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REPORT OF THE FIRST MEETING OF THE CODEX COMMITTEE
ON PESTICIDE RESIDUES

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The Hague, 17-21 January 1966

The Codex Committee on Pesticide Residues held its first meeting in The Hague, Netherlands, 17-21 January 1966. Drs A. Kruijsse was in the chair.

The meeting was attended by Government experts and advisers from the following sixteen countries: Australia, Belgium, Canada, Denmark, France, Federal Republic of Germany, Ireland, Israel, Netherlands, New Zealand, Poland, Sweden, Switzerland, Thailand, United Kingdom, United States of America.

The following organizations were also represented: FAO, WHO, EEC, IUPAC, ISO/TC 34 and GEFAB.

A list of participants is set out in the Appendix VI. (omitted)

1. The meeting was opened by Dr. R.J.H. Kruisinga, Director-General of Public Health, who welcomed delegates to this first session of the Committee on behalf of the Ministry of Social Affairs and Public Health. Dr. Kruisinga referred to the work done by the WHO Expert Committee on Pesticide Residues and the FAO Working Party on Pesticide Residues. The data supplied by these committees provided the basic information which would need to be considered by the Codex Committee.
2. The Committee unanimously elected Dr. F.E. Turtle as Rapporteur for the meeting.
3. The Codex Committee took note of the terms of reference and working procedure laid down by the Codex Alimentarius Commission.

These read as follows:

Responsibility - "To recommend international tolerances for pesticide residues in specific food products. A further responsibility is the preparation of a list of priorities of those pesticide residues found in food commodities entering international trade for the guidance of the WHO Expert Committee on Pesticide Residues when considering future work." (See Appendix V of the Report of the 3rd Session of Codex Alimentarius Commission, Alinorm 65/30, p.80)

Working Procedure - (See Paragraph 36 of the Report of the 3rd Session of Codex Alimentarius Commission, Alinorm 65/30, p.23).

"The Commission, having been informed that in future the WHO Expert Committee on Pesticide Residues would meet jointly with the FAO Working Party on Pesticide Residues (hereafter referred to as the Joint Meeting on Pesticide Residues), decided to modify the procedure set out in paragraph 39 of the Report of the Second Session of the Commission and recommended the following revised procedure;

- (a) The Codex Committee on Pesticide Residues should, in the light of the work already being done by the various FAO and WHO Committees, plan the future work. It should prepare a list of pesticides together with priorities for further consideration by the Joint Meeting on Pesticide Residues. Priorities should be given in the list to those pesticides which leave substantial residues in food of importance in international trade.

Any Government which wishes to suggest that an international tolerance be established for a particular pesticide on specific food products should submit full information regarding technological justification, levels of residues resulting from their use, tolerances, consumption of food concerned, methods of analysis for residues to the Codex Committee on Pesticide Residues, Ministry of Social Affairs and Public Health, The Hague, Netherlands, with copies to the Plant Production and Protection Division, FAO, Rome. At the same time, two copies off all toxicological and related data should be sent to Nutrition/Food Additives, WHO, Geneva. If the Codex Committee considers that a case has been established on the basis of need, it will ask the Joint Meeting on Pesticide Residues to consider the pesticide concerned.

- (b) The Joint Meeting on Pesticide Residues should, as expeditiously as possible, establish acceptable daily intakes, tolerances on specific foods based on good agriculture practice checked against the acceptable daily intake and methods of analysis. They should transmit their report to the Codex Committee on Pesticide Residues.

- (c) The Codex Committee on Pesticide Residues would then recommend, where necessary, tolerances for acceptance by Governments for the pesticide in specific foods and submit such tolerances to the Codex Alimentarius Commission.
- (d) The Codex Alimentarius Commission would invite Government comments on these tolerances in accordance with its Procedure for the Elaboration of Standards."
4. The following Reports of the joint Meetings of the FAO Committee on Pesticides in Agriculture and the WHO Expert Committee on Pesticide Residues were available to the meeting: FAO Meeting Report No. Pl/1965/10, WHO/Food Add./26.65; FAO Meeting Report No. Pl/1965/10/1, WHO/Food Add./27.65 and FAO Meeting Report No. Pl/1965/10/2, WHO/Food Add./28.65.
- Dr. Goulding, on behalf of WHO, explained that these reports represented a review by the WHO Expert Committee of the acceptable daily intakes published in the earlier report FAO Meeting Report No. Pl/1963/13, WHO/Food Add./23 (1964) and also included were other pesticides, under which the fumigants, used for the treatment of cereals. The document entitled "Evaluation of the Toxicity of Pesticide Residues in Food" (FAO Meeting Report Nr. Pl/1965/10/1, WHO/Food Add./27.65) now replaced the document FAO No. Pl/1963/13, WHO/Food Add./23 1964.
- Dr. Whittemore introduced the draft report of the second session of the FAO Working Party on Pesticide Residues (FAO No. Pl/1965/12). Although it was only available to the Codex Committee in draft form, he explained that the final version would not contain any basic differences.
- Dr. Hurtig, Chairman of the FAO Working Party on Pesticide Residues, explained the procedures which had been followed in order to arrive at proposals for tolerances for some pesticide residues in cereals. Dr. Hurtig pointed out that the proposed tolerances in raw cereals took account of the reduction of the residue which occurs during storage and processing prior to human consumption. For this reason the proposed tolerances for the raw cereals in certain cases may be greater than the permissible level (i.e. at the time of consumption) as calculated from the acceptable daily intake.

5. After full discussion it was concluded that the procedure for the establishment of tolerances contained in paragraph 3 above should be slightly modified so that Governments would supply toxicological data to the Codex Committee as well as to WHO in order that their adequacy could be checked before requesting the WHO Expert Committee on Pesticide Residues to make evaluation.

