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Report on meetings of expert committees and study groups¹

Report by the Secretariat

HIGH-DOSE IRRADIATION: WHOLESOMENESS OF FOOD IRRADIATED WITH DOSES ABOVE 10 kGy

Geneva, 15-20 September 1997²

Main recommendations

1. A Joint FAO/IAEA/WHO Study Group was convened to assess the safety and nutritional adequacy of food irradiated to doses above 10 kGy. Drawing on more than four decades of research, including some 500 references, the report identifies several conditions and procedures that constitute good irradiation practices for specific applications. It also considers the principles of risk assessment which are important for compliance with the Agreement on Application of Sanitary and Phytosanitary Measures of the World Trade Organization.
2. This report should be seen as a companion document to an earlier report of a Joint FAO/IAEA/WHO Expert Committee on the Wholesomeness of Food Irradiation which examined the safety aspects of irradiation of food up to an overall average dose of 10 kGy.³ That report did not address the safety of irradiation at doses above 10 kGy because of the lack of sufficient data to perform evaluation at that time and because most of the important applications of irradiation required doses less than 10 kGy. The two reports, along with a scientific update of the 1981 report,⁴ present sound scientific evidence that food irradiated to any dose appropriate to achieve the intended technological objective is both safe to consume and nutritionally adequate. The study group further concluded that no upper dose limit need be imposed, and that irradiated foods are deemed wholesome throughout the technologically useful dose range from below 10 kGy to envisioned doses above 10 kGy. The study group recommended that the use of food irradiation, with direct benefits for food

¹ The Regulations for Expert Advisory Panels and Committees provide that the Director-General shall submit to the Executive Board a report on meetings of expert committees containing observations on the implications of the expert committee reports and recommendations on the follow-up action to be taken.

² WHO Technical Report Series, No. 890, 1999.

³ WHO Technical Report Series, No. 695, 1981.

⁴ *Safety and nutritional adequacy of irradiated food*. Geneva, World Health Organization, 1994.

safety and food availability, be actively encouraged through steps involving standardization, communication, and education in this area.

3. Regarding radiation chemistry, the report reviews studies of the chemical changes in foods and food constituents detected after high-dose irradiation, giving particular attention to the complex physical and physicochemical processes observed in muscle foods. Consistent with the principles of commonality and predictability, the report concludes that the testing of individual foods is not necessary.

4. Regarding the nutritional effects of high-dose irradiation on macro- and micronutrients, the report confirms the commonality and predictability of radiation effects. It also supports the conclusion that irradiated foods are, from a nutritional viewpoint, substantially equivalent or superior to thermally sterilized foods.

5. Examining the effects of irradiation on microorganisms and the factors influencing their radiation resistance, the report concludes on the basis of extensive evidence that high-dose irradiation is no different from thermal processing in producing shelf-stable, microbiologically safe foods.

6. The toxicological safety review of findings from a considerable number of animal investigations and clinical studies using human volunteers, supports the conclusion that irradiated foods using a variety of sources under a variety of conditions are toxicologically safe for human consumption.

7. The report stresses the importance of packaging in facilitating irradiation processing, protecting irradiated food from recontamination, and maintaining the quality of the food. In this regard, the report describes the processing and environmental conditions and control procedures that are essential for ensuring that a food product is sterilized within the targeted dose range.

Significance for public health policies

8. The report and the various reviews and assessments it contains provide valuable information on the importance of high-dose food irradiation as a food technology, its safety with regard to human health and the environment, and the regulatory and manufacturing controls necessary to assure its proper use. It highlights the two applications of food irradiation that can contribute significantly to human health and well-being, namely: the elimination or reduction of certain foodborne pathogens, thus making food safer; and the preservation of food through the destruction of pests and retardation of food deterioration, thus increasing the supply of high quality food.

9. Responding to growing concern over the microbiological safety of food supply, the report reviews extensive evidence on the safety and efficacy of average doses higher than 10 kGy which are needed to ensure that food items, particularly meat and poultry, are rendered consistently free of pathogens. High-dose irradiation is also used for the decontamination of low-moisture products, such as spices, herbs, and dried vegetables, the preparation of sterilized meals or meal components for hospitalized patients, and the production of shelf-stable hygienic products that reduce the need for refrigeration and frozen storage. This application is also important for public health as it can facilitate safe food distribution under tropical and subtropical conditions.

