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Agenda Item 4

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

EXECUTIVE COMMITTEE OF THE CODEX ALIMENTARIUS COMMISSION

Fifty-fifth Session, FAO Headquarters, Rome, 9-11 February 2005

MATTERS ARISING FROM THE REPORTS OF CODEX COMMITTEES AND TASK FORCES

Matters Referred by the Commission

Antimicrobial resistance

Background

1. The request to the Commission and to the Executive Committee for guidance on how to deal with antimicrobial resistance arose from the requests of:
 - the Codex Committee on Pesticide Residues (CCPR), which requested FAO and WHO to evaluate the substances concerned (*gentamycin, oxytetracycline*) for their use on agricultural commodities, taking into account the potential for the development and transmission of antimicrobial resistance¹; and
 - the Codex Committee on Food Hygiene (CCFH), while considering the Risk Profile on the Antimicrobial Resistant Bacteria in Food. The paper has been forwarded to the Executive Committee “to assist their decision on the coordination of work between the Codex and Committees and other international organizations (OIE)”².
2. This matter was considered by the 48th Session of the Executive Committee³ in June 2001. In relation to the first matter, the Executive Committee was of the opinion that the use of antimicrobials on agricultural commodities should be subject to evaluation within a risk analysis framework; the question was whether the normal process used for the evaluation of pesticides was the appropriate one. In the second case, the Executive Committee agreed that consideration should be given to the consideration of antimicrobial

¹ ALINORM 01/24A, para. 222

² ALINORM 01/13A, paras 132-142

³ ALINORM 01/4, paras 36-37

resistant micro-organisms in food within a risk analysis framework on a case-by-case basis as micro-organism/food combinations were being assessed.

3. The Executive Committee agreed however that the issues raised by these Committees required a more general and multidisciplinary and multi-agency response. It noted the on-going work of the Committee on Residues of Veterinary Drugs in Foods (CCRVDF) and the Task Force on Animal Feeding. Moreover, it was aware of the recommendations contained in the *WHO Global Principles for the Containment of Antimicrobial Resistance in Animals Intended for Food*⁴ and the work of the OIE. It noted that in the past, attempts to coordinate work between Codex Committees with diverse mandates had not always been successful and that the establishment of new task forces to deal with these specific issues had helped to resolve the issues at hand. Without prejudice to the possibility of establishing a new Task Force, it recommended that FAO and WHO should give consideration to convening as soon as possible a multidisciplinary expert consultation in cooperation with OIE and if required the IPPC, to advise the Commission on possible directions to be taken including the establishment of a new task force if necessary. The consultation should consider all uses of antimicrobials in agriculture and veterinary use (including aquaculture) and take into account the role played by antimicrobials as essential human and veterinary medicines. It noted that the convening of an additional expert consultation in the forthcoming biennium would be subject to the availability of funds.

4. FAO/WHO and OIE convened two workshops: Joint WHO/FAO/OIE Expert Workshop on Non-human Antimicrobial Usage and Antimicrobial Resistance, Geneva, 1 - 5 December 2003 and 2nd Joint FAO/OIE/WHO Workshop on Non-human Antimicrobial Usage and Antimicrobial Resistance: Management Options, Oslo, 15-18 March 2004. Both workshops addressed the need for a multidisciplinary approach to coordinate the work of all organizations involved, in order to carry out a comprehensive risk analysis specifically based on the Codex Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius.

5. The 54th Session of the Executive Committee⁵ in June 2004 noted that the 36th Session of the Committee on Food Hygiene⁶ supported the establishment of a Codex/OIE Task Force to develop broad risk management options for antimicrobial resistance related to non-human use of antimicrobials. The Executive Committee also noted that the 20th Session of the Committee on General Principles did not support the establishment of joint standards with other intergovernmental organizations.

6. The Executive Committee was informed that the Committee on Pesticide Residues and the *ad hoc* Intergovernmental Task Force on Animal Feeding did not propose specific actions as follow-up to the outcome of the two expert workshops on antimicrobial resistance convened by FAO, OIE and WHO. The Executive Committee also noted that the Committee on Residues of Veterinary Drugs in Food had initiated the elaboration of a Code of Practice for the containment of antimicrobial resistance and its forthcoming session would consider the proposed draft Code at Step 4.

7. The Representative of WHO recalled that the two FAO/OIE/WHO workshops had been convened at the request of the 48th Session of the Executive Committee and urged the Executive Committee to invite the Commission to take necessary actions, in cooperation with the OIE, to address the issues regarding the terminology, risk assessment policy and risk management options for the containment of antimicrobial resistance. The Coordinator for Asia also stated that a project document for this issue would be introduced by the Delegation of the Republic of Korea during the 27th Session of the Commission, and supported the view of the Representative of WHO.

8. The Representative of FAO stated that Codex should carefully evaluate the need for and implications of joint OIE/Codex standards and should explore ways to make better use of its current subsidiary bodies to address the issue before taking further steps towards establishing a joint task force.

9. While noting that antimicrobial resistance is an important matter to be addressed by Codex, the Executive Committee was of the view that there are several possible options for the Commission to deal with this matter, including the establishment of a Codex task force with active participation of the OIE, or the use of

⁴ WHO document WHO/CDS/CSR/APH/2000.4

⁵ ALINORM 04/27/4, paras 68-73

⁶ ALINORM 04/36/13, para. 159

existing Codex subsidiary bodies such as the Committee on Food Hygiene, the Committee on Residues of Veterinary Drugs in Foods and the Task Force on Animal Feeding. The Committee noted that OIE would participate in the 27th Session of the Commission and present its views during the session.

