REPORT OF THE COMMITTEE TO EVALUATE THE SAFETY ASPECTS OF ENDOSULFAN

Department of Health & Family Welfare,
Government of Gujarat
Gandhinagar, Gujarat, INDIA

15th March 2011

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By

Prof. Ramesh K. Goyal, *Chairman*
Shri Hemant G Koshia, *Member Secretary*

Members of the Committee

Shri B. R. Shah
Dr. Paresh V. Dave
Dr. N. C. Patel
Dr. M. C. Varshneya
Shri J. B. Patel
Dr. Nandkumar Chodankar
Dr. Purusottam R. Pednekar
Dr. V. V. Ranade
Dr. Suresh K. Nigam

Submitted to

Department of Health & Family Welfare,
Government of Gujarat
Gandhinagar, Gujarat, INDIA

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Contents

Certificate

This is to certify that the contents given in this report on

"Evaluation of the safety aspects of endosulfan"

represents the unanimous views of the Committee constituted by

Department of Health & Family Welfare,
Government of Gujarat
Gandhinagar, INDIA.

The conclusions are based on the literature surveyed, fact finding visits made to endosulfan manufacturing plants at Ankleshwar and Bhavnagar, Samvardhan Trust study on farmers as users of endosulfan, interactions with local community and discussions held by of the members of the committee.

We certify that this report represents

a true, accurate and faithful record of the information obtained.

Prof. Ramesh K. Goyal
Chairman

Shri Hemant Koshia
Member Secretary

Executive Summary

The committee was appointed with a clear objective ***"To evaluate the health and safety aspects of Endosulfan"***. Accordingly

1. The Primary investigation included

    - Analysis of evaluation reports of residues of endosulfan in blood samples of **workers** and **farmers** exposed to endosulfan continuously over a number of years,
    - Interactions with **workers and their families** as well as **community representatives** facing exposure to endosulfan and its various metabolites.

2. The Secondary investigation included a thorough review and examination of all available secondary data, committee reports and review reports.

Based on this investigation the committee has arrived at the conclusion that **there are no health effects on humans as a result of exposure to endosulfan and its metabolites.**

The importance of this study arises as two of the three manufacturing plants of India are located in Gujarat.

The committee concluded that there is no risk posed to workers, farmers and other users of Endosulfan as well as the community at large due to exposure to endosulfan and its metabolites and hence **recommends the continued manufacture, use and trade in endosulfan active and its various formulations.**

The committee reviewed the various media reports arising out of Kasargod, Kerala, alleging that a host of health problems can be attributed to the aerial spraying of endosulfan. The committee -also looked at various reports in the media suggesting that the issue in Kerala is driven by vested interests and the call for a ban is against the interest of small and marginal farmers. After reviewing all the reports the committee is of the firm opinion that to ban a molecule has to be on the basis of sound science and not on the basis of media reports.

The committee noted that the WHO (World Health Organization), FAO (Food and Agricultural Organization), IARC (International Agency for Research on Cancer) and US EPA (US Environment Protection Agency) - have indicated that endosulfan is **not carcinogenic, not teratogenic, not mutagenic and not genotoxic.**

One of the actions which precipitated the formation of this committee was a rally by over 8000 men, women and children in the city of Bhavnagar demanding the withdrawal of a report published by NIOH because the conclusions of the NIOH report titled **"*Final Report of the Investigations of Unusual Illnesses Allegedly Produced by Endosulfan Exposure in***

Padre Village of Kasargod district (N. Kerala)" was cited as a reference for seeking a ban on Endosulfan in the State of Kerala.

The committee did a critical analysis of the NIOH report as well as comments on the NIOH report by expert committees constituted by the Government of India including Dr O P Dubey committee. The committee also reviewed other publications including the review article titled ***"An Assessment of the Developmental, Reproductive and Neurotoxicity of Endosulfan"*** by Marilyn H Silva and Derek Gammon of the Department of Pesticide Regulation California Environmental Protection Agency, USA which critically examined the NIOH reports on the subject. The committee further took into account opinion of noted "residue expert" Scientist Dr S K Handa, Fellow of National Academy of Agricultural Sciences, former WHO consultant to the Ministry of Health, Government of India. The committee also looked into extracts of raw data obtained from the NIOH by an RTI applicant and submissions made by Saurashtra Chamber of Commerce and Industry to the Prime Minister of India on the flaws and non-compliances in the NIOH report.

According to Dr S K Handa "since there was no direct confirmation of the presence of residues of endosulfan in the report made by scientists at NIOH, the residues of endosulfan reported by NIOH cannot be accepted"(Chemistry Information on Endosulfan is available for review). The CODEX Committee of Pesticide Residues emphasized that when analysis are performed for monitoring **on enforcement purposes** it is especially important that confirmation data should be generated before reporting data on residues of pesticides.

Further new available data on the Gujarat Study titled ***"Evaluation of Residues of Endosulfan in Human Blood Samples collected from the persons of Mengani and Hadmadia villages, Gondal Dist. Rajkot"***; an independent study on farmers exposed to endosulfan confirms that there are no residues of endosulfan in blood. This data on farmer exposure is in addition to residue studies of endosulfan in blood samples from workers of endosulfan manufacturing plants in Gujarat, which also did not report any endosulfan residues.

Conclusion & Recommendation

This committee concludes that there are no health problems that can be associated to the exposure to endosulfan and is satisfied that there are no occupational health or safety issues arising out of exposure to endosulfan.

