



EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Food and feed safety, innovation
Director

Brussels,
SANTE/E4/MW/od/(2018)2852559)

Dear Ms Kafka,

Subject: Your letter concerning the use of thiram as a seed treatment

Thank you for your letter dated 24 April 2018 in which you raise concerns of the seed industry about the proposal to withdraw the approval of the active substance thiram in the European Union.

I am aware that thiram is used as a seed treatment for a number of crops in the European Union and that the non-renewal of the approval of the substance will create some challenges for the seed sector.

However, in accordance with the EU legislation on pesticides¹, active substances for use in plant protection products can only be approved if it has been demonstrated that, under realistic conditions of use, they have no harmful effects on human and animal health or the environment. The Commission has and will continue to remove substances from the market for which it cannot be demonstrated that the approval criteria enshrined in the legislation are satisfied.

The conclusion² of EFSA on thiram following a comprehensive scientific evaluation and peer review by Member States and EFSA highlighted a number of concerns related to human health and the environment from use of the substance both as a foliar spray and as a seed treatment. With regards to seed treatment a high risk was identified for birds and mammals and the risk assessment for consumers could not be completed because further data is needed on one metabolite of thiram. Furthermore, the assessment of the impact of water treatment processes on drinking water, in particular the formation of the hazardous compound NDMA, could not be finalised and based on the available studies it could also not be concluded whether or not thiram acts as an endocrine disruptor.

¹ Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC. OJ L 309, 24.11.2009, p. 1.

² <http://www.efsa.europa.eu/en/efsajournal/pub/4700>

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The Commission has carefully considered all available information and has also met with the applicants for renewal of approval on several occasions to discuss the matter. However, based on the EFSA conclusion and the information that has been made available by the applicant, stakeholders and Member States, it is not currently possible to confirm that plant protection products containing thiram will not have any unacceptable effects on human and animal health or the environment.

With regards to your request to take into account new scientific information, please note that Article 13 (5) of Regulation (EU) No 844/2012³ (the 'Renewal Regulation') does not allow for this possibility. You also state that there are few alternatives to thiram available as alternative substances are not authorised or only for few crops and that these are more expensive. However, this confirms that there are potential alternatives available which can be authorised by Member States and, in any case, there is a danger that cannot be controlled by these alternatives or any other reasonable means then Member States may consider a limited and restricted authorisation of thiram in line with Article 53 of Regulation (EC) No 1107/2009 (emergency authorisation). Finally, the request for a procedure to enable treatment of seeds for export to third countries only is being discussed with Member States and will also be considered as part of the ongoing REFIT evaluation of the existing pesticides legislation.

In conclusion, let me confirm that we duly note the concerns you raise for seed treatment of crops and have taken them into account in the deliberations on thiram. Accordingly, the proposal made to Member States includes a provision to allow for a period of transition for the placing on the market and the use of seeds treated with thiram in order to enable the seed supply chain to adapt.

However, given the concerns identified and taking into account the other aspects as mentioned above, the Commission has maintained the proposal not to renew the approval of thiram.

Yours sincerely,



Sabine Jülicher

Cc: Mr Klaus Berend, Mr Wolfgang Reinert, Mr Mark Williams (DG SANTE)
Mr Klaus Schlünder (Chairman of the ESA Board)
Mr Garlich von Essen (ESA Secretary General)

³ <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2012:252:0026:0032:EN:PDF>