10. The Executive Committee agreed that before deciding on the procedure to follow the Commission should develop a clear and common understanding of what should be achieved by Codex in regard to the question of antimicrobial resistance related to non-human use of antimicrobials. The Executive Committee further agreed that it would be useful to prepare a Circular Letter to request the views of Members and Observer on what is expected as future achievements by Codex in this area.

11. The 27th Session of the Commission had considered the matter of antimicrobial resistance as follows⁷:

12. The Representative of WHO informed the Commission that the two FAO/WHO/OIE workshops had been convened, at the request of the 48th Session of the Executive Committee⁸, in order to advise the Commission on possible directions to be taken on this issue. He stressed the need to address the matters regarding the terminology, risk assessment policy and risk management options for the containment of antimicrobial resistance.

13. The Representative of the OIE drew the attention of the Commission to the fact that the OIE had already adopted sections on the containment of antimicrobial resistance in the OIE Code and indicated that the OIE would support recommendations of the second Workshop held in Oslo. The Representative pointed out that in principle the OIE would accept the proposal to establish a Joint *ad hoc* Task Force on antimicrobial resistance, to operate on the procedures to be agreed upon by the two bodies, with specific terms of reference in accordance with the outcome of the Oslo Workshop: to define risk assessment policy to be used by JEMRA; to develop risk management options; to consolidate existing texts in this area; and to develop guidance for the use of antimicrobials in animal production.

14. The Commission noted the willingness of the Delegation of the Republic of Korea to host an *ad hoc* Task Force on Antimicrobial resistance, if such a Task Force was to be established in future.

15. Many delegations supported the recommendation by the 54th Session of the Executive Committee as the way to proceed on this matter⁹.

16. The Commission noted that there was a unanimous support for the cooperation with the OIE, but that financial implications and impact on country participation, especially for developing countries should be carefully considered before taking a final decision towards establishing a new Task Force is taken. The Commission also noted the kind offer of the OIE that the cost for joint activities could be shared between the organizations.

17. The Commission agreed that there were several possible options for the Commission to deal with this matter, including the establishment of a Codex task force with active participation of the OIE, or the use of existing Codex subsidiary bodies such as the Committee on Food Hygiene, the Committee on Residues of Veterinary Drugs in Foods and the Task Force on Animal Feeding.

18. The Commission further agreed that before deciding on the procedural mechanisms to further work, there should be a clear and common understanding of what should be achieved by Codex in regard to the question of antimicrobial resistance related to non-human use of antimicrobials.

19. In order to facilitate the discussion, the Commission requested Secretariat to prepare, as soon as possible, a Circular Letter which would include two questions:

- What should be achieved by Codex to address the issue of antimicrobial resistance related to non-human use of microbials (e.g. risk assessment principles, risk management options);
- What mechanisms should be used by Codex to achieve the above outcome?

The Circular Letter would also contain the following information:

⁷ ALINORM 04/28/41, paras 210-219

⁸ ALINORM 01/4, paras 36-37.

⁹ ALINORM 04/27/4, paras 68-73.

- the outline of ongoing work on this matter in relevant Codex Committees, their Terms of Reference in relation to their work on antimicrobial resistance; and
- the executive summary prepared by FAO and WHO from the two Workshops.

20. The Commission agreed that the comments received in reply to the Circular Letter would be considered at the 55th Session of the Executive Committee with the understanding that it would provide the advice to the next session of the Commission.

21. The Representative of the OIE stated that the OIE Working Group on Animal Production Food Safety would continue its work on microbial resistance, while waiting for further decisions by Codex.

22. Subsequently, the Codex Secretariat, as requested by the Commission, issued the Circular Letter CL 2004/32-EXEC “Request for comments on how to address the issue of antimicrobial resistance within Codex”.

23. The following countries and international organizations replied to the above Circular Letter: Australia, Brazil, European Community, New Zealand, Norway, Republic of Korea, United States, IDF, IFAH and OIE. These comments are presented in the Annex of this document.

24. While there is general agreement in supporting activities aimed at preventing or reducing antimicrobial resistance, there is divergence in the views expressed on what mechanisms should be used by Codex to achieve the above outcome. Some respondents are in favour of establishing an ad hoc Intergovernmental Task Force while others are in favour of using existing Codex infrastructure such as convening a joint CCFH/CCR/VDF Working Group with active participation of OIE. Some are of the view that the Commission should adopt the “Code of Practice to Minimize and Contain Antimicrobial Resistance” earliest possible and that countries should be invited to help applying good practices on the use of antimicrobials based on international guidance.

25. There seems to be no clear agreement on the Terms of reference for such an *ad hoc* Task Force or a Codex body. In the event that the need for further work within Codex is recognised, it will be necessary to clarify the definition of “antimicrobial” and decide on the inclusion or exclusion of disinfectants in the scope of such new work.

26. In the light of the comments received, the **Executive Committee** is invited to consider and formulate proposals to the Commission how to proceed with the issue of antimicrobial resistance.