This committee recommends the continued manufacture, use and trade in Endosulfan active and its various formulations

4. Background Information

Basis for Study and Formation of Committee

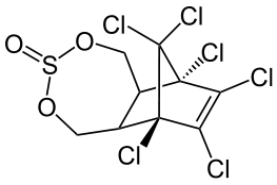
The Honorable Minister of Health Shri Jay Narayan Vyas received a representation from Sishuvihar, an NGO from Bhavnagar, Gujarat opposing the conclusions of a health study on endosulfan performed by scientists of National Institute of Occupational Health (NIOH), based in Ahmadabad. Sishuvihar in their letter stated that endosulfan is being manufactured in Bhavnagar and India over 30 years and almost 24,000 persons are connected with their manufacturing and indicated that all of them are healthy and there are no health effects observed. Sishuvihar had supported the call by endosulfan workers for a withdrawal of the NIOH report on endosulfan and had enclosed copy of the workers petition to the Collector of Bhavnagar district in this regard.

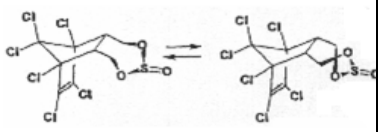
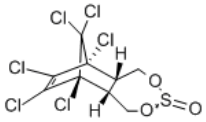
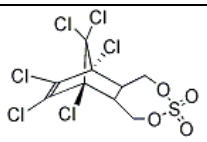
As two of the three endosulfan manufacturing plants of India are in Gujarat and as farmers in Gujarat are large users of endosulfan, the Honorable Minister suggested that the matter requires a neutral and independent study on health and safety aspects of endosulfan by a team of experts in related fields. Accordingly committee of experts under the Chairmanship of Prof. Dr R K Goyal, Vice Chancellor of M.S. University, Vadodara was set up with Shri H G Koshia, Commissioner, Food and Drugs Control Administration, Gujarat, Gandhinagar as its Secretary vide Resolution No. DRG-102010-2825-JH, Sachivalaya, Gandhinagar dated 23rd December, 2010. The committee comprised of noted experts in the field of Pharmacology, Toxicology, Chemistry, Agriculture as well as Occupational Health and Safety.

No.	Name and designation	Address	Position in Committee
1.	Prof. Ramesh K. Goyal, Vice Chancellor	The Maharaj Sayajirao University,of Baroda, Vadodara 390002	Chairman
2	Shri H. G. Koshia, Commissioner,	Food & Drugs Control Administration, Gandhinagar	Member Secretary
3	Shri B. R. Shah, Director,	Agriculture Department, Gandhinagar.	Member
4	Dr. Paresh V. Dave, Additional Director	Directorate of Health, Gandhinagar	Member
5	Dr. N. C. Patel, Vice Chancellor,	Junagadh Krushi University, Junagadh	Member
6	Shri M. C. Varshneya, Ex. Vice Chancellor	Anand Agriculture University, Anand	Member
7	Shri J.B. Patel Chairman/ Dr. C. J. Shishoo [Former Chairman]	Consumer & Education Research Centre, Ahmedabad	Member
8	Dr. Nandkumar Chodankar, Director	Board of Global DIA, (US, Europe, Japan, India & China)	Member
9	Dr. Purushottam R. Pednekar, Ex. Director,	Syngenta Biosciences Pvt. Ltd.	Member
10	Dr. V .V. Ranade, Retd. Professor,	Department of Pharmacology & Toxicology, Bombay Veterinary College, Mumbai.	Member
11.	Dr. Suresh K. Nigam, Ex. Dy Director, NIOH	Consultant Pathologist Zydus Cadila Research Center at Moraiya, Ahmedabad	Member

5. Introduction to Endosulfan

WHO has classified endosulfan as non-organochlorine compound and sulphrous acid ester of chlorinated cyclic diol. Chemically it is 6,7,8,9,10,10-hexachloro-1,5,5a,6,9,9a-hexahydro-6, 9-methano-2,4,3-benzodioxathiepine-3-oxides), comprising of a binary mixture of two stereo isomers, alpha Endosulfan (64-69%) and beta Endosulfan (29-32%).

Molecular Structure: 

CS Number	115-29-7		
U.S. EPA PC Code	079401		
CA DPR Chem Code	259		
Mol. Formula	$C_9H_6Cl_6O_3S$		
Molecular mass	406.96 g·mol^{-1}		
Structural formulas of the isomers and the main transformation product			
	α-Endosulfan	β-Endosulfan	Endosulfan sulfate
CAS Registry numbers	959-98-8	33213-65-9	1031-07-8
CAS for Technical Grade	1031-07-8		

It acts as a poison to a wide variety of insects and mites on contact. Although it may also be used as a wood preservative, it is used primarily on a wide variety of food crops including tea, coffee, fruits, and vegetables, as well as on rice, cereals, maize, sorghum, or other grains.

Endosulfan is a broad spectrum, generic insecticide used in a variety of crops to control over 60 different pests. The unique chemistry of Endosulfan has ensured that the farmer is able to protect his farm ecosystem while dealing with pest infestation. Farmers used Endosulfan extensively in cross pollinated crops where successful Honey bee pollination plays an important role. Endosulfan is the only 'in-use' generic pesticide known to be soft on pollinators such as Honey bees and beneficial insects. India is the second largest producer of fruits and vegetables in the world. It is also one of the largest producer and exporter of honey. Hence, there is a great need of a bee-soft pesticide for the Indian farmers.

It is extensively used in agriculture to control insect pests. It has been recommended for controlling insects pest in various crops namely paddy, grams, sugarcane, cotton, groundnuts, mustard, brinjal, cabbage, cauliflower, wheat, maize, tea, mango, cashew etc.

Formulations of endosulfan include emsulsifiable concentrate, wettable powder, ultra-low volume (ULV) liquid, and smoke tablets. It is compatible with many other pesticides and may be found in formulations with dimethoate, malathion, methomyl, monocrotophos, pirimicarb, triazophos, fenoprop, parathion, petroleum oils, and oxine-copper. It is not compatible with alkaline materials. Technical endosulfan is made up of a mixture of two molecular forms (isomers) of endosulfan, α- (alpha) and β- (beta) isomers.

Registration status, approved usage

Endosulfan is registered for import, manufacture for use in the country and export. Endosulfan is a wide spectrum insecticide, which acts mainly as a contact and stomach poison and controls many important chewing and sucking insect's pests in various crops. Three formulations of Endosulfan are registered under the Insecticides Act, 1968 for use against various crop pests.

Three formulations i.e., 35% EC, 4% DP and 2% DP of Endosulfan are registered under the insecticides Act for controlling insect pests in various crops viz., rice, wheat, jowar, pulses, sugarcane, cotton, jute, maize, vegetables, tobacco, cardamom, tea, coffee, cashew, mango, cocoa, citrus, groundnut, mustard, safflower, til etc,.

6. Objectives

The objective of the committee was to

1. To critically review the NIOH report, its conclusions and discuss them in the light of published scientific reviews, media reports and Government expert committee reports.
2. To deliberate toxicity data and toxicokinetics of endosulfan.
3. Determine if endosulfan can cause health problems such as cancer, infertility, genotoxicity and other reproductive illnesses
4. To analyze the data available on Environmental aspects of Endosulfan.
5. Evaluate the safety aspect of endosulfan by examining the occupational health and safety issues arising out of exposure to endosulfan by workers and farmers.
6. Make recommendations based on the findings

7. Methodology Adopted

The committee in order to achieve its objectives undertook an exhaustive study on all aspects by way of a primary investigation as well as a thorough review of all available secondary data including committee reports and other review reports.

The Primary investigation included

- Analysis of evaluation reports of "residues of endosulfan" in blood samples of **workers** and **farmers** exposed to endosulfan continuously over a number of years,

- Interactions with **workers and their families** as well as **community representatives** facing possible exposure to endosulfan and its various metabolites

The Secondary investigation included a thorough review and examination of all available secondary data, committee reports and review reports

As a part of primary investigation, under advice from the Chairman Prof. Dr R K Goyal, two study groups, comprising of two members of the committee were sent to both the manufacturing plants of endosulfan in Ankleshwar and Bhavnagar respectively. The Ankleshwar endosulfan plant was visited by Dr M C Varshneya and Dr S K Nigam and the Bhavnagar endosulfan plant was visited by Dr V V Ranade and Dr P R Pednekar. Both visits were undertaken simultaneously on 26th February 2011 (without giving any prior notice).

The objectives of this visit were

1. To meet and interact with the workers at the endosulfan manufacturing plant to determine the number of years over which these workers have been exposed to Endosulfan
2. To examine all available official retained medical records (as per the Factory Act) relating to the health of the workers
3. To examine all available official retained medical records relating to study of presence or absence of endosulfan residues among workers exposed to manufacturing of endosulfan
4. Where possible, to meet and interact with worker's families, local community, NGO's and other citizens and take into account their views in relation to endosulfan particularly with health and safety aspect

Both teams had extensive interactions with the workers, their families and where possible NGO's and local community and compiled valuable information on health and safety aspects of endosulfan.

In addition to the blood reports of farmers (the actual users), data relating blood reports of workers exposed to endosulfan manufacturing was also obtained.

The detailed report of the visit to Ankleshwar and the visit to Bhavnagar is available for review.

The secondary investigation included a critical review of

- NIOH study on endosulfan titled, ***"Final Report of the Investigations of Unusual Illnesses Allegedly Produced by Endosulfan Exposure in Padre Village of Kasargod district (N. Kerala)"***.
- Article in Environmental Health Perspectives ***"Effect of Endosulfan on Male Reproduction Development"***
- Review article **"*An Assessment of the Developmental, Reproductive and Neurotoxicity of Endosulfan*"** by Marilyn H Silva and Derek Gammon of the Department of Pesticide Regulation California Environmental Protection Agency.
- EPA –Human Health Risk Assessment [HED], June'10.
- Dr. N. Mackey, Cambridge Environment Assessments

The committee met for four times (30/12/2010; 19/1/2011; 14/2/2011 and 26/2/2011). Two groups of members made a surprise visit to the manufacturing plant of Coromandel International Ltd. Ankleshwar and Excel Crop Care Ltd., Bhavnagar separately on 26/2/2011.

8. Observation of the Committee

8.1 Critical Review of the NIOH Report

Reports of unusual diseases in certain villages of Kasargod district of northern Kerala allegedly caused by spray of pesticide, Endosulfan, over the cashew plantations were published in *Down to Earth* (February 28th, 2001), *The Hindu* (July 22nd, 2001), *India Today* (July 23rd, 2001) and several other magazines, local newspapers and TV channels.

These reports were investigated by National Institute of Occupational Health (NIOH), Ahmadabad, through a three member committee constituted in 2001.

