

OPERATION OF THE PRIOR INFORMED
CONSENT PROCEDURE FOR BANNED
OR SEVERELY RESTRICTED CHEMICALS
IN INTERNATIONAL TRADE

DECISION GUIDANCE DOCUMENTS

Fluoroacetamide

JOINT FAO/UNEP PROGRAMME
FOR THE OPERATION OF
PRIOR INFORMED CONSENT



UNEP

United Nations Environment Programme



Food and Agriculture Organization
of the United Nations

**OPERATION OF THE PRIOR INFORMED CONSENT PROCEDURE FOR BANNED OR
SEVERELY RESTRICTED CHEMICALS IN INTERNATIONAL TRADE**

**DECISION GUIDANCE
DOCUMENTS**

Fluoroacetamide

**JOINT FAO/UNEP PROGRAMME FOR THE OPERATION OF
PRIOR INFORMED CONSENT**

Food and Agriculture Organization of the United Nations

United Nations Environment Programme

Rome - Geneva 1991

DISCLAIMER

The inclusion of these chemicals in the Prior Informed Consent Procedure is based on reports of control action submitted to the United Nations Environment Programme (UNEP) by participating countries, and which are presently listed in the UNEP-International Register of Potentially Toxic Chemicals (IRPTC) database on Prior Informed Consent. While recognizing that these reports from countries are subject to confirmation, the FAO/UNEP Joint Working Group of Experts on Prior Informed Consent have recommended that these chemical be included in the Procedure. The status of these chemicals will be reconsidered on the basis of such new notifications as may be made by participating countries from time to time.

The use of trade names in this document is primarily intended to facilitate the correct identification of the chemical. It is not intended to imply approval or disapproval of any particular company. As it is not possible to include all trade names presently in use, only a number of commonly used and published trade names have been included here.

This document is intended to serve as a guide and to assist authorities in making a sound decision on whether to continue to import, or to prohibit import, of these chemicals because of health or environmental reasons. While the information provided is believed to be accurate according to data available at the time of preparation of this Decision Guidance Document, FAO and UNEP disclaim any responsibility for omissions or any consequences that may flow therefrom. Neither FAO or UNEP, nor any member of the FAO/UNEP Joint Group of Experts shall be liable for any injury, loss, damage or prejudice of any kind that may be suffered as a result of importing or prohibiting the import of these chemicals.

The designations employed and the presentation of material in this publication do not imply the expression of any opinion whatsoever on the part of the Food and Agriculture Organization of the United Nations or the United Nations Environment Programme concerning the legal status of any country, territory, city or area or of its authorities, or concerning the delimitation of its frontiers or boundaries.

ABBREVIATIONS WHICH MAY BE USED IN THIS DOCUMENT

(n.b.: chemical elements and pesticides are not included in this list)

ADI	acceptable daily intake
ai	active ingredient
b.p.	boiling point
bw	body weight
° C	degree Celsius (centigrade)
CCPR	CODEX Committee on Pesticide Residues
DNA	Designated National Authority
EC	emulsion concentrate
EEC	European Economic Community
EPA	U.S. Environmental Protection Agency
ERL	extraneous residue limit
FAO	Food and Agriculture Organization of the United Nations
g	gram
µg	microgram
GAP	good agricultural practice
GL	guideline level
ha	hectare
HEOD	
IARC	International Agency for Research on Cancer
i.m.	intramuscular
i.p.	intraperitoneal
IPCS	International Programme on Chemical Safety
IRPTC	International Register of Potentially Toxic Chemicals
JMPR	Joint FAO/WHO Meeting on Pesticide Residues (Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and a WHO Expert Group on Pesticide Residues)
k	kilo- (x 10 ³) kilogram
kg	kilogram
l	litre
LC ₅₀	lethal concentration, 50%
LD ₅₀	lethal dose, median
m	metre
mg	milligram
ml	millilitre
m.p.	melting point

MRL	Maximum Residue Limit. (For difference between draft MRLs and Codex MRLs, see the introduction Annex I.)
MTD	maximum tolerated dose
ng	nanogram
NOEL	no-observed-effect level
NOAEL	no-observed-adverse-effect level
NS	Not Stated
OP	organophosphorus pesticide
PHI	pre-harvest interval
ppm	parts per million (Used only in reference to concentration of a pesticide in an experimental diet. In all other contexts the terms mg/kg or are used).
sp gr	specific gravity
STEL	Short Term Exposure Limit
TADI	Temporary Acceptable Daily Intake
TLV	Threshold Limit Value
TMDI	Theoretical maximum daily intake
TMRL	Temporary Maximum Residue Limit
TWA	Time Weighted Average
UNEP	United Nations Environment Programme
WHO	World Health Organization
WP	wettable powder
wt	weight
<	less than
<<	much less than
≤	less than or equal to
>	greater than
≥	greater than or equal to

