



# **Report on meetings of expert committees and study groups**

## **Report by the Director-General**

The Director-General submits this report relating to two meetings of expert committees<sup>1</sup> and two meetings of study groups.<sup>2</sup> For each expert committee the recommendations contained in its report are described, with emphasis on their potential contribution to improving the public health situation in Member States, and the implications for WHO's programmes.

The Executive Board is invited to address its comments to the Director-General's report.

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<sup>1</sup> In compliance with paragraph 4.23 of the Regulations for Expert Advisory Panels and Committees (*WHO Basic Documents*, 41st ed., 1996, p. 104).

<sup>2</sup> In conformity with resolution EB17.R13, operative paragraph 4.

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<sup>1</sup> Network of Aquaculture Centres in Asia and the Pacific.

## WHO EXPERT COMMITTEE ON BIOLOGICAL STANDARDIZATION

### Forty-sixth report

Geneva, 17-24 October 1995<sup>1</sup>

#### Summary of conclusions and recommendations

1. The WHO Expert Committee on Biological Standardization which reviews developments in the field of biological substances used in medicine, establishes International Reference Materials and develops requirements and guidelines for the production and control of such biologicals, held its forty-sixth meeting in Geneva in October 1995.
2. The use of International Reference Materials for designating the activity or identity of biological preparations used in prophylaxis, therapy or diagnosis, ensures comparability of the activities of these substances worldwide. The Committee noted that in 1994 about 11 000 International Reference Materials had been distributed to more than 80 countries by the four WHO International Laboratories for Biological Standards. The wide use of International Reference Materials shows the key role of these materials in harmonizing the quality of biologicals at the international level. Based on the results of international collaborative studies, the Expert Committee established 10 new or replacement International Reference Materials and one was discontinued.
3. In addition, it adopted revised requirements for yellow fever vaccine and for sterility tests for mycoplasmas (part of the General Requirements for the Sterility of Biological Substances) and a summary protocol for the batch release of final lots of viral vaccines. Revised requirements for cell substrates used for the production of biologicals were also considered but not adopted. Instead, the Committee recommended further consultation in view of a forthcoming international meeting on the safety of biologicals prepared from mammalian cell substrates. Preliminary draft guidelines for the production and quality control of synthetic peptide vaccines were also noted by the Committee. It recognized the need for such guidelines because of the increasing availability of material for clinical trials, often from small producers and academic institutions that lacked experience in implementing quality assurance. The interpretation of data from clinical trials would be compromised if the consistency of the material employed could not be relied upon from batch to batch.
4. The Committee noted that a review had been carried out of the producers of yellow fever vaccine listed in its forty-second report. Some had been inspected and some had ceased production. Seven institutions were approved for production of yellow fever vaccine.
5. Other items considered by the Committee included standardization and priorities for action in the area of diagnostic preparations, the need in some fields for rapid development of interim reference materials before the full programme for establishing an international standard could be completed, and a report of a WHO informal consultation on cytokine standards. The Committee agreed that in the area of diagnostics, priority should be given to the standardization of the testing of blood and blood products because of their major importance for public health, especially in testing for HIV and hepatitis B and C viral markers.
6. The Committee also considered a report from a WHO informal consultation on low levels of reverse transcriptase enzyme (RTase) activity found in some viral vaccines derived from chicken cells, notably measles, mumps, combined measles-mumps-rubella and yellow fever vaccines. This activity, generally associated with retroviruses, had been detected using new ultra-sensitive assays and further work was being undertaken to assess the sensitivity, specificity and reproducibility of these assays and to place in perspective the presence of low levels of RTase activity in some vertebrate cells and the products derived from them. Taking into consideration the available information, the Committee concluded that the requirements published by WHO for the manufacture and control of vaccines produced in chicken cells continued to be appropriate. It also concluded that those

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<sup>1</sup> WHO Technical Report Series, No. 872 (in press).

vaccines should continue to be used to prevent the diseases against which they are directed since their beneficial effects in preventing morbidity and mortality associated with those infections are well established and that there was no evidence to suggest that they contain an avian virus of any medical significance to humans.