Following observations made by various delegates, it was agreed that although the residues at the time of consumption were the important ones when considering the acceptable daily intakes, it was necessary in international trade in cereals to take the moment of unloading at the point of entry of the commodity into the importing country as the stage for enforcement of a tolerance. With other commodities another stage might be included.

6. In response to a question concerning materials, which should be regarded as pesticides and therefore considered by this Committee, reference was made to efforts being made by other committees of FAO and WHO to define the word.

It was agreed that for the present the term would have to be interpreted in a general way to cover products used for the control of pests, both before and after harvest and for certain other purposes such as weed control and growth regulation. In cases of doubts before agreement has been reached the Codex Alimentarius Commission should decide on the procedure for dealing with individual cases.

Basic principles for the adoption of Tolerances of Pesticide Residues

7. The Codex Committee examined in detail a paper prepared by the Netherlands Secretariat on the basic principles for the adoption of tolerances of pesticide residues. This document was not adopted or fully accepted by the Committee but it was agreed, that because it contained many useful ideas for further consideration, it should appear as an Appendix to this report (Appendix V).

During the discussion of this paper it was concluded that a decision to establish a tolerance for a pesticide residue in a particular crop would normally constitute a formal recognition of the use of the pesticide on that crop. If the use of a pesticide were permitted however, and if

it was considered necessary that the residues should be at an absolutely minimum level, any tolerance should be set at a level not greater than the minimum level that can be determined by internationally adopted analytical methods. The U.S. delegation drew the Committee's attention to the fact that a zero tolerance can be useful as a protection against the possible mis-use of a pesticide. In these circumstances a background residue must be taken into account. Therefore the Committee considered that the tolerance should not be "zero", but at a level not greater than the lower limit which can be determined by an internationally accepted analytical method.

8. The Committee decided that if sufficient toxicological data were not available for an acceptable daily intake to be established by the WHO Expert Committee on Pesticide Residues, or insufficient data were available for the FAO Working Party on Pesticide Residues to recommend an acceptable analytical method, then the Codex Committee would not be able to establish a tolerance.
Nevertheless various differences in existing national tolerances represent a potential barrier to international trade and an attempt seems necessary to achieve uniformity in the figures.
To pursue this objective the Committee recommended that member governments be asked to consider and comment upon the idea elaborated in the concluding paragraph of section 2 of Appendix V, viz "that provisional international tolerances might be reached which, although not based on acceptable daily intake figures would provide a measure of agreement, whilst ensuring that foods are as sound as possible under the prevailing economic and other conditions."
9. The Committee discussed the possibility of exempting certain pesticides from a tolerance provided no residue occurs at the time of consumption. "No residue" in this context would need to be proved by an internationally acceptable method of analysis.

10. The Committee considered that there was a need to establish definitions for the following two concepts in order to avoid confusion by the use of the word "tolerance" which has been used in both contexts:

- (a) the amount of a residue internationally agreed upon as acceptable on the food or on raw food materials at the point of entry into a country,
- (b) the amount of residue acceptable in the food at the moment of consumption.

The Committee recommended that the views of Governments be sought on the use of the term "trade or import tolerance" for residues under (a), and the term "acceptable consumer residue" for those under (b) above.

11. During discussion of the principles for deciding priorities of chemical compounds for consideration, the need to limit the number of substances on the list and to select preferably those compounds already under consideration was drawn to the attention of the Committee by FAO.

Some delegations felt that priority should be given according to the commodities involved, whereas others recommended giving greater priority to compounds. It was agreed that the choice of compounds would be made in accordance with the following principles.

- A. Subject to the requirements of B and C, pesticides and their residues in food should be considered rather than commodities.
- B. Chemicals chosen should be pesticides widely used on foodstuffs in international trade which leave residues which might be hazardous, taking into account the amount of the foodstuffs which are consumed.
- C. Priority has to be given to chemicals and commodities on which commercial, chemical or toxicological problems exist or are arising.

The Committee discussed at length the implication on existing national legislations of accepting international tolerances. It was explained that under the general principles of the Codex Alimentarius a government accepting an international tolerance for a pesticide residue would undertake, within its territorial jurisdiction, not to hinder imports

complying with the international tolerance by any legal provisions relating to the health of the consumer or to other food standard matters.

Considerations of proposals for tolerances for grain and grain products

12. In accordance with the procedure set out in paragraph 3 above, the Committee had four compounds to consider for which the FAO Working Party on Pesticide Residues had recommended a tolerance and a method of analysis for residues on raw grains. These compounds were malathion, methyl bromide, hydrogen cyanide and ethylene dibromide.

For this purpose grains were held to include the seeds of graminaceous plants and buckwheat which appear as food grains. These include the seeds of wheat, oats, rye, barley, rice, corn and seeds from various Sorghum species, but do not include oilseeds and pulses.

After a full consideration of the information available, it was agreed that those tolerances for malathion, inorganic bromide and hydrogen cyanide as contained respectively in Appendices I, II, III and IV to this report should be recommended and sent to Governments together with the other observations of the Committee contained in the Appendices. The relevant reports of the WHO Expert Committee on Pesticide Residues and the FAO Working Party on Pesticide Residues should at the same time be drawn to the attention of Governments. The Codex Committee would reexamine its recommendations at the next meeting in the light of comments received from Governments. The Committee decided to refer residues of unchanged methyl bromide and of ethylene dibromide back to the FAO/WHO Joint Meeting on Pesticide Residues for further consideration.

13. During its consideration of further information required, the Committee thought that if compounds rather than residues in specific commodities were to be considered by the Joint FAO/WHO Meeting on Pesticide Residues, then it would be necessary to consider also the unintentional residues arising in food for consumption as a result of carry over from animal feeding stuffs. The Committee took note of the fact that the Codex Committee on Food Additives, within its revised

terms of reference, would be dealing with intentional and unintentional residues of animal feed adjuncts in food for human consumption. It was considered however that in so far as pesticides might be concerned the Codex Committee on Pesticide Residues should take these unintentional and intentional residues into account when considering all sources of the chemical entering into the daily diet. It was therefore decided to request the Codex Alimentarius Commission to regularize this procedure at its next session.