On the directives of the Director General, ICMR, an environmental epidemiological study was carried out by National Institute of Occupational Health (NIOH), Ahmadabad with the following objectives:

1. To confirm the reported disease pattern in the exposed populations and evaluate the magnitude of the problem by comparison with reference populations through a well designed epidemiological study.
2. To search for etiological factors if the exposed populations show abnormal disease patterns and generate hypothesis.
3. To confirm the presence of Endosulfan residues in environmental and biological samples and estimate their levels.

National Institute of Occupational Health (NIOH), Ahmadabad conducted an epidemiological study in select population of school children in two villages of Kasargod district, Kerala. NIOH submitted its first report in Dec'2001 and final report in July'2002. Based on the data collected for this study NIOH also published other reports which are related reports.

As one of the objectives of this study was to critically examine the NIOH report, the report and all peer reviews were studied in great detail. The committee also went through representations made by The Saurashtra Chamber of Commerce and Industry to the Prime Minister of India on the NIOH study as well as analysis of the NIOH study on the basis of raw data obtained by an RTI applicant.

A thorough analysis of the NIOH report and reviews revealed that it suffers from:

I. *Serious design flaws.*
II. *Selection bias.*
III. *Selective and inadequate presentation of data.*
IV. *Selective suppression of facts*
V. *Invalid assumptions/findings that lack the logic of science*

I. Design flaws in NIOH's epidemiological study

The primary objective of NIOH study (p.5) was "to confirm the reported disease pattern in the exposed populations and evaluate the magnitude of the problem by comparison with reference populations through a well designed epidemiological study".

Epidemiology is the study of extent of association, between exposure to suspected toxicant and the presence of adverse health effects in a given group of people. Selection of sample groups (exposed group and unexposed control group) is most crucial step in any epidemiological study. The unexposed control group should be comparable with the exposed group in all aspects except for the exposure.

A detailed analysis of the *NIOH study revealed grave mismatch* between the exposed group and control group. It was observed that there is no **true "unexposed group"** in NIOH's epidemiological study and hence *the study has not addressed/ achieved the basic objective of the study – of evaluating the magnitude of disease pattern in exposed population by comparison with control population*.

II. Inadequate presentation of data & facts

While the report gives details (p.12) about levels of Endosulfan residues in drinking water samples taken from Vaninagar (exposed) during 2001, it does not give similar data for the samples taken from Meenja.

A total of 262 blood samples were taken (p.80) for analysis by NIOH. Its report does not give complete results and raw data of the findings. The report only gives (p.17) mean values that too for only 247 samples.

In any epidemiological study, the definition of a study population must begin with some characteristic which all its members have in common. NIOH has not clarified the **"commonality"** that all the students of study group share qualifying themselves to be ideal **"exposed group"**.

III. Selection Bias

Selection bias can occur when those selected are different from those excluded within the study area. Padre village has two schools. One is in Vaninagar area and another in Swarga. The visit report of ICMR team (9 – 11th Aug 2001) stated that while in the school in Vaninagar there were many mentally or physically handicapped children, in the school at Swarga there were no physically abnormal children. This is an important difference. For the study to be unbiased students from both the schools should have been selected for the exposed study group. An important observation recorded was that Swarga School is closer to PCK plantations than Vaninagar School.

IV. Selective suppression of facts

NIOH report has not brought out certain facts/information concerning Endosulfan usage in the area taken up for study

V. Invalid assumptions/findings that lack the logic of science

Studies carried out by AICRP on pesticides residue shows that Endosulfan does not persist for long in Indian environmental conditions. Under the situation it is highly improbable that Endosulfan residues may have persisted for more than 5 months at appreciable levels and moved along with running water to a distance of 3- 4 kms to Vaninagar from the treated area that too in undulating terrain full of vegetative cover. On page No 13, the NIOH report states *"since the water is used for irrigation purpose there is likelihood of exposure through food"*. Endosulfan is not a water soluble systemic insecticide to move from irrigation water into crop plants.

The NIOH report was peer reviewed by two epidemiologists Dr. N. K. Arora and Dr. S. N. Dwivedi of AIIMS, New Delhi.

Dr. Arora pointed out that in order to establish cause-effect relationship, it is necessary that "the observations have to be interpreted cautiously in the light of potential confounders and the limitations of the study". He has raised basic questions on the report such as selection of children, refusal rate, and sample selection, spray duration etc. He further stated that "the subjective findings" should be interpreted with caution".

Dr. S. N. Dwivedi pointed out several *"pit falls"* in the NIOH study such as study design, sample size and methods, selection of control group, data analysis etc. and opined that NIOH study could not be used for making any policy decision. Further, in the NIOH report the limit of determination followed for residue analysis has not been given and also no confirmatory tests have been carried out.

Other Comments on NIOH Study

For generation and interpretation of pesticide residue data, experimental procedures must be followed as per established good laboratory practices (GLP) norms. These include proper sampling, recovery studies at the limit of determination and reproducibility. GC and GC-MS chromatograms of the standards, samples and blanks must be available for the entire study to arrive at the logical conclusions.

In case of the NIOH study these norms were not followed and hence the study should not be considered. The conclusions of the study do not reflect the observations made while undertaking the study.

