PROVISIONAL SUMMARY RECORD OF THE ELEVENTH MEETING

Palais des Nations, Geneva
Monday, 18 May 1970, at 9 a.m.

CHAIRMAN: Dr P. K. DURAISSWAMI (India)

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Note: Corrections to this provisional summary record should reach the Chief, Editorial Services, World Health Organization, 1211 Geneva 27, Switzerland, before 3 July 1970.
1. **DRAFT SECOND REPORT OF COMMITTEE A (Document A23/A/3)**

Dr CASTILLO (Venezuela), Rapporteur, read out the draft second report of Committee A.

**Decision:** The report was adopted unanimously.

2. **QUALITY CONTROL OF DRUGS (Resolution WHA22.50; Document A23/P&B/8 (continued))**

Dr MACUCH (Czechoslovakia) said that his country had welcomed WHO's requirements for Good Practices in the Manufacture and Quality Control of Drugs, the direct consequence of which had been the establishment of a drug control body under the Czechoslovak directorate—general for the pharmaceutical industry. That body's task was to co-operate closely with the State Institute for the quality control of drugs and to introduce technological improvements where possible. The aim first and foremost was to control drug quality at all stages of manufacture and to ensure that the documentation on the products was of the desired standard. First experience of control had indicated certain problems which might also have been experienced by others. The documentation — standards, pharmacopoeia monographs, quality specifications, etc. — was overtaken rapidly by scientific developments, while the pharmacopoeia, for instance, could only be reissued every five years. Directives were issued to enable the official laboratory to use all the control methods that would best ensure drug quality, and it had been emphasized that the pharmacopoeia specifications represented the minimum requirements. The importance of control during manufacture was not always sufficiently appreciated. It should also be realized that packaging often required as strict a control as the product itself. The quality of various additives, such as pill coatings, preservatives, colouring matter and flavourings, should also be studied in close co-operation with the health services, which had valuable experience with food products. Attention should be paid to all the sectors concerned — industry, pharmacies and warehouses. Up-to-date recommendations could be very useful. A system of certification of the quality of pharmaceutical products in international trade would provide protection to importing countries. On the basis of its own experience, his country could confirm that, despite certification by the manufacturer, a proportion of the drugs imported had sometimes fallen below standard. Czechoslovakia imported 200–300 different kinds of drugs annually, and had imported 2000 batches in 1969 for almost all of which satisfactory quality specifications existed. Nevertheless it had been found that 13 per cent. of the samples had failed to meet those specifications. There had also been instances in which the quality requirements had not been indicated in the specifications. Under the terms of its new pharmacopoeia, Czechoslovakia required that non-sterile drugs should not contain more than 1000 pathogenic germs per gram or per millilitre. The Nordic countries were even stricter. The majority of other countries made no provision in their pharmacopoeia concerning bacteriological quality. It was realized, however, that WHO was giving close attention to the problem but that its work on the subject had not yet been completed. The draft concerning the certification of drugs on the part of exporting countries undoubtedly conformed to resolutions WHA18.36 and WHA19.47, which emphasized the necessity of establishing adequate quality control systems for pharmaceutical preparations.

Dr AKIM (United Republic of Tanzania) said that the subject was of considerable interest for developing countries. When it had been discussed at the Twenty-second World Health Assembly, a number of speakers had pointed out that the responsibility for ensuring the high quality of drugs must rest with manufacturing and importing countries alike. His country, which was an importing country, had been considering what measures it should take in that respect. It was grateful to the Director-General for his initiative in sponsoring seminars and other training schemes in drug quality control, and hoped that the educational needs of developing countries would not be forgotten in future activities of that kind. He understood that many developing countries were in the process of establishing national control laboratories; they could derive great benefit from specific training schemes.
Professor BLAGOJEVIC (Yugoslavia) said that the requirements for Good Practices in the Manufacture and Quality Control of Drugs were very useful and would be of great service to many countries that had not yet included in their laws on drugs specific conditions to be fulfilled by all drug manufacturers. A new law on drugs was being promulgated in Yugoslavia, and the proposals of the WHO Expert Committee had been accepted. It had also been noted that WHO had strengthened its training programme for drug control personnel and that a number of seminars had been organized. Such activities were very important for countries which lacked experience or qualified personnel in drug control. WHO's efforts in that area were valuable, and it was to be hoped that the Organization would take advantage of the experience and qualified personnel of all countries prepared to offer such services. Yugoslavia, which had a strict and well organized drug control system, was ready to take part in such a programme, as a way of enabling those with no well developed control services to protect themselves against poor-quality drugs. WHO were working in close collaboration with the International Pharmaceutical Federation, which had done a great deal of work on the standardization of chemical and biological control methods and on other matters concerning drug quality.

Dr BADAWI (United Arab Republic) said that chemical preparations for the pharmaceutical industry were either prepared locally in his country or imported by the General Organization for Drugs, in both cases on the basis of pharmacopoeias or authorized references. They were analysed by the Ministry of Health laboratories before release by the control section in the factories before manufacture.

Every preparation, whether locally manufactured or imported, had first to be registered. A scientific committee of professors of the Faculty of Medicine and Pharmacy and the Ministry of Public Health examined information and certificates on such preparations, and the pharmacological action and research carried out on them. The preparations were then analysed in the Ministry of Health laboratories and, if found to conform to the required standards, registered.

All local preparations were examined after manufacture, first in detail in the control laboratories in the factories, secondly in the general centre of research and control, which periodically tested the stability and purity and the methods of analysis, thirdly in the Ministry of Public Health laboratories. Samples from factories, pharmacies or hospitals were sent by the General Administration of Pharmacy or local inspectors in each territory.

Before drugs were accepted in the Ministry of Health general stores and governmental establishments they were analysed in the Ministry of Health laboratories and not released until they had been proved to be in conformity with official pharmacopoeias or with registered formulas.

To ensure conformity, pharmacy inspectors took samples periodically for analysis from prescriptions prepared in the pharmacies.

The United Arab Republic exported a number of drugs to several other countries. Such drugs were registered and had to comply with all the laws in application inside the country. Before exportation, they were analysed in control laboratories inside the factories, in the research control centre and in the Ministry of Health laboratories.

The Ministry of Health laboratories were responsible for the analysis and control of medicaments and chemicals sent to them by the inspection and registration sections, the Ministry of Health general stores and other government establishments. Analysis was conducted according to the Egyptian Pharmacopoeia or any other recognized pharmacopoeia or registration file. The laboratories consisted mainly of two divisions: the chemical section, which dealt with the chemical and physicochemical assay of drugs, and the biological section, which dealt with the biological assay of drugs, both pharmacological and bacteriological. Laboratories thus existed for the testing of chemicals, vitamins, hormones, antibiotics and insecticides and for toxicological, pharmacological, pyrogen and sterility assays or tests. The staff included physicians, pharmacists, pharmacologists and chemists, specialists in physics and in veterinary products and clerical staff. The activity was sponsored by WHO.
Dr RACOVEANU (Romania) said that quality control of drugs in Romania was carried out by a system in conformity with resolution WHA22.50, developed over the past 20 years. A State Institute was responsible for drug control and pharmaceutical research and there were also 17 drug control laboratories throughout the country. There was a drug committee in the Ministry of Health which had the task of examining all new drugs, issuing authorizations for distribution, studying any harmful effects observed and taking any necessary measures. Laboratory control of products manufactured in Romania was based on the national Pharmacopoeia, of imported products on the pharmacopoeia of the exporting country. New additions of the Romanian Pharmacopoeia were issued periodically. The existence of a well developed network of control laboratories made it possible for the country not only to carry out control with sufficient frequency but to offer the services of those laboratories to WHO and to countries that did not possess such services. That offer included the possibility not only of carrying out drug control but also of accepting fellows for training. Quality control of drugs in health protection was of such importance that emphasis had to be placed on the necessity of meeting, through WHO, the requirements for good practices recommended in resolution WHA22.50; his country's specialists were at present drawing up observations which would shortly be submitted to WHO with a view to further study of the problem at the Twenty-fourth World Health Assembly.

Dr SIDERIUS (Netherlands) observed that many countries had taken steps to implement a control and certification system in line with resolution WHA22.50. The time had come, however, to evaluate the overall effects of the scheme on the quality control of pharmaceutical products entering international trade. Taking into consideration the Director-General's report (A23/P&B/8) and the Committee's discussion on the subject, his delegation, together with the delegations of Austria, Hungary, India, Sweden, the United Kingdom of Great Britain and Northern Ireland and the United States of America, would like to submit the following draft resolution on the subject:

The Twenty-third World Health Assembly,
Recalling resolution WHA22.50;
Having examined the report of the Director-General on the quality control of drugs;
Noting that several Member States have already taken or are taking steps towards implementing a control system and certification scheme in line with the recommendations in resolution WHA22.50; and
Stressing the need for further information from Member States on the implications on a national level of the adoption of the recommendations,
1. INVITES Member States to inform the Director-General on steps taken with respect to resolution WHA22.50 and their possible administrative implications, including suggestions for improvement of the texts on Good Practices in the Manufacture and Quality Control of Drugs and the certification scheme; and
2. REQUESTS the Director-General to review in the light of information obtained the requirements for Good Practices in the Manufacture and Quality Control of Drugs and the certification scheme and to report to the Twenty-fourth World Health Assembly.

