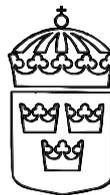


Committee terms of reference



Combination effects and dealing with substances by group

**ToR
2018**

Decision at a government meeting on 29 March 2018

Summary

An Inquiry Chair will investigate how risk assessments for hazardous chemicals being carried out by group can be increased, and how 'combination effects' can be taken into account.

Among other things, the Inquiry Chair will:

- identify opportunities, obstacles and previous measures in relevant EU legal instruments for dealing with substances by group;
- propose strategies for future group-based regulation and, where necessary, any amendments to relevant EU legal instruments for dealing with substances by group;
- sum up the state of scientific knowledge, identify opportunities and obstacles in different relevant EU legal instruments and previous measures in the area of combination effects; and
- propose strategies to enable regulation based on, or taking account of, combination effects, propose other strategies to reduce the risks and, where necessary, propose amendments to relevant EU legal instruments.

The Inquiry is to present its report by 29 September 2019.

Background

Traditionally, substances have been dealt with one at a time. Account is rarely taken of overall exposure to the same substance

or similar substances from different sources or routes of exposure, known as 'cumulative exposure'.

There is growing awareness of the fact that there can be combination effects, although knowledge about this remains low. This means that the current risk assessment methodology systematically underestimates the risks of exposure to hazardous chemical substances. The issue of how different substances interact in the human body or the environment is not taken into account when risk assessments are conducted for chemical substances and they are regulated.

Dealing with substances by group, according to chemical structure, mode of action, qualities or area of use would lead to a considerable improvement of chemical controls. In the Government Bill *Towards a toxin-free everyday environment* (Govt Bill 2013/14:39), the Government outlines the measures needed to achieve the interim targets of the environmental quality objective *A non-toxic environment*. The Government states, among other things, that general knowledge-building is needed concerning the combination effects of chemicals. Moreover, methods that take account of combination effects and cumulative exposure in risk assessments must be developed and the relevant regulatory frameworks must be amended. In recent years, there has been an increase in knowledge about and interest in the effects on human health and the environment of simultaneous exposure to several different chemicals. These effects are called combination effects or cocktail effects.

Risk assessments for chemicals are usually carried out for one substance at a time and do not take account of the combined effect of several chemicals. The possibility of carrying out overall assessments of several substances is currently limited by the lack of simple tools to assess the overall risk.

In December 2009, the Council of the European Union adopted conclusions on combination effects of chemicals (17820/09). In response to the environment ministers' Council conclusions from December 2009, in spring 2012 the European Commission presented a communication on combination effects (COM/2012/0252). The communication contains commitments aimed at strengthening guidance and coordination between

various EU legal instruments, but no commitments on reviewing relevant EU legal instruments. The Commission has not implemented the measures contained in the communication. The 7th General Union Environment Action Programme (PE-CONS 64/1/13) establishes that strategies are needed to tackle combination effects, and methods need to be developed and applied. On numerous occasions, the European Parliament has pointed out that the EU's chemicals legislation must take account of the combined effects of different chemicals on human health and the environment.

The environmental quality objective *A non-toxic environment* includes eight interim targets on hazardous substances. Dealing with substances by group and combination effects are included in two interim targets. The interim target *Knowledge about substances' health and environmental qualities* states that decisions taken at EU and international level must contain measures to ensure that "conditions are in place by 2015 for relevant regulatory frameworks to take account of combination effects in exposure to chemicals". The interim target *Development and application of the EU's chemical rules* states that the REACH Regulation and other relevant EU legislation will be applied or, if necessary, revised by 2020 so that "it is possible to a greater extent to assess and test groups of substances with similar inherent qualities, chemical structure or area of use". In chapter 9.2 of the Bill *Towards a toxin-free everyday environment* (Govt Bill 2013/14:39), the Government describes the measures needed for the interim target to be achieved and to facilitate dealing with relevant groups of substances.

Combination effects and how substances are best dealt with by group have long been subjects of discussion. These are complex issues and very little has happened in recent years. An Inquiry Chair will therefore investigate how risk assessments of hazardous substances can be carried out by group and how combination effects can better be taken into account.

More details on the remit

Remit on dealing with substances by group: identify opportunities, obstacles and previous measures in relevant EU legal instruments.

Traditionally, hazardous substances have in most cases been dealt with one at a time. There is a risk here of ‘false substitution’. This is when a hazardous substance is banned and substituted with a very similar substance with the same desirable technical qualities. Unfortunately, the new substance often has the same or similar hazardous qualities. To avoid this, a holistic approach to groups of substances is needed. For substances to be dealt with by group, any opportunities and obstacles currently in relevant EU legal instruments need to be identified. The approach of dealing with substances by group is not new; some trials have been successful, whereas others have not. To learn lessons and to benefit from previous experiences, these trials should also be surveyed. The Inquiry is to:

- identify what opportunities and obstacles there are in relevant EU legal instruments for dealing with substances by group;
- survey previous trials, whether successful or not, of dealing with substances by group in relevant EU legal instruments; and
- report conclusions from these surveys.

Remