countries where the use of hormone products in stock production is absolutely forbidden, with no distinction being made as to type of drug or physiological action.

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3. Countries which have no legal norms on the question. In Argentina, decree 4224/61 prohibits, in general, the use of hormone compounds for fattening purposes. At present, legislation is being revised in order to allow for exceptions to be made in specific cases when a product is shown to be harmless and to pose no risk to human health.

The situation becomes even more complex due to the fact that the position a country takes on the use of hormone products is influenced not only by scientific criteria but also by aspects such as national and international trade policies.

In analyzing criteria for defining the use to be made of anabolics, it is therefore important to take into account, fundamentally, the ethical question, the probable effect the product will have on production and its possible implications for public health.

IMPORTANCE, USE AND REGULATION OF HORMONE PRODUCTS IN THE AMERICAN COUNTRIES

Iván Barreto Rodrigues

IMPORTANCE, USE AND REGULATION OF HORMONE PRODUCTS IN THE AMERICAN COUNTRIES

Iván Barreto Rodrigues*

First of all, we would like, in our own name and on behalf of the Ministry of Agriculture, to greet the participants in this meeting and, in particular, to congratulate IICA for organizing a gathering, of this magnitude and international importance, on the use and regulation of hormone products in animals.

In Brazil, the use of hormones or similar substances, whether natural or artificial, is governed by decisions No. 545 (July 5, 1961) and No. 02 (January 6, 1972) of the Minister of Agriculture, which prohibit, throughout the national territory, the use of these products for purposes of growth acceleration, weight increase and sexual neutralization of animals intended for slaughter. The use of these products is permitted only for therapeutic purposes, under prescription and guidance by a veterinarian.

The Secretariat for the Protection of Animal Health, through the Directorate for Veterinary Products (DIPROD), and under the terms of decree-law No. 467 of February 13, 1969 and decree No. 64.499 of May 14, 1969, is responsible for monitoring the manufacture of these substances and for taking such measures as may be necessary to enforce the existing legislation.

In the meantime, it is important to remember that the only product that was registered with the Secretariat for the Protection of Animal Health of the Ministry of Agriculture as a stimulant for growth promotion was Ralgro. The active ingredient of this product is zeranol, which is produced naturally through fungi living as parasites on maize, and its residues fall within limits considered safe.

Despite the fact this product had been registered for almost 20 years in countries with a tradition of cattle raising (United States, Mexico, Argentina, England, France, and Australia, among others) and that it had been registered in Brazil since 1976 without meat importers ever having even required a certificate of guarantee as to the presence of residues or their metabolites in Brazilian meat products, at present the license to manufacture it has expired and its manufacture, importation and marketing in Brazil is therefore prohibited.

On the other hand, considering the studies made by a working group of specialists in various scientific fields (Ministry of Health, federal universities, research and technical institutions, technical secretariats, LANARA and the Ministry of Agriculture), which suggested that registration should be permitted only for products containing natural steroids (estradiol-17-B, progesterone and testosterone) and taking into account the profit which cattle raisers obtain from the use of these substances -an average

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gain of 15% per carcass of treated animals- and in order to prevent the indiscriminate and illegal use of DES (diethylstilbestrol) and its derivatives, proven to be carcinogenic, teratogenic and mutagenic, the Minister signed decision No. 268/86, of June 11, 1986, which allows for the registration of products containing natural or artificial substances, hormonal or not, to be used to increase weight in cattle and for research and therapeutic purposes.

It should be stressed that the aforementioned decision prohibits the formulation and use of stilbene-based products for anabolic purposes and/or therapeutic uses and, furthermore, conditions the registration of such products to compliance with decree 64.499/69, as well as with the relevant technical standards.

It is important to stress that the technical standards accompanying the aforementioned ministerial decision require that the applicant submit a technical report indicating what statistically significant field work has been done in Brazil by competent institutions to prove the effectiveness of the product. In addition, applicants must present an assay certificate showing that there are no residues harmful to human health in meats and meat products at a sensitivity level of parts per trillion (ppt).

In view of the criticisms received from technical sectors, exporters and consumers concerning the aforementioned decision, and considering a communication received from the International Meat Trade Association (IMTA) regarding the EEC prohibition against the importation, beginning in 1988, of meat from countries which use hormones or anabolics to fatten cattle, the Minister issued decision No. 321, of July 8, 1976, creating a special commission to review the matter.

The commission received the advice of specialists from several countries of the world, represented by Drs. P-Shubik, President of the World Toxicology Society; Dr. André Rico, President of the French Toxicology Society; Dr. Emilio Gimeno, President of the International Office of Epizootics (OIE); Dr. Harry Mussman, Director of the Animal Health and Plant Protection Program of the Inter-American Institute for Cooperation on Agriculture (IICA); and Dr. G. E. Lamming, President of the EEC Scientific Committee on Anabolics and professor of animal physiology at the University of Nottingham, England. After intense debates carried out in Sao Paulo and Pedro-Leopoldo, Minas Gerais, the commission reached the conclusion that, when used correctly, the active ingredients in natural anabolics (estradiol, testosterone and progesterone) and the xenobiotics (zeranol and trenbolone) do not entail a risk to human health.

It should be noted that, in addition to the studies carried out by the international scientific community, the FAO/WHO Expert Committee on Food Additives (IEFCA), which some time ago had worked on an evaluation of the active ingredients zeranol and trenbolone, decided, at its twenty-seventh meeting, to accept, provisionally, the use of trenbolone acetate and zeranol as anabolics in the production of meat for human consumption, on the basis of the results of toxicological studies. However, it requested additional detailed studies on the nature and concentration of residues of these products and their metabolites. The final results of these studies will soon be published and distributed.

In view of the above, the Minister decided, through Decision No. 450 of November 27, 1986, to revoke ministerial Decision No. 268 of June 11, 1986.

In conclusion, we may say that despite the economic benefits obtained from the use of anabolics in meat cattle, the Ministry of Agriculture considers it wise to wait for the conclusive findings of the international scientific community on the risks which these biological residues in food may entail for human health.

At present, the National Biological Residue Monitoring Plan (PNCRB) of the Ministry of Agriculture is only monitoring, through LANARA, residues of DES -diethylstilbestrol. The residues in liver are studied systematically, using the same methodology adopted in the United States, i.e., gas chromatography. The samples to be analyzed are collected at establishments inspected by the Federal Inspection Service, at a rate of approximately 700 per year.

Each assay costs approximately US$150. This work is aimed at facilitating the work of mapping out the country to show the occurrence of residues at levels which represent a risk to human health (over 2.0 ppb).

At this sensitivity level (2.0 ppb), it is not possible to detect residues in tissues which can only be found at levels below 1.0 ppb. To do this, it will be necessary to use more sensitive methodologies, such as radio-immunoassay, which allow for the detection of residues at a sensitivity level of parts per trillion (ppt).

In Brazil, as in other developing countries, it is difficult to carry out laboratory control of hormone products because of the costs this involves. These controls, which are required by meat-importing countries, especially the United States, should be standardized.

It is extremely important that countries try to standardize their control programs, at least as regards the most fundamental aspects, such as:

a. Which hormones should be controlled, as a matter of priority?
b. Which are the best methodologies for analyzing residues?
c. What sampling criteria should be followed?
d. What levels of tolerance should be allowed for residues in edible tissues?
e. What minimum requirements should be established for firms to register the products, in terms of efficiency and consumer health safety?

As you will note, this issue, in addition to being of fundamental importance to countries taking part in the international meat market, raises some very controversial questions. Therefore, we cannot let this opportunity go by without expressing our concern to the international scientific community regarding the need to obtain technical and scientific support in order to improve our work in this area.

Finally, it is worth stressing that the livestock industry of the South American countries must not fail to recognize the importance of this technological alternative. As demonstrated in the developed countries, chemical castration used in stockraising to promote weight gain in animals to

be slaughtered, especially cattle, represents the most modern advance, as regards the increasing of productivity, taking into account the parameters of age, slaughtering and rate of utilization.

On the other hand, we are aware that the use of these hormone substances, under prescription and with the supervision of a veterinarian, at intervals guaranteed to be safe and compatible with a complete metabolism in the animal's organism, does not entail any risk to the health of the final consumer.

RECOMMENDATIONS BY THE REPRESENTATIVE OF THE REPUBLIC OF HAITI

Dr. Robert Joseph

RECOMMENDATIONS BY THE REPRESENTATIVE OF THE REPUBLIC OF HAITI

Dr. Robert Joseph

Research studies have showed that no residues of synthetic estrogens were found in meat or in viscera, when these substances were administered in feed in doses of 10 to 20 mg/animal/day and administration of the product was stopped 48 hours before slaughtering the animal.

In the case of intramuscular implants, residues were found in considerable quantities, and it was difficult to detect the implants during sanitary inspection at the slaughterhouse.

In the case of subcutaneous implants made according to the relevant instructions 90 days before the planned date of slaughter, high concentrations were found only in the pellets. These remained in the place where the implant had been made and were easily eliminated through careful inspection or systematic ablation of implant sites.

Concentration in other tissues was relatively low.

With regard to natural estrogens administered by subcutaneous implant between 50 to 70 days before the planned date of slaughter, these were metabolized and disappeared quickly from the animal's organism without leaving detectable traces.

Taking into account the effectiveness of anabolics in improving animal productivity, and considering that residues of certain types of hormones have caused pathological manifestations in consumers, it appears that a total prohibition of such products could give rise to a black market, which would entail even greater risks to public health. To avoid this situation, the following measures should be taken:

- application of the EEC directive should be postponed 5 years;
- anabolics which leave residues known to be toxic in meat should be completely eliminated from the market;
- the manufacture and distribution of these products should be regulated, and their use should be restricted exclusively to veterinarians;
- a program should be carried out to educate producers and activist consumers.

CONTROL OF VETERINARY MEDICATIONS AND THEIR RESIDUES IN MEXICO

Dr. Jorge L. Ymay Seemann

CONTROL OF VETERINARY MEDICATIONS AND THEIR RESIDUES IN MEXICO

Dr. Jorge L. Ymay Seemann

It is well known that the demand for foodstuffs to meet the nutritional requirements of the population is increasing daily. Animal proteins play a fundamental role in providing a well-rounded diet.

Thus, in order to preserve the health of animal species used for food production, certain compounds have been developed for use in the prevention and treatment of diseases. The benefits of such products may be seen in the reduction in the number of sick animals and the resulting increase in productivity.

Unfortunately, some of these medications leave residues which subsequently go through the food chain and have a negative impact on health.

Some of the aforementioned compounds may be considered non-renewable resources. It is therefore important to set up adequate systems to control their use, as well as mechanisms for monitoring their presence in animal tissues intended for human consumption.

In Mexico, chemical and pharmaceutical products for use with animals are registered and controlled under the provisions of the Plant and Animal Health Act, which provides that any compound to be used in veterinary medicine must meet certain requirements established in the Regulations for the Control of Chemical, Pharmaceutical, Biological and Food Products and Equipment and Services for Animals. These requirements have to do with safety and effectiveness. These regulations apply to the processing, marketing, importation and exportation of the aforementioned products.

In addition, from 1984 onwards, the Program for the Control of Toxic and Biological Residues and Pollutants was implemented. This program is carried out through units where livestock are produced and processed under federal inspection; in these units, slaughtering is carried out under the best possible hygienic and sanitary conditions. To date, there are 54 federal-inspection type establishments throughout the country.

The objectives of the Program are to protect public health by guaranteeing that meat products and by-products are free of potentially harmful substances. The Program also strongly supports producers, in order that they may offer products of the highest quality on the local and external markets, since the Program's guidelines are based on internationally accepted and recognized inspection systems, including a residue analysis laboratory which has been operating since the program began.

