

PAN Europe

Pesticides Action Network Europe

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July 2005

To: Minister/Representative in the EU Standing Committee on the Food Chain and Animal Health

Subject: Danger of inclusion of vinclozolin & procymidone in Annex I to Council Directive 91/414/EEC.

Dear Minister/Representative:

We write you in order to call attention to a potential threat to European citizens' health and safety resulting from the proposal of the European Commission to include vinclozolin and procymidone in Annex I to Council Directive 91/414/EEC. The proposal is going to be presented in the next meeting of the Standing Committee on the Food Chain and Animal Safety (Pharmaceutical Section), 14 and 15 July, despite strong evidence of harmful effects to the environment and human health and scientific evidence of endocrine disrupting properties of these two substances especially the non-repairable damage done at young age.

Detectable levels of residues of vinclozolin and procymidone are consistently found in European fruits and vegetables. In 2002, 11% of all bean samples were found contaminated with detectable levels of vinclozolin. 13% of all pears, 5% of all peach and 4% of all bean samples were found contaminated with detectable levels of procymidone. Procymidone was the ninth most frequently reported pesticide¹.

Vinclozolin and its metabolites are well-characterized anti-androgenic substances. The suspected reproductive toxicity of vinclozolin has driven regulation for over a decade. The US EPA considers vinclozolin to be an endocrine-disrupting chemical interfering with lipid metabolism and/or storage and inducing reduced sperm count, decreased prostate weight and delayed puberty in test animals². A further question emerging from the EPA review is whether vinclozolin shares a common mechanism of toxicity with the fungicides procymidone and possibly iprodione, and what might be the likely impact of additive exposure. A recent scientific study from the US EPA suggested already a cumulative effect between vinclozolin and procymidone, as anti-androgens sharing a common androgen receptor mediated mechanism of action. The conclusions of this study will be instrumental in setting cumulative risk

¹ DG SANCO Report 17/04 *Monitoring of Pesticide Residues in Products of Plant Origin in the European Union, Norway, Iceland and Lichenstein – 2002 Report*.

² *Overview of the Vinclozolin Risk Assessment, US Environment Protection Agency, Office of Pesticide Programs Reregistration document, 26 July 2000.*

assessment for these substances in the future³.

Vinclozolin is one of the substances with evidence of endocrine disrupting or evidence of potential endocrine disrupting properties listed in the Communication from the Commission to the Council (Com (2001) 262 final) on the implementation of the Community Strategy for Endocrine Disruptors – a range of substances suspecting of interfering with the hormone systems of humans and wildlife (COM (1999) 706). In a recent study published in Science Magazine (June 2005) the conclusions on transgenerational actions of vinclozolin in rats' male fertility offers further reasons for concern⁴. Four generations of male offspring from vinclozolin treated mothers were examined with the reduction in sperm quality and quantity observed in all generations with comparable severity. In addition, 8% of the male offspring in each generation were completely infertile.

Although procymidone is listed in the Commission Communication (Com (1999) 262) as a substance with insufficient data in the BKH report, this report was recognised as a starting point in a priority setting exercise. Later, procymidone was recognised as one of the substances with high exposure concern and with evidence of endocrine disrupting properties listed in the Commission working document on the implementation of the Community Strategy for Endocrine Disruptors (SEC (2004) 1372). There is indeed matter for concern. Results from a recent study conducted in South Korea indicate that procymidone may act as a stronger androgen receptor antagonist in male rats when compared to known endocrine disruptors such as vinclozolin, linuron, or p,p'-DDE⁵.

It is also against Directive 91/414/EEC to include a pesticide in the list of positive substances without the necessary data. Denmark representatives, for example, will vote against the inclusion of these two substances on the basis that risk assessment for vinclozolin and procymidone gives insufficient protection of wild mammals. For the case of vinclozolin the risk assessment gives insufficient protection for birds, as happens with substances with endocrine disruption effects of this type. Furthermore the risk assessment for effects on fish shows insufficient protection because of the endocrine disruption effects, even if risk reduction measures are demanded (introduction of protection zones along water courses). The employment of risk reduction measures is difficult, if not impossible, to monitor in the field and the use of these substances cannot be considered safe on the basis that these measures will be implemented.

The root problem is in the missing provisions for the substitution principle in the current text of Directive 91/414/EEC resulting in the pesticide producer's right to market their products ranking higher in priorities than the protection of human health and wildlife. This gap in the current legislation should be rectified in the ongoing process of revision of the Directive 91/414/EEC. PAN Europe will continue to advocate for the introduction of the substitution principle in the legislation, defending that a "substance of concern" should include substances where there is evidence of suspected endocrine disrupting, neurotoxic, immunotoxic, persistence or

³ Rosen MB, Wilson VS, Schmid JE; Gray LE; *Gene expression analysis in the ventral prostate of rats exposed to vinclozolin or procymidone*; *Reprod Toxicol*, 2005, Jan-Feb; 19(3): 367-379.

⁴ Anway MD, Cupps AS, Uzumcu M, Skinner MK; *Epigenetic Transgenerational Actions of Endocrine Disruptors and Male Fertility*; *Science*, 2005, 308: 1466-1469.

⁵ Kang IH, Kim HS, Shin JH, Kim TS, Moon HJ, Kim IY, Choi KS, Kil KS, Park YI, Dong MS, Han SY; *Comparison of anti-androgenic activity of flutamide, vinclozolin, procymidone, linuron, and p, p'-DDE in rodent 10-day Hershberger assay*; *Toxicology*, 2004, Jul 1, 199(2-3): 145-159.

bioaccumulation properties according to the more stringent criteria as defined in OSPAR and REACH.

Conclusions

Endocrine disrupting chemicals are a threat to human health and wildlife. Wide-ranging effects have now been demonstrated in animal tests, wildlife and humans and precautionary action should be taken. The evaluation of vinclozolin and procymidone in the Standing Committee (session 14-15 July) is a real opportunity to start taking action.

The traditional risk assessment performed by the European Commission is not enough to get a real evaluation of the disrupting effects, moreover denies current scientific knowledge. We therefore ask you to reject the inclusion of these substances in the EU positive list and to demand extra studies for pesticides with scientific evidence in peer-reviewed literature for endocrine disruption and focus these studies on the early developmental stage of life, taking into account specific endpoints relevant for endocrine disruption like learning capability, motility, behaviour, birth deformations, semen quality, *etc.* dependant on the kind of endocrine disruption of the pesticide under study. The Nordic countries in Europe share this view. As long as these studies are not delivered by industry and properly evaluated we think any exposure to humans or wildlife has to be prevented and call upon you to adopt this position.

Thanking you in anticipation and best wishes

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