### **Significance for public health policies**

7. WHO's biological standardization activities are important to both developing and developed countries. Biological substances form an increasing proportion of new therapeutic and prophylactic measures and the concept of using well characterized preparations of biological substances as references against which batches of research materials and manufacturers' products are assessed remains fundamental to assuring their quality whether they be prepared by conventional or novel biotechnologies. This, combined with the implementation of recommendations for the production and quality control of biologicals, provides the foundation upon which the deployment of biologicals in public health programmes, such as the vaccines used in the Expanded Programme on Immunization, can be undertaken with confidence. The conclusions and recommendations of the Committee regarding the detection of low levels of RTase activity in some vaccines provides an example of the importance of reaching an expert international consensus on important issues. The annual report of the Committee thus provides important information for national control authorities, manufacturers, nongovernmental organizations and academic entities. A summary of the highlights of the forty-sixth report was published in the *WHO Weekly Epidemiological Record* in April 1996.

### **Implications for the Organization's programmes**

8. The continual work of the Expert Committee provides up-to-date recommendations on biological substances used in medicine, as well as new International Reference Materials. Ways of strengthening such work both on physical and on written standards should be considered in the light of the rapid expansion and increasing complexity of the biologicals field.

9. The importance of the information and recommendations in the report stresses the need for the decision of the Expert Committee to be made available as rapidly as possible, and widely disseminated to all users of International Reference Materials and requirements, such as national control authorities, national control laboratories and manufacturers of biologicals. Thus the decision was taken to publish a summary of the report in the *WHO Weekly Epidemiological Record*. More must also be done to ensure that such reports reach the appropriate technical staff in Member States, and the assistance to Member States in strengthening the capabilities of their national control authorities and laboratories to deal with the complexities of biologicals must continue so as to prevent biological products of inadequate quality or safety reaching the market.

10. The adoption by the Expert Committee of revised requirements for yellow fever vaccine, together with the approval of seven institutions for the production of yellow fever vaccine for the protection of international travellers, enables WHO to fulfil its role in this area.

## **PROGRAMMING FOR ADOLESCENT HEALTH**

### **Report of a WHO/UNFPA/UNICEF Study Group Geneva, 28 November - 4 December 1995<sup>1</sup>**

#### **Summary of conclusions and recommendations**

11. The Study Group concluded that adolescence, characterized by rapid growth and development, including mental development and social relationships, is a time of great opportunity to strengthen present and future health, but also one presenting risks. Much of the behaviour established during this period (relations between the sexes, sexual conduct, eating habits and the use of tobacco, alcohol and other drugs, and ways of dealing with conflicts and risks) affect health throughout life as well as influencing the health of children born subsequently to young people.

12. The Group recognized that adolescent health and development are threatened by a set of interrelated problems that stem from unwanted and unsafe sexual behaviour, substance use, accidents and violence, poor nutrition and some endemic diseases and disorders, for example, tuberculosis and depression. These problems were identified as priorities for adolescent health and development in view of the greater susceptibility of adolescents to these problems than other population groups, the greater likelihood of more serious consequences, and the need to deal with the problems differently to meet the special needs of adolescents.

13. It was noted that systematic efforts in a diversity of settings, including the home, schools, community organizations and health centres, offered considerable potential for the prevention of disability and early death and that measures were necessary to provide adolescents with opportunities to acquire accurate information and good skills, obtain counselling, have access to health services and live in a safe and supportive environment. Many such measures were crucial for both the healthy development of adolescents and the primary prevention of many health problems affecting them.

14. The Group acknowledged the increasing efforts to meet adolescents' needs in countries, but conceded that inadequate scale and sustainability of related programmes, especially in developing countries, prevented measurable improvements in health. It recommended concerted action to support country-level programming by the three agencies, WHO, UNFPA and UNICEF.

#### **Significance for public health policies**

15. The consensus in the Study Group that action to meet adolescents' developmental needs should also discourage them from adopting the behaviour - and protect them in situations - that lead to major health problems, will assist Member States to integrate health and human development in public policies that affect this age group, which represents a quarter of their population.

