

# FACTSHEET Mancozeb.

## 1. Introduction.

The fungicide Mancozeb is part of a group of chemicals called Dithiocarbamates (DTCs) that also includes Zineb, Maneb, Metiram, Thiram and Propineb. Mancozeb is a combination of Zineb and Maneb. Zineb was never approved in the EU (2001), Propineb and Thiram were banned in 2018, Maneb in 2017, while Metiram is still on the market. Mancozeb is registered on the market since 1961. DTCs are contact fungicides and react with amino acids and enzymes of fungi on the leaves of the plant. DTCs are used against a wide variety of fungi on many crops such as apples, pears, grapes, potatoes, wheat, onions and flower bulbs. The spraying is done frequently, up to 8 – 10 times in a season.

## 2. Toxicity.

- ETU

A major toxicological concern of DTCs is the common metabolite (and industrial contaminant) ETU, ethylenethiourea. It has the potential to cause the development of a goiter, a condition in which the thyroid gland is enlarged. ETU produces birth defects and cancer in experimental animals. ETU has been classified as a probable human carcinogen by US-EPA<sup>1</sup>.

- EFSA

While Mancozeb has been on the market for decades the European Food Safety Authority (EFSA) only produced an opinion on the substance for the first time in 2019. Mancozeb exposure causes thyroid toxicity and thyroid tumors at high dose. Neurotoxicity and malformations in the offspring have also been observed in animal testing. In fact, EFSA identified six (!) “critical areas of concern”<sup>2</sup>, i.e. six reasons why Mancozeb should not be approved by the EU. It is a full endocrine disrupting pesticide, it is classified as a toxic to reproduction (see below RAC assessment), it poses high risks to birds and mammals, non-target arthropods and soil macroorganisms among others. One does not see that many reason for a ban for any other pesticide in the market. The conclusion on being an endocrine disrupting pesticide alone is already enough for a ban (Regulation 1107/2009, Annex II, 3.6.5) since this conclusion will mean that any contact with humans is prohibited, generally resulting in a ban. Part of the EFSA opinion has been blackened because the industry is “bullying” EFSA and the Commission stating that part of the text needs to be treated confidentially, threatening them to go to court. This shows that industry (UPL, Indofil) has started a major campaign to prevent or at least delay a ban.

- ECHA/RAC.

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<sup>1</sup> [https://www.cdc.gov/biomonitoring/ETUPTU\\_BiomonitoringSummary.html](https://www.cdc.gov/biomonitoring/ETUPTU_BiomonitoringSummary.html)

<sup>2</sup> <https://www.efsa.europa.eu/en/efsajournal/pub/5755>

The Committee for Risk Assessment (RAC) from the European Chemical Agency has the mandate to decide on the classification of chemical substances, including pesticides for harmonised classification and labelling. The RAC-committee decided to give Mancozeb a “toxic to reproduction category 1B” (R1B) classification<sup>3</sup> because of the severity of brain malformations seen in the offspring, caused by ETU. The conclusion on being a classified reprotoxic pesticide, is already enough for a ban (Regulation 1107/2009, Annex II, 3.6.4) since this classification will mean that any contact with humans is prohibited, which is almost equal to a ban.

- Independent literature.

Given the fact that Mancozeb is an old pesticide, many independent (academic) studies are published. EU Commission and EFSA like to ignore these studies<sup>4</sup> for false reasons, putting the industry studies (that are made in a massive conflict of interest) at a platform. The Ramazinni study mentioned below presents clear evidence of the carcinogenicity problems, while a long range of studies document the thyroid problems in different test animals. Since DTC's are neurotoxicants a connection with Parkinson is made in several studies<sup>5</sup>.