10. In addition to reducing the risk of foodborne disease, the potential role of food irradiation in promoting nutritional status is also significant, and important for public health. Good nutritional status can ward off infections and reduce the risk of some noncommunicable diseases such as cancer. It requires that food should be safe, available and affordable. The food preservation capabilities of

irradiation can contribute to this by improving both the quality and quantity of the world's food supply.

Implications for the Organization's programmes

11. In regard to its contribution to food safety, food irradiation may be one of the most significant contributions to public health made by food science and technology since the introduction of pasteurization. The Member States of WHO are encouraged to consider all possible measures to eliminate or reduce pathogens in food, and improve their supplies of safe and nutritious food.

12. WHO must continue to bring into focus the potential health benefits of a technology which is controversial among consumers. As already stressed by WHO, food irradiation should not be seen as a panacea to all the various food safety and supply problems humanity is facing. On the other hand, food irradiation is a perfectly sound food processing technology which can make available to consumers food products which have an additional margin of safety.

13. WHO must help disseminate accurate information on this technology and promote dialogue with consumers in order to prevent unwarranted rejection or limitation which might endanger public health and deprive consumers of the choice of foods processed for safety.

WHO EXPERT COMMITTEE ON BIOLOGICAL STANDARDIZATION

Forty-eighth report

Geneva, 27- 31 October 1997¹

Main recommendations

14. The WHO Expert Committee on Biological Standardization reviews developments in the field of biological substances used in medicine, and recommends procedures to assure their quality, safety and efficacy, including the establishment of international reference materials.

15. The use of international reference materials for designating the activity of biological preparations used in prophylaxis or therapy, or for ensuring the reliability of diagnostic procedures, allows comparability of data globally. Based on the results of international collaborative studies, the Expert Committee established 14 new or replacement international reference materials. Six existing reference materials were discontinued.

16. The Committee adopted requirements for the production and control of inactivated tick-borne encephalitis vaccine. Tick-borne encephalitis is an acute viral infection caused by two closely-related viruses of the Flaviviridae family and transmitted to humans by ticks. The disease is endemic in forested areas in central Europe and in Asia, where vaccination is considered an important public health measure. The requirements have been formulated to take account of current manufacturing processes and controls and provide for production of vaccine in chicken embryos or on continuous cell lines.

¹ WHO Technical Report Series, No. 889 (in press).

17. Guidelines for thromboplastins and plasma used to control oral anticoagulation therapy were adopted. They represent the current state of the art, reflect major changes to the previous requirements established in 1983, and were drawn up after extensive consultation and discussions with international associations and experts. The guidelines pave the way for more effective treatment of millions of patients suffering from thrombotic disorders.

18. The Committee also adopted an amendment to the requirements for the potency test to be performed by manufacturers on recombinant hepatitis B vaccines. Since the original requirements were established in 1989, *in vitro* potency tests based on ELISA have been developed. The amendment to the requirements permits the use of such tests validated by correlation with the immune response in humans, or with results obtained in mouse immunogenicity tests.

Significance for public health policies

19. WHO's biological standardization activities are important to both developing and developed countries. The WHO Expert Committee was established in June 1947 and during the past 50 years its work has had a significant impact on improving public health globally. Today, however, the increasing complexity and sophistication of biologicals, and the number of biological products coming into clinical use, present a considerable challenge, especially for the developing world. The sensitivity and high profile at international level of the biologicals field call for effective control measures based on a sound scientific foundation.

20. The Fiftieth World Health Assembly (1997) adopted resolution WHA50.20 on the quality of biological products moving in international commerce. It acknowledged the need to strengthen WHO's standardization activities to meet the challenges of the twenty-first century and requested an independent review of WHO's activities in this field. The Committee noted that the review was under way and would recommend measures to strengthen WHO's ability to respond to scientific developments in a timely manner and advise effectively on procedures for assuring the quality, safety and efficacy of biological and biotechnological products used in medicine.