16. While the health problems affecting adolescents will vary from country to country in terms of prevalence and effects and community reaction, the relation of cause and effect, involving the same people in the same settings, makes it likely that simultaneous measures will be cost-effective, especially in countries with limited resources.

17. Pending the implementation of programmes which take into account common causes of health problems affecting adolescents, specific measures can be introduced into activities against certain health problems such as tuberculosis, malaria and schistosomiasis in order to reduce their prevalence.

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<sup>1</sup> WHO/UNFPA/UNICEF. Action for Adolescent Health: Towards a Common Agenda. Recommendations from a joint Study Group, Geneva: WHO, 1997 (document WHO/FRH/ADH/97.9).

18. Response in the public and private health sector to the health and development needs of adolescents will necessarily include efforts to improve quality of care and flexible financing, organization and delivery of services. The lessons learned will benefit other populations.

### **Implications for the Organization's programmes**

19. With respect to WHO's **normative role**, many programmes have already contributed to knowledge about the determinants of adolescent health and measures to protect it. However, the full range of such measures has not yet been developed, and implementation in countries is fragmentary. Attention must be paid to the provision of health services and to systematic strategies to improve the social environment of adolescents, which is at the origin of many health problems. Focus on adolescents within WHO programmes not traditionally directed at adolescent health problems may be considered. Additional efforts are required to monitor the status of adolescents' health and the coverage and quality of country programmes since the available information is often not age-specific.

20. With respect to WHO's role in **technical cooperation**, coordinated information and technology for Member States should be reviewed and strengthened, as should the capacity of regional offices to integrate the information and to support country programme development and implementation. There are opportunities to strengthen capacity and commitment at country and regional levels through collaboration with UNFPA and UNICEF, in particular. The Coordinating Committee on Health provides a venue for the planning and monitoring of such endeavours.

## **WHO EXPERT COMMITTEE ON LEPROSY**

### **Seventh report**

**Geneva, 26 May - 3 June 1997<sup>1</sup>**

### **Significance for public health policies**

21. The observations, conclusions and recommendations of the Committee are of considerable significance for public health policies. The endorsement of the Committee of the global strategy for the elimination of leprosy has come at the right time to intensify further activities based on the global strategy. The campaign approach to reaching hitherto undetected cases, as well as the WHO special action projects for the elimination of leprosy to reach patients in under-served communities, should be expanded further and additional partners encouraged to participate. Several countries where leprosy is endemic have already implemented leprosy elimination campaigns, and some of these have been nationwide; special action projects are also being implemented, many of them in collaboration with nongovernmental organizations.

22. Reaching every patient in need presupposes simplification of diagnostic and treatment techniques, and demands less stringent operational requirements. The robustness of multidrug therapy,<sup>2</sup> as demonstrated over the past 15 years, has enabled the Committee to suggest more flexible methods of treatment delivery. Classification based on clinical grounds, without an absolute requirement for skin-smear microscopy, also enables wider coverage of treatment and simplified operations. In terms of treatment, the recommended single-dose treatment for newly detected cases classified as having single-lesion paucibacillary leprosy will assist in better treatment compliance and wider coverage. Similarly the possibility of shortening the duration of treatment of multibacillary leprosy from 24 to 12 months without significantly affecting treatment efficacy will also greatly assist in

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<sup>1</sup> For text of recommendations, see Annex 1.

<sup>2</sup> The WHO regimens for multibacillary and paucibacillary leprosy have proved to be "robust", maintaining their efficacy even when drugs have not been taken regularly or for significantly less time than recommended.

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increasing treatment compliance and treatment completion, as well as coverage. In addition, by curing leprosy earlier, the new treatment regimens recommended will also help in reducing the prevalence levels faster.

23. The recommendations of the Committee with regard to integration are important in combating the fear and isolation associated with the disease, thus enabling general health workers at all levels to contribute to its elimination. The recommendations on monitoring progress towards the elimination of leprosy using simple indicators and independent observations will help in identifying problems requiring timely solution.