FLUOROACETAMIDE

PRIOR INFORMED CONSENT DECISION GUIDANCE DOCUMENT

1. IDENTIFICATION

- 1.1 Common Name: Fluoroacetamide
- 1.2 Chemical Type: -
- 1.3 Uses: Rodenticide, insecticide
- 1.4 Chemical Name: 2-fluoroacetamide
- 1.5 CAS No.: 640-19-7
- 1.6 Trade Names/Synonyms: Compound 1081, Baran, Fluorokil 100, Fussol, Megatox, Navron, Rodex, Yanock
- 1.7 Mode of Action: Converts in vivo to fluoroacetic acid, leading to the formation and accumulation of fluorocitric acid and inhibiting the Krebs cycle
- 1.8 Formulation Types: Dyed cereal base (30g a.i./kg), bait pellets (20g a.i./kg)
- 1.9 Basic Producers: Jewninh-Joffe Ltd. (Israel), Tamogan Ltd. (Israel)

2. SUMMARY OF CONTROL ACTIONS

- 2.1 General: Control actions banning or severely restricting fluoroacetamide have been reported by 7 countries: 4 have banned it and 3 have approved its use only in severely restricted circumstances. Annex 1 summarizes specific actions of reporting countries.
- 2.2 Reasons for the Control Action: The use of fluoroacetamide has been curtailed principally because of its high acute toxicity to man and to other mammals and birds.
- 2.3 Uses Banned: In those countries reporting a control action, most uses have been discontinued except those specifically authorized uses or conditions of control as noted in Section 2.4.
- 2.4 Uses Reported to be Continued in Effect: In the US, since 1980 the compound may be used only to control roof rats, where humans and other mammals are unlikely to be exposed; in addition, it can be applied only by certified applicators or by those working under their direct supervision, and only upon following specified safety precautions, including daily disposal of all poisoned animals. In Israel and Japan, the compound can be used only with a special permit, and in Japan, only for specified uses. See Annex 1.
- 2.5 Alternatives: Sodium fluoroacetate (Compound 1080) was developed and used as early as the 1940's before superseded by fluoroacetamide. Although the compounds have different chemical formulas, both are used primarily as rodenticides and are assumed to present similar

hazards. Fluoroacetamide has lower mammalian toxicity and a longer latency period, and is less likely to cause sublethal poisoning.

2.6 Contacts for Further Information: FAO/UNEP Joint Data Base, IRPTC Geneva; Designated National Authorities in countries taking control actions.

3. **SUMMARY OF FURTHER INFORMATION ON FLUOROACETAMIDE**

3.1 Chemical and Physical Properties: Fluoroacetamide is a colorless crystalline powder, very soluble in water, soluble in acetone, moderately soluble in ethanol, slightly soluble in aliphatic and aromatic hydrocarbons.

3.2 Toxicological Characteristics

3.2.1 Acute Toxicity: Acute oral LD₅₀, rat: 13 mg/kg.

WHO classification: Class Ib, highly hazardous

Formulations: For solids, above 10% a.i., Class Ib; between 1 and 10%, Class II; below 1%, Class III. For liquids, above 50%, Class Ia; between 5 and 50%, Class Ib; between 0.5 and 5%, Class II; below 0.5%, Class III

3.2.2 Short-Term Toxicity: Fluoroacetate, a closely related compound, is a highly toxic rodenticide resulting in convulsions, cyanosis, ventricular fibrillation and death following ingestion. In humans, clinical effects may be noted as soon as 1/2 hour following exposure but may be delayed as long as 20 hours. Estimated lethal dose in man is 5 mg/kg but even one mg of the pure compound may cause severe toxicity. Fluoroacetamide does not produce convulsions but causes unconsciousness followed by death in coma; it affects poisoned animals less slowly and with less neurological symptoms than does fluoroacetate. In vitro tests indicate chromosomal damage.

3.2.3 Chronic Toxicity: No information on record

3.2.4 Epidemiological Studies: None on record

3.3 Environmental Characteristics:

3.3.1 Fate: highly stable in soil and water

3.3.2 Effects: Main effects are on nontarget wildlife, since many types of animals may consume bait or prey on sick or dead animals. The compound is highly toxic to most animals except frogs and toads. Dogs and cats are very susceptible to direct poisoning but barn owls, buzzards, black kites and some reptiles have been found to be resistant.