27. In formulating such proposals, the Executive Committee may wish to note that the 15th Session of the Committee on Residues of Veterinary Drugs in Food has forward the Proposed Draft Code of Practice to Minimize and Contain Antimicrobial Resistance¹⁰ for adoption by the 28th Session of the Commission at Step5/8 with the omission of Steps 6 and 7, and that the 21st Extraordinary Session of the Committee on General Principles has forwarded the draft Guidelines for Cooperation with International Intergovernmental Organizations¹¹ for adoption by the 28th Session of the Commission. The original proposal prepared by the Codex Secretariat and presented to the Committee on General Principles had provided for the elaboration of a joint standard or related text with a cooperating organization through the work of a joint subsidiary body. However, the Committee at its 20th Session agreed to delete this option in view of practical difficulties arising from applying the proposed procedure for the elaboration of joint standards, namely increased costs and substantial delays in the standard setting process¹².

¹⁰ ALINORM 05/28/31, para. 117 and Appendix VIII

¹¹ ALINORM 05/28/33, para. 104 and Appendix VIII

¹² ALINORM 04/27/33A, pars 97-109

ANNEX

Comments received in response to CL 2004/32-EXEC**“Request for comments on how to address the issue of antimicrobial resistance within Codex”**

**Submitted by Australia, Brazil, European Community, New Zealand, Norway,
Republic of Korea, United States, IDF, IFAH and OIE**

AUSTRALIA

Australia welcomes the opportunity to provide comment on the management of AMR issues within Codex. AMR is of increasing worldwide public health concern and it is important that countries have an agreed and consistent approach to managing and minimising its occurrence and spread.

The following comments are provided in response to the questions contained in CL 2004/32-EXEC for consideration by the 55th Session of the Executive Committee:

1. What should be achieved by Codex to address the issue of antimicrobial resistance related to non-human use of antimicrobials (e.g. risk assessment principles, risk management options)?

Australia recognises that some work is already underway in various Codex Committees, including the Codex Committee on Residues of Veterinary Drugs in Foods (CCRVDF) Code of Practice to Minimize and Contain AMR, and various Codex Committee on Food Hygiene (CCFH) microbiological risk assessments, some of which have been developed in conjunction with FAO/WHO Expert Committees. However, while CCFH risk assessments must consider measures that would reduce the likely contribution of microorganisms to foodborne illness, AMR is not a specific consideration under the current Codex standard setting process.

In CCPR, the setting of maximum residue limits (MRLs) for antibiotics (gentamicin and oxytetracycline) has been hampered due to opposition from several delegations for their inclusion on the priority list for evaluation by JMPR. Australia is of the view that this issue needs to be addressed in a scientific and transparent manner, as Codex should not be seen to be making risk management decisions without a formal scientific risk assessment.

A number of risk assessment principles and risk management options have already been developed by a number of countries and international bodies. WHO and OIE have over the last seven years, been working towards international guidelines, including the WHO Global Principles for the Containment of AMR in Animals intended for Foods and the OIE Guidelines on AMR. It is important that this work is recognised by Codex and that any future work by Codex takes these guidelines into consideration. However, it is also acknowledged that there is still a lot that needs to be achieved in the area of non-human AMR and there are still many gaps in the scientific knowledge. For example, there is a need to identify priorities for international risk assessments of AMR in food and undertaking such assessments in a timely manner.

The recent Joint FAO/OIE/WHO Expert Workshops on Non-Human Antimicrobial Usage and AMR (Geneva, December 2003 and Oslo, March 2004) on risk assessment and risk management, respectively, arose from a recommendation of the 53rd Session of the Executive Committee of the Codex Alimentarius Commission (CAC). The CAC recognised that AMR requires a multi-disciplinary and multi-agency approach. The workshops were the first steps towards the agreement and alignment of work done by different international bodies. Amongst the outputs of the workshops, were recommendations and options for future risk management actions to be considered by the CAC. Australia considers it important that Codex notes and considers the findings of the workshops in any future work on AMR.

Some key conclusions of the Geneva workshop were:

- That the consequences of AMR are particularly severe when pathogens are resistant to antimicrobials critically important in humans, The workshop recommended that WHO appoint a group of experts to develop a list of “critically important” classes of antimicrobials for humans;
- That surveillance of non-human usage of antimicrobials and AMR in foods and animals is necessary for the identification of resistance problems and as a basis for choosing and evaluating interventions to limit the development and spread of resistance; and
- That risk assessment approaches that adequately address the broad range of potential human health impacts need to be further developed with a view to enabling efficient risk management of AMR in the international arena. OIE should continue its work in this area in coordination with FAO and WHO.

Some key conclusions from the Oslo workshop were:

- That stringent implementation of good agricultural practices, including good animal husbandry and good veterinary practices, will help reduce the necessity for antimicrobials;
- That there is a need for governments and all stakeholders to rapidly implement the WHO Global Principles and OIE Guidelines; and
- That a Codex/OIE Task Force should be established to develop risk management options for AMR related to non-human use of antimicrobials. Both the International Code of Practice and General Principles of Food Hygiene should be reviewed to take AMR into account.

Many countries have in place programs to address AMR, although these are mainly focused on monitoring and surveillance. Codex should continue to encourage and support countries in obtaining data from such surveillance programs in order to better inform world benchmarks for risk assessment and risk management. Only when a representative number of countries have such systems in place can decisions be made about thresholds of resistance and appropriate antimicrobial use levels. Of priority, are capacity building, coordination of existing work, and agreement on the global adoption and alignment of aspects of this work.

One of the conclusions from both workshops was that WHO and OIE should develop lists of critically important antibiotics for humans and animals, respectively. It is important that WHO and OIE do not work in isolation of each other. Australia is of the view that the development of the WHO and OIE lists should proceed in close consultation in order to achieve the best possible outcome for the protection of both human and animal health. Such lists of critically important antibiotics will be very beneficial for informing Codex in respect of antimicrobials entering the Codex process.