24. The Committee has asked for a fresh strategy for rehabilitation of leprosy patients using a community-oriented approach so that it can be widely implemented. This calls for collaboration between various agencies, including nongovernmental organizations concerned specifically with leprosy, as well as for community-based rehabilitation.

25. The Committee's call to sustain antileprosy activities beyond the year 2000 in order to deal with the remaining problems will need further definition of residual problems in geographical terms or for cost-effective approaches. For this purpose a careful monitoring mechanism including a geographical information system (GIS) will have to be maintained beyond the year 2000.

26. The recommendations of the Committee to consolidate and strengthen further collaboration and coordination with various agencies, including national and international nongovernmental organizations, highlights the continuing importance of these organizations in contributing to the elimination of leprosy and of dealing with the residual problems beyond the year 2000.

### **Implications for the Organization's programmes**

27. The observations, conclusions and recommendations of the Expert Committee on Leprosy have important implications for WHO's action programme for the elimination of leprosy and other programmes concerned.

28. The endorsement of the global strategy for the elimination of leprosy is very appropriate, particularly in relation to the future course of action for WHO in attaining the target of reducing the prevalence of leprosy to below one per 10 000 population by the year 2000, as defined by resolution WHA44.9. Within the strategy, WHO will have to intensify its efforts, focusing on certain activities or a combination of activities to ensure success, to which the determining of countries and/or areas to receive priority through an organized system of information collection and monitoring will further be crucially important. In all of these approaches, the Organization will have to make optimal use of available resources and mobilize additional resources.

29. To ensure the intensification of activities, both the elimination campaigns and special action projects will have to be expanded further in collaboration with other agencies, and particularly nongovernmental organizations.

30. The simplification of diagnostic and treatment techniques and the introduction of less stringent operational requirements make it possible for WHO further to encourage integration of antileprosy activities in general health services. WHO will also have to continue to ensure the provision of drugs for multidrug therapy to countries free of charge and to make them available in health services in order to increase accessibility and coverage.

31. The improved treatment regimens specified by the Committee should enable WHO further to increase coverage everywhere and, at the same time, to reduce prevalence more rapidly, as well as vigorously promoting the new regimens in the countries where leprosy is endemic so that they are implemented as soon as possible.

32. Rehabilitation of leprosy patients within community-based rehabilitation programmes will continue to be promoted. WHO will continue to disseminate technical material for general health workers as well as specialists in rehabilitation, and to work with other agencies, and particularly nongovernmental organizations, to increase coverage.

33. The question raised by the Committee concerning the sustainability of leprosy elimination beyond the year 2000 is an important one, and WHO will have to continue certain crucial activities, including monitoring through a geographical information system (GIS), so that the gains are sustained and further advances made.

## **FOOD SAFETY ISSUES ASSOCIATED WITH PRODUCTS FROM AQUACULTURE**

### **Joint WHO/FAO/NACA (Network of Aquaculture Centres in Asia and the Pacific) Study Group Thailand, 22-26 July 1997<sup>1</sup>**

#### **Summary of conclusions and recommendations**

34. A Study Group on food safety issues associated with products from aquaculture was jointly organized in July 1997 in Thailand by WHO, FAO and the Network of Aquaculture Centres in Asia and the Pacific (NACA). The meeting was attended by experts from 15 countries.

35. Aquaculture is one of the fastest growing food production methods in the world; production has increased at an average rate of 9.6% per year in the past 10 years. Its increasing global importance is in closing the gap between supply and demand for fish and fishery products and providing a source of nutritious foods of high quality, also for export. With over-fishing in most regions, initiatives to strengthen environmentally-friendly and sustainable aquaculture development, particularly by small-scale producers, should be pursued so as to ensure a greater protection of world food sources. Approximately 90% of global aquaculture production is based in Asia, where it provides an important source of dietary animal protein in the region, and an income for millions of small-scale farmers. Commercial aquaculture contributes significantly to the economies of many producing countries, where highly-valued species are a major source of foreign exchange.

