



# WORLD HEALTH ORGANIZATION

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## **Report on meetings of expert committees and study groups<sup>1</sup>**

**Report by the Secretariat**

### **EVALUATION OF CERTAIN FOOD ADDITIVES AND CONTAMINANTS**

**Joint FAO/WHO Expert Committee on Food Additives**  
**Fifty-third report**  
**Rome, 1-10 June 1999<sup>2</sup>**

#### **Main recommendations**

1. The Committee evaluated toxicologically the following food additives: the glazing agent hydrogenated poly-1-decene, the sweetening agent erythritol, the thickening agent curdlan, and two miscellaneous substances ( $\gamma$ -cyclodextrin and sodium sulfate). It allocated acceptable daily intakes (ADIs) or temporary ADIs to all these substances except hydrogenated poly-1-decene. It also prepared new or revised specifications for the identity and purity of the food additives that were evaluated and considered specifications for 36 other food additives.
2. Evaluating the safety of sodium iron EDTA (ethylenediamine tetraacetate), the Committee concluded that it could be considered safe when used in supervised food-fortification programmes in response to a need for iron supplementation in a population, as determined by public health officials.
3. The Committee evaluated 184 flavouring agents in two groups using the Procedure for the Safety Evaluation of Flavouring Agents. On the basis of the toxicological, metabolic, and intake data on these flavouring agents and their structural characteristics, the Committee concluded that all posed "no safety concern".
4. The potential allergenicity of refined peanut oil and refined soya bean oil was considered, and the Committee concluded that manufacturing processes that would consistently yield safe products

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

<sup>2</sup> WHO Technical Report Series, No. 896, 2000.

have not been defined. Studies of immunological tolerance to representative refined peanut and soya bean oils will be needed for a full evaluation.

5. The contaminants lead, methylmercury and zearalenone were evaluated. The previous provisional tolerable weekly intakes of 25 and 3.3 µg/kg of body weight for lead and methylmercury, respectively, were maintained. Reviewing the results of a quantitative risk assessment for lead, the Committee concluded that the concentrations found currently in food have negligible effects on the neurobehavioural development of infants and children. The information available on methylmercury was insufficient for an evaluation of neurodevelopmental effects on the children of mothers who had a low intake. For zearalenone, a provisional maximum tolerable daily intake of 0.5 µg/kg of body weight was established.

6. National intake assessments of four food additives (annatto extracts, canthaxanthin, erythrosine, and iron oxides) were evaluated. Recommendations on intake made by the Committee are being used by the Codex Committee on Food Additives and Contaminants in the development of its draft general standard on food additives.

7. The toxicological and related information that served as the basis for the Committee's evaluations of the safety of these food additives has been summarized separately.<sup>1</sup> Specifications have been published by FAO.<sup>2</sup>

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

8. The Committee's work emphasizes the public health significance of the risk assessment of chemicals used in food. It highlights the complexity of that process, which includes assembling and analysing all relevant data; interpreting studies of, for instance, carcinogenicity, genotoxicity, reproductive toxicity and teratogenicity; extrapolating to humans the effects observed in experimental animals; and characterizing hazards to humans on the basis of available toxicological and epidemiological data.

9. Although all Member States face the problem of assessing potential risks of chemicals in food, at present only a few scientific institutions can assess the relevant toxicological and related data. Therefore, it is important that Member States are provided with valid information on both the general aspects of risk assessment and specific food additives and contaminants so that risks can be assessed at the national level.

10. The Committee's recommendations are used by the Codex Alimentarius Commission for setting international food standards. Such standards are established only for substances that have been evaluated by the Committee and have been allocated an ADI (food additives) or for which a tolerable intake level has been set or potencies have been estimated (contaminants). This restriction ensures that food commodities in international trade meet strict safety standards.

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<sup>1</sup> *Safety evaluation of certain food additives*. WHO Food Additives Series, No. 444, 2000.

<sup>2</sup> *Compendium of food additives specifications, Addendum 7*. FAO Food and Nutrition Paper, No. 52, Add. 7, 1999.