### **3. Mancozeb in our food.**

The problem with Mancozeb is that no detection method exists. The entire group of DTCs therefore is analysed through a substitute, the CS2 compound, a common breakdown product. An extra problem is that CS2 could also be a natural background substance. While most DTCs are banned, one has to take into account that these pesticides can be found in imported food. This can be the case if there are internationally recognised MRLs (so-called CODEX CXLs) or there is an ‘import tolerance’ following industry's request via a Member State. So it remains difficult to find out which DTC is analysed in the monitoring of pesticide residues. With this background, in the last published EFSA monitor on pesticide residues<sup>6</sup>, 19,2% of all samples analysed for DTCs were positive (> LOQ). In pears 35,5% of the samples had DTC residues; the “acute reference dose” in pears was even exceeded. This was also the case for oranges, beans and kiwis. For long-term toxicity (ADI), with the assumption that only a specific DTC was present (in this case Mancozeb), Mancozeb ‘filled’ 12,9% of ADI (upper-bound scenario). Food items with substantial amounts of DTC's are beans, carrots, kiwi, oranges, pears, potatoes, rice and rye. The very toxic metabolite ETU is not analysed by member states and EFSA.

### **4. Use of Mancozeb and alternatives.**

Mancozeb is used in many crops against different types of fungi. The most well-known is Phytophthora infestant in potatoes (the one that caused famine in Ireland in the 19th century). It is also active against Alternaria solani (potatoes), Cercospora (beet), Mildew, Botrytis (flower bulbs) etc. Due to resistance against fungicides, fungi are a major problem in agriculture. Many fungicides are applied simultaneously in a cocktail or one after another. Examples of such pesticides, applied next to Mancozeb, are Fluazinam, Zoxamide, Metalaxyl, Azoxystrobin, etc. Mancozeb has less problems with resistance given its multi-mode of action/ broad spectrum. The fungicide

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<sup>3</sup> [Committee for Risk Assessment RAC Opinion ... - ECHA](#)

<sup>4</sup> [Missed & Dismissed](#)

<sup>5</sup> [Pouchieu, 2018](#)

<sup>6</sup> <https://www.efsa.europa.eu/en/efsajournal/pub/5743>

Chlorothalonil was recently banned as it was found to be carcinogenic and it is more likely that farmers will protest against the ban of another fungicide, this time Mancozeb. It is after all, one of the most used pesticide (in the Netherlands for instance about 20% of the total volume of used pesticides). The only viable and long-term alternatives for Mancozeb (and other fungicides) is the use of resistant crop varieties. For potatoes, for example, there are many dozens varieties available with a different resistance to Phytophthora. No need to mention that organic agriculture uses the varieties with the best resistance (and early harvest to avoid Phytophthora). This variety in crop resistance counts for all crops. The reason why farmers do not choose the best resistant variety is the yield. For the moment they choose the highest yield, which are generally produced by sensitive varieties. Other agricultural practices such as plant distance or choosing windy fields are also usefull to avoid funghi problems. For some funghi, non-chemical biocontrol alternatives like Trichoderma<sup>7</sup> are available.

## 5. Regulatory observations.

Mancozeb has been a controversial pesticide for decades. The renowned Ramazzini institute published a study in rats in 2002, concluding that *“Mancozeb caused an increase in (1) total malignant tumors, (2) malignant mammary tumors, (3) Zymbal gland and ear duct carcinomas, (4) hepatocarcinomas, (5) malignant tumors of the pancreas, (6) malignant tumors of the thyroid gland, (7) osteosarcomas of the bones of the head, and (8) hemolymphoreticular neoplasias. On the basis of these data, Mancozeb must be considered a multipotent carcinogenic agent”*<sup>8</sup>. Unfortunately, the EU has historically not taken independent literature into account because of its outrageous policy to give priority to GLP- (the studies performed under “Good Laboratory Practice” principles) industry-funded studies and disregard the work of independent academics<sup>9</sup>. In 2008 Mancozeb was put on a “to be banned” list in Sweden because of the reprotoxic and endocrine disruption effects. The carcinogenicity of ETU has also been discussed for years and is now well known.