36. The Study Group considered food safety issues associated with farmed finfish and crustaceans, particularly the possibility of biological and chemical contamination during production, the determination and quantification of hazards and measures for their control, including current national and international programmes.

37. The principal conclusions from the meeting were that an integrated approach is needed, with close collaboration between the health, agriculture and aquaculture, food safety, and education sectors; and that measures, based on the Hazards Analysis and Critical Control Point (HACCP) system, should form an integral part of "farm-to-table" food safety.

#### **Significance for public health policies**

38. As natural fish stocks are reaching the limits of exploitation, people will rely to a far greater extent on products from aquaculture as a source of food of high nutritional value. Most consumers and public health authorities consider fish as originating from the high seas and as being safe to eat and nutritious. This is now changing, and the situation is likely to continue to change. Approximately one in four fish that reach the table originate from aquaculture, and people are coming to rely to a far greater extent on farmed species.

39. Many different aquaculture systems exist, from small "family-sized" fish-ponds to the intensive cage-culture industries for farming salmon, for example. The use of integrated farming systems where animal and human faeces is used to fertilize ponds has increased, especially in Asia. The safety of products for human consumption from the different aquaculture systems is of obvious public health significance, and public health authorities must

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<sup>1</sup> For text of recommendations, see Annex 2.



be aware of the risks to human health from such products and ensure that food safety is integrated into related management practices.

40. In formulating public health policies, the following need to be taken into account:

- (1) the uncontrolled sale of chemotherapeutic agents and their use in intensive and semi-intensive aquaculture for improving “feed uptake” and controlling fish diseases, and the resulting accumulation of chemical residues in products;
- (2) the development of resistance to veterinary drugs used in aquaculture and the spread of resistant pathogens in the food-chain and the environment;
- (3) the use of recycled sewage of human and animal origin for stimulating primary production of plankton as fish feed in extensive aquaculture systems and the resulting contamination of products with human pathogens such as bacteria and parasites;
- (4) contamination of fish-ponds with agrochemicals such as pesticides, and possible accumulation of these compounds in farmed fish, particularly in rice-fish systems;
- (5) the fact that public health problems connected with integrated animal husbandry and aquaculture systems are unique;
- (6) the consumption of raw or inadequately cooked aquaculture products that harbour the infectious stages of trematodes.

### **Implications for the Organization’s programmes**

41. The rapid growth of aquaculture is accompanied by more widespread dissemination of traditional semi-intensive farming systems, particularly in rural areas, including various integrated and wastewater-fed systems so that it is important to consider the following implications in particular:

- (1) improvements in sanitation lead to a reduction in the use of night-soil as pour-flush latrines and septic tanks become more prevalent, although night-soil reuse is widespread in some Asian countries;
- (2) wastewater-fed systems in periurban areas have increased with the greater use of wastewater, although there is increasing competition for suburban land owing to rapid expansion of cities, which constrains pond construction;
- (3) intensification in aquaculture using formulated feeds and a similar trend in animal husbandry have led to an expansion of production systems using integrated feedlot, especially in East and South-East Asia.

42. The activities of WHO’s Programme of Food Safety and Food Aid to ensure the safety of aquatic food sources has implications for other programmes:

- the International Programme on Chemical Safety, with respect to chemical residues in foods;
- the Division of Control of Tropical Diseases, and specifically the work on intestinal parasites and the role of aquatic products in the spread of foodborne trematodiasis;
- the Division of Emerging and other Communicable Diseases Surveillance and Control, with the possibility that resistant pathogens will develop and spread infections through the food-chain;

- the programmes on sanitation and rural environmental health, with respect to the use of recycled sewage in integrated fish-farming systems;
- the Joint FAO/WHO Codex Alimentarius Commission, with respect to the development of international codes of hygienic practice for aquaculture.