2. What mechanisms should be used by Codex to achieve the above outcome?

Australia is of the view that Codex should consider work previously undertaken by FAO, WHO and OIE in this area. In particular, Codex should carefully consider the conclusions and recommendations of the two Joint FAO/OIE/WHO Expert Workshops, particularly given that the work was recommended by the CAC.

In progressing the work of AMR within Codex, Australia believes that existing FAO/WHO scientific expert advisory bodies (JEMRA/JECFA/JMPR) need to develop suitable risk assessment principles to deal with AMR. In the first instance, Codex, in consultation with FAO and WHO, needs to consider whether JEMRA is the most appropriate expert body to undertake AMR risk assessments, and if so, whether it has the requisite expertise. In addition, Codex should also consider the work of member countries in this area.

AMR is an important public health issue that needs to be addressed in a systematic and scientific way. Towards that aim, Australia strongly supports the establishment of a Joint Codex/OIE Taskforce with active participation of the FAO, WHO and OIE, and international experts as required in order to develop the best way forward on AMR, recognising the substantial amount of work already achieved internationally.

BRAZIL

Brazil would like to express the following comments in regard to the two questions below:

Question 1 - What should be achieved by Codex to address the issue of antimicrobial resistance related to nonhuman use of antimicrobials (e.g. risk assessment principles, risk management options):

- An important step was already given with the decision taken by the 15th meeting of the CCRVDF in order to advance at Steps 5/8 of the procedure the "PROPOSED DRAFT CODE OF PRACTICE TO MINIMIZE AND CONTAIN ANTIMICROBIAL RESISTANCE", for adoption by the 28th Session of the CAC.
- Brazil detaches that the main objective to be achieved by the Codex may be to promote and to facilitate the adoption of Good Agricultural Practice (GAP) and good practices in the use of veterinary antimicrobial drugs, as well as the implementation of National Antimicrobial Resistance Monitoring and Surveillance Programs by governments particularly in developing countries. These measures make it possible to reduce the necessity of antimicrobials use in agriculture and aquaculture, with the aim of limiting the dissemination of resistant microorganisms and of protecting the consumers health.
- In our view there seems to have some overlapping of actions in the development of international efforts between FAO, WHO, OIE and CAC (Oslo, Norway¹³) and this situation should be considered to minimize duplication of efforts and avoid wasting of resources. It is important to take in account the necessities and capacity of the developing countries.

Question 2 – What mechanisms should be used by Codex to achieve the above outcome:

- Brazil considers that it will be an important step in order to achieve the above outcome to speed up the adoption by the Commission of the a "Code of Practice to Minimize and Contain Antimicrobial Resistance" and to stimulate its application by the countries.
- There are, also, other important mechanisms as for example: to stimulate the development of methods of analysis of feasible application by the authorities of the developing countries and the development of statistics analysis of data on monitoring programs that may subsidize the decisions of risk management. There is need to facilitate implementation of surveillance programs by the governments with the aid of the WHO Global Principles for the Containment of Antimicrobial Resistance in Animals intended for food and the OIE Guidelines on Antimicrobial Resistance.

EUROPEAN COMMUNITY

As a general principle, the European Community strongly supports activities aimed at preventing antimicrobial resistance in a balanced way in all concerned areas: human medicine, veterinary medicine related in particular to animal and food productions, and plant protection.

It is also European Community understanding that Codex as other international organisations works under the general principles of Risk Analysis, which include risk assessment, risk management and risk communication. Those principles apply equally to the issue of antimicrobial resistance related both to non-human and human use of antimicrobials.

It should be noted that the comprehensive work developed so far by the Codex Committee on Residues of Veterinary Drugs in Foods (CCRVDF), on a '*Code of Practice to Minimize and Contain Antimicrobial Resistance*', was in particular drafted on the basis of the OIE provisions of the Terrestrial Code on Prudent Use of Antimicrobials. The European Community is very grateful that the CCRVDF at its recent 15th session proposed the said draft Code of Practice to the Codex Alimentarius Commission for final adoption at Step 5/8.

Furthermore the European Community recommends that any existing ongoing activities within any Codex Committee or ad-hoc Group on this issue should be urgently finalised, and that before deciding to start any specific future work on the matter within one or the other Committees, the Codex Alimentarius Commission

¹³ Second Joint FAO/OIE/WHO Expert Workshop on Non-Human Antimicrobial Usage and Antimicrobial Resistance: Management options, 15 – 18 March 2004, Oslo, Norway.

should fully consider any international work already developed/adopted by other international organisations in order to prevent avoidable discrepancies and overlaps between internationally recognised standards.

At the 27th Session of the Codex Alimentarius Commission, it was noted that there was unanimous support for the cooperation with the OIE in particular on the issue of antimicrobial resistance. However financial and legal implications of the creation of an ad-hoc joint task force raised concerns of several delegations. The European Community is therefore of the view that pending consensus on the modalities of the establishment of a new body, it would be more realistic that existing Codex subsidiary bodies, such as CCRVDF, be used to fulfil the defined objectives. In addition, in light of the debates at the 21st Session of the Codex Committee on General Principles, more informal relations between Codex and other international organisations seem to be favoured.

