

**LANTBRUKARNAS
RIKSFÖRBUND**
FEDERATION OF SWEDISH FARMERS

15 November 2005

Mr. Robert Madelin
cc: Mrs Patricia Brunko
cc: Mr Louis-Maria Smeets
EU Commission DG SANCO

F-1641-212-97
F-1394-34-95
F-1581-468-96
F-2083-574-00
F-1670-311-97

e-mail: ethel.forsberg@kemi.se
e-mail: karl.gunnar.burman@lrf.se

Dear Mr Robert Madelin,

We write to you because of our deep concern about the chemicals which alter the hormonal balance in organisms. Under the Council Directive 91/414/EEC, the endocrine disruptors vinclozolin, procymidone, linuron, flusilazol and fenarimol have been under evaluation for many years. Sweden has sent comments to the Commission at several occasions requesting a higher safety margin, since the existing methodology is not sensitive enough to detect the lowest effect levels of these endocrine disruptors^{1,2,3}. Further, the Swedish ministers for Agriculture, Food and Consumer Affairs and for the Environment in collaboration with ministers from Denmark and Finland and the minister of agriculture from Lithuania have presented their concern regarding the inclusion of these pesticides in Annex I of Council Directive 91/414/EEC⁴.

Furthermore, it has previously been shown that vinclozolin, procymidone, linuron, flusilazol and fenarimol are toxic to reproduction and give rise to cancer in test animals. In addition, **new data not evaluated in the present process for plant protection product under Council Directive 91/414/EEC** show that the endocrine disruptor vinclozolin induces transgenerational effects on reproduction *via* the exposed mother to up to four generations in male rats⁵. The relevance of these new serious effects has been discussed at KemI last week (the 9th of November) with the experts Prof. Tomas Ekström and Prof. Ulrik Kvist from Karolinska University Hospital and Dr. Maria Bondesson representing the EU research network CASCADE. The conclusion from the meeting was that the newly documented effects, published in the highly ranked scientific journal *Science*, of vinclozolin are of high concern and reflects a mechanism highly relevant for humans.

¹ SE comment "Swedish comments to address the uncertainty in risk assessments of endocrine disruptors in plant protection products (23 February 2004)

² SE comment "Swedish proposal for an approach to address the uncertainty in risk assessments of Endocrine disruptors in Plant Protection Products", (16 February 2001)

³ Information and proposals for reaction regarding new data on vinclozolin inducing transgenerational effects and altering sex-differential social play and sexual behaviours in rat and other relevant data on procymidone and fenarimol, (5th June 2005)

⁴ Letter from the Nordic Ministers and the Minister from Lithuania (Dated 28 September 2004)

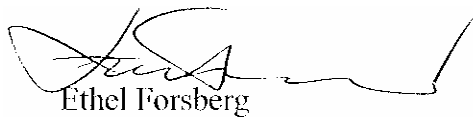
⁵ Anway, M.D., Cupp A.S, Uzumcu, M and Skinner, M.K. Epigenetic transgenerational actions of endocrine disruptors and male fertility. *Science* **308**, 1466 (June 2005)

It was also concluded that more investigations are needed in this new area on vinclozolin and on other endocrine disruptors showing the same pattern of effects in test animals.

In conclusion, Sweden believes that an inclusion of vinclozolin, procymidone, flusilazol and fenarimol in Annex I to the Council Directive 91/414/EEC is unacceptable under the proposed conditions of use. If the Commission is going to propose an inclusion of these endocrine disruptors the new data has to be scrutinized and carefully discussed in the EFSA panel and later in the Evaluation group before any decision is recommended.

We ask for your cooperation in this matter and urge you to strive for a high level of protection for both farmers and consumers and the environment when regarding active substances for inclusion in Annex I of Council Directive 91/414/EEC.

Yours Sincerely,



Ethel Forsberg

Director General
Swedish Chemicals Inspectorate
Sweden



Karl-Gunnar Burman

Managing Director
Federation of Swedish Farmers (LRF)
Sweden