Implications for the Organization's programmes

21. The Expert Committee on Biological Standardization provides up-to-date recommendations on the quality and safety of biological substances used in medicine, and ensures the availability of necessary international reference preparations. Its work enables WHO to fulfil its constitutional responsibilities in this area.

22. The importance of the information and recommendations in the report stresses the need for the decisions of the Committee to be made available as rapidly as possible, and widely disseminated to national control authorities, national control laboratories and manufacturers of biologicals. It was therefore decided to publish a summary of the report in the scientific literature before formal publication in the WHO Technical Report Series.

23. The observations, conclusions and recommendations of the Expert Committee also have important implications for a number of WHO activities, in particular in the areas of vaccines and immunization, with regard to the provision of timely requirements and reference preparations for assuring safety and quality of vaccines; and of safety of blood and blood products, with regard to the provision of reference preparations for standardizing essential diagnostic assays for the detection of virological contaminants.

EVALUATION OF CERTAIN VETERINARY DRUG RESIDUES IN FOOD

Joint FAO/WHO Expert Committee on Food Additives

Fiftieth report

Rome, 17-26 February 1998¹

Main recommendations

24. The Committee made recommendations on residues of several veterinary drugs in food of animal origin. The report also contains general consideration of items relating, *inter alia*, to the neurotoxicity of anthelmintic agents belonging to the avermectin and milbemycin classes of compounds and the evaluation policy of the Committee in recommending maximum residue limits (MRLs) for veterinary drugs in food.

25. The Committee evaluated five anthelmintic agents (eprinomectin, febantel, fenbendazole, oxfendazole, and moxidectin), seven antimicrobial agents (gentamicin, procaine benzylpenicillin, sarafloxacin, spectinomycin, chlortetracycline, oxytetracycline, and tetracycline), three antiprotozoal agents (diclazuril, imidocarb, and nicarbazin), one glucocorticosteroid (dexamethasone), one production aid (recombinant bovine somatotropin), and one tranquilizing agent (azaperone). Acceptable daily intakes (ADIs) were established either at the current or previous meetings for all of these substances. MRLs were recommended for all but dexamethasone, for which an acceptable analytical method for monitoring purposes was not available.

26. WHO has also published summaries of the toxicological and related information upon which the safety assessment of the veterinary drugs was made.² FAO will soon publish summaries of the residue information which formed the basis for the recommended MRLs.³

Significance for public health policies

27. The Committee noted the complexity of the risk assessment process, which required assembling and analysing all the relevant data; interpreting studies of carcinogenicity, mutagenicity, reproductive toxicity, developmental toxicity, antimicrobial activity, and other effects; extrapolating to humans effects observed in experimental animals; and assessing risk to humans based on available toxicological, epidemiological, and microbiological data.

28. Although the need is universal, only a few scientific institutions can undertake such assessments at this stage. It is therefore important to provide all Member States with valid information on both the general aspects of risk assessment and the specific veterinary drugs covered in this report.

29. The recommendations of the Committee are used by the Codex Alimentarius Commission for establishing international food standards, including standards for residues of veterinary drugs in foods. Such standards are established only for substances that have been evaluated by the Committee and have been allocated an ADI. This ensures that food commodities in international commerce meet strict safety standards.

¹ WHO Technical Report Series, No. 888, 1999.

² *Toxicologic evaluation of certain veterinary drug residues in food*. WHO Food Additives Series, No. 41, 1998.

³ *Residues of some veterinary drugs in animals and foods*. FAO Food and Nutrition Paper No. 41/11 (in press).

Implications for the Organization's programmes

30. The evaluation of chemicals in food by the Committee is an ongoing activity. Four meetings of the Joint FAO/WHO Expert Committee on Food Additives are scheduled each biennium to evaluate residues of veterinary drugs in food, food additives, and contaminants.

31. WHO cooperates with and contributes to the Joint FAO/WHO Food Standards Programme, which acts as the secretariat for the Codex Alimentarius Commission. Because the Committee's evaluations are required for progress with proposed standards, its evaluations are crucial to the work of the Codex Alimentarius Commission.

32. Regional offices and WHO Representatives in countries use the Committee's evaluations when advising Member States on food safety regulatory programmes.