Dr BAUHOFER (Austria) recalled that the European Free Trade Association (EFTA) had recently held a meeting at Geneva to discuss a Convention for the Mutual Recognition of Inspections in Respect of the Manufacture of Pharmaceutical Products, which concerned both the work already undertaken and the discussions in progress in WHO. He would be glad to know whether WHO had had any working contacts with EFTA on the subject.
Dr VASSILOPOULOS (Cyprus) said that the subject under discussion was of great importance, particularly to those countries which did not themselves manufacture pharmaceutical preparations but imported them from various countries.

During the past few years, his country's market had been flooded with hundreds of such products of unknown and doubtful efficacy, and the Government had therefore enacted a law for the control of the quality and price of drugs. A new analytical laboratory had been constructed, in which the quality control services would be accommodated, together with other services. In that connexion the WHO fellowships for chemists and pharmacists to study abroad and WHO's provision of the necessary equipment for the control of pharmaceutical products were of great value. His country was pleased that a WHO seminar on drug control at which Cyprus had been represented had met in Pakistan in March 1970.

Dr BLOOD (United States of America) said that his delegation continued to support the certification scheme, developed under Article 23 of the Constitution, of which it had declared itself in favour at the Twenty-second World Health Assembly. The principles of pharmaceutical quality control and the requirements for Good Practices in the Manufacture and Quality Control of Drugs were the result of a great deal of work by WHO and provided an excellent basis for the scheme. The standards in the United States were somewhat more demanding on certain points, but were generally in full accord with the standards being developed and proposed by WHO. His delegation foresaw no difficulty in participating in the certification scheme and was happy to be included as a co-sponsor of the draft resolution introduced by the Netherlands delegate.

Dr BULWANYI (Uganda) observed that many of the problems in the quality control of drugs were highly technical. Uganda exported no drugs and imported almost all those used in the country. The manufacturer and the consumer alike were interested in the problem. For sales to continue at a high level the product must be effective and cause no untoward effects. If a drug was found to produce side effects or to be less effective than a drug made by another manufacturer, the consumer would naturally shift to the safer or more effective brand. A manufacturer with declining sales should thus be actively interested in the subject. Buyers of one of his products with declining sales might also be cautious about other drugs of his. Quality control was thus of great importance to drug manufacturers from the point of view of maintaining and extending sales.

The interest of buyers in safety and efficacy was obvious. Unfortunately, a foreign buyer could not directly influence practice in the manufacture and quality control of the product bought. An extreme possibility was that manufacturers might go on producing and distributing to foreign markets a drug that had been banned for distribution in their own country because of its side effects. That was bad practice which the manufacturer's country should not allow, especially as buyers might be unaware of the ban in the country of origin.

Drug manufacturers rendered a very valuable service to humanity by producing safe and effective drugs, but that highly rewarding work involved a great deal of responsibility towards consumers, some of whom might not be in a position to know what they were consuming. His delegation therefore hoped that manufacturers would do their work conscientiously. Little was known in Uganda about what had already been done in that respect, but his delegation wished to commend the firms that had so far produced consistently safe and effective drugs and the countries in which good practices were followed. Other firms and countries should begin to follow their example as soon as possible, in their own interests and in those of consumers and of all humanity.

His delegation commended the steps already taken by WHO to promote the requirements for Good Practices in the Manufacture and Quality Control of Drugs and hoped that further steps would be taken.
Dr CAVIGLIA (Uruguay) supported the draft resolution introduced by the Netherlands delegate, since it dealt with a subject of great importance for his country. WHO and PAHO had been discussing the question of setting up a drug control centre in Uruguay. That project, which was to be carried out co-operatively by his Government, PAHO and UNDP, with a financial contribution from IBRD, had been delayed pending the necessary legislation. The law for the establishment of the centre in Montevideo had now been adopted and it was hoped that the centre would be in operation in about two years' time.

Professor MONDET (Argentina) believed that the quality control of drugs should be the responsibility of the exporting country and that it was quite unacceptable that such countries should authorize the export of products prohibited in their own domestic market.