The NIOH report suffers from following serious deficiencies:

1. *The validated analytical methods for estimation of Endosulfan in soil, water and biological have not been properly described.*
2. *Limit of quantification of α-Endosulfan, β-Endosulfan and Endosulfan sulfate has not been correctly established by GC & GC-MS.*
3. *Recovery values of α-Endosulfan, β-Endosulfan and Endosulfan sulfate at the limit of determination have not been established.*
4. *Concentration and response curve of Endosulfan has not been established.*
5. *It has been reported in NIOH report that detection limit of α-Endosulfan, β-Endosulfan and Endosulfan sulfate was 1, 1 & 3 ppb respectively. However, values as low as 0.0004 ppb has been reported (below detectable limit). This is not acceptable and is not scientifically valid.*
6. *Blank values/procedural blanks and untreated samples should not exceed 30% of limit of quantification. It is found that the blank values exceed much above this level. Raw data obtained under Right to Information Act indicates that contribution from blank is higher than all sample values reported in NIOH report.*
7. *Standard deviation from mean is too high indicating that the data is neither validated and nor dependable.*
8. *Different studies were conducted with similar broad objectives of establishing the cause-effect relationship of Endosulfan exposure to reported unusual health problems in Kasargod district. However, it is noted that no uniform protocol was adopted. The sample size of population study and the number of different samples were not specified in the protocol/objectives provided.*
9. *At many places, what is reported in the Final Report when examined revealed that it is not in accordance with the raw data (the raw data was obtained under right to information act).*
10. *The minimum detectable limit of Endosulfan sulfate reported in the study was 3 ppb. However, values as low as 1.57, 2.79 and 2.9 ppb were reported in the blood samples*
11. *Good Laboratory Practices*

It is likely that different substances with structural similarity generally appear in or merge with the same peak due to similar retention time. Hence as per Good Laboratory Practices on Pesticide Residue Analysis, it is emphasized that when analysis are performed for monitoring or enforcement purposes (quantitation), it is especially important that direct confirmation of residues detected should be carried out by GCMS/LCMS before reporting data on residues of pesticides.

All the previously appointed committees which reviewed the NIOH study on Endosulfan have observed that NIOH has not done any direct confirmation of Endosulfan residues. In the absence of confirmation, the residues of Endosulfan reported by NIOH cannot be accepted.

Human Epidemiology: In a review article on ***"An Assessment of the Developmental, Reproductive and Neurotoxicity of Endosulfan****"(available for review),* Marilyn H Silva and Derek Gammon of Department of Pesticide Regulation, California Environmental Protection Agency critically examined the epidemiological results reported by Dr. H Saiyed *et al of NIOH in their study titled "Effects of Endosulfan on Male Reproductive Development"*. They concluded that the criticisms and the preliminary aspect of the data limit the usefulness of the study for the purpose of risk assessment.

Conclusion on NIOH report

Methodology used in NIOH study is not validated as per standard practice. The mandatory confirmatory tests were not conducted. Many **"residue values"** fall below the minimum detection limits of the instrument used. The contribution from the blank was higher than the samples. Raw data collected under RTI Act indicates that the Final Report suffers from incorrect representation of facts. There are unexplained and unacceptable discrepancies between numbers of samples collected, number of samples tested and number of samples reported. The sample size is not consistent and widely fluctuates. **NIOH report on Endosulfan is thus incorrect and misleading and should be considered invalid.**

The conclusions of the NIOH study cannot be used to determine that exposure to endosulfan can cause health problems.

8.2 Toxicity data and Toxicokinetics of Endosulfan

The pesticides are backbones of agriculture and food production. The pesticide chemicals are known poisons for insects and pests when applied in recommended concentrations. It is expected that beneficial creatures like honeybees, earthworm, and frogs are not affected or less affected. It is also expected to posse's selective action on pests in recommended concentration an minimum or no harm to the animals, birds and human populations.

Endosulfan has been classified by The US EPA as Category I: "Highly Acutely Toxic" compound based on LD_{50} value of 30 mg/kg for female rats. The World Health Organization classifies it as Class II "Moderately Hazardous" based on a rat LD_{50} of 80 mg/kg

The pesticide "Endosulfan" is used in agriculture for more than 50 years showing broad spectrum active without development of any resistance. It is also sparing useful honeybees. In recent years some episode of endosulfan related (supposed to be) toxicity as noticed in village Padre in Kerala State as reported by local medical practitioners. Endosulfan in bulk is manufactured mostly in India and used in Indian agripractice and exported to some countries. Kerala is hardly using 1% Endosulfan and 99% is used in other parts of India like Maharashtra, Karnataka, Punjab, Andhra Pradesh, Tamil Nadu, Gujarat, etc. It is very interesting to note that there are no reports of pesticide (Endosulfan) toxicity in the other states, farmers, sprayers and factory workers.

Endosulfan is not a systemic pesticide (not absorbed by roots) and there are no chances of entry of Endosulfan through plant and food chains from soil source.

As per WHO recommendations

- ADI 0.006 mg / kg
- NOEL 0.6 mg / kg
- LD50 in rats 80 mg
- Classification – Category 2 chemical moderately hazardous pesticide.
- Endosulfan is not persistent (WHO)

Endosulfan is reported as non carcinogenic by WHO and many reputed national and international laboratories.

8.3 Environmental Aspects of Endosulfan: Effect on soil

Metabolism in Soil

There are several scientific reports that establish the fact that under tropical environmental conditions, Endosulfan degrades rather fast (Gupta *et. al*., 1977, Kathpal *et. al*., 1997). Persistence data varies depending on geographical region and persistence data generated in a temperate country like Canada may be different and much higher when compared to a tropical country like India. Half life Endosulfan sulfate (a metabolite of Endosulfan) in tropical climate it is only 20 days (W. Lehr, 1992).