### **Implications for WHO's programmes**

11. The Committee evaluates chemicals in food on a continuing basis. Four meetings of the Joint FAO/WHO Expert Committee on Food Additives, two on food additives and contaminants, one on contaminants, and one on residues of veterinary drugs in food, have been scheduled for 2000-2001.
12. WHO is a partner in the Joint FAO/WHO Food Standards Programme, which administers the Codex Alimentarius Commission. The Committee's work is crucial for that of the Commission.
13. Regional offices and WHO Representatives also use the Committee's evaluations when advising Member States on food safety regulatory programmes.

## **EVALUATION OF CERTAIN VETERINARY DRUG RESIDUES IN FOOD**

### **Joint FAO/WHO Expert Committee on Food Additives Fifty-fourth report, Geneva 15-24 February 2000<sup>1</sup>**

#### **Main recommendations**

14. The Committee made recommendations on residues of several veterinary drugs in food of animal origin. It also considered items relating to the interpretation of data on inhibition of cholinesterase activity and issues relating to harmonizing its work with that of the Joint FAO/WHO Meeting on Pesticide Residues with regard to substances used both as veterinary drugs and as pesticides.
15. The Committee evaluated one anthelmintic agent (ivermectin), four antimicrobial agents (flumequine, lincomycin, oxytetracycline and tilmicosin), six insecticides (cyhalothrin, cypermethrin,  $\alpha$ -cypermethrin, dicyclanil, permethrin and metrifonate (trichlorfon)), and one production aid (melengestrol acetate). ADIs or temporary ADIs were established to complement those agreed at previous meetings or the Joint FAO/WHO Meeting on Pesticide Residues on all of these substances. Maximum residue limits (MRLs) or temporary MRLs were recommended for all compounds for which such values had not been set at previous meetings, but the temporary MRLs for tilmicosin, cypermethrin and  $\alpha$ -cypermethrin were not extended because the required information was not available.
16. WHO has published the summarized toxicological and related information upon which the safety assessments of the veterinary drugs were made.<sup>2</sup> FAO has published summaries of the information that formed the basis for the recommended MRLs.<sup>3</sup>

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<sup>1</sup> WHO Technical Report Series, No. 900, in press.

<sup>2</sup> *Toxicological evaluation of certain veterinary drug residues in food*. WHO Food Additives Series, No. 45, 2000.

<sup>3</sup> *Residues of some veterinary drugs in animals and foods*. FAO Food and Nutrition Paper, No. 41/13, 2000.

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

17. The significance for public health policies is the same as that for the Committee's work on food additives and contaminants (see paragraphs 8-13 above).

### **Implications for WHO's programmes**

18. The implications are the same as those for the Committee's work on food additives and contaminants (see paragraphs 8-13 above).

## **THE USE OF ESSENTIAL DRUGS**

### **WHO Expert Committee on the Use of Essential Drugs**

#### **Ninth report**

**Geneva, 15-19 November 1999<sup>1</sup>**

19. The WHO Expert Committee on the Use of Essential Drugs met to review the previous report and to update the tenth Model List of Essential Drugs. The report describes the concept of essential drugs and its relevance to national drug policies, and outlines the criteria for the selection of the listed substances and their pharmaceutical dosage forms. The Committee divided its time between reviewing the current role and functions of the Model List of Essential Drugs and updating the list in the usual manner.

### **Main recommendations**

- **Review of the current role and functions of the Model List of Essential Drugs**

20. The Committee noted the great success of the model list in establishing and promoting the concept of essential drugs, an idea that has been adopted and adapted globally. Both the selection process and the contents of the list itself serve as very useful models, and the Committee considered how these two functions could best be served in the future.

21. The Committee endorsed the current efforts by WHO to link the selection of drugs on the model list to its treatment guidelines and recommended that this approach be continued, to the extent possible, in order to facilitate implementation of such guidelines. It also expressed support for WHO's efforts to develop evidence-based guidelines on treatment of diseases and recognized the value of this activity itself.

22. Decisions to include drugs in the model list should be based on properly identified evidence. The specifications for the submissions to the Committee should be better defined, and the proposal for each drug should include a valid pharmacoeconomic analysis. The reasons for the Committee's final decisions should be carefully recorded.