## ANNEX 1

**WHO EXPERT COMMITTEE ON LEPROSY: SEVENTH REPORT<sup>1</sup>****26 May - 3 June 1997****CONCLUSIONS AND RECOMMENDATIONS<sup>2</sup>**

- (1) The global strategy for the elimination of leprosy, based on the implementation of multidrug therapy (MDT) with case-finding, is proving to be extremely successful in reducing the prevalence of leprosy and should be continued.
- (2) There is a serious need to detect and treat the remaining undetected cases, for which special approaches, along with the extension of MDT services to all general health facilities are required.
- (3) The progressive simplification of diagnostic and treatment techniques has continued to facilitate reaching more leprosy patients.
- (4) On the basis of a multicentre trial, the Committee considered that a single dose of a combination of rifampicin, ofloxacin and minocycline is an acceptable and cost-effective alternative regimen for the treatment of single-lesion paucibacillary leprosy. Furthermore, based on the available information, it is possible that the duration of the current MDT regimen for multibacillary leprosy could be shortened to 12 months.
- (5) There is a need for a fresh strategy for disability prevention and rehabilitation that would ensure a practical, community-oriented approach aimed at reaching the largest number of persons in need with cost-effective interventions.
- (6) The monitoring of elimination through essential indicators should continue. The information reported should be validated and analysed further by independent monitors in order to identify problem situations needing action.
- (7) In endemic countries, antileprosy activities should become, and should remain beyond the year 2000, an integral part of general health services and should also involve the communities to the fullest extent possible. Coordination between various agencies, including national and international nongovernmental organizations, should be consolidated.
- (8) It is recommended that research in leprosy be continued, especially in improving patient care and in addressing post-elimination issues.
- (9) It is important to sustain antileprosy activities beyond the year 2000 in order to deal with the remaining problems, including newly detected cases and persons with leprosy-related disabilities and impairments.

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<sup>1</sup> The full report of the Expert Committee is in preparation for publication in the WHO Technical Report Series.

<sup>2</sup> These recommendations reflect the collective views of the Expert Committee and do not necessarily represent the decisions or the stated policy of WHO.

## ANNEX 2

**FOOD SAFETY ISSUES ASSOCIATED WITH  
PRODUCTS FROM AQUACULTURE****Joint WHO/FAO/NACA Study Group<sup>1</sup>****22-26 July 1997****CONCLUSIONS AND RECOMMENDATIONS<sup>2</sup>**

- (1) There is a need for an integrated approach to controlling hazards associated with products from aquaculture which requires close collaboration between the health, agriculture and aquaculture, food safety, and education sectors.
- (2) Food safety assurance measures should be included in fish farm management programmes and should form an integral part of the fish “farm-to-table” food safety continuum.
- (3) The food safety assurance measures should be based on the Hazards Analysis and Critical Control Point (HACCP) system, although all participants recognized the difficulty in applying such measures to subsistence aquaculture.
- (4) The risks to human health from chemicals used as fertilizers and water treatment compounds in aquaculture production are low.
- (5) Risks from chemotherapeutants used in aquaculture are associated with residues in edible portions of fish flesh and these can be significant, especially in countries where the sale and use of these compounds are uncontrolled.
- (6) There is the added risk of antimicrobial resistance developing in the bacterial flora of fish farms and of such antibiotic-resistant bacteria entering the food-chain.
- (7) Pesticides required in aquaculture can pose food safety hazards, and more information is needed on the types of compounds used, and studies should be conducted to determine if pond treatments with pesticides result in residue levels that are potentially harmful to human health.
- (8) There is an urgent need to raise the awareness of the fish farming community, especially small-scale rural subsistence farmers, to the concept of “Fish as Food” and to the impacts of consumption of contaminated foods on human health.
- (9) Education in the basic principles of food safety assurance should be integrated into existing regional and national training courses for aquaculture development and WHO is urged to provide leadership in this initiative.
- (10) Fish-borne trematodiasis is an important disease in various parts of the world, causing morbidity and serious health complications which are sometimes fatal. Basic research is required on the survival of encysted metacercariae of these parasites in edible portions of fish during traditional processing and preparation; WHO is requested to coordinate research in this area.

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