At present, assays are made to detect residues of pest killers, veterinary medications and environmental and industrial pollutants, through analytical methods and techniques recommended by governmental agencies of certain countries or by international agencies. This enables us to obtain results that are accepted internationally.

As science and technology have advanced, it has become possible to discover the adverse side-effects of compounds used in veterinary medicine. Thus, ceilings and/or tolerance levels have been established for edible tissues which have caused us to increase the lists of compounds which must be submitted for residue analysis; in some cases, it has been necessary to take drastic measures, such as prohibiting the use of certain products.

As regards the residue monitoring program in our country, tolerance limits are set, in some cases, in accordance with the requirements of importing countries and, in others, on the basis of recommendations made by international agencies such as FAO/WHO.

These monitoring systems and mechanisms enable us to use effective and safe products in the treatment and prevention of animal diseases, without other problems arising later on.

We are sure that no country would want to use substances whose temporary benefits would subsequently be obscured by negative side effects.

With this in mind, we would like to refer specifically to the group of compounds known as anabolics or anabolic agents of a hormonal nature.

We have mentioned the increase in the demand for foodstuffs and the need to optimize productivity by preserving the health of the food-producing animal species through the use of safe compounds. We have also mentioned the increasingly important and necessary international trade in this type of products and the efforts being made by different countries to comply with existing standards in this regard.

The use of hormonal anabolics, mainly implants, provides, at least in our country, a way to increase productivity, inasmuch as it increases the rate of growth of animals, as well as the efficiency with which they convert food into meat. This management practice helps considerably in dealing with factors which have a negative effect on the parameters of production mentioned above.

It is estimated that in our country, the average response per dose of implanted anabolics is 10 kg; translated in terms of the treatment index, this is approximately 35.000.000 extra kg produced annually. From the standpoint of productivity, this is quite significant.

In economic terms, the cost per extra kg of weight increase obtained from the use of implants is US$100, while the estimated cost per kg of weight increase without the use of implants is approximately US$4.400.

Commercially, the adoption of suitable management practices, including the use of compounds such as the anabolics, represents a greater profit margin for producers, since production costs decrease, making sales prices competitive and allowing for an increase in per capita consumption of meat.

Many scientific tests have been made on the effects of anabolics. In our opinion, most of them provide sound evidence that anabolics do not have a toxic effect and do not cause adverse side effects if applied carefully.

In our opinion, the use of anabolics whose active ingredients are endogenous hormones such as estradiol, progesterone and testosterone, and xenobiotics whose formulas include trenbolone acetate and zeranol, do not present problems of potential toxicity provided they are used correctly and provided the necessary time is allowed for elimination, in order to prevent the accumulation of residues. Their use, on the other hand, can contribute significantly to increasing productivity, as has been shown in many countries. Finally, the EEC prohibition against the use of such compounds and the restrictions on the sale of animals and animal products in countries where they are used would create serious non-tariff trade barriers which would have equally serious economic implications.

REMARKS ON THE REGULATION OF ANABOLIC AGENTS IN THE UNITED STATES

Marvin A. Norcross, VMD, PhD
Martha Arcos, DSc, JD
Theodore M. Farber, PhD

REMARKS ON THE REGULATION OF ANABOLIC AGENTS IN THE UNITED STATES

Marvin A. Norcross, VMD, PHD**
Martha Arcos, DSc, JD*
Theodore M. Farber, PhD*

Recently, the Council of the European Economic Community (Directive 85/649) decided to ban within member states the use of all anabolic agents for growth promotion. This decision has been preceded by and has led to numerous questions and discussions regarding the safety of such products for various uses. The question generally asked is:

Does the use of estradiol, progesterone, testosterone, zeranol or trenbolone for growth promotion in food-producing animals have any harmful effect on consumers of meat from treated animals?

From the perspective of the United States, the answer to that question is no when these compounds are used according to label directions. I would like to elaborate on that answer from a human food safety point of view. I will limit my discussion to the three endogenous steroids and two synthetic anabolic agents because of their widespread use and their public health significance.

Historically, as early as 1932 it was shown that there was a causal association between the endogenous sex steroids and the neoplastic process (1). Since then a significant amount of experimental data has accumulated indicating that estrogen administration is routinely followed by reproducible tumors in five species of animals and in eight organ sites. These include tumors of the mammary gland, cervix, endometrium, ovary, pituitary, testicle, kidney and bone marrow in either mice, rats, rabbits, hamsters, or dogs (2-4).

Thus, sex steroids have been considered for several years either to be carcinogens or suspect carcinogens and until 1962, our laws (the Delaney Clause) prohibited the approval of substances found to be carcinogenic in the food supply of either man or animals. However, the United States Congress modified the law (the Anti-Cancer Delaney Clause) in 1962 and permitted the use of carcinogenic compounds as animal feed additives and veterinary drugs, provided that, "no residue of the additive will be found by methods... approved by the Secretary... in any edible portion of such animal after slaughter or in any food yielded by or derived from the living animal". This amendment to the Delaney Clause is called the Diethylstilbestrol (DES) Proviso.

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** Paper presented by Marvin A. Norcross, VMD, PhD.

Until recently we have defined "no residue" as a gravimetric zero residue of 2 parts per billion (ppb) which was the lower level of sensitivity of the approved assay for DES, the most potent carcinogen used at that time in food-producing animals. However, evidence was received by FDA that levels lower than 2 ppb of DES were in the edible tissue of food-producing animals and DES was banned in the United States in 1979. Today, there is no legitimate food animal use for DES.

Also, in 1979, FDA published a Notice of Opportunity for Hearing on a proposed withdrawal of the approvals of several other animal drugs. These drugs contained estradiol, progesterone and testosterone or their esters which are converted to the free hormones following administration to the animals. This action was taken on the basis that the products were not shown to be safe since reliable information on residues did not exist at that time.