23. The Committee concluded that the model list should indicate priority conditions and priority drugs for which equitable availability and affordability should be ensured before resources are spent

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<sup>1</sup> WHO Technical Report Series, No. 895, 2000.

on other treatments. In addition to this core list, a special identification should indicate drugs that are cost-effective and safe, but which are not necessarily affordable and for which special training or health care services would be needed for their proper use.

24. The Committee also welcomed suggestions that the available evidence supporting the inclusion of drugs already on the list be identified and made available, and agreed that several therapeutic groups would benefit from a general review. The list contains some drugs that are used to treat uncommon conditions, but omits effective drugs for some other uncommon conditions. The Committee was not able to identify the basis for such inclusions or exclusions, but noted that frequency, severity and subjective perception of importance of the condition and the efficacy of treatment had been used to a varying extent in past decision-making. The Committee decided that it was inappropriate to review this aspect of the list at the meeting.

25. The Committee discussed extensively the need for more explicit criteria for determining which diseases or conditions are appropriately included in the “health needs of the majority” and for which medication for their treatment should be included in the model list. Similarly, clearer criteria or points to consider are needed for the selection of drugs for inclusion. Recognizing the desirability of making the basis of its decision-making more apparent and taking into account the recent availability of the systematic reviews of the Cochrane Collaboration and the other technological advances in medical decision-making, collectively named evidence-based medicine, the Committee recommends, as a matter of urgency, an overall review of the methodology of its decision-making. Then the methodology to be used by future Committees should be defined, including the process for submitting a proposal and the nature of the content of the latter. In this context, the Committee recognized that implementation of these recommendations carries implications for resources.

- **Model List of Essential Drugs** (eleventh list)

26. The bulk of the report contains the revised model list and the text highlights specific considerations made during its revision. In the light of the discussion on the need for a more evidence-based approach to include drugs on the list, few changes were made to the tenth model list. However, nevirapine was added for the prevention of mother-to-child transmission of HIV. This decision was based on the results of a study sponsored by WHO and the recommendations of the WHO/UNAIDS/UNICEF/UNFPA Technical Working Group. Four-drug fixed-dose combinations for the treatment of tuberculosis were also added to the list, following a request by the Stop TB initiative. A paragraph on the value of nicotine replacement therapy in smoking cessation was also added to the text.

### **Significance for public health**

27. Essential drugs are those drugs that satisfy the health care needs of the majority of the population; they should therefore be available at all times in adequate amounts, and in appropriate dosage forms, at a price that individuals and the community can afford. Following the model of WHO’s process, national lists of essential drugs should be drawn up and periodically updated, with the advice of experts in public health, medicine, pharmacology, pharmacy and drug management. More than 150 countries have developed their own national lists of essential drugs. These lists are used for, *inter alia*, the procurement of needed drugs, reimbursement purposes in health insurance schemes, training of health workers, formulation of standard treatment guidelines, and encouraging local pharmaceutical production. In other words, the lists of essential drugs are used to identify the priorities for the national pharmaceutical sector. The selection of essential drugs is increasingly based on

comparative evidence on the efficacy, safety and cost-effectiveness (rather than cost) of recommended treatments of priority diseases.

### **Implication for WHO's programmes**

28. The recommendations to review the procedures for updating and disseminating the WHO Model List of Essential Drugs, and to strengthen the link between WHO's treatment guidelines and the model list have implications for the Organization. A separate report will be presented to the Executive Board at its 109th session in January 2002 on the review of these procedures, which was started in 2000. The selection of drugs for the model list has implications for the setting of pharmacopoeial and relevant reference standards, and for the WHO Model Formulary. Many Member States follow closely the selection of essential drugs for consideration for their national lists of essential drugs.

## **CHEMISTRY AND SPECIFICATIONS OF PESTICIDES**

### **WHO Expert Committee on Vector Biology and Control**

#### **Sixteenth report**

**Geneva, 6-10 December 1999<sup>1</sup>**

#### **Main recommendations**

29. To improve further the quality of pesticides used in public health, WHO should ensure the wide distribution of its specifications, and should strengthen and expand pesticide quality-control programmes. For reasons of human and environmental safety as well as efficacy and economy, pesticide products of good quality are essential.