He stressed the importance of disseminating information on useless or outmoded drugs, even though they might produce no adverse reactions. Many were still being sold on a large scale throughout the world as a result of successful advertising campaigns; the President of the United States of America had recently submitted a report to the Senate showing the magnitude of the problem in that country and in the rest of the continent.

It was essential that those countries which practised quality control of drugs, such as his own, should inform WHO and the Office of Public Health on the most frequently observed defects of imported drugs. In his country, one of the most commonly noticed shortcomings was the inaccuracy of the specification of the amount of active ingredients on the wrappers and in the advertising literature. Since the actual amounts contained were often substantially smaller than those indicated, there was a danger of physicians making mistakes in prescribing the dosage to be taken. There was also a need for revision of University curricula, to ensure that doctors had a better practical knowledge of therapeutics and could thus better judge the value of the drugs they prescribed.

In Argentina, the Institute for the Quality Control of Drugs was already in its fourth year of operation. It was a comprehensive and costly service requiring a large technical staff, half of which worked permanently at headquarters while the rest worked abroad in the field. Running costs were estimated at one per cent. of the cost of all drugs sold in the country and the annual budgetary allocation for the Institute had risen to some two and a half million dollars.

His delegation supported the draft resolution submitted by the delegations of Austria, Hungary and other countries and hoped that at the Twenty-fourth World Health Assembly a further resolution would be approved calling on countries to provide specific information on the various questions raised in the course of the discussion.

Dr BERNARD, Assistant Director-General, replying to general points raised by delegates during the debate reminded the Committee that, in view of the short time that had elapsed since the Twenty-second World Health Assembly, the Director-General's report contained in document A23/P&BR/8 could be considered only as an interim report, as it could not be fully representative as yet of the reactions of Member States. He was grateful to delegations for the valuable additional information they had provided in the course of the discussion and to those who had indicated that, in general, the documents prepared so far by the Director-General and approved by the Twenty-second World Health Assembly provided a satisfactory basis for the development of systems of drug quality control at the national level in both exporting and importing countries. The delegate of Switzerland, among others, had suggested that the rules for good practice could be more detailed; that would be desirable but, on the other hand, to be widely applicable under the very different circumstances obtaining throughout the world, a text of that nature must be couched in general terms. The Director-General would take into account in preparing his next report all the comments and recommendations that had been made, which he hoped would subsequently be submitted in writing.
He appreciated the offers made by some Member countries to work in close co-operation with WHO and to put their experience and equipment at the service of those countries which still lacked the necessary resources, particularly by providing training facilities in the particular skills of drug control. The Director-General particularly welcomed such offers since, as his report indicated, he was aiming not only at a study of the replies received on the subject of good manufacturing practices but also at defining ways of ensuring that all countries possessed means for adequate control. WHO was co-operating with UNDP in sustained efforts to set up control laboratories on a regional basis, but such projects were only valuable if the new laboratories were manned by adequately trained staff. That was why the Director-General had over the last year put such emphasis on training activities. He recalled, too, the increasing co-operation between WHO and the United Nations Industrial Development Organization (UNIDO), which was trying to promote the development of pharmaceutical industries in countries where previously none had existed. WHO was to ensure, in that connexion, that rules of good manufacturing practice and quality control were adopted from the outset by the new pharmaceutical industries.

In relation to the inquiry of the delegate of Austria on whether WHO had any contact with EFTA in relation to drug quality control, he recalled that EFTA, on the one hand, and the Association of Pharmaceutical Industries of the European Common Market, on the other, had become very concerned with the problem and had joined with other organizations throughout the world in establishing the International Federation of Pharmaceutical Manufacturers. WHO had been kept fully informed on the development of their various activities and had been invited by the Federation to explain its objectives to the latter's General Assembly in 1969. It was interesting to note that all the activities undertaken either by EFTA or by the Association of Pharmaceutical Industries or by the International Federation over the previous two years were in harmony with the resolutions adopted by the World Health Assembly. It was an indication that manufacturers were conscious of their responsibilities with regard to quality control, as the delegate of Uganda had stressed they should. In reply to a point raised by the delegate of Yugoslavia concerning the International Pharmaceutical Federation, he observed that WHO had very close official and working relations with that organization.

There was thus a whole group of co-ordinated activities developing in connexion with the central problem of quality control of drugs. It was to be hoped that they would prove very fruitful in the years to come.