Endosulfan is degraded in the soil with a half-life of 30-70 days, as shown in laboratory trials. In warm climates, Endosulfan does not accumulate in the soil even after many years of application. In cooler climates, a soil residue plateau of 0.2-0.6 mg/kg Endosulfan degraded in soil under field condition in 30 days of application when applied at the rate of 1-2 l/ha (Ghose *et. al*., 1999). Half life of 38 days has been reported in oil palm agro ecosystem soil (Cheau *et. al*., 2001).
Environmental factors (solar radiation, temperature, soil moisture, soil microbial activity etc.) directly influence the duration of persistence of any chemical in the environment. Castro. J *et. al*., 2002, noticed an increase of alpha and beta endosulfan degradation rate with temperature. Biodegradation of alpha and beta Endosulfan was noticed to be influenced by application of different organic materials (Al-Hassan RM *et. al.*, 2004). Endosulfan has no adverse effect on soil respiration (Ricardo Joseph, 2010). It was noticed that microbial degradation enhanced in the presence of fertilizers (Elsaid, O.E.G. *et. al*., 2009).

Soil Degradation half-lives (days)

Conditions	Range	Typical	Reference
Field		50	EXTOXNET, 2007
Field (aerobic)	75-110		GFEA, 2004
Fields in UK		65-126 (Summer) 68-87 (fall)	Footprint, 2007
Laboratory (4 soils, aerobic)	117-391		GFEA, 2004
Laboratory (20 oC)	28-50		Footprint, 2007

	Alpha Isomer	Beta Isomer	Alpha and Beta Endosulfan	Alpha-Beta-sulfate Endosulfan	
5 Soils (pH5-7, aerobic)	35-67	1040265	75-125	288-2148	US EPA (2001)
5 Soils (pH 5-7, aerobic)	105-124	136-161	144-154		EPA (2001) EPA (2001)

Photo degradation of Endosulfan on soil surfaces is not an important process. A 30 day study on a pH 6.4 slit loam soil indicated that both Alpha and Beta Endosulfan were stable to natural sunlight (US EPA, 2001). While both Endosulfan isomers are resistant to photo degradation, their metabolites Endosulfan sulfate and Endosulfan diol area susceptible to photolysis (WHO, 1988). Endosulfan persisted longer in soil than in water. From soil it is not expected to enter food chain since it is non systemic and is not absorbed by the plant roots.

Persistence in Soil

Dissipation of the total Endosulfan residues occurred to an extent of 92-97% in the first four week period. Residue half life DT50 varied from 39 to 42 days. (Trilochan S.K *et. al.*, 1997). Persistence and downward movement of Endosulfan residues were studied in a sandy loam soil under wheat cultivation at two locations on the bank of river Ganga and Farrukabad (India). The residues of Endosulfan in soil (0-15 cm) persisted for 60 days with half life of 10.3 to 10.6 days. (Agnihotri, N P *et. al.*, 1996). The initial deposition and dissipation of endosulfan residues in fodder maize (cv, African Tall) and in cropped soil was studied in Jhansi, UP, India. Endosulfan was applied at 490 and 980 g.a.i ha-1 (two sprays for each rate). Approximately 93-95% of the initial residues disappeared from the foliage within 15 days. The alpha isomer of Endosulfan degraded faster than the beta isomer in both foliage and soil. The toxic metabolite Endosulfan sulphate was observed from the 3rd day after the first application. The rate of dissipation with the time followed the first-order reaction kinetics. The half life of residue disappearance and safe waiting period ranged from 3 -4 and 11 to 14 days, respectively (Raikwar, M.K *et. al.*).

Soil/Sediments

Endosulfan released to the soil is subject to biodegradation. The biodegradation of Endosulfan in soil and water is dependent on climatic conditions and type of micro organisms present. Both biotic and abiotic processes are expected to decrease Endosulfan concentrations in soil environments. Half life (DT50) of Endosulfan ranged from 39 days to 42 days in cotton soils of Haryana, India (Trilochan S. K. *et. al.*, 1997). Half life of Endosulfan ranging from 9.6 days to 12.7 days was observed in experiments conducted in

Ludhiana, Punjab (Komal Vig *et. al*., 2001). A 2004 field study conducted by International Institute of Biotechnology and Toxicology (IIBAT), Chennai showed that the half of Endosulfan varied from 11 to 14 days in various soils. "In the field, the degradation half life is shortened to 7-21 days under Southern European summer conditions. However, at colder fall and winter temperatures, the half life increased to 75-93 days. (Joint FAO/WHO Meeting on Pesticide Residues 2006, p.118). A multi-year study showed only a slight increase in soil residue levels…even in North Europe with cold to moderate temperatures. There does not, therefore, appear to be significant long term accumulation of Endosulfan and its sulfate in soil (Joint FAO/WHO Meeting on Pesticides Residues 2006. P118).

8.4 Health Effects of Long Term exposure of endosulfan on farmers and workers

Samvardhan Trust Study on Farmers

While a lot of secondary information was reviewed, the most important evidence that there are no health problems associated to exposure to Endosulfan comes from results of blood reports of farmers and workers exposed to Endosulfan over a number of years. While laboratory information and scientific studies are always representative there cannot be any better information or real evidence than the experience of individuals who have been exposed to Endosulfan over a long period of time.

Farmers are the end users of Endosulfan and depend on Endosulfan as an important cost effective solution for their pest management problems. There are over 60 lakh farmers in the state of Gujarat growing a variety of crops including pollinated crops and it is estimated that over 80% of these use Endosulfan. Small and marginal farmers who are keen to maintain the balance in their farm ecosystem use Endosulfan extensively as it is safe to pollinators such as honeybees and beneficial insects such as lady bird beetle, Chrysoperla, Trichograma etc.