30. Where pesticides must be used in public health, WHO, in collaboration with industry and other relevant institutions, should further promote safety and judicious use.

31. To ensure harmonization of procedures used in the development of specifications for agriculture and public health pesticides, collaboration between WHO and FAO should be strengthened and formalized. Such harmonized procedures will improve the quality of the specifications; enhance their acceptability by governments, industry and traders; provide transparency to the process and the decisions; and make the development of such specifications more efficient and cost-effective to industry and to FAO and WHO.

32. WHO should facilitate and promote the search for alternative pesticides and control measures that pose minimal risk to human health and the environment and that are cost-effective. In this context, collaboration with relevant research institutions and industry should be strengthened.

33. Considering the limited number of pesticides developed in recent years and the need to extend the useful life of the available compounds, WHO, working with other relevant institutions, should strengthen monitoring of pesticide resistance in vectors and pests of public health importance and promote effective and practical resistance-management strategies.

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<sup>1</sup> WHO Technical Report Series, No. 899, 2001.

34. To improve the management of pesticides globally, WHO and FAO, with the assistance of industry and national authorities, should promote intersectoral programmes for monitoring the use of agricultural, public health and household pesticides.

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

35. The continuing global public health importance of vector-borne diseases means continued reliance on chemical control of vectors. Pesticide products of good quality are essential (see paragraph 29), yet the amount of poor-quality pesticides sold in developing countries is alarmingly high and the ability of most of these countries to exercise control over the quality of pesticides is limited. Both governments and international and regional organizations are, therefore, urged to adopt WHO's pesticide specifications to ensure that good quality products are produced and traded. WHO regional collaborating centres for the quality control of pesticides have been established in Argentina, Belgium, Pakistan and the United States of America to provide the relevant facilities to countries that need pesticide quality control.

36. Health sector reforms pose new difficulties in the selection, purchase, procurement, use and monitoring of insecticides. This complication warrants the need for a multisectoral approach to decision-making on pesticide management. National insecticide policies and guidelines are also needed in order to ensure the cost-effective and safe use of pesticides in public health and to maximize the period over which they remain effective.

### **Implications for WHO's programmes**

37. The WHO Expert Committee on Vector Biology and Control provides up-to-date recommendations on the quality and safety of public health pesticides, and ensures the availability of international standards for quality control and international trade. It enables WHO to fulfil its constitutional responsibilities in this area. The importance of the information and recommendations in the report emphasizes the need for WHO to disseminate widely the recommendations of the Committee to national regulatory authorities, national control laboratories and manufacturers of public health pesticides.

38. The Committee's recommendation on collaboration between WHO and FAO on the use of pesticides has already led to the signature of a Memorandum of Understanding on "Cooperation in a joint programme for development of pesticide specifications". Its implementation will facilitate better working together.

39. The recommendations relating to the development of urgently needed alternative pesticides (paragraph 32) and the promotion of their safe and judicious use in public health (paragraph 30) highlight WHO's unique coordinating role and leadership on this matter.

## HOME-BASED AND LONG-TERM CARE

### WHO Study Group

Ma'ale Hachamisha, Israel, 5-10 December 1999<sup>1</sup>

40. Ideally, home-based care should be an integral component of all health and social systems. To start with, however, there should at least be programmes for health promotion and disease prevention. Progressive steps are: support of informal caregiving in a community-based and “locally owned” manner; introduction of community-based care, including home-care; facilitation of chronic or extended treatment; and then introduction of rehabilitative care, general hospitals and finally tertiary services. The last element of long-term care to be introduced should be institutional care. Allocation of public resources for services should follow the same sequence as the introduction of services. It is too late for many countries to adopt this rational approach, but nevertheless all countries should be encouraged to fill gaps in their existing systems or to implement services, beginning with those that involve the least intervention before moving on to more complex activities.

41. The pattern of development in industrialized countries is not necessarily appropriate or even desirable for developing countries. In developed countries, most systems of long-term care segregate age groups and have separate health and social services for acute and long-term care. Efforts to change these systems should be increased, but developing countries can avoid adopting them in the first place by integrating home care into their primary health care systems.