Dr HALBACH, Director, Division of Pharmacology and Toxicology, replying to a point raised by the delegate of Australia at the tenth meeting with regard to radiation sterilization, explained that WHO had been working on the matter for some time in close co-operation with the International Atomic Energy Agency (IAEA), which was itself closely concerned with establishing suitable methods of food irradiation, protection of dosage standards and so on. The problem of drawing up the necessary legislative procedures to be adopted in the application of new techniques was again being dealt with at the international level by IAEA and WHO jointly.

Replying to a question by the same delegation about the possibility of producing a guide on biological requirements, i.e., control of the production, efficacy and safety of serological preparations and vaccines, he explained that WHO had been working on the problem for some ten years and had amassed a substantial collection of detailed requirements for the production and control of the so-called "biologicaLs". It had been asked whether the requirements could not be made more homogeneous and produced in a form similar to that of the good practices for the manufacture and control of drugs. He thought the idea useful, but the variability and specificity of biologicals made the elaboration of a set of good practices much more difficult than in the case of drugs. With regard to bacteriological impurities, WHO was again working on the subject and hoped that a list of stringent tests would one day be included in the International Pharmacopoeia.
The delegate of Czechoslovakia had referred to the deplorable findings in his country on analysis of imported drugs. Both he and the delegate of Argentina had remarked on the high percentage of imported drugs containing substandard amounts of the drug. It would indeed be very useful if such findings could be reported to a central clearing-house of information.

The delegate of Argentina had also referred to the urgent need for better training of doctors in practical therapeutics. In that connexion, he drew attention to the recently published WHO report in the Technical Report Series, on clinical pharmacology. That report made it clear that the development, practice and teaching of clinical pharmacology should be encouraged in the interests of rational therapy. It also urged that every attempt should be made to establish the new discipline as rapidly as possible as an integrated branch of clinical medicine and experimental pharmacology.

The same delegate had also raised the question of the efficacy of drugs and the delegate of Uganda had spoken on the matter from the consumer's point of view, stressing that in most cases consumers were completely at the mercy of the manufacturers and of those prescribing the drugs. He recalled that the matter had already been broached in connexion with the WHO service for the dissemination of information on the decisions of governments to prohibit or limit the use of a drug because of the adverse reactions observed in connexion with it. Since, however, the lack of efficacy of a drug might well in some cases be more harmful than its producing a straightforward adverse reaction, he suggested that the matter be taken up again in the discussions on the programme and budget, since it was different from pharmaceutical quality control.

Lastly, he welcomed the statement made by the delegate of Uruguay to the effect that legislation had recently been passed in his country authorizing the establishment of a drug control research centre in Montevideo. The centre would function within the framework of the WHO programme encouraging countries to work together to obtain better standards of drug quality control.

Professor MONDET (Argentina) reverted to the important question of the continued use of drugs of no therapeutic value, some 23,000 of which had already been eliminated from his country's pharmacopoeia but many more of which certainly existed. He pointed out that, even when doctors no longer prescribed drugs shown to be of no value, the pharmaceutical firms concerned still pressed their sale on pharmacists and retailers. He was therefore very anxious to know the opinions of technicians and experts from other countries on the drugs still in circulation that had been proved to be useless.

Dr HALBACH, Director, Division of Pharmacology and Toxicology, agreed that the inefficacy of drugs still on the market was of prime importance, particularly since their administration might well preclude the possibility of effective treatment. Resolution WHA16.36, on the dissemination of information received from governments on decisions to withdraw or limit the use of particular drugs, had not called for information with regard to the efficacy of the drugs in question; and in fact, very few decisions to prohibit the use of a drug had cited its lack of efficacy as the reason. It would, therefore, be advisable to amplify the resolution to include lack of efficacy as a reason for reporting the withdrawal of a drug to WHO and subsequently disseminating that information to Member States. WHO was very concerned that the discipline of clinical pharmacology, the practice of which would reveal the uselessness of marketed drugs, should be extended and accepted as much as possible.

Dr BLOOD (United States of America) said that his country was also very much concerned with the matter of drug efficacy. Since the subject was somewhat different from that of quality control, his delegation had intended to introduce a draft resolution on the matter at a later stage. He would, however, be prepared to make the text of the proposed draft resolution available whenever the Committee was prepared to discuss it.
Dr BEDAYA NGARO (Central African Republic) supported the draft resolution before the
Committee, but he wished to propose a few small amendments to reflect the spirit of the
discussion that had taken place on the subject.

Thus, he proposed the insertion after the last preambular paragraph of a new first
operative paragraph to read as follows:

"CONGRATULATES the Director-General on his report; ...." 

The two original operative paragraphs would then become numbers 2. and 3. respectively,
and the latter would be modified slightly as follows:

"REQUESTS the Director-General to continue to review ...." 

Dr SIDERIUS (Netherlands) said that he and the other co-sponsors of the draft resolution
would be very glad to accept the amendments proposed by the delegate of the Central African
Republic.

Decision: The draft resolution submitted by the delegations of Austria, Hungary,
India, Netherlands, Sweden, the United Kingdom of Great Britain and Northern Ireland
and the United States of America, as amended by the delegation of the Central African
Republic, was adopted.

3. DRAFT RESOLUTION ON THE HUMAN ENVIRONMENT (Documents A23/13 and A23/A/Conf. Doc. No. 18)

Dr SIDERIUS (Netherlands) introduced the following draft resolution on behalf of his own
delegation and those of Austria, Belgium, Brazil, Burundi, Chile, Democratic Republic of the
Congo, Federal Republic of Germany, Finland, Hungary, India, Indonesia, Iran, Ireland,
Luxembourg, Mexico, Nigeria, Norway, Pakistan, Peru, Poland, Rwanda, Romania, Switzerland and
the Union of Soviet Socialist Republics:

The Twenty-third World Health Assembly;

Recalling the principles enunciated in the Constitution, including the definition of health;

Recalling further the responsibility of the Organization to promote, in co-operation
with other specialized agencies where necessary, the improvement of the various aspects
of environmental health;

Recognizing that the World Health Organization should provide international
leadership in the prevention and control of environmental factors adversely affecting
human health; and

Recalling further Article I of the Agreement between the United Nations and the
World Health Organization, which provides:

"The United Nations recognizes the World Health Organization as the specialized
agency responsible for taking such action as may be appropriate under its
Constitution for the accomplishment of the objectives set forth therein";

1. EXPRESSES its growing concern that the consequences of artificial factors in the
environment are adversely affecting the conditions of human health;
2. REQUESTS the Director-General to develop and submit to the Twenty-fourth World Health Assembly a long-term programme for environmental health, including a world-wide system of surveillance and monitoring in close collaboration with national efforts, as well as establishing a code of environmental health, with the financial implications of such a programme;

3. EXPRESSES the wish that in this respect due consideration should be given to the effect of water, soil, food and air pollution, noise and other negative environmental factors on human health and to the need for establishment of environmental health criteria, guidelines for preventive measures, and methods of determining priorities and allocating resources based on health problems and needs in both developing and developed countries.

During the general debate a number of delegations had drawn attention to existing and potential threats to human health and the Netherlands delegation had expressed its concern about the threat to health from artificial factors in the environment. Environmental pollution was one of the major challenges to society, and WHO should assume its responsibilities for international leadership, under Article 2(a) of its Constitution and Article I of its Agreement with the United Nations, by providing a programme for the prevention and control of environmental factors adversely affecting human health.

Environmental pollutants were already a threat to health in many parts of the world, through the enormous and increasing quantities discharged into the air, water and soil. The river Rhine alone, for example, was responsible for a monthly discharge of 8000 kg of mercury, 90 000 kg of arsenic, 20 000 kg of cadmium and at least 900 kg of persistent insecticides into the North Sea and large quantities of even more dangerous chemical waste materials were dumped directly into the seas. The environment was being continuously exposed to growing quantities of pesticides; food was being contaminated by residual pesticides and by artificial additives; the air was being contaminated by many different kinds of chemical and other artificial pollutants. Not enough was known of the long-term effects of all those substances on physical and mental health. The ecosystem's diminishing capacity to deal with the pollutant load was likely to lead to vast changes in the environment, with disastrous effects on the human ecosystem and on human health. Immediate action was needed.

Although environmental health problems might be partly local in character, they were becoming more and more important regionally and inter-regionally, as, for example, in relation to the quality of water in large rivers such as the Nile or the Ganges. Persistent pesticides and heavy metals affected the quality of sea water and thus the quality and quantity of the fish on which humans depended for food. Residual pollutants in food had widespread effects through inter-regional trade. The quality and quantity of drinking water had become a serious world problem.

All those new and serious threats called for a new long-term strategy by WHO. In accordance with Article 2 (f) of the Constitution, WHO should maintain a world-wide system for the surveillance and monitoring of artificial environmental factors affecting human health, in close co-operation with Member States. Monitoring should include the measurement of dangerous pollutants in the environment - in water, air and food - and in human tissues; epidemiological surveillance of the prevalence and ill effects of disease in areas with different pollutant loads; and studies in the field of comparative geographical pathology. He instanced a study in the Netherlands which had revealed that the dieldrin content of mother's milk was four times the acceptable daily intake for infants.

National action was of primary importance in environmental health but many smaller countries would be dependent on international action such as world-wide surveillance and monitoring. The Austrian delegation in the plenary meeting had stressed the importance of such action and the Director-General had mentioned it in his reply. Could the Director-General give the Committee further information on the subject? WHO already had experience
of surveillance and monitoring in communicable diseases, such as smallpox; and the Health Assembly had just approved a programme for the international monitoring of adverse reactions to drugs. No long-term programme on environmental health would be complete without surveillance and monitoring of adverse environmental factors.

The programme should also cover evaluation, promotion and co-ordination of research on the influence of pollutants on health as a basis for international environmental health standards and criteria; and the development of methods of detecting and quantifying pollution potentially detrimental to human health. In many respects WHO's function would be the not unfamiliar one of acting as a clearing-house for information collected by national and international bodies.

There was no organization better suited or better equipped for the role of leadership in the present field than WHO. That had been stressed by the Belgian representative in the plenary meeting, by the United States representative at the last session of the Executive Board and by the delegates of Denmark and most other members of the Regional Committee for Europe.

In order to provide for intensified effort by WHO, the draft resolution invited the Director-General to submit a proposed programme and budget to the Twenty-fourth Health Assembly. He envisaged a long-term programme, initially for at least five years, into which the relevant regional activities should be fitted. A co-ordinated international programme would ensure the most effective use of available resources and knowledge, contribute to the highest attainable standard of health and result in savings for Member States. Without international action the smaller countries would have little hope of solving their environmental problems.

Dr BAUHOFER (Austria), speaking as one of the sponsors of the draft resolution, said that his Government attached great importance to the problems of environmental hazards and therefore welcomed the Director-General's statement on the need for international agreement on the subject. He hoped that the new detection and warning system mentioned in the Director-General's annual report would be set up as rapidly as possible. WHO should take the lead and should act as a clearing-house for information.

Dr BROTHERSTON (United Kingdom of Great Britain and Northern Ireland) asked for clarification on certain points in the draft resolution. A proposal of the potential magnitude implied in operative paragraph 2 needed to be very carefully explored to ascertain what would be a suitable programme, whether it would be practicable for WHO, and what it would cost. It was not clear whether the paragraph invited such investigation or more immediate action. He therefore proposed the following amendments to that paragraph: in the second line, the words "a study of the practicability of" to be inserted after the word "including"; in the third line, the words "as well as" to be replaced by the words "and also of". If those amendments were accepted, his delegation would welcome and support the draft resolution.

Dr KIVITS (Belgium) said that his delegation had already at the plenary meeting stressed the importance his Government attached to the problem of environmental pollution. With so many persons, departments and organizations concerned about new dangers to human health, there was a risk of duplication of activities, multiplication of organizations, dispersal of resources and, ultimately, inadequate results. WHO was the organization which should take the lead in studies and recommendations for the protection of human health. It was essential that the Organization's representatives should go to the Stockholm conference with a precise programme of work. It was WHO's task to provide environmental health standards for governments and other bodies in respect of soil, water, air and food pollutants. The draft resolution, of which he was a sponsor, confirmed WHO's responsibility and would strengthen its position among the organizations of the United Nations system.
Professor MACUCH (Czechoslovakia) strongly supported the draft resolution. It was not possible to combat the continuous pollution of the environment without the most careful evaluation and wise planning of activities. Every effort should be made to standardize criteria and indices of pollution and co-ordinate methods of fighting them and legislative and administrative measures. He was confident that the Director-General would find ways and means of issuing directives to Member States without impinging on national sovereignty or on the competence of national health authorities. Dealing with pollution of the environment was essentially a technical problem, but the study of the adverse effects of pollutants on human beings and health control of the environment were matters for the health authorities. To wage an effective campaign, more knowledge was needed on the physiopathology of the effects of pollutants on human health and on the epidemiology of contamination of the environment. He hoped that the Director-General would emphasize those aspects when preparing a long-term programme.

Mr Johnson (United States of America) shared the concern about environmental pollution expressed in the draft resolution. The draft resolution sought to apply sound programme planning and evaluation to environmental health so as to ensure that all available resources were brought to bear on the problems of the environment in the light of their short-term and long-term effects on the world. Success in promoting the health and wellbeing of all people required the best possible use of available knowledge and technology. It was important to be sure that maximum use was being made of them and that medical care problems were not accentuated through failure to give full consideration to the causative factors in the environment.

Certain points in the draft resolution needed clarification. In operative paragraph 1, the word "artificial" before "factors" seemed redundant: any factor in the environment, whether artificial or natural, that adversely affected human health should be of concern. In operative paragraph 2 the reference to a world-wide monitoring system was still not quite clear. It had been clarified to some extent by the Netherlands delegate, whose statement suggested that it referred to the monitoring of information relating to the adverse health effects of environmental pollutants and not merely to the survey and monitoring of environmental conditions. He agreed that such monitoring involved national action and could not be done by WHO alone. It must also take into account the monitoring programmes conducted under other international auspices.

In connexion with operative paragraph 3, he assumed from the statement by the Netherlands delegate that the Director-General's attention was being called to the great health and economic benefits to be derived from continued concern for basic environmental sanitation programmes, particularly those which stimulated the development of community water supply, sewage disposal, vector control, food sanitation, housing and similar programmes.

Professor REXED (Sweden) shared the concern of the sponsors of the draft resolution at the deterioration of the environment and fully agreed with the Netherlands delegate's statement, particularly in relation to the need for concerted international effort. As an example of the need for large-scale international co-operation, he mentioned the Baltic Sea. Tests carried out in Sweden had revealed drastic changes in the composition of its waters, involving threats to wild life and even to human health. It was essential to recognize the importance of full international co-operation and the need for precise planning by all those working together, both nationally and internationally.
The situation was well described in paragraphs 98 and 99 of the Director-General's report to the Executive Board at its Forty-fifth Session (Official Records No. 182). WHO's role should be one of leadership in accordance with its Constitution, but the situation was very complex. To mention only a few of the factors involved, it was impossible for WHO alone to analyse and propose solutions for controlling the effects of industrial pollution, which involved vast economic and development problems associated with control; and the same applied to urbanization, population, and other problems. Hence it was right that the Director-General should have mentioned the United Nations Conference as one where WHO's role was to analyse "coolly, objectively and scientifically". The terms of WHO's leadership must be defined. It was essential to co-operate with other organizations, and that was why the United Nations General Assembly had decided to convene the Conference, in order to decide on the global strategy needed to save the environment. It was impossible to delineate WHO's role until the global strategy had been decided at the United Nations Conference.

He fully agreed with the draft resolution, but stressed the importance of full co-operation with other United Nations agencies. He therefore proposed the addition of a new final pre-ambular paragraph on the following lines: "Also recalling Article IV of the Agreement between the United Nations and the World Health Organization, as well as bearing in mind resolution WHA22.57 concerning the United Nations Conference on the Human Environment to be held in 1972." He agreed with the United Kingdom representative that a programme should be prepared, but he felt that no decision should be taken on its full scope and form before the 1972 Conference.

He also asked what action he had taken on resolution WHA22.57, in particular its second operative paragraph.

Professor PACCAGNELLA (Italy) said that the problems of environmental health were of great importance to his country. Many studies were being carried out on the physical, chemical, meteorological and technological aspects of air pollution, and research was being conducted on its effects on materials, plants and animals as well as on its economic effects; but very little was being done about the effects on human beings. Action by public health authorities would be more effective if there were more scientific knowledge on these fundamental aspects.

The problems of water pollution by domestic and industrial wastes were acute and difficult everywhere. His Government was studying new laws and regulations, but the authorities were conscious of their lack of knowledge of the effects on human health. Studies were being made in Italy and other countries on environmental pollution by pesticides, but little was known of their short-term and long-term effects on the population.

He stressed the importance of evaluating noise in relation to its effects on the cardiovascular, digestive and nervous systems and to psychological disorders or reactions. WHO's promotion and co-ordination of research in all those fields would be of the greatest value during the coming years. Physical and chemical environmental changes assuredly affected the whole ecological system regardless of frontiers; that was why many international and national agencies and institutions must take part. The task of WHO was to stimulate, to co-ordinate, to help Member States in planning and implementing programmes to control environmental pollution, and to establish internationally acceptable environmental quality criteria and guide lines. He urged that the problem of community noise - which had been somewhat neglected - should be included in research programmes.

He supported the draft resolution, as amended by the delegates of the United Kingdom and Sweden. It was in harmony with previous Health Assembly resolutions and with United Nations General Assembly resolution 2581 (XXIV).

The meeting rose at 11.15 a.m.