However, since then our position on the use of human endogenous steroidal hormones in food-producing animals and the data required for their approval have undergone significant changes. Also, the drugs' sponsors have provided additional residue information on their products.

In the last few years there has been a developing interpretation of the "DES Proviso" to the Delaney Clause. This new interpretation permits a more rational use of information regarding the mechanism of action of steroidal hormones in carcinogenesis - both in the interpretation of "no residue" and in the requirement for a "method of analysis" to enforce compliance.

We now make a distinction between endogenous steroids and synthetic compounds with gonadal activity and we rely on the known promotional characteristics of endogenous steroids in the evaluation of the risk from additional levels found in edible tissue.

Also, new and more sensitive methods of steroid analysis in animal tissues have demonstrated that estradiol concentrations from presently regulated implants are below the 10 pg/g (ppt) level. The new assay procedures have shown that the levels of endogenous sex hormones that humans will be exposed to through ingestion of tissue from treated animals are biologically insignificant compared to the amounts of sex steroids produced by human beings via de novo synthesis or compared to the amounts of endogenous sex steroids found in foods considered to be traditionally safe.

The Promotional Activity of Sex Steroids in Carcinogenesis

We believe that the accumulated evidence from the scientific literature demonstrates that steroid hormones are not initiating carcinogens but act as promoters once the carcinogenic process has been initiated by chemical, physical or viral agents. Promoting agents and co-carcinogens are not carcinogenic by themselves but potentiate the effect of a primary carcinogen. Their action appears to be reversible and thresholdable in nature (8-10).

Convincing evidence exists that tumors caused by the sex steroid develop only in endocrine target tissues, and it is reasonable to believe that the sex steroids cause tumor formation through an epigenetic mechanism associated with

the molecular biology of endocrine activity, i.e., steroid-hormone receptor interaction. This steroid-hormone receptor interaction, which is central to endocrine activity, is a thresholdable, dose-related, reversible phenomenon (11-13).

The Biological Insignificance of the Levels of Endogenous Steroids Found in Edible Tissue

The second scientific reason associated with our change of viewpoint regarding the regulation of sex steroids is the impact of new analytical methodology. During this period radioimmunoassay (RIA) methods were developed which provided reliable evidence that the increase in the levels of endogenous hormones in the edible tissue of implant-treated cattle is small and biologically insignificant when compared to the human production rates of these hormones.

Estradiol-17-B levels in the muscle, liver, kidney and fat of implanted steers averaged from 5-20 pg/g with levels in fat approximately three times greater than muscle. This level in treated steers is approximately 2-3 times the normal values in control animals. The levels of progesterone and testosterone in the muscle of treated steers were 120 and 100 pg/g, respectively. The levels of estradiol in the tissue of treated animals are extremely low compared with the human de novo synthesis rate of this hormone as seen in Table 1.

Table 1

Estradiol Production Rates in Humans (14-18)

Women	ug/24 hours
Follicular phase	445
Luteal phase	270
Late Pregnancy	37.800
Postmenopausal	8
Prepubertal girls	31
Men	
Adult	48
Prepubertal boys	6

A 500 g portion of estradiol treated meat contains an amount of estradiol that is 15.000 times less than the average daily production rate in men and several million times less than the production rate in pregnant women. Even in the most sensitive human group, prepubertal boys, the additional estradiol derived from the ingestion of treated meat is more than a thousand times less than the daily production rate in those subjects.

Estrogen plasma levels and production rates can vary more than 3-fold with

substantial daily fluctuation. With this continuous normal background variation of estrogens in humans, it is difficult to conceive of a hazard posed by ingestion of implant treated beef where daily added estrogen is not only negligible when compared to the daily production rate but also negligible compared to its fluctuations.

A similar situation applies for progesterone and testosterone although the absolute levels are higher as can be seen in Tables 2 and 3.

Table 2

Progesterone Production Rates in Humans (14-18)

Women	mg/24 hours
Follicular phase	0.418
Luteal phase	19.480
Late pregnancy	94.000
Postmenopausal	0.326
Prepubertal girls	0.253
Men	
Adult	0.416
Prepubertal boys	0.150

Table 3

Testosterone Production Rates in Humans (14-19)

Women	mg/24 hours
Non-pregnant	0.24
Late pregnancy	0.32
Postmenopausal	0.14
Prepubertal girls	0.032
Men	
Adult	6.48
Prepubertal boys	0.065

The hormonal residues found in the edible tissue of steers and heifers treated with an implant are also quite small compared to other sources of hormones that are a part of the daily human diet. See Table 4.

Table 4

Some Food Sources Containing Sex Hormones

	Progesterone	Estradiol
Meat		
non-pregnant heifer		4.2 pg/g
pregnant heifer		53.0 pg/g
Milk		
non-pregnant cow	9.5 ng/ml	37 pg/ml
pregnant cow		67 pg/ml
human milk		25 pg/ml
Butter	133.0 ng/ml	82 pg/g
Wheat Germ		40 ng/g*
Soil bean oil		20.000 ng/g*

* Estradiol Equivalent

The Safety Evaluation of Endogenous Hormones

As described in our written Animal Drug Safety Policy, we now follow a well-defined process for the determination of the potential carcinogenicity of drug residues and the establishment of a "virtually safe level" of exposure by statistically extrapolating data obtained from chronic bioassay studies. This procedure is appropriate when the carcinogen is genotoxic or when information regarding the mechanism of carcinogenic action is not adequate. However, the agency believes that the endogenous sex steroids, which are not genotoxic agents, act as promoters via their hormonal properties. This explains their ability to cause cellular proliferation in endocrine sensitive tissues.