In the EU, before Regulation 1107/2009, the policy was always to derive a “safe level” for pesticides. Cancers and developmental effects were observed in studies, but mostly considered to be “only” at high levels, even though if no or very few long-term low-dose chronic exposure experiments were carried out to confirm this assumption. Industry also made false claims<sup>10</sup> and some experimental outcomes are questionable<sup>11</sup>. Nevertheless, in 2002 EU accepted the data of the applicants of Mancozeb and only lowered the reference values because of the effects seen at “high dose”. By this

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<sup>7</sup> <https://www.koppert.com/challenges/disease-control/blight-of-pepper/>

<sup>8</sup> FIORELLA BELPOGGI, MORANDO SOFFRITTI, MARINA GUARINO, LUCA LAMBERTINI, DANIELA CEVOLANI, AND CESARE MALTONI, **Results of Long-Term Experimental Studies on the Carcinogenicity of Ethylene-bis-Dithiocarbamate (Mancozeb) in Rats**, *Ann. N.Y. Acad. Sci.* **982**: 123–136 (2002).

<sup>9</sup> [Missed & Dismissed](#)

<sup>10</sup> *“There were two multigeneration studies in the draft assessment report. The experts were very unsatisfied with the information given in the draft assessment report. They pointed out that the information given in the conclusions is sometimes contrary to the findings in the text and stated that it is difficult to come to a conclusion on the basis of the information given in the draft assessment report. No effects on fertility and on number or survival of pups were reported in the first study up to a dose level of 1200 ppm that caused changes in thyroid, liver and kidneys and decreased body weight of adults. In the second study there was a clear effect on pup viability and pup weight at a parental toxic dose level of 1100 ppm”*

<sup>11</sup> *“Malformations (agnathia, cleft palate, meningoencephalocele, dilated brain ventricles) were seen at a high dose level of 512 mg/kg bw/d in rats, while embryo-/fetotoxicity (delayed ossification, abortions) occurred at lower maternally toxic doses levels in rats and rabbits. With regard to the teratogenicity study in the rat (Manish V. Patel M.Sc. 1999), the experts found it hard to believe that there were no findings at 500 mg/kg bw/d. The meeting agreed on a lowest relevant developmental NOAEL of 60 mg/kg bw/d based on the rat study. The meeting concluded that mancozeb is teratogenic and proposed to label mancozeb with R63 (cat. 3)”*.

way Mancozeb got an approval in 2006 and was used widely in Europe (all EU member states<sup>12</sup>). Mancozeb should have been re-assessed before 2016 (normal 10-year period), but Commission decided to extend the approval because of a claimed high workload. The last extension in 2019<sup>13</sup> drew the attention of the EU Parliament and EP plenary decided to object the extension, especially since Mancozeb is a classified reprotoxin (the EU policy was changed with Regulation 1107/2009 into a ban for R1-classified reprotoxins). Now, finally, it is decision-time for Mancozeb and the pesticide will be discussed for the first time in the Standing Committee<sup>14</sup>, and a Qualified Majority of member state Votes (QMV, approximately 65%) will be needed to get a ban adopted by the EU. No doubt industry will fight at every level to avoid a ban or get a derogation or delay at the minimum and try to cast doubt on the facts. They will likely involve farmers to lobby for their products and they might go to court. To balance this, clear signals are needed from the public to demand a ban.

## 6. Conclusion.

**Mancozeb is one more example of the failure of the "pesticide system". The substance has been approved based on a weak and flawed system that does not correctly appraise the toxicity of the pesticide. Only years afterwards, independent studies have demonstrated its toxicity to humans and the environment. But for one more substance, public servants from the European Commission and Member States have turned a blind eye on the issue and disregarded the toxicity of the product to support industrial agriculture at the expense of citizens' health and the environment. Only 20 years after independent evidence of unacceptable harm has been published will the Commission and Member States start discussing the possibility to ban the substance.**

**Because of the massive and constant failure of the pesticide system, PAN Europe advocates for the development of agroecology and high-level Integrated Pest Management (IPM) where prevention is at the base of the agriculture systems."**

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<sup>12</sup> [https://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/public/?event=activesubstance\\_detail&language=EN&selectedID=1531](https://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/public/?event=activesubstance_detail&language=EN&selectedID=1531)

<sup>13</sup> <https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1575892902511&uri=CELEX:32019R2094>

<sup>14</sup> [ScoPAFF](#)