14. In connection with unintentional residues, the Committee endorsed a recommendation that WHO should at a future meeting consider and advise on levels of residues which may be regarded as negligible from a toxicological viewpoint.

Priorities for future work

15. Dr Whittemore and Dr Agthe explained the activities of the working parties and committees of FAO and WHO.

Dr. Agthe explained that a priority list should be presented by the Codex Committee for the next two expert meetings.

Due to the fact that, in the light of the expected change in basic principles WHO had planned to reevaluate the toxicological data of compounds which were hitherto under study, the number of new compounds which could be studied in the next meeting of the expert committee would be strictly limited.

With respect to this situation and to reduce the load on the FAO secretariat the U.K. delegation proposed that individual governments should initiate and adequately document proposals on new compounds which had not yet been considered by the FAO Working Party on Pesticide Residues. This documentation should include information on experimental work and the extent of use throughout the world.

The USA delegate also suggested that governments might be able to provide certain data on compounds already considered by the FAO Working Party on Pesticide Residues. These proposals were unanimously accepted. The governments which had the closest relations with the relevant manufacturers should usually undertake this work.

After considering several proposals the following priorities were accepted for consideration by the joint meeting.

Priority I DDT
 lindane
 aldrin + dieldrin
 heptachlor
 malathion
 carbaryl
 hydrogen phosphide (as derived from aluminium phosphide)
 ethylene dibromide
 methyl bromide
 piperonyl butoxide
 pyrethrins
 diphenyl
 organic mercury compounds

Priority II endrin
 chlordane
 parathion
 dichlorvos (DDVP)
 demeton - S - methyl
 diazinon
 dimethoate
 M.G.K. 264
 dithiocarbamates
 endosulfan
 carbon disulfide
 carbon tetrachloride
 ethylene dichloride

16. Allocation of future work

The members of certain delegations, as listed hereunder, thought that their respective governments would be willing to supply information concerning stated pesticides. With those pesticides which had previously been considered, only additional information would be

required. But with newly considered substances, comprehensive data would be needed by the Codex Committee on Pesticide Residues and by the expert committees of WHO and FAO. This should include information concerning experimental work on toxicity, world wide usage and residues occurring in important foodstuffs moving in international trade.

lindane	United Kingdom
aldrin + dieldrin	Netherlands, assisted by the United Kingdom
diphenyl	Israel
DDT	USA
malathion	USA
ethylene dibromide	USA
methyl bromide	USA
organic mercuri compounds	United Kingdom, assisted by Sweden
dichlorvos	United Kingdom, assisted by the Netherlands
diazinon	Switzerland

17. Date of the next meeting

The second meeting of the Codex Committee on Pesticide Residues would be held in the end of September or early October 1967 .

Recommendations :

That the procedure for the establishment of tolerances, set out in paragraph 36 of the Report of the 3rd Session of the Codex Alimentarius Commission (Alinorm 65/30 p.23), should be slightly modified so that member Governments should supply toxicological data to the Codex Committee as well as to WHO in order that their adequacy could be checked before requesting the WHO Expert Committee on Pesticide Residues to make an evaluation (paragraph 5 of this report).

That the Codex Alimentarius Commission be asked to decide on the proposal that the Codex Committee on Pesticide Residues should deal with residues of pesticides in food for human consumption arising from the presence of intentional and unintentional residues in animal feed (see paragraph 13).

That WHO should consider and advise on the levels of residues of pesticides which may be regarded as negligible from a toxicological viewpoint (see paragraph 14).

That member governments be asked to consider and comment upon the idea elaborated in the concluding paragraph of section 2 of Appendix V of this report, that provisional international tolerances might be reached, which although not based on acceptable daily intake figures would provide a measure of agreement, whilst ensuring that foods are as sound as possible under the prevailing economic and other conditions (see paragraph 8 and Appendix V section 2).

That the view of member governments be sought on the use of the term "trade or import tolerance" for residues under (a), and the term "acceptable consumers residue" for those under (b) underneath.

(a) the amount of residue internationally agreed upon as acceptable on the food or on raw food materials at the point of entry into a country.

(b) the amount of residue acceptable in the food at the moment of consumption (see paragraph 10).

That action should be taken on the conclusions and recommendations in Appendices I (malathion), II (methyl bromide), III (hydrogen cyanide) and IV (ethylene dibromide).

M A L A T H I O N

1. Information considered by the committee

- a. Evaluation of the toxicity of pesticide residues in food.
FAO Meeting Report No. PL/1965/10/1, WHO/Food Add./27.65 page 136-141.
- b. Draft report of the second session of the FAO Working Party on Pesticide Residues. FAO Meeting Report No. PL/1965/12 page 58-62.
- c. Method of analysis recommended by the FAO Working Party on Pesticide Residues. FAO Meeting Report PL/1965/12 page 62.
- d. Data collected by the secretariat of the Codex Committee on Pesticide Residues.

2. The committee took particular notice of the following data:

- (a) National tolerance levels established or considered.

country	product	tolerance in ppm	reference
Brazil	stored wheat	8	FAO draft rep. PL/1965/12
Canada (established)	small grains	8	ref. 1
France	wheat	8	FAO draft rep. PL/1965/12
	flour	2	FAO draft rep. PL/1965/12
Germany	grain	2	ref. 2
India	cereals	3	FAO draft rep. PL/1965/12
Kenya	cereals	12.5	FAO draft rep. PL/1965/12
Netherlands	grain	8	ref. 3
Turkey	cereals	8	ref. 4
United Kingdom	cereals	8	FAO draft rep. PL/1965/12
U.S.A. (established)	barley, corn, oats, rice, rye, sorghum grains, wheat (post- + pre- harvest)	8	ref. 5
USSR	grain	8	ref. 6

- (b) The acceptable daily intake established at the second Joint Meeting of the FAO committee on Pesticides in Agriculture and the WHO Expert Committee on Pesticide Residues is 0 - 0.02 mg/kg body-weight (FAO draft rep. PL/1965/12).

