
Position Paper
26th amendment to Council Directive 76/769/EEC
EU Consultation Process

The EU chemicals policy is based on the principles that any risk reduction measures based on risk benefit principles should be applied only if risks have been identified in a scientific risk assessment. Hazardous properties alone do not justify any risk management actions, including marketing and use restriction.

For nonylphenol (NP) a comprehensive risk assessment was performed taking into account all known and foreseeable uses of NP and its main derivative, the NP-ethoxylates. All toxicological and ecotoxicological data were considered, including the issue of "endocrine modulation". Any potential risk for consumers, including risks that may arise by the intake of NP via food was assessed in detail. It was concluded that there is no risk for consumers by the intake of NP via food or by the use of products containing NP-derivatives.

The risk assessment identified risks to the aquatic environment due to the high, well-known aquatic toxicity of NP. It was concluded that effects mediated via the endocrine mechanisms are of no relevance for the risk assessment since they only occur at concentrations that already cause general toxic effects.

A risk reduction strategy was developed by UK to address the risks to the aquatic environment. The proposed strategy would reduce environmental releases to water by almost 80 %. This risk reduction strategy is incorporated into the commission proposal of the 26th amendment to Council Directive 76/769/EEC.

In the current EU consultation process additional measures are proposed. However, it has to be mentioned that scientific justifications for the extension of the marketing and use restrictions are lacking, and in fact, in some cases even contradict the results and conclusions of the EU scientific risk assessment.

Since in a detailed assessment of potential risks to consumers no such risks were identified, there is neither a need nor a justification to restrict the use of NP-derivatives in applications which are sold to consumers. The recent findings by a German research group (Guenther et al., 2002) that quantified the daily intake of NP by consumers via food clearly supported the findings of the EU risk assessment, since the actual values were shown to be 20fold below the estimated intakes used in the respective risk assessment section. The analytical identification of NP in food alone does not justify the ban of products that may eventually be responsible for the very low concentrations of NP in food.

Additional risk reduction measures may be proposed to address the "endocrine effects" of NP. However, the current risk assessment clearly addressed these effects and concludes that adverse effects via endocrine activities are of no concern for the risk assessment since they only occur at concentrations higher than those that already lead to general aquatic toxicity. Therefore any risk reduction measure that addresses the aquatic toxicity of NP is suitable to protect against any potential endocrine effects as well.

The assessment of endocrine activity for human health shows that adverse effects are observed at dose levels where systemic toxicity is already evident. No risk can be deduced at existing exposure levels in man. This has been fully accepted by the CSTEE, the Scientific Committee on Scientific Committee on Toxicity, Ecotoxicity and the Environment.

NP and NPEs are listed on the OSPAR list for many years due to the high aquatic toxicity of NP. The high aquatic toxicity is addressed in the risk reduction proposal and once the measures have been implemented environmental concentrations will decrease below levels of concern. Despite being listed on other lists as well, NP does not fulfil the EU PBT (persistence, bioaccumulation, toxicity) criteria.

The listing of NP on various lists per se should not be used as justification for additional risk reduction measures. Neither the risk assessment nor the general EU policy on existing chemicals justify requests to limit the emissions of NP to zero.

It is therefore proposed not to change or amend the current commission proposal for the 26th amendment to Council Directive 76769/EEC, since this is neither required to lower the risks nor scientifically justified.