### Main recommendations

42. The Study Group recommended that care should be acknowledged as a priority human need that everyone has an obligation to satisfy – men and women alike. Furthermore, all sectors of society and government should recognize and support care and caregiving as essential elements of development, including long-term care for people with any type of functional dependence and support for their caregivers.

43. Policies should be developed that include home-based long-term care as an integral part of a country's health and social systems and health reform efforts. These policies should cover not only services but resources and priorities for resource allocation.

44. Creative community-based initiatives for long-term care should be encouraged and respected. The Study Group also recommended that the possibility of their full-scale implementation should be examined.

45. National policies and initiatives at all levels should be based on existing structures and resources and serious consideration should be given to integrating home-based long-term care into primary health care.

46. The Study Group recommended adoption of an approach that focuses on health promotion and disability postponement over the life course and on the needs of functionally dependent people and those who care for them, regardless of the etiology of the dependence and of the age of the client or caregiver.

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<sup>1</sup> WHO Technical Report Series, No. 898, 2000.

47. Home and community services should be designed and implemented, with the aim of meeting the needs of functionally dependent people and their families, before institutional services are established.

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

48. The next two decades will see dramatic changes in the health needs of the world's populations, with noncommunicable diseases, mental illness and injuries becoming leading causes of disability. The size of the older population is expected to increase by up to 300% in many developing countries. In addition, HIV/AIDS will continue to be a major cause of disability (and death). Everywhere the need for long-term care is increasing steeply.

49. These changes require a very different approach to health sector policy and health care services since a disease-specific approach, alone, is no longer appropriate. The one common denominator resulting from these demographic and epidemiological changes is functional dependency and the growing need for care to manage everyday living.

### **Implications for WHO's work**

50. The developments described above mean that long-term care must become an integral part of *all* WHO's work related to:

- health systems development;
- the growing double burden of disease (i.e., infectious diseases, e.g. HIV/AIDS, tuberculosis and malaria; chronic noncommunicable diseases, e.g. cardiovascular disease, cancer and diabetes; mental illnesses and debilitating diseases, e.g. epilepsy, depression and dementia; and chronic disability as consequences of violence, e.g. road accidents and war);
- gender and social development – caregiving being usually women's work has major implications for countries' social and economic development.

## **THE CONTROL OF CHAGAS DISEASE**

### **WHO Expert Committee on the Control of Chagas Disease Second report, Brasilia 20-28 November 2000<sup>1</sup>**

51. Chagas disease occurs throughout Latin America but its clinical and epidemiological characteristics vary from one endemic area to another. Efforts to interrupt its transmission have succeeded in several countries and must continue as cost-effective tools are available for chemical vector control and blood bank screening for *Trypanosoma cruzi*-infected blood.

52. Transmission of Chagas disease was interrupted in Uruguay in 1997, in Chile in 1999, and in 8 of the 12 endemic states of Brazil in 2000. Data indicate that vector- and blood transfusion-related

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<sup>1</sup> Based on an unedited text; the form of words but not the technical meaning may change in the final report as published in the Technical Report Series.

transmission will be interrupted in Bolivia and Paraguay by 2003. By cutting the transmission of Chagas disease in the countries of the Southern Cone Initiative, the disease incidence has been reduced substantially in the whole of Latin America, and the number of deaths has gone down from 45 000 in 1990 to 21 000 in 2000.

53. The report provides technical guidelines for the planning, implementation and evaluation of national control programmes aiming at interrupting transmission. It includes a critical review of current knowledge of the disease and its pathogenesis, the parasites and criteria for their classification, and the vectors and reservoirs of infection. Strategies for the interruption of transmission and their cost-effectiveness are also discussed.

### **Main recommendations**

54. Progress in interrupting transmission of Chagas disease in several countries of Latin America in the past 20 years has been remarkable. National control programmes and research institutions in the endemic countries need continued support so that the goal of eliminating the disease by the year 2010 can be met, as required by World Health Assembly resolution WHA51.14.