3.4 Exposure:

3.4.1 Food: Accidental consumption of prepared baits is the most likely source of exposure by ingestion.

- 3.4.2 Occupational/Use: Skin contact may be important routes of absorption for both mixers and applicators. Time-weighted average TLV has been set at 2.5 mg/m^3 , with excursion limits no more than three times the TLV for a total of 30 minutes during a work day.
- 3.4.3 Environment: Humans may come into contact with baits treated with the compound. The compound's high solubility in water indicates danger of water contamination near manufacturing, preparation and application sites. In the UK, farm animals were reportedly poisoned by effluents from a factory. About 800 dogs were reported to have died after consuming meat contaminated by sodium fluoroacetate or fluoroacetamide.
- 3.4.4 Accidental Poisoning: Monoacetin has been suggested as an antidote for Compound 1080 and fluoroacetamide if administered before significant amounts of fluorocitrate form, but this pharmaceutical is not available in all markets. Acetamide and ethyl alcohol may be also of value. If the poison was ingested shortly before treatment, the toxicant should be removed from the gut. If convulsions are already occurring, the seizures should be controlled by giving oxygen, administering anticonvulsant medications and aiding pulmonary ventilation, followed by gastric lavage and catharsis.
- 3.5 Measures to Reduce Exposure: Fluoroacetamide should be handled and stored as a highly toxic material. Procedures for personal protection and hygiene, including the wearing of protective gloves when handling and other precautionary measures should be observed. Wash hands after each use. If clothing is contaminated, remove it and wash the skin, including hair and nails, vigorously. Wash clothing repeatedly with soap. Discard contaminated lather. The compound and its formulation should not be mixed with food normally consumed by humans.

Human exposure can be reduced by avoiding use near human habitations or by placing the rodenticide in areas that are not accessible to humans, such as closed sewers, and by regular, proper disposal of dead animals. Store in a closed container in a closed area.

- 3.6 Packing and Labelling: Follow FAO Guidelines on Labelling Practice for Pesticides and Guidelines the Packaging and Storage of Pesticides.
- 3.7 Waste Disposal Methods: Guidelines are under development. This section will be updated when guidelines are available.
- 3.8 Maximum Residue Limits (mg/kg): Not applicable.

4. MAJOR REFERENCES

Anon. Farm Chemicals Handbook. Willoughby, OH, USA Meister Publishing Co. (1989)

Food and Agriculture Organization, Guidelines for the disposal of waste pesticides and pesticide containers on the farm. FAO, Rome (1985)

Food and Agriculture Organization, Guidelines for the packaging and storage of pesticides. FAO, Rome (1985)

Food and Agriculture Organization, Guidelines on good labelling practice for pesticides. FAO, Rome (1985)

Hall, R.J., Effects of Environmental Contaminants on Reptiles. U.S. Fish and Wildlife Service Special Science Reports, Wildlife, 228:12 (1980)

U.S. Environmental Protection Agency, Fluoroacetamide (Compound 1081), Position Document 2, NTIS No. PB80-216831. USEPA, Arlington, VA, (1980)

World Health Organization, Recommended Classification of Pesticides by Hazard. WHO, Geneva (1988)

World Health Organization/Food and Agriculture Organization, Sodium Fluoroacetate. Pesticide Data Sheet No. 16, (1975)

Worthing, C.R. The Pesticide Manual: A World Compendium. 8th edition. The British Crop Protection Council (1987)

ANNEX 1
SUMMARY OF CONTROL ACTIONS AND REMAINING USES FOR
FLUOROACETAMIDE, AS REPORTED BY COUNTRIES

BANNED:

China	(1982)	Banned as agricultural chemical.
Mexico	(1982)	Banned as agricultural chemical.
Panama	(1987)	Banned as agricultural chemical.
Thailand	(1985)	Banned as consumer chemical.

WITHDRAWN:

None reported.

SEVERELY RESTRICTED:

USA (NS) Labelling amended to allow use only inside of sewers against the Norway and roof rat. This use is restricted and may be applied only by a certified applicator or a competent person acting under the instructions and control of a certified applicator.

Only remaining uses allowed:

None reported.

Specific uses allowed:

None reported.

Use permitted only with special authorization:

Japan (1956) Manufacture and import prohibited without authorisation by the Government. The use is limited to exterminating insects which are noxious to such plants as citrus fruits.

Israel (1967) Use and sale prohibited without a permit from the Government.

Ed. 1, July 1991