Safe conditions of use of estradiol, progesterone and testosterone can be established without the need for additional animal studies. A safe level of the natural endogenous steroid can be established by utilizing information in the literature on the de novo production rates of these steroids in the human being as well as information on the kinetics of steroid-receptor interactions. No increased physiologic effect would be expected in individuals chronically ingesting tissues containing 1% or less of the amount of sex steroids produced through daily de novo synthesis in the most sensitive segment of the population. A 1% increment in the cellular levels of these steroids will not activate enough receptors to bring about an increase in hormonal activity and

cell proliferation. If 1% of the daily production rate of the three principal endogenous sex steroids is taken in prepubertal boys or girls, safe daily exposure levels for the entire population can be obtained. These amounts as seen in Table 5 represent the incremental increase permitted above the amount naturally present in a 500 g portion of edible tissue from the treated animal.

Table 5

	Daily Production Rate	Incremental Exposure Permitted
Estradiol	6 ug	0.06 ug
Progesterone	150 ug	1.5 ug
Testosterone	32 ug	0.3 ug

If higher incremental exposures are anticipated from the use of endogenous anabolic agents, these compounds should be subjected to the same series of tests that are required for synthetic anabolic agents.

The Safety Evaluation of Synthetic Anabolic Agents

The problems associated with the establishment of a safe level of exposure to synthetic anabolic agents are more complicated than those associated with natural endogenous sex steroids.

Unlike the endogenous anabolics there is no daily *de novo* synthesis of these synthetic agents which can serve as a convenient denominator to be used in the risk analysis of the agent. In addition, information on the metabolic fate and persistence of metabolites will not be generally available. Therefore, we require toxicological testing and it is necessary to demonstrate that the residue depletes below the concentration determined to be safe.

Further, it is mandatory to demonstrate that the synthetic hormonal agent is not genotoxic. This can be accomplished through the application of a battery of *in vitro* mutagenicity tests. If these tests prove negative for genotoxicity, then animal testing would follow.

Chronic bioassays for oncogenicity would be required in two rodent species if genetic toxicity tests are positive, or if data from the other bioassays indicate a preneoplastic lesion in other than an endocrine sensitive tissue.

In the absence of a carcinogenic response, or if tumors are observed only in endocrine sensitive tissues, the acceptable daily intake (ADI) from the results of the most sensitive study in the most sensitive species can be calculated. The ADI is the highest dose from that study showing a no-observed-effect divided by the appropriate safety factor. The required toxicity studies include a determination of a hormonal no-observed-effect level (HNOEL) in a non-human primate species.

It is our belief that the approach described here for the regulation of anabolic drugs is rational, logical and scientifically defensible. This approach embraces the proper level of concern for public health while at the same time recognizes the practical necessity of using anabolics in the rearing of livestock and poultry.

In summary, we permit (1) without additional data, an added amount of each endogenous sex steroid in animal-derived human food that is equal to one percent of its de novo production in the most sensitive segment of the human population; and (2) synthetic anabolic agents, if they are shown to be non-genotoxic, to be regulated on the basis of a hormonal no-effect level demonstrated in a non-human primate.

There are in the United States several currently approved hormonally active products, e.g.,

Estradiol Implants

Following treatment of the animal, the added estradiol is less than the safe level of 120 ppt in edible tissues; therefore, this drug was approved without a tolerance and without requiring a regulatory method for assaying tissues.

Testosterone propionate with estradiol benzoate

This combination meets the criteria of our current requirements as described above, i.e., tissue estradiol and testosterone levels are less than 120 ppt and 0.6 ppb respectively.

Progesterone with estradiol benzoate

This combination meets the criteria of our current requirements as described above, i.e., tissue estradiol and progesterone levels are less than 120 ppt and 3 ppb respectively.

Zeranol

Zeranol, not an endogenous hormone, is approved with a 65 day withholding period and a regulatory assay sensitive to 20 ppb. Although data continue to be generated and reviewed on this compound, there are no plans by the United States Food and Drug Administration to take regulatory steps to curtail the use of zeranol.

Trenbolone

Trenbolone is not yet approved in the United States; however, after thorough review of the data we have concluded that trenbolone, when approved and used according to label directions, will meet our human food safety requirements for synthetic hormones.

Although the European Community Directive 85/649 is a major development in the food animal industry, it will have no effects on the regulation of anabolic agents in the United States. Under our law, if a product is shown to be safe and effective in the United States, it must be approved. Similarly, the product can only be banned if it is no longer shown to be safe or effective. We have no restrictions on the number or types of drugs on the market as there are in some countries. For approval, the product need only to be shown to be safe and effective as defined in our laws and regulations.

In conclusion, we have determined that the anabolic agents that I mentioned above can be safely used in food-producing animals. Further, the vast majority of scientists addressing this issue arrive at the same conclusion following a thorough review of the scientific information currently available.

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USE AND REGULATION OF HORMONE PRODUCTS FOR ANIMALS IN URUGUAY

Dr. Roberto Caffarena

USE AND REGULATION OF HORMONE PRODUCTS FOR ANIMALS IN URUGUAY

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In 1962, by a decree dated April 5, the Oriental Republic of Uruguay prohibited the manufacture, import, sale and use of preparations containing natural or synthetic estrogens, regardless of the method of administration, which are intended for use in the sexual neutralization or fattening of animals whose meat or by-products are to be used for human consumption; the only exception is the importation, manufacture, sale and use of estrogens for therapeutic purposes.

To date, the Bureau of Animal Health has registered the following:

- Anabolic hormone products for use in animals to be slaughtered, as shown in Table 1.
- Hormone products for therapeutic use, as shown in Table 2.
- Products which interfere with normal physiological behaviour, as noted in Table 3.

The data provided in these tables show how limited is the use of such products in Uruguay.

Considering that the use of the aforementioned compounds may leave residues in the meat of treated animals, the National Program on Biological Residues, begun in 1978 with a study of pest killers, undertook also to do research on residues of androgenic, estrogenic and tyreostatic agents. Thus, in 1983, work was begun on a study aimed at detecting traces of D.E.S. in samples of beef kidneys extracted by veterinary inspectors belonging to the staff of the Animal Industry Bureau from 15 slaughterhouses in different parts of the country. The National Program on Biological Residues is doing research on stilbene with the executive support of the Dr. Miguel C. Rubino Center for Veterinary Research, which is using the gas chromatography method to detect traces of this substances.