The committee considered that a 60 kg man eating 400 g would consume the acceptable daily intake if this food all contained 3 ppm.

During the storing, transportation and milling of treated cereals, considerable reductions from the initial dosage levels occur. The decrease of the residue under storage conditions depends on the temperature of storage and appears mainly to be due to hydrolysis to biologically inactive products. (Rowlands 1964 and 1965, ref 7 and 8).

In the United Kingdom the mean residues found in ship cargoes ranged from 0.1 - 5.1 ppm (FAO draft rep. PL 1965/12).

In ship cargoes from different parts of the world sampled in the Netherlands the amount of residue did not exceed 3.2 ppm, with the exception of a few transports arriving from a short distance (ref. 3).

Rye treated with 11 ppm. contained after 13 month of storage about 3 ppm. After milling 1-2 ppm was found in the flour and bread baked from this flour contained 0.1-0.4 ppm (ref. 9).

Cooking results also in substantial losses. The amounts found in finished pasta and in bread made from wheat with initial dosage levels of about 8 ppm (i.e. below 0.4 ppm) have been well under the permissible level (FAO draft rep. PL/1965/12).

Application during the growing period and up to seven days from harvesting of cereals should leave residues which are much lower than those which are added in many countries during post-harvest treatments. Therefore pre-harvest treatments are a minor source of residues in cereals in commerce (FAO draft rep. PL/1965/12).

3. Recommendations of the Committee

A residue level of 8 ppm, as was accepted by the FAO Working Party (FAO draft rep. PL/1965/12), is recommended for raw grain by this committee.

The committee is well aware that malathion is also used on fruit and vegetables and in public health and veterinary fields. Taking into account the substantial loss of malathion in grain products during processing and the rapid degradation of malathion in fruit and vegetables the committee was of the opinion that the tolerance established on cereals would not preclude the use of malathion on other crops.

Method of analysis

A method of analysis for the determination of malathion in grain has been recommended by the FAO Working Party on Pesticide Residues (FAO draft rep. PL/1965/12 p.47 and Appendix A 3 p. 84-86).

Further work desirable

More information is needed on the fate of malathion during processing of grain and grain products.

The committee endorsed the recommendations of the Joint FAO/WHO Meeting and the FAO Working Party. "Further information is desirable on the levels of malathion occurring in cereals in international commerce. Information on the occurrence of residues in milled byproducts (bran, shorts, etc.) in commerce and concerning the feeding of such products to animals under practical conditions is also desired". (FAO draft rep. PL/1965/12).

"Reproduction studies in rats, were also considered desirable" (FAO Meeting rep. PL/1965/10/1, WHO/Food Add./27.65).

The committee was informed that reproduction studies with malathion were in progress in the U.S.A.

4. References

1. 1964 Office consolidation of the Food and Drugs Act and of the Food and Drug Regulations with Amendments to September 1964. Issued by Department of National Health and Welfare. Canada.
2. Unpublished data from Germany.
3. 1966 Residues of insecticides in cereals, imported in the Netherlands 1964/65. Second Report CCPR.66.17 (Jan. 1966)
4. 1965 Informathion bulletin B.I.B.R.A. (4) 1965 p.207.
5. 1957 Federal Register 11-22-57. 120.111
6. 1965 Grain Storage Newsletter VII (3) July 1965 p.60.
7. 1964 Rowlands, D.G.
The degradation of malathion on stored Maize and Wheat Grains.
J.Sci. Food Agric., 15 p. 824-829.
8. 1965 Rowlands, D.G.
The in vitro and in vivo oxydation and hydrolisis of malathion by wheat grain esterases.
J. Sci. Food Agric. 16 p. 325-329.
9. 1965 Maier Bode, H.P.
Pflanzenschutzmittel-Rückstände.
Eugen Ulmer Verlag 455 p.

HYDROGEN CYANIDE

(including calcium cyanide)

1. Information considered by the committee

- a. Evaluation of the hazards to consumers resulting from the use of fumigants in the protection of food. (FAO Meeting Report PL/1965/10/2, WHO/Food Add./28.65 p. 52/61).
- b. Draft report of the second session of the FAO Working Party on Pesticide Residues. (FAO draft rep. PL/1965/12 p. 58-62)
- c. Method of analysis recommended by the FAO Working Party. (FAO draft rep. PL/1965/12 p.57).
- d. Data collected by the secretariat of the Codex Committee on Pesticide Residues.

2. The committee took particular notice of the following data:

- (a) National tolerance levels established or considered.

Hydrogen cyanide

country	product	tolerance in ppm	reference
Brazil	cereals	25	FAO draft rep. PL/1965/12
Canada (established)	barley, corn, rice, rye, wheat	25	ref. 1
Czechoslovakia	grain	20*	ref. 2
India	cereals	10	FAO draft rep. PL/1965/12
Netherlands	grain	75	ref. 3
	flour	6	ref. 3
U.S.A. (established)	barley, buckwheat, corn (includes popcorn), grain sorghum (Milo), oats, rice, rye, wheat	100	ref. 4

* New proposal for grain 10 ppm

H Y D R O G E N C Y A N I D E

(including calcium cyanide)

1. Information considered by the committee

- a. Evaluation of the hazards to consumers resulting from the use of fumigants in the protection of food. (FAO Meeting Report PL/1965/10/2, WHO/Food Add./28.65 p. 52/61).
- b. Draft report of the second session of the FAO Working Party on Pesticide Residues. (FAO draft rep. PL/1965/12 p. 58-62)
- c. Method of analysis recommended by the FAO Working Party. (FAO draft rep. PL/1965/12 p.57).
- d. Data collected by the secretariat of the Codex Committee on Pesticide Residues.