The European Community is convinced that the International Community would gain from the development at international level of a harmonised and cooperative approach on antimicrobial resistance in order to implement and/or further develop appropriate and coordinated recommendations in all relevant sectors mentioned above, including in particular human medicine. To progress on this global issue, the contributions that the different international organisations can make on related issues such as monitoring, preventive measures, research and inter-sectorial co-ordination need to be clearly defined and summed up in such a global approach.

NEW ZEALAND

New Zealand recognizes the importance of addressing the issue of antimicrobial resistance but does not currently see the need to address it by establishing an ad hoc Intergovernmental task force. Although Codex has yet to formulate objectives for such a task force, we believe that the current approach of Codex to address specific issues of antimicrobial resistance on a case by case basis using existing Committees is the appropriate strategy. Although development of generic approaches would assist in facilitating consistent work across Codex, formation of a task force to achieve this would only add to the already heavy workload of the Commission and its subsidiary bodies. We do not believe that the suggested topic is a current priority in these terms.

NORWAY

Referring to the Circular Letter of July 2004 (CL 2004/32-EXEC) from the Codex Secretariat, Norway would like to submit the following comments.

Norway acknowledges that antimicrobial resistance is an emerging public health problem of international dimension and that a multidisciplinary and holistic approach is needed in order to contain antimicrobial resistance.

Both resistant zoonotic bacteria as well as resistant commensal bacteria, which can serve as a reservoir of resistance genes, can be transferred from animals to humans through the food chain. There is ample scientific evidence showing that antimicrobial use in food animals can generate antimicrobial resistance that subsequently can cause public health problems by spread through the food chain. Therefore, antimicrobial resistance is also a food hygiene issue. For this reason, Norway has supported that the Codex Alimentarius, and in particular the Codex Committee on Food Hygiene, addresses antimicrobial resistance as a microbiological problem affecting the safety of foods in international trade.

In its Circular Letter, the Codex Secretariat asks for responses to the following two questions:

1. What should be achieved by Codex to address the issue of antimicrobial resistance related to non-human use of antimicrobials (e.g., risk assessment principles, risk management options)?
2. What mechanisms should be used by Codex to achieve the above outcome?

1. Codex needs to address antimicrobial resistance related to non-human use of antimicrobials in several contexts. As Codex is an international body working within the whole risk analysis framework as regards the safety of foods in international trade (risk assessment, risk management, risk communication), and because antimicrobial resistance related to non-human use of antimicrobials is a food safety issue, Codex should be involved in relevant risk analysis activities in relation to non-human use of antimicrobials.

The joint FAO/WHO/OIE workshop, which was held in Geneva in December 2003, assessed very thoroughly the public health risks associated with non-human use of antimicrobials. A number of other previous WHO, FAO and OIE initiatives have earlier outlined the general directions for prudent use of antimicrobials in animals. It is Norway's opinion that what is currently needed internationally is the development of more specific risk management options in this area to be used at both national as well as the international level. We believe Codex should play an active role here. This would help increasing the recognition of non-human use of antimicrobials as a food safety issue and thereby help improving food safety, at the national as well as the international market. It will also enable the establishment of a more direct link between preventative measures being implemented in primary production and subsequent risk reduction in the food chain. Furthermore, it will have positive effects beyond food safety, as it will promote the important work for the containment of antimicrobial resistance, which due to the complexity of the problem, requires an international and holistic approach.

2. The issue of antimicrobial resistance related to non-human use of antimicrobials is complex. As a consequence, it affects the Committee on Food Hygiene (CCFH), the Committee on Residues of Veterinary Drugs (CCRVD) as well as the Task Force on Animal Feeding. Antimicrobial resistance is by nature a microbiological problem and the CCFH, as a committee working with general microbiological food safety issues, should therefore also address risks associated with antimicrobial resistant bacteria in the food chain. Drug residues represent mainly a toxicological problem. But since CCRVD addresses requirements for safety assessments of new drugs, it is natural that their activities also include issues pertaining to antimicrobial resistance.

Norway fully supports the conclusions and recommendations from the two joint FAO/WHO/OIE workshops on antimicrobial resistance related to non-human antimicrobial use, that were held in December 2003 and March 2004, respectively. Amongst others, these workshops recommended that a Codex/OIE Task Force on Antimicrobial Resistance should be established to develop risk management options on antimicrobial resistance related to non-human antimicrobial use. Furthermore, it was concluded in the second meeting that: "Risk communication and transparency are critical to the achievement of effective risk management. Moreover, both the International Code of Practice and General Principles of Food Hygiene should be reviewed to take antimicrobial resistance into account." Norway also supports these statements.

Norway believes it is critical that FAO, WHO, their subsidiary body Codex and OIE work together in relation to the proposed Task Force. Such cooperation will ensure that the complex problem at stake receives the best and broadest approach. It will also increase the chances of a successful process and outcome, and ensure the most effective implementation of the risk management options that are to be developed. Thus, such cooperation will promote food safety as well as the containment of antimicrobial resistance, both nationally as well as internationally.

Norway has noted the willingness of the Republic of Korea to host the suggested *ad hoc* Task Force on Antimicrobial resistance. Norway fully supports that the Republic of Korea be the host of the Task Force, if such a Task Force is to be established. We have strong confidence in that Korea will execute its role as a host for the Task force both excellently and efficiently. Furthermore, we see importance in the fact that a country outside Europe and North-America be the host of the Task Force as this will help increase the recognition of non-human antimicrobial use as a problem affecting the whole world.