55. Endemic countries should continue vector-control and surveillance activities irrespective of the extent to which vectorial transmission has been interrupted. Countries that have successfully interrupted transmission should maintain national vector-surveillance activities for as long as may be necessary to ensure that their territory remains free of transmission of the disease, by intradomestic vectors.

56. Endemic countries should continue screening in blood banks for *Trypanosoma cruzi* so as to ensure that transmission of the parasite through blood transfusion is also interrupted.

57. Efforts should be made at national level to ensure that infected individuals in the early indeterminate phase of the disease and in adulthood are treated with the only currently available drug (benznidazole). Treatment should be administered to such infected individuals living in areas where vector-related transmission has been interrupted. At the same time research into new effective drugs should be continued.

58. National systems and methods for the quality control of diagnostic reagents and insecticides should be developed and implemented before their approval for use in clinical management, blood-bank screening and spraying activities.

59. Epidemiological and clinical studies on congenital Chagas disease should be encouraged in those countries where vector-borne transmission of the disease has been interrupted.

60. The economics of different methods of implementing validated control strategies should be analysed by the ministries of health of endemic countries.

61. WHO's research and training activities, including those of the UNDP/World Bank/WHO Special Programme for Research and Training in Tropical Diseases, should continue to be supported.

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

62. As was implicit in resolution WHA51.14, support needs to be focused on applied entomological and epidemiological research into the control of both domiciliated and non-domiciliated triatomine vector species in the Andean countries and Central America.

63. As the vectors of Chagas disease in these countries are not strictly domiciliated, control strategies will need to be formulated or adapted to suit the local entomological conditions where the vectors can reinfest dwellings from sylvatic ecotopes.

64. The analysis and recommendations presented in the report can contribute to subregional projects, including the Southern Cone, Andean countries and Central American initiatives, detailed in paragraphs 65-70 below.

### **The Southern Cone Initiative**

65. This initiative, bringing together Argentina, Bolivia, Brazil, Chile, Paraguay, and Uruguay, was launched in 1991 in order to implement a strategy for eliminating Chagas disease that was based on interrupting vector transmission and systematic screening of blood donors. As a result, it has prevented 325 000 new cases of infection by *T. cruzi* each year and 127 000 cases of cardiomyopathy and sudden death. The model implemented in the Southern Cone has already been adapted to the other two subregional initiatives (see paragraphs 68-70 below).

66. The economic impact is equally noteworthy. Recent cost-effectiveness studies in Brazil show that the countries involved have saved more than US\$ 1140 million in health care expenditure and social security costs. Investment in the initiative from national sources by these countries between 1992 and 2000 totalled some US\$ 350 million.

67. At present, the major challenge is to ensure the sustainability of the programme in the epidemiological context of a very low incidence of *T. cruzi* infections and an institutional context of health sector reform, where the decentralization of operations may result in lower priority for elimination activities.

### **The Andean countries Initiative**

68. This initiative was begun in 1997 in Bogota, by Colombia, Ecuador, Peru and Venezuela. Data from Venezuela indicate that, after vector control activities, seroprevalence rates for *T. cruzi* infection in children under 10 years have decreased steadily in the past four decades from 20.5% (1958-1968) to 3.9% (1969-1979), 1.1% (1980-1989) and 0.8% (1990-1999). From 1990 to 1999 the incidence of infection in the 0-4-year age group has been reduced by 90%, to less than 1.0%. *T. cruzi* transmission is confined to the states of Barinas, Lara and Portuguesa.

### **The Central American Initiative**

69. Resolution No. 13 of the XIII Meeting of the Health Sector in Central America (RESSCA) (Belize, 1997) launched the Central American initiative for the control of vector- and blood transfusion-related transmission of *T. cruzi*.

70. The elimination of *Rhodnius prolixus* bugs from Guatemala, Honduras and Nicaragua is feasible by 2005. Surveillance activities for the sylvatic vector *Triatoma dimidiata* should be maintained for

the years to come. At present there are no routine vector-control activities in Belize, Costa Rica and Panama.

**Implications for WHO's programmes**

71. Resolution WHA51.14 endorsed a strategy to ensure the interruption of transmission of Chagas disease that combined applied field research and control activities. The goal is to eliminate transmission by the year 2010.

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