2. The committee took particular notice of the following data:

- (a) National tolerance levels established or considered.

Hydrogen cyanide

country	product	tolerance in ppm	reference
Brazil	cereals	25	FAO draft rep. PL/1965/12
Canada (established)	barley, corn, rice, rye, wheat	25	ref. 1
Czechoslovakia	grain	20*	ref. 2
India	cereals	10	FAO draft rep. PL/1965/12
Netherlands	grain	75	ref. 3
	flour	6	ref. 3
U.S.A. (established)	barley, buckwheat, corn (includes popcorn), grain sorghum (Milo), oats, rice, rye, wheat	100	ref. 4

* New proposal for grain 10 ppm

calcium cyanide

country	product	tolerance in ppm	reference
Canada (established)	barley, corn, rice, rye	25 ¹⁾	ref. 1
U.S.A. (established)	barley, buckwheat, corn, (includes popcorn), grain- sorghum (Milo), oats, rye, wheat	25	ref. 5

1) calculated as HCN

(b) The acceptable daily intake established at the second Joint Meeting of the FAO Committee on Pesticides in Agriculture and the WHO Expert Committee on Pesticide Residues is 0 - 0.05 mg/kg body weight.

Although the gas is highly absorbed by most foods, by comparison with other fumigants, most of it airs off from cereals and similar dry foodstuffs quite rapidly. Grain with a high moisture content absorbs more of the gas during the exposure period and retains it for a longer period. (FAO draft rep. PL/1965/12)

Samples of fumigated wheat contained residues up to 135 ppm. This residue was reduced by milling to a maximum of 39 ppm in whole wheat flour and further reduced by baking to a maximum of 2 ppm (ref. 6).

Fumigation of wheat caused damage to the baking quality especially at high dosage and moisture contents, but after thorough aeration of the flour for one month no damage was observed. (ref. 7)

3. Recommendations of the committee

Residues of 75 ppm hydrogen cyanide in raw grain and 6 ppm in flour, as were accepted by the FAO Working Party (FAO draft rep. PL/1965/12), are recommended as tolerances by this committee.

In order to avoid residues of unchanged calcium cyanide the moisture content of grain at time of application should not be less than 12%.

Method of analysis

A method of analysis for the determination of hydrogen cyanide in grain has been recommended by the FAO Working Party on Pesticide Residues.

This method is sensitive to about 0.2 ppm of hydrogen cyanide. (FAO draft rep. PL/1965/12 p.57 and Appendix A 2 p. 82-83).

4. References

1. 1964 Office consolidation of the Food and Drugs Act and of the Food and Drug Regulations with amendments to September 1964. Issued by Department of National Health and Welfare. Canada.
2. 1965 Czechoslovakia, USSR, COMECON Countries. Tolerances for pesticide residues (according to the proposal of the positive list, 1965); Unpublished report.
3. 1966 Residues of insecticides in cereals, imported in the Netherlands 1964/65. Second Report CCPR. 66.17. (Jan. 1966)
4. 1960 Federal Register 4 - 22 - 60 120.101 120.130
5. 1956 Federal Register 1 - 26 - 56 and 6 - 28 - 56 120.125
6. 1960 Alpert, Y, U.S. Government Memorandum 195 p.
7. 1942 Burns Brown, W and J.D. Mounfield
1943 Unpublished reports Pest Infestation Laboratory Slough England.
1944

METHYL BROMIDE

1. Information considered by the committee

- a. Evaluation of the hazards to consumers resulting from the use of fumigants in the protection of food (FAO Meeting Report PL/1965/10/2, WHO/Food Add./28.65 p. 62-67).
- b. Draft report of the second session of the FAO Working Party on Pesticide Residues (FAO draft rep. PL/1965/12 p. 67-71).
- c. Method of analysis recommended by the FAO Working Party (FAO draft report PL/1965/12 p. 71).
- d. Data collected by the secretariat of the Codex Committee on Pesticide Residues.

2. The committee took particular notice of the following data:

- (a) National tolerance levels, established or considered.
 - (1) Unchanged methyl bromide
No national tolerance figures
 - (2) Inorganic bromide derived from the use of methyl bromide
and from all other sources.

country	product	tolerance in ppm	reference
Brazil	cereals	50	ref. 1
Canada (established)	barley, corn, grain sorghum, oats, rice, rye, wheat	50	ref. 2
Czechoslovakia	cereals	20	ref. 3 and FAO draft rep. PL/1965/12
Germany	grain	50	ref. 4
India	cereals	50	ref. 1
Netherlands	grain	50	ref. 5
New Zealand	for any food	20	ref. 1
United Kingdom	cereals	50	ref. 1
U.S.A. (established)	corn, barley, oats, rice, rye, wheat	50	ref. 6
	popcorn	240	ref. 6

- (b) The Second Joint Meeting of the FAO Committee on Pesticides in Agriculture and the WHO Expert Committee on Pesticides Residues (FAO/WHO 1965) was unable to make recommendations for acceptable daily intakes for residues of free uncombined methyl bromide.

With regard to inorganic bromide, the meeting considered that the possible risks might be assessed on the basis that the total daily intake of this ion from all sources should not exceed 10 mg Br per kg bodyweight per day (FAO draft rep. PL/1965/12).

The FAO Working Party on Pesticide Residues concluded as follows:

"During the exposure period some of the fumigants is sorbed by the cereal products. This amount increases with the dosage used under given circumstances and a higher moisture content usually results in a higher residue. Immediately after the termination of the exposure period the residue consist partly of unchanged methyl bromide and partly of a fixed residue resulting from some kind of reaction with constituents of the food. The unchanged methyl bromide disappears rapidly leaving a fixed residue which does not decrease on further airing. This fixed residue behaves as inorganic bromide. The fixation of the methyl bromide is due mainly to reaction with the protein fractions."