In conclusion, Norway supports the urgent establishment of a Codex/OIE Task Force on Antimicrobial Resistance to develop risk management options on antimicrobial resistance related to non-human antimicrobial use. Furthermore, Norway supports that the Republic of Korea be the host of the Task Force.

We would also take this opportunity to convey that Norway is eager to actively participate in the Task Force.

REPUBLIC OF KOREA

a) What should be achieved by Codex to address the issue of antimicrobial resistance related to non-human use of antimicrobials (e.g. risk assessment principles, risk management options)

The Korean government has a consensus to the conclusion of the 2nd Oslo workshop that Codex/OIE Task Force should be established to develop risk management options for antimicrobial resistance related to non-human use of antimicrobials. Risk communication and transparency are critical to achieve effective risk management. For the risk assessment of AMR organisms, it needs to;

- Establish an international surveillance program on the non-human usage of antimicrobial agents
- Establish an international surveillance program on antimicrobial resistance in bacteria from food and animals
- Implement strategies to prevent the transmission of resistant bacteria from animals to human through the food production chains
- Implement WHO global principles for the containment of antimicrobial resistance in animals intended for foods and follow OIE guidelines on the responsible and prudent antimicrobial use
- Implement specific management strategies to prevent the emergence and dissemination of bacteria resistant to critically important antimicrobial agents for people
- Implement the risk assessment approaches that are needed to support selection of risk management options
- Enhance the capacity of countries, particularly developing countries, to conduct surveillance of antimicrobial use and resistance, to implement intervention strategies to contain antimicrobial resistance and to implement risk assessment approaches to support selection of risk management options
- Risk management of antimicrobial resistance on the international area

We also agree with the recommendations of OIE that the new work contributes to the safety of human health by satisfying the following objectives:

- Promoting sound regulatory framework, guidelines, recommendations through harmonization of national antimicrobial resistance monitoring and surveillance programs in animals and in animal-derived foods,
- Monitoring the quantities of antimicrobials used in animal husbandry and environment around it
- Standardization and harmonization of laboratory methodology for the detection and quantification of antimicrobial resistance
- Responsible and prudent use of antimicrobial agents in veterinary medicine, risk analysis methodology for the potential impact on public health of antimicrobial resistant bacteria of animal origin.

In a conclusion, through national and international interdisciplinary cooperation with active participation with developing countries, the risk management options should be developed to manage human health risks from non-human usage of antimicrobials and the resulting antimicrobial resistant bacteria. Through the science based risk assessment at international level, Codex/OIE Task Force should develop guidelines or recommendations, as appropriate, and establish or amend legitimate food standards (code) or food related policies.

b) What mechanisms should be used by Codex to achieve the above outcome?

The Korean government has an opinion that the Codex subsidiary bodies such as CCFH, CCRVDF, and *ad hoc* Intergovernmental Task Force on Animal Feeding have lots of on-going issues and works; therefore, the Task Force should be a single and independent body to work out the current multi-factorial matters of antimicrobial resistance requiring a multidisciplinary approach efficiently and intensively. Furthermore, at 27th Commission, there was unanimous support for the active cooperation with OIE and the procedural mechanism should be considered as an '*ad hoc* Intergovernmental Task Force'.

UNITED STATES

In response to CL 2004/32-EXEC, "*Request for comments on how to address the issue of antimicrobial resistance in Codex*", the United States offers the following comments:

1. What should be achieved by Codex to address the issue of antimicrobial resistance related to nonhuman use of antimicrobials (e.g. risk assessment principles, risk management options)

Because antimicrobial resistance from the non-human use of antimicrobials has the potential to affect both consumer health and fair practices in food trade, Codex has the mandate to address this complex issue. Also, the working principles for risk analysis recently adopted by Codex ensure that determination of risk from the non-human use of antimicrobials and proposed risk management options will be science-based, employ scientific evidence in risk assessments tailored to each usage scenario, and be developed in a transparent manner.

The United States supports the work on antimicrobial resistance in the Codex Committee on Residues from Veterinary Drugs in Food (CCRVDF) and the development of a Code of Practice to Minimize and Contain Antimicrobial Resistance.

The U.S. believes that the Codex Committee on Food Hygiene (CCFH) should continue to discuss how best to address issues of resistant strains of pathogens. CCFH should examine current risk assessment policies and determine if additional policies might be required to address resistance within the scope of a microbiological risk assessment. CCFH should also work with the Joint FAO/WHO Expert Meeting on Microbiological Risk Assessment (JEMRA) to determine if additional risk assessment methodologies might be required. Recognizing that there has been considerable work on antimicrobial resistance by international organizations and member countries, yet this work has not been coordinated, CCFH should request that JEMRA examine published risk assessments on antimicrobial resistance, comment on these assessments and propose risk assessment principles and procedures for antimicrobial resistance to be used within Codex. JEMRA should seek to include experts from the agencies of countries that have produced the assessments. JEMRA should also ensure that CCFH and CCRVDF are appropriately represented in the consultations convened to make these proposals.

2. What mechanisms should be used by Codex to achieve the above outcome?

If it is determined that additional risk assessment policies are needed to adequately address questions of antimicrobial resistance within Codex risk assessments, the United States believes that this would best be accomplished by convening a joint CCFH/CCRVDF Working Group, with the active participation of the World Animal Health Organization (OIE). It is important for Codex to agree on the risk assessment aspects of antimicrobial resistance before implementing the development of risk management options. Once the risk assessment methodologies and policies are agreed upon, the relevant Codex subsidiary bodies (currently CCFH, CCRVDF and the Codex Committee on Pesticide Residues (CCPR)) should consider how to incorporate risk assessments that include consideration of antimicrobial resistance into the risk management decisions that fall within their respective mandates.