This technique was approved and developed by this laboratory, which is constantly adapting its analytical methodology to comply with international standards and standards set by meat-buying countries, in order to further refine its work so as to detect residues at increasingly lower levels.

The Animal Industry Bureau co-ordinates this program, as well as the taking of samples, their transmittal to the laboratory, the design of sampling plans, handling of results and filing of data.

So far, samples have been taken from male and female cattle as follows: kidney tissue is extracted as a sample unit (1 kidney) from an animal in the troop chosen at random for sampling purposes. This sampling is done with homogeneous troops, so that all animals come from the same producer, in order to be certain of their origin.

Table 4 provides information on the work done up to September 1986.

It would be noted that, for experimental purposes, seven samples of prostates and Bartholin's glands were taken by the cryostatic method, in order to observe histopathological changes that might be caused by the products discussed in this paper.

From the above discussion, it may be seen that the use of hormone products, whether for anabolic or therapeutic purposes, is negligible in Uruguay.

TABLE 1

USE OF ANABOLIC HORMONES IN ANIMALS TO BE SLAUGHTERED

Active ingredient	Brand name	Year of registration	Pharmaceutical application	Species on which used	Clinical use	Quantity of raw material imported	Quantity of finished product imported
Zeranol	Ralgro	1972	Implant	Cattle and sheep	Anabolic	0	1/1/84 to 9/30/86 0

TABLE 2

HORMONE PRODUCTS FOR THERAPEUTIC USE

Active ingredient	Brand name	Year of registration	Pharmaceutical application	Species on which used	Clinical use	Quantity of raw material imported	Quantity of finished product imported
DES	Estilbestrol 0.5%	1972	Injection	Females any species.	Therapeutic - gestation and delivery.	1985 - 30 kg 1986 - 5 kg	0
BOLDENONE	Equipoise	1977	Injection	Horses.	Delayed-action anabolic. Used for weakened horses. Not to be administered to horses to be used for meat. Not to be administered to mares.	0	No imports since 1984.
METHYL-HYDROXI-ANDROSTENEDIONE	Dianabol	1978	Injection	Cattle, swine, horses, dogs, cats.	Anabolic. Situations of stress and fatigue.	0	No imports since 1984.
NANDROLONE	Laurabolin	1985	Injection	Dogs, cats, cattle, sheep, horses, swine.	Anabolic. Situations of fatigue.	0	1986 - 50 jars x 10 ml each.

TABLE 3

PRODUCTS WHICH INTERFERE WITH NORMAL PHYSIOLOGICAL BEHAVIOR

Active ingredient	Brand name	Year of registration	Pharmaceutical application	Species on which used	Clinical use	Quantity of raw material imported	Quantity of finished product imported
LUPOSTRIOL	Prosolvin	1983	Injection	Cows, mares, sows, female sheep.	Controls reproductive function in essentially normal animals. Luteolytic agent.	0	1986* 25 jars x 20 ml. Only import.
FENPROSTALEN	Syncrocept-8	1981	Injection	Cows.	Controls reproductive function in essentially normal animals. Luteolytic agent.	0	1986* 750 jars x 20 ml. Only import.
TRIAPOST	Iliren	1985	Injection	Cows, mares, sows, female sheep.	Controls reproductive function in essentially normal animals. Luteolytic agent.	0	1986* 150 jars x 50 ml. Only import.
TESTOSTERONE	Testosterona Dispert	1971	Injection	Cattle, sheep, horses, swine, dogs, cats.	Androgenic therapy.	1983 - 1 kg 1985 - 4 kg 1986 - 6 kg	0

* From date of registration to September 30, 1986, only import.

TABLE 4

D.E.S. RESEARCH BY NATIONAL PROGRAM ON BIOLOGICAL RESIDUES

Year	No. of sample units assayed	Total No. animals in sample	Cows	Steers	Young animals	Bulls	Samples in violation
1983	24	689	177	432	80	-	0
1984	56	2361	349	2012	-	-	0
1985	105	3749	41	3598	57	53	0
1986	36	1194	152	993	-	49	0
TOTAL TO SEPT. 1986	221	7993	719	7035	137	102	0

Analytical method - Gas-phase chromatography.

CURRENT SITUATION WITH REGARD TO THE MARKETING AND USE OF ANABOLICS IN VENEZUELA

Dr. Evencio Arvelo

CURRENT SITUATION WITH REGARD TO THE MARKETING AND USE OF ANABOLICS IN VENEZUELA

Dr. Evencio Arvelo

Venezuela, with a population of 15 million, consumes approximately 1.600.000 cattle. Of these, 1.100.000 are slaughtered in industrial plants, and 500.000 are slaughtered in slaughterhouses controlled by the municipal governments or semiclandestine locations which are usually not suited for the purpose. In addition, 300.000 are smuggled out to Colombia.

The use of anabolics has increased dramatically; it may be said, without exaggeration, that among the first group of cattle processed, 70% of those classified as being for direct consumption were under treatment. Of the remaining 500.000, 15% had been under the effect of anabolics during handling.

The following patented anabolics are registered for sale and trading on the national market:

INJECTABLE DRUGS FOR THERAPEUTIC USE

NAME	DISTRIBUTING LABORATORY	DRUG
Dianabol	CIBA = GEIGY	Withdrawn from the market by the company
Equipoise	SQUIBB	Undecilinato de baldenona

IMPLANTS FOR USE IN ANIMAL PRODUCTION

Ralgro	IMC - Pfizer	Zeranol
Synovex S.	Syntex Lab - WIMCO	Progesterone-Estradiol
Synovex H.	Syntex Lab - WIMCO	Testosterone-Estradiol
Implix BM	Roussel-Venezuela	Progesterone-Estradiol
Implix BF	Roussel-Venezuela	Testosterone-Estradiol
Anavex - Males	Virbae	Progesterone-Estradiol
Anavex - Females	Virbae	Testosterone-Estradiol
Compuldose	Lyly-Elanco	Estradiol in slow-release resins

REGISTRATION IN PROCESS

All trenbolone-based products.