"When fumigated wheat has been milled the residues found in the various milling fractions, present at that stage as inorganic bromide, have been found to vary; the residues in flour and other fractions for human consumption, however have always been appreciably lower than those in the original wheat." (FAO draft rep. PL/1965/12)

Sorption is higher when flour itself is fumigated. Residues of about 50 ppm of inorganic bromide have been found after treatment corresponding to normal practice (ref. 7).

In ship cargoes arriving in the Netherlands from different parts of the world unchanged methyl bromide could not be detected at the moment of unloading. Residues of inorganic bromide with a maximum value of 8 ppm were found, but it is not certain that these residues originate from the use of methyl bromide (ref. 5).

In the U.S.A. the F.D.A. has found in the cereal and cereal products portion of the total diet samples in a two years period, amounts of bromide ranging from 6.4 - 111.0 ppm (ref. 8).

3. Recommendations of the Committee

A residue level of 50 ppm inorganic bromide (from all sources), as was accepted by the FAO Working Party (FAO draft rep. PL/1965/12), is recommended as a tolerance for raw grain by this committee.

Since no acceptable daily intake has been established for the unchanged compound and since no tolerance has been recommended, the Committee was of the opinion that the Joint FAO/WHO Meeting should reconsider this question in the light of new analytical data as set out in the further work required.

Method of analysis

A method of analysis, based on that of Mapes and Shrader 1957, was accepted by the FAO Working Party as suitable for measuring residues of total bromide in cereals after fumigation (FAO draft rep. PL/1965/12 p. 71 and Appendix A 4 p. 86-88).

Further work desirable

The Committee endorsed the recommendations of the Joint FAO/WHO Meeting and the FAO Working Party.

"Further information would be desirable on figures for residues of bromide resulting from the use of methyl bromide on raw wheat and flour in commercial practice. The residues resulting from the use of mixed fumigants also appear to require further examination." (FAO draft rep. PL/1965/12).

"Furthermore studies on the chemical nature of the residue in foods other than cereals and biochemical studies on the changes produced by methyl bromide in food should be undertaken." (FAO Meeting Report PL/1965/10/2, WHO/Food Add./28.65)

The Committee, having welcomed statements from the Netherlands and Israel delegates, that work on new sensitive analytical methods for unchanged methyl bromide was in progress in their countries, would like to receive information from the use of such sensitive methods on grain and grain products in international trade. Should these results show residues of unchanged methyl bromide, long term toxicity studies with methyl bromide may be required.

4. References

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cide residues (according to the proposal of the positive list,
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5. 1966 Residues of insecticides in cereals imported in the Netherlands,
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7. 1955 Burns Brown, W. et al.
The fumigation of flour with methyl bromide
Chem. and Ind. 12 p. 324-325.
8. 1965 Cook, J.W.
Recent total diet studies in the United States of America.
Appendix D of FAO draft rep. PL/1965/12 p. 98-100.

ETHYLENE DIBROMIDE

1. Information considered by the committee

- a. Evaluation of the hazards to consumers resulting from the use of fumigants in the protection of food (FAO Meeting Report PL/1965/10/2, WHO/Food Add./28.65 p. 36-42).
- b. Draft report of the second session of the FAO Working Party on Pesticide Residues (FAO draft rep. PL/1965/12 p. 43-47).
- c. Method of analysis recommended by the FAO Working Party (FAO draft rep. PL/1965/12 p. 46).
- d. Data collected by the secretariat of the Codex Committee on Pesticide Residues.

2. The committee took particular notice of the following data:

(a) National tolerance levels, established or considered.

(1) Unchanged ethylene dibromide

No national tolerance figures.

(2) inorganic bromide derived from all sources.

country	product	tolerance in ppm	reference
Brazil	cereals	50	ref. 1
Canada (established)	barley, corn, grain- sorghum, oats, rice, rye, wheat	50	ref. 2
Czechoslovakia	cereals	20	ref. 3 and FAO draft rep. PL/1965/12
Germany	grain	50	ref. 4
India	cereals	50	ref. 7
Netherlands	grain	50	ref. 5
New Zealand	for any food	20	ref. 7
United Kingdom	cereals	50	ref. 7
U.S.A. (established)	corn, barley, oats rice, rye, wheat popcorn	50 240	ref. 6 ref: 6

(b) The Joint Meeting of the FAO Committee on Pesticides in Agriculture and the WHO Committee on Pesticide Residues (FAO/WHO 1965) were not able to recommend an acceptable daily intake for unchanged ethylene dibromide. With regard to inorganic bromide it was considered that the possible risk might be assessed on the basis that the total daily intake of this ion from all sources should not exceed 10 mg Br per kg bodyweight per day.

The Joint FAO/WHO Meeting expressed the view that inorganic bromide residues derived from the use of ethylene dibromide as a fumigant were unlikely to make any significant contribution to the total bromide content of the diet. (ref. FAO draft rep. PL/1965/12)

The very limited pre-harvest uses of ethylene dibromide are not likely to lead to significant residues in food. Sorption of ethylene dibromide is high and it disappears slowly by aeration. (FAO draft rep. PL/1965/12)

The uptake of ethylene dibromide by grain is increased with increasing moisture content; moderate decrease in particle size very markedly increases the uptake of ethylene dibromide. (ref.8)

Samples of wheat, corn, rough rice, oats and grain sorghum showed a maximum residue in wheat of 55 ppm ethylene dibromide one month after commercial fumigation; maximum residues in the other commodities were lower. (ref. 9)

In ship-cargoes arriving in the Netherlands from different parts of the world, ethylene dibromide could in general not be detected at time of import. Residues of inorganic bromide with a maximum value of 8 ppm were found however, but it is not certain that these residues originated from ethylene dibromide.