WHO EXPERT COMMITTEE ON MALARIA

Twentieth meeting

Geneva, 19-27 October 1998¹

Main recommendations

33. Despite considerable progress in malaria control over the past decade, malaria remains a serious public health problem, particularly in Africa, south of the Sahara, where about 90% of clinical cases occur. Malaria, either alone or in combination with other diseases, is estimated to kill at least 1.1 million people worldwide each year, with over 2000 million people remaining at risk. This report reviews the progress made since 1992 in implementation of the global malaria control strategy and analyses the effect of health sector reforms on malaria control programmes. It also discusses the importance of the Roll Back Malaria project.

34. With regard to disease management and drug resistance of malaria parasites, the report recommends that greater efforts should be made by national governments, health services and partners in malaria control to ensure that all populations at risk have easy access to antimalarial drugs of good quality, which are locally effective and affordable, and formulated and packaged to optimize compliance. Monitoring of the efficacy of recommended treatment options should become a regular activity of all malaria control programmes. In the general health services, particular attention should be given to training in the management of severe febrile disease, including emergency measures at the primary care level.

35. The report also provides guidance on how to predict, prepare for, control and prevent malaria epidemics which threaten large areas of the world.

36. Among disease prevention measures, the use of intermittent treatment for pregnant women in their first or second pregnancy with an effective, preferably one-dose, antimalarial drug is recommended in highly endemic areas. Integrated and selective vector control is recommended as a means of reducing reliance on persistent chemical insecticides. Large-scale operational use of insecticide-impregnated materials should be actively promoted, especially in stable malaria areas in

¹ WHO Technical Report Series, No. 892 (in press). Extract of conclusions and recommendations in Annex.

Africa, south of the Sahara. Restrictions on DDT for public health use should be accompanied by technical and financial mechanisms to ensure that effective malaria control is maintained.

37. In terms of surveillance, the report stresses that accurate epidemiological information is essential for assessing public health needs and monitoring malaria control programmes. It recommends the use of a number of standardized case definitions and indicators. It also emphasizes the need for operational research at national level, to make programme activities effective and responsive to changing epidemiological situations.

Significance for public health policies

38. Health sector reforms are under way in many malaria-endemic countries to improve the effectiveness of publicly financed health services in contributing to health outcomes in a resource-efficient manner. The report deals with the potential implications for malaria control activities of the following aspects of health sector reform: organizational reforms, with special reference to decentralization of planning and budgeting authority; health financing reforms; and increased partnerships with communities and private health care providers. The effective management of malaria control activities requires that, in the process of decentralization, some functions such as coordination should be carried out at central level. Decentralization has important benefits for malaria control as the decision-making and planning capacity is based where problems occur. It is essential, however, that responsibility for the implementation of malaria activities at the district and subdistrict levels should be accompanied by adequate funding and logistical support.

39. Regarding health-care financing reforms, the report stresses that the capacity to provide prompt and effective treatment is crucial to the success of malaria control efforts, and it is important to maintain or build up this capacity whatever the changes introduced in the financing system. The report assesses the impact of user charges on the quality and timeliness of care obtained through publicly funded facilities. It concludes that public funds must be used in a way that ensures availability, affordability, and high quality of antimalarial drugs. A critical analysis of countries' experience with decentralization of the health care system and health care financing reforms should be undertaken in order to elaborate appropriate guidance on this process.

40. Community groups and the private sector are increasingly involved as partners in malaria control. This is a slow but continuous process. Malaria control programmes need to evolve in order to work effectively with private sector providers and make them aware of advances in knowledge about malaria and case management. Simultaneous provision of widely available curative treatment, insecticide-treated materials and chemoprophylaxis for pregnant women may be possible as community involvement increases.

Implications for the Organization's programmes

41. Malaria has been identified as a high-priority disease by governments of endemic countries, and there is growing political commitment to control it. The Roll Back Malaria project, a worldwide partnership launched by WHO, aims to reduce the global burden of malaria through interventions adapted to local needs and strengthening of the health sector.

42. The experts welcomed the initiative taken as a major development in the fight against malaria. The report endorses the technical basis of the project.