It should be noted that there is a significant amount of smuggling, or clandestine entry, of the above brands as well as of others, from Colombia and the United States.

The prices of the drugs sold and produced in Venezuela were compatible with the cost structure underlying the fattening of cattle in Venezuela. To a certain degree, this allowed for an increase in the use of these products, and the lower prices of smuggled medications encouraged their abuse. Today, this practice not only persists but is becoming more serious, as it has been discovered that diethylstilbestrol (DES) has been smuggled in.

Moreover, as in any economic issue where supply and demand are at work, there is a psychological factor. In this case, there has been excessive optimism regarding the weight gains of treated animals.

The magic attraction of these drugs has also influenced cattle raisers and even university-trained professionals and veterinarians; this further encourages their consumption and use. There is an almost mythical belief that the application of three or more small pills on the back of the ear will bring an "almost certain" increase in the animal's weight. The situation is similar to that of the therapeutic use of drugs among humans, which leads to abuse. In this case, the idea of overdosing, or mixing doses, is promoted, usually with no basis in theory or practice, but with high expectations, sometimes far beyond any reasonable hope.

Trends in the Marketing and Use of Anabolics in the Near Future

The drop in the value of the bolivar with respect to the dollar caused a sharp increase in the price per dose, and this could create a high public health risk in Venezuela. Let us take a look at the projections of this economic phenomenon, even though it may not seem to have any direct bearing on the problem of the intensive use of anabolics.

1. Stock growers have the habit of using anabolics as a tool for improving efficiency in production.

2. Although there are no in-depth studies aimed at determining the biological and economic effects of anabolics used in veterinary medicine and animal production in the tropics, it appears that their use, within reasonable limits, is beneficial. It should be noted that reports of such benefits are entirely subjective or are based on very partial and local studies; in some cases, these studies are controlled by the drug distributors.

3. With the devaluation of the bolivar, imported products have risen in price. This raises the cost of meat production, due to the use of anabolics, regardless of the source of supply. Thus, the sale price of legal merchandise rises at each stage in the marketing process.

4. Prices of drugs brought in from the United States on the black market have also increased considerably, although not as much as those of legally imported ones. However, this also discourages buyers, who usually make their purchases directly from large and small distributors, especially in Florida and Texas.

   Material brought in from Latin American countries comes mainly from Colombia.

   It used to be that the difference in exchange rates encouraged smuggling from Colombia to Venezuela; now, however, with the increase in the cost per dose, Venezuelan stock growers have no favorable alternative to turn to, except in the case of products containing diethylstilbestrol, which has not increased in price.

   In the past, stock growers had also encountered problems with quality control of smuggled goods, since their very origin precluded claims against the seller. While this might have been tolerated in the past, it is not likely to happen today.

   In conclusion, the use of anabolics in animal production for the purpose of increasing the weight of steers will decline, regardless of the source of supply.

   In Latin America, however, there are networks of smugglers specializing in the sale of prohibited pharmaceuticals. The most notorious are those handling stimulants, depressives and hallucinogenic drugs used secretly and illegally by humans.

   But there are other, apparently better established organizations, which play with the health of the Latin American people. These organizations take advantage of our system's vulnerability to corruption to do their work.

   One of these handles the clandestine marketing or diethylstilbestrol (DES), mentioned above.

5. The possibility of purchasing DES at a low price is a reality. The cost is the same, or lower, than the price previously paid for internationally accepted patented anabolics. This is very tempting to stock growers in these times of economic crisis.

   Moreover, the promoters of the illegal drug speak about minor problems in connection with the toxicology of DES. They never mention its carcinogenic action or its effect on secondary sexual characteristics. There is no question that DES has real, strong and proven anabolic activity, and this is a further incentive to its clandestine use.

6. In countries with a strong tradition and principles as regards both stock-raising and health, the authorities are obliged to act without mercy against the use of DES in animal production. Despite this, there are still many cases of beef carcasses which show traces of DES. In Venezuela, as we have noted, the problem of human consumption of DES via the consumption of meat could be very serious.

7. Any change in the system of distribution, marketing and direct use of anabolics must provide certain guarantees, as follows:

   a. The system for distributing and marketing of anabolics must ensure access by all producers, at fair prices. Marketing chains must be adjusted so as to reduce the number of middlemen involved and the amounts spent on advertising and other promotional activities, which increase prices.

   b. The proper use of this type of medication should be ensured, so as to allow for increased production and yield, both for the benefit of stock growers and to ensure safety for consumers of meat products. It must be noted, in this regard, that the healthiest and best-fed animals will benefit the most from the administration of anabolics.

   c. For the purposes mentioned in the two preceding paragraphs, the national government has implemented a system for controlling certain high-risk products which, with some variations, might be applied in the case of anabolics.

   d. The legal basis for such a system would be:

      - The Plant and Animal Health Protection Act, approved by the National Congress on June 18, 1942.

      - The decree on the National Registry of Brands and Signs, approved by the Governing Junta on June 7, 1952, and the regulations covering this decree, issued by decree on May 4, 1976.

      - The decree on Animal Health Regulations, approved by the Council of Ministers on July 22, 1951.

      - Resolution No. 80 of the Ministry of Agriculture and Livestock, concerning veterinary medical certificates, dated February 18, 1964.

      - The Presidential resolution on the importing of animals, dated February 5, 1968.

      - The resolution of the Ministry of Agriculture and Livestock, on the importation of animal products and by-products, dated November 4, 1964.

      - Decree No. 1659, on importation of animals from Colombia, approved by the Governing Junta on April 21, 1958.

      - The Presidential decree on partial regulations to laws on fertilizers and other agents potentially beneficial to plants, animals, soils or water, and on health and animal protection, dated May 13, 1975.