When whole or ground wheat was fumigated experimentally at 8 g/m³ or 16 g/m³ for 24 hours, more than 95% of the ethylene dibromide could be recovered unchanged after 10 days. Most of it was retained in the bran. Very little was converted to ionised bromide. Residues in the whole grain after 10 days aeration were 5.8 ppm of unchanged ethylene dibromide, and in milled samples after 35 days 4.5 ppm. (FAO draft rep. PL/1965/12)

Heating the residues of ethylene dibromide forms some ethylene glycol which may possibly influence the menthionine of the wheat protein. During cooking and baking much of the residue disappears but the data are insufficient to come to a conclusion on the actual residues concerned. (FAO draft rep. PL/1965/12)

3. Recommendations of the committee

After use as a fumigant considerable residues of ethylene dibromide are found in treated grains. Although there are indications that much of the residues are lost during shipment and storage, there is no evidence that significant residues are not present in products at the time of consumption.

Since no acceptable daily intake has been established for the unchanged compound and since no tolerance has been recommended the Committee was of the opinion that the Joint FAO/WHO Meeting should reconsider this question.

A residue level of 50 ppm inorganic bromide (derived from all sources) as was accepted by the FAO Working Party (FAO draft rep. PL/1965/12) is recommended as a tolerance for raw grain by this committee.

Method of analysis

For the determination of total and inorganic bromide, the method of Heuser (1961) was recommended by the FAO Working Party.

The limit of detection by this procedure is of the order of 1 ppm as bromide (FAO draft rep. PL/1965/12 p.47 and Appendix A 1 p.80-82).

Further work required

The Committee endorsed the recommendations of the Joint FAO/WHO Meeting and the FAO Working Party, which were as follows:

"When the Working Party made no recommendation for a tolerance for unchanged ethylene dibromide it was understood that there was no real need for a figure, even in respect to raw (i.e. unprocessed) cereals.

In the event of there being such a need, detailed information on the effects of processing will be required and its consideration by the Working Party will be subject to the view of the Joint Meeting of the FAO Committee on Pesticides in Agriculture and the WHO Expert Committee on Pesticide Residues (FAO/WHO 1965) against permitting such residues at the time of consumption.

The Working Party would like to receive further data on the occurrence of residues in raw and processed cereals after use of the fumigant under practical conditions.

The Working Party is of the opinion that gas-liquid chromatographic methods should be particularly useful for the determination of residues of unchanged ethylene dibromide in cereals. The method offers the prospect of increased sensitivity and a means for the simultaneous determination of other fumigants which may be present. It should be possible to develop a rapid, selective, quantitative technique for traces of halogenated fumigants, together with suitable desorption techniques, and to combine these into a single method for the determination of residues in treated cereals and the Working Party recommends accordingly." (ref. FAO draft rep. PL/1965/12)

"Feeding studies should be carried out on two mammalian species to determine the effect of long-term feeding of ethylene dibromide with particular reference to reproduction." (ref. FAO Meeting Report PL/1965/10/2, WHO/Food Add.28.65).

The committee noted with satisfaction that work is in progress in the Netherlands to develop a new sensitive analytical method for residues of ethylene dibromide. It was further noted that reproduction studies are in progress in Israel.

4. References

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and ethylene dibromide.
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BASIC PRINCIPLES FOR THE ADOPTION OF TOLERANCES
OF PESTICIDE RESIDUES

Explanatory note

As stated in paragraph 7 of the report, this paper was not adopted or fully accepted by the Committee.

It was decided to include it here because of the importance of the subject and because the paper contained various ideas which warranted further consideration. This paper was drafted by the Netherlands Secretariat and amended in its presentation, but not in its principle, by the rapporteur and secretariat during the meeting. Its contents are not conclusions of the Committee unless this is stated in the body of the report.

1) Statement of the problem

To feed the people of the world at the present time recourse must be made to pesticides both in the production of crops and to protect them from damage once they have been harvested. While some of the chemicals used for this purpose do not contaminate the final crop, others, even when used in good agricultural practice, leave residues in food at the time of consumption. In this connection the expression "residues" applies to residues of the chemical compounds themselves and to metabolites, breakdown products or other chemical substances derived from them. Pesticides are also used in the protection of livestock. Residues from this use and from animal feed treated with pesticides may also be present in foodstuffs of animal origin. The human diet may therefore contain pesticide residues from various sources.

Residues of pesticides in unprocessed foodstuffs usually result in smaller residues at the time when foods from them are consumed. When proposing tolerances for residues in foodstuffs it is therefore necessary to indicate the point at which the tolerances are valid and enforceable.

For international trade in grain and grain products it is proposed that the tolerances be applicable at the point of entry of the commodity into the importing country. Because many commodities, such as raw grain, are not consumed in their imported state but are further processed with a resultant reduction in residue content, the tolerance for residues at the point of entry may sometimes exceed the level that would be acceptable at the time of consumption.

The detection of the presence of a pesticide residue depends on the sensitivity and the specificity of the analytical method. When investigations into the good agricultural practice in the use of a pesticide has established that there need be no residue, it may be possible and useful in some cases to establish a tolerance as a protection against mis-use of the material. When this is done the tolerance should be at the minimum level that can be determined by an internationally adopted analytical method. Background residues must be taken into account when setting such a tolerance.

Pesticides whose residues are known to disappear or to be converted into harmless substances during storage, processing or cooking of certain treated commodities may be exempted from the requirement of pesticide tolerance on those commodities.

The establishment of residue tolerances for use in a worldwide basis requires careful consideration of many factors by many national and international groups. It must be recognized that there are differences in legally established or accepted tolerances for the same pesticide in different countries. The acceptance of international tolerances under the Codex Alimentarius Commission should help to adjust differences in tolerance which have arisen as a result of individual national action on widely varying principles.

No doubt it will take several years to review and to take action upon all the pesticides currently in use. Accordingly the fact, that a tolerance or an exemption from a tolerance has not been established should not be interpreted as indicating that the pesticide is not acceptable for use. On the other hand a decision to allot a tolerance to a pesticide residue in a particular crop indicates tacit recognition of the use of the pesticide on that crop at least to the limits of the tolerance permitted.