An important outcome of the primary investigation was a meeting with Samvardhan Trust and NGO based in Bhavnagar who had undertaken a study titled ***"Evaluation of Residues of Endosulfan in Human Blood Samples collected from the persons of Mengani and Hadmadia villages, Gondal Dist. Rajkot".*** This was an independent study undertaken by Samvardhan Trust to investigate if farmers exposed to spraying of endosulfan had any residues of endosulfan in their blood.
Samvardhan Trust had commissioned an IIBAT (International Institute of Biotechnology and Toxicology) based in Tamil Nadu. IIBAT is an internationally recognized GLP laboratory. The Department of Analytical Chemistry of IIBAT under the Study No 1104008 on Residue Endosulfan concluded that ***"Analysis of all the blood samples collected from the people of Mengani and Hadmadia villages, Gondal Dist. Rajkot",*** showed no detectable residues of endosulfan (alpha-endosulfan, beta-endosulfan and endosulfan sulfate) by GC-MS-EI method.
A full copy of the report submitted on 9th February 2011 is available for review. The study was approved by the Institute's Ethics Committee (IEC).

In addition the committee also reviewed studies on blood samples of workers exposed to Endosulfan for many a years. Several of these studies were conducted over a period of years

and this study was also done by IIBAT. This also revealed that there are no residues of Endosulfan in the blood samples of the workers exposed to Endosulfan.

It is important to note that while farmers use the formulated product 35% EC and at dosages which are sometimes as low as 2 ml per hectare, factory workers are exposed to Endosulfan active whose concentration is 94% min and typically 96%. They are exposed to Endosulfan during the process of manufacturing, packing, storing, transport as well as formulating of technical active into 35% EC and packing the formulations into ready for sale packs. In all these stages they are exposed to Endosulfan. Further they typically work in shifts extending to 8 hour. In comparison to farmers, factory workers are exposed to significantly higher levels of Endosulfan and as such their occupational health and safety data is an important to evaluate the effects of Endosulfan. (Copy of these reports is available for review)

In all cases that were reviewed it was clear that there are no health problems and it can be safely concluded that exposure to Endosulfan does not pose any health problems.

8.5 Related References and Reports

The committee extensively examined the review report on Endosulfan by Dr O P Dubey committee which was set up by the Government of India. The committee also referenced reports of scientific bodies like JMPR (Joint Monitoring of Pesticide Review Program). The JMPR Toxicological evaluations are sponsored jointly by international agencies such as FAO, WHO and IPCS (International Program for Chemical Safety). The panel of scientists who prepare JMPR report and the group which peer reviews this report are drawn from international pool of experts in the field of toxicology. The review and recommendation by these three organizations (FAO, WHO, IPCS) have direct relevance to India as we are a member country.

Media Reports

The committee also reviewed a number of reports appearing in the media during the month of January 2011 representing a range of views. Three reports one appearing in Indian Express New Delhi edition of 30th January 2011 titled **"Kerala's Pesticide Puzzle"** a second another appearing in various editions of The Hindu Business Line titled **"Proxy Battle over Endosulfan"** by former Rajya Sabha member and founder Shetkari Sanghatana Dr Sharad Joshi and a third titled **"India says trade compulsions are forcing a ban on endosulfan"** appearing in The Hindu Business Line Mumbai edition dated 25th January 2011 are attached in **-6**, **-7** and **-8**. These reports are representative of recent media reports appearing in the media during the month of January 2011.

Review of other reports and expert committee reports:

Among the various reports, the Committee reviewed the following reports (These are available for review):

- Dr C.D. Mayee Committee Recommendations
- Dr O P Dubey Committee Report
- Dr Marilyn H Silva *et. al*. review article
- Dr Ramesh article on residues in Kasargod
- Representations by Indian Chemical Council
- Representations by Saurashtra Chamber of Commerce and Industry
- Extracts of information obtained under the Right to Information Act pertaining to NIOH raw data
- NIOH Initial Report
- NIOH Final Report
- Chemistry Information on Endosulfan
- Dr H Saiyed "Effect of Endosulfan on Male Reproductive Development"
- Dr S K Handa article
- EPA The Human Health Risk Assessment [HED], June'10
- Dr N Mackey, Cambridge Environmental Assessment

8.6 Other Aspects including Social Aspect and Agro economics

Endosulfan is the third largest selling insecticide worldwide. It accounts for a global market in excess of 40 million liters valued at over US$ 300 million (` 1350 crores). Indian companies account for over 70% of this market which has come at the cost of the European manufacturers. The replacement value of Endosulfan by patented alternative is estimated to be in excess of US$ 1 billion (` 4500 crores). As a result, Endosulfan is today in the eye of the storm in the battle of "patented" versus "generic" pesticides."

Europe is a leader in the international chemicals trade which includes crop protection chemicals. The global crop protection market is valued at over US$ 40 billion (` 180,000 crores). The top three companies which dominate this business are all European and account for over 50% of the global market. This market share has been built with a strong focus on patented and proprietary crop protection chemicals supported by strong regulations, driven by the European standards." "This has been the motivation for European multinationals to replace "low priced generics" with their "expensive patented alternatives.

Endosulfan is widely used in India on cross pollinated crops and it is soft on pollination honey bees and natural predators The states marked in green have been using Endosulfan in the range of 1000 KL to 1200 for over 30 years. There have been no reports of any effects on human or environment in these regions. The states marked in black are Kerala and Sikkim. Use of Endosulfan in Kerala is suspended and Sikkim has no significant use of pesticides due to its climate.

As can be seen from the map, the consumption of Endosulfan in India is largely in Status of Andhra Pradesh, Maharashtra, Madhya Pradesh, Rajasthan, Gujarat, Punjab, UP & Uttaranchal, Bihar & Jharkhand and West Bengal. No health problems have been reported from these States. All reports of health problems linked to endosulfan are mainly from Kerala where its use was insignificant.

9. Conclusions of the Committee

After

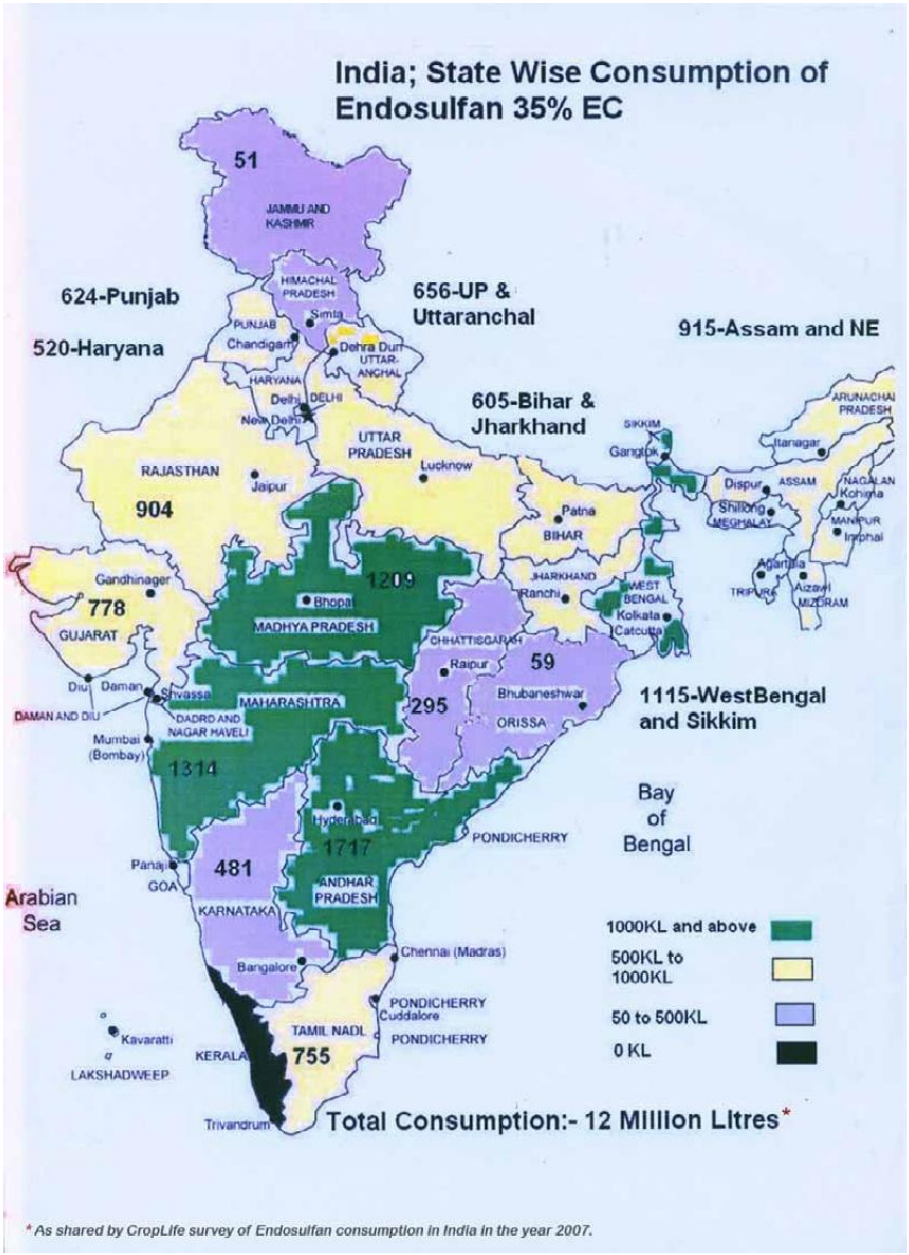
- *a thorough review of all aspects relating to health and safety arising out of exposure to endosulfan,*
- *a critical examination of the NIOH report*
- *review of reports of expert committees established by the Government of India*
- *examining all available safety, health and toxicology information on endosulfan*
- *review of media reports*
- *interactions with workers, their families, NGO's and community members, and*
- *analysis of data gathered from blood samples of farmers and workers exposed to Endosulfan over a number of years*

this committee concludes that there are no health problems that can be associated to the exposure to Endosulfan and is satisfied that there are no occupational health or safety issues arising out of exposure to Endosulfan.

10. Recommendation

The committee recommends the continued manufacture, use and trade in Endosulfan active and its various formulations

States using Endosulfan



The map shows the nationwide consumption of Endosulfan. As we can clearly see, the largest states, Maharashtra, Andhra Pradesh and Madhya Pradesh consuming over 1000 kilo liters of the pesticide followed by other states consuming a large amount, while Kerala has been using negligible amounts of Endosulfan. India is the second largest exporter for fruits and vegetables with production in excess of 198 million tons. The green states are majority the fruit and vegetable producing states and depend on cross pollinated crops.

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