- Resolution No. 252 of the Ministry of Agriculture and Livestock, on controls exercised by the General Sectoral Office for Livestock Development of the Ministry of Agriculture and Livestock and the National Agricultural Research Fund, providing for the monitoring of the manufacture, marketing and application of strain 19 vaccine and any other vaccine to be used against brucellosis.

e. It has been scientifically demonstrated that these anabolic drugs potentially have the following properties:

- oncogenic chemical activity;
- cumulative effect; and
- sexual-hormone-type activity.

Because of the implications of the properties mentioned under the oncogenic chemical activity and the cumulative effect, anabolics entail a risk to human and animal health similar to that of any etiological agent, such as bacteria, fungi and parasites. Hence, it is appropriate that they should be legally regulated, as mentioned above.

f. Special attention should be given to the law and regulations pertaining to the exercise of veterinary medicine and membership of the relevant college. These stipulate the requirements which must be met by veterinary doctors and how they are to exercise their profession.

It should be noted that only veterinary doctors are allowed to engage in therapeutic practices. Thus, the administration of medication, in this case anabolic drugs, is strictly limited to veterinary doctors, who are solely responsible for the prescription, application and after-effects of such drugs. The system could be based on the following concepts:

- The Ministry of Agriculture and Livestock would monitor the manufacture, marketing and application of anabolic agents to be used in veterinary medicine and animal production.

- The laboratories and producers and/or national distributors would have to comply with specific regulations as regards registry and authorization for the production and marketing of zootherapeutics and other agents designed to benefit animals.

  When a product is authorized, a copy of the manufacturing protocol and/or quality control record would have to be sent to the Ministry of Agriculture and Livestock. This record must specify lot number, description of container, volume in container, composition, date of manufacture, expiration date, proof of sterility, vacuum and any other information deemed necessary.

- The Ministry would keep a certain number of samples for purposes of quality control and would set certain others aside. All necessary papers must be filled out.

- The Ministry would specify the physical, chemical and biological characteristics of the product once it is ready to be applied.

- The laboratory or its representative would sell the products to the College of Veterinary Doctors. A copy of this transaction, specifying the characteristics of the product sold, would be sent to the Ministry of Agriculture and Livestock.

- The College of Veterinary Doctors would distribute among veterinarians duly registered and licensed by the Office for Livestock Development of the Ministry of Agriculture and Livestock a list and description of the material sold and the animals for which it is intended.

- Any veterinarian who administers anabolics to animals meant to be used for meat would be required to fill out a certificate specifying the name of the product, as well as its composition and dosage. The certificate should also identify each animal, the part of the body to which the medication was applied, and the place and date on which this was done. He shall also clearly mark the animal.

- The College of Veterinary Doctors would be required to keep a record, in triplicate, of all the necessary documentation on movements of anabolic drugs, indicating the number, lot, dates of manufacture and expiration, and persons to whom they were sold, as well as any other data considered necessary. This documentation would be distributed as follows: the original to the Office of Livestock Development, the second copy to the Regional Chief for Livestock, and the third copy for the file of the College of Veterinary Doctors.

- Anabolics should be considered part of a special procedure; they should be seen as a technological and medical package. When the anabolic is implanted, the following procedure should be followed:

  1) Physical and clinical examination of the animal.

  2) Elimination of ectoparasites.

  3) Treatment of endoparasites.

  4) Indication as to treatment to be given for other etiologies and feeding required to guarantee the success of the procedure.

  5) Supervision of vaccinations (if necessary).

  6) Indication and administration of the anabolic or a combination of same.

  7) Weighing of the animals.

  8) Identification with regard to requirement mentioned in 7).

  9) Issuance of relevant certificate.

The medications mentioned in 2), 3) and 4) would be supplied by the veterinarian. The cost would be added to the fee for the professional work done, which would be governed by a single national rate, to be agreed upon by the College and the Ministry of Agriculture and Livestock; this fee must be reviewed at least once a year.

- Through the Paulo Llamozas Institute for Professional Improvement, courses would be given periodically on the problem of anabolics in veterinary medicine and animal production. The Ministry of Agriculture and Livestock would require the relevant credentials in order to carry a record of those interested in carrying out the procedures mentioned above.

- In conclusion, the use of anabolic implants in veterinary practice must be considered a typical procedure in veterinary medicine which must be planned, carried out, and evaluated solely by veterinary doctors, who would be solely responsible for the outcome of said practice.

This would ensure the objectives which we propose, as follows:

Objectives of a New System for the Marketing and Use of Anabolic Agents in Animal Production and Veterinary Medicine

The goals of such a system are the following:

1. To protect the health of consumers of beef products, especially by avoiding excessive use of the drug or excessive residues in meat. In addition, to prevent the use of diethylstilbestrol and other prohibited pharmaceuticals, for the same reason.

2. To obtain a true and large-scale picture of the possible effect of anabolics on meat production in the country, taking into account the many obstacles encountered because of its being in the tropics.

3. To guarantee optimum health and feeding of animals to be treated, in order to ensure a significant increase.

4. To ensure proper procedures in the application of anabolics under the expert direction of a competent veterinarian.

5. To develop the exercise of veterinary medicine as a private profession, as it should be. Also, this ensures that one person, who is duly identified, will be responsible for any possible after-effects.

FINAL NOTE

We feel it is important to publicize these ideas among the different trade associations, in order to make them realize that economic issues are not the only ones involved, and that this plan can make a significant contribution to the public health of the Venezuelan people, and can help prepare our productive and industrial system for exporting.

FECHA DE DEVOLUCION			

Autor

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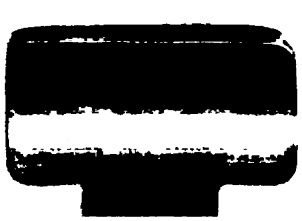
Fecha Devolución	Nombre del solicitante



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