If the residue in a particular crop should be reduced to the absolute minimum, a tolerance should be set at the level which is the minimum that can be determined by internationally adopted analytical methods.

The producer, under the guidance of the appropriate advisory agency should apply the pesticide in a way, at a concentration, at intervals and at a period before harvest that keeps the residue as low as possible. This approach requires a thorough biological knowledge of the pest or disease under the prevailing regional and climatic conditions and of the response to pesticides under these conditions.

Differences in agricultural practice, in soils and climates, in pest and disease problems, and in the application of biological and chemical knowledge result in differences in residues of pesticides in products from different countries. National tolerances based solely on the actual pesticide residues found in crops in a particular locality can therefore sometimes be a handicap to international trade in foodstuffs which, although not necessarily carrying harmful residues, may have them in excess of tolerances in force in receiving countries. This difficulty can be dealt with in two ways. Either the producing country can control the use of the pesticide more effectively in crops destined for international commerce, or the importing country can accept imported foodstuffs containing residues higher than its own national tolerances would permit.

This position leads to a requirement to revalue national tolerance levels, which, in turn, necessitates, international agreement on the principles for establishing residue tolerances. As a first step, a country proposing a tolerance for a residue of a particular chemical on a crop it wishes to export or import could submit sufficient evidence of the actual residues together with a justification or comments on their magnitude. It would then expect the importing or exporting country to re-examine its tolerance levels or agricultural practices in the light of the new information supplied. This could lead to the reconsideration of the figures for national tolerances. The establishment of an international tolerance based on public health needs is the logical conclusion of such a process.

2. Outline of International Procedure for Determining Tolerance Levels

Some principles governing consumer safety in relation to pesticide residues were established in 1961 by a FAO/WHO Joint Meeting on Pesticide Residues. This subject was considered again by a FAO/WHO Joint Meeting in 1963. This FAO/WHO Joint Meeting held a second session in March 1965. It prepared a revised edition of the 1963 report, i.e. FAO Meeting report No PL/1965/10/1, WHO/Food Add./27.65 .

In 1961, FAO/WHO adopted as a general principle for the establishment of residue tolerances that the contamination of human and animal food should be restricted to the lowest possible level and that the amount of a residue should not be higher than that which results from good agricultural practice provided that the final amount is accepted as safe for long-term consumption by man. The FAO/WHO report of 1963 added: "Since pesticides are, from their very nature, poisonous to some forms of life, any intake by man in the food may be considered undesirable. For this reason the rate of application of the pesticide to the crop should be as low as possible, and the interval between its last application and the consumption of the crop should be as long as possible so that the residue is reduced to a minimum".

The FAO/WHO Joint Meeting on Pesticide Residues, then started work to establish acceptable daily intakes from which residue tolerances could be derived. This took the form of a series of monographs evaluating the toxicity of pesticide residues in term of acceptable daily intakes. If sufficient and satisfactory toxicological information was available the expert committees proposed for each pesticide an acceptable daily intake expressed in mg/kg/day.

The Joint Meeting has published in its reports a full account of the evidence available for consideration. For the study of an international tolerance, it is suggested that the Codex Committee should accept the acceptable daily intake figure from the Joint Meeting provided that no further important toxicological evidence has become available in the interval. However, the Codex Committee should recognize that acceptable daily intakes can only be estimates in the light of the information available when they are made. Therefore it is useful to know on what

experiments the conclusions have been based and to study the comments and evaluations of FAO and WHO.

At the two meetings in 1963 and 1965, the FAO/WHO Expert Committee considered 56 pesticides, but proposed acceptable daily intakes for only 18-22 of them. Although the Joint Meeting on Pesticide Residues in future is likely to establish acceptable daily intakes for other pesticides therefore, it is feared that for some pesticides, which occur as residues in foods for human consumption, "acceptable daily intakes" may not be available in the near future from the Joint Meeting on Pesticide Residues.

Nevertheless many of these latter pesticides are already included in official lists of residue tolerances which are established for the protection of the consumer in various countries. These lists are potential barriers to international trade in foodcrops, and some attempt to achieve uniformity in the figures is very necessary. This may well be done by the preparation of draft or provisional international tolerance figures which, although not based on "acceptable daily intake" figures, would provide a measure of agreement whilst ensuring that foods are as sound as possible under various economic and other conditions.

3. Establishment of a tolerance in accordance with an "Acceptable Daily Intake" figure.

The procedure for establishing a tolerance is linked with the consideration of the upper level which should not be exceeded. The FAO/WHO Joint Meeting calls this maximum the "permissible level". The actual tolerances however are such that in most cases this permissible level will not be reached. For the calculation of the upper level of pesticide residues in grain and grain products expressed in ppm (mg per kg of food) the FAO Working Party on Pesticide Residues at its meeting in May 1965 used the following formula:

$$\frac{\text{"acceptable daily intake in mg/kg/d x body weight in kg}}{\text{consumption of the treated food in kg/d}} \quad "$$

The same working party adopted 60 kg as an international body weight and 400 g as the food factor for cereal products to be used in the denominator of the formula.

As pointed out by the FAO Working Party, the figure of 400 g for the daily intake of cereals and cereal products is an arbitrary one and represents a high intake for a 60 kg person. The calculation also assumes that the particular pesticide is present in all 400 g of the foodstuffs consumed per person per day. The Working Party pointed out that a different figure for the intake of food might be used when precise information was available on the extent to which a particular food consumed in a given country had been treated.

Individual consumption of different crops may show considerable fluctuations within the population of one country. Nevertheless it may be satisfactory for the relevant national authorities to use either the average consumption of a single crop or the 9th decile of its consumption as the food factor for a particular country. Because there are wide differences in dietary patterns and because detailed information on individual consumption is lacking, however the Codex Committee is invited to adopt the figure of 400 g for the intake of grain and grain products, when considering international tolerances.