As two standards setting bodies explicitly recognized within the trade agreements, the United States supports enhanced cooperation between OIE and Codex, recognizing the different mandates of the two organizations. The mandate of OIE includes antimicrobial resistance. However, a Joint Codex/OIE *ad hoc* Task Force on

Antimicrobial resistance does not appear to be warranted at this time. First, Codex must address the issue of incorporating antimicrobial resistance considerations into microbiological risk assessments. Second, the Codex Committee on General Principles must develop guidance on the conduct of such a task force. At that time, a joint Codex/OIE task force may be appropriate to assure that the risk assessment and risk management approaches of the two organizations are consistent and to address issues at the interface of food safety and animal health.

Added Comment: Before Codex embarks on developing policies on antimicrobial resistance, it is important that there be an agreed upon definition. The U.S. believes that “disinfectants” should be excluded from the definition of antimicrobial for the purposes of this work.

INTERNATIONAL DAIRY FEDERATION (IDF)

Significant progress has been achieved in identifying strategies to manage the risks associated with non-human antimicrobial use and antimicrobial resistance through the joint FAO/OIE/WHO Workshops and through activities of Codex Committees. Various international bodies have shared responsibilities, expertise and competencies to contribute to the management of antimicrobial resistance related to non-human use of antimicrobials. For practical reasons it is necessary to have interdisciplinary cooperation between the organisations recognising established leadership in different areas.

The establishment of a Codex/OIE ad hoc Task Force has been proposed and its most valuable contribution would be to clarify the roles and responsibilities of the particular Codex Committees, OIE and WHO. This would facilitate agreement for the development of principles, guidelines and standards by the relevant bodies. It would avoid duplication and delays in areas where good progress has already been achieved.

It is recommended that Codex establish a joint Codex/OIE ad hoc Task Force with Terms of Reference to determine which Codex Committee or other international organisation should take leadership for the development of principles and guidelines for specific aspects of the management of antibiotic resistance related to non-human use of antimicrobials. The Task Force might provide coordination to assure that the different areas do not overlap.

Potential tasks for which leadership might be identified include;

- The establishment of critically important classes of antimicrobials for people;
- The establishment of critically important classes of antimicrobials for veterinary purposes;
- Good veterinary practices for antimicrobial use;
- Reviewing knowledge concerning specific antimicrobial molecules;
- Reviewing antimicrobial resistance, bacterial ecology and assessing risk;
- Development of farm management and through-chain options for food hygiene – change focus from one that treats animals that show symptoms of disease to one taking preventative efforts in housing, feeding and management;
- Developing Guidelines where appropriate for Food Safety Objectives
- Revising protocols for testing the efficacy of use of antimicrobial drugs so long term effects on production and milk quality parameters are evaluated

INTERNATIONAL FEDERATION FOR ANIMAL HEALTH (IFAH)

IFAH, the International Federation for Animal Health, is the federation representing manufacturers of veterinary medicines, vaccines and other animal health products in both developed and developing countries across five continents.

Following are IFAH's responses to the two questions that the Executive Committee asked in their circular letter on antimicrobial resistance within Codex:

1. What should be achieved by Codex to address the issue of antimicrobial resistance related to non-human use of antimicrobials (e.g. risk assessment principles, risk management options)?

As antimicrobial resistance from the non-human use of antimicrobials has the potential to affect both consumer health and fair practices in food trade, IFAH believes that Codex has the mandate to address this complex issue. Also, the risk analysis framework that Codex recently adopted ensures that any determination of risk from the non-human use of antimicrobials and any proposed risk management options will be science-based and developed in a transparent manner.

Codex has made major contributions to the developing science of quantitative microbial risk assessment. IFAH believes that Codex should expand this work to include development of risk assessment methodology for resistant pathogens. We believe that resistant pathogens should be viewed as a subset of the microbial hazard in general and that any incremental risks, if any, over and above the risk from the overall microbial hazard be determined. The two Joint WHO/FAO/OIE Expert Workshops on Non-human Antimicrobial Usage and Antimicrobial Resistance focused primarily on risk management options; there was little discussion and no recommendations on how best to conduct risk assessments. The risk analysis framework in Codex requires a thoroughly developed risk assessment before any final risk management options are decided. Codex needs to make sure that the risk assessment component of the risk analysis of antimicrobial resistance is accepted by both the risk assessors, the risk managers and other interested parties before risk management options are decided. This has not been done yet.

2. What mechanisms should be used by Codex to achieve the above outcome?

A Joint Codex/OIE ad hoc Task Force on Antimicrobial resistance was recommended by the second workshop on Non-human Antimicrobial Usage and Antimicrobial Resistance. IFAH recognizes that OIE has conducted excellent work on the specific issue of risk analysis on the use of antimicrobials in animals as shown in the recent adoption of the risk analysis principles in the OIE terrestrial code. Moreover, IFAH has noted the willingness of the OIE to collaborate with Codex and also the generous offer of Korea to host the joint task force. However, IFAH recognizes also that the Codex Committee on General Principles has stated that guidance for the conduct of such a task force would have to be developed prior to the implementation, which puts lengthy timelines to the final setup of such a task force. IFAH has also noted that some Member States have expressed concerns, especially on the procedural difficulties, during the 2004 Codex Commission meeting. IFAH recognizes the very high value of the potential joint task force but estimates that the positions expressed by the Member States of Codex makes the establishment of a Joint task force an unlikely event in the near future.

IFAH believes that the Codex Committee on Food Hygiene (CCFH) and the Joint FAO/WHO Expert Meetings on Microbiological Risk Assessment (JEMRA) are the subsidiary bodies that should develop the risk assessment methodology for determining the extent of risk from specific drugs and resistant pathogens. CCFH should request JEMRA to examine published risk assessments on antimicrobial resistance, comment on these assessments and propose procedures for antimicrobial resistance to be used within Codex. Once they have developed a proposed methodology, the subsidiary bodies of Codex responsible for risk management (CCRVDF, CCPR and CCFH) should comment on the risk assessment procedures as envisioned by the risk analysis process. Once the risk assessment procedures are agreed upon, Codex could recommend these procedures to member countries.

In addition to their contribution to developing risk assessment methodology, CCRVDF should continue their work on the Code of Practice to Minimize and Contain Antimicrobial Resistance.

IFAH respectfully suggests that all subsidiary bodies named above take into account the work of OIE in relevant areas, as Codex has done in the past, in order to minimize discrepancies and achieve the best possible outcome.

IFAH is grateful that it had the opportunity to comment on these important questions, and hopes that its contribution can help achieve the best outcome for consumer safety and trade issues.

WORLD ORGANIZATION FOR ANIMAL HEALTH (OIE)

Introduction

Consistent with its rules, the OIE is willing to develop close contact with all organisations concerned, such as *Codex Alimentarius*, WHO and FAO, and governments of OIE Member Countries (167 countries are currently members of OIE).

This close cooperation, which is actively being developed, will help to obtain the benefits of synergies amongst the different organisations.

Outcome of the WHO/FAO/OIE consultation on Non-human Antibiotic Usage and Antimicrobial Resistance

In this spirit and following a suggestion of the WHO and *Codex Alimentarius* Commission (CAC), a world-wide consultation of experts has recently been launched in Geneva, Switzerland (2003) and Oslo, Norway (2004) by WHO, FAO and OIE with the view to gather all available scientific data and to prepare a common action plan for the future.

The 1st Workshop on Non-Human Antimicrobial Usage, held in December 2003 in Geneva, included a preliminary scientific assessment of all non-human uses of antimicrobials in animals (including aquaculture) and plants, and their role in antimicrobial resistance, based on the available scientific information. Based on the outcome of the 1st workshop in Geneva, as well as other relevant input (e.g. reports of previous WHO and OIE workshops), the 2nd workshop, held in Oslo in February 2004, considered the broad range of possible risk management options for antimicrobial resistance from non-human use of antimicrobials. To ensure that the conclusions of the 2nd Workshop reflected the perspectives of interested parties, the major stakeholder groups (e.g. members of the pharmaceutical industry, farmers, food processors, consumers, regulatory agencies, and veterinarians) participated to the meeting.

In particular, it focused on potential directions of future *Codex*, FAO, WHO and OIE work in this area, in order to prevent and minimise antimicrobial resistance at the global level.

Particularly, the meeting emphasised the need for rapid implementation of the principles in the WHO Global Principles and OIE Guidelines by governments and all stakeholders. WHO and OIE should keep the documents under continuous review in consultation with relevant stakeholders.

The OIE supports the outcomes of this Workshop.

OIE Position

Aware of the importance of antimicrobial resistance both for animal health and public health, the OIE has already started (1998) to address the matter through a specific scientific *ad hoc* group and an international conference in Paris in October 2001. The outcome of this work has been formally adopted by the OIE Member Countries and is presented as standard and guidelines in the “Terrestrial Animal Health Code” and in “The Manual of Diagnostic Test and Vaccines for terrestrial animals” as the OIE International Standards on Antimicrobial Resistance. Being part of the OIE international standards those guidelines are recognised by the WTO. The OIE is willing to continue this task while reinforcing its collaboration with CAC.

For this purpose, a mechanism should be established to ensure that the already approved guidelines are duly taken into account and in case two documents already exist on a same subject, a common document should be established and recognised by OIE and Codex.

Before developing new guidelines, OIE and Codex should officially exchange information in order to avoid gaps or duplication in their efforts.

In all cases, the development of mechanisms for adoption of International Standards should take in account adoption procedures of both organisations in order to preserve both autonomy and independence of the two “sisters” under the SPS Agreement framework.

Awaiting CAC’s position, the OIE will carry on its work within their Specialized Commission and Working Groups (Animal Production Food Safety Working Group) which already associate representatives of FAO, WHO and elected chairman of relevant *Codex Alimentarius* bodies, including the president of CAC.

Annex: International Standard and Guidelines approved by OIE member countries and recognised by the WTO

Terrestrial Animal Health Code :

Guidelines for the harmonisation of antimicrobial resistance surveillance and monitoring programmes: [Appendix 3.9.1.](#)

Guidelines for the monitoring of the quantities of antimicrobials used in animal husbandry: [appendix 3.9.2.](#)

Guidelines for the responsible and prudent use of antimicrobial agents in veterinary medicine: [Appendix 3.9.3.](#)

Risk analysis for antimicrobial resistance: [Appendix 3.9.4.](#)

Manual of Diagnostic Tests and Vaccines for Terrestrial Animals :

Laboratory methodologies for bacterial antimicrobial susceptibility testing: [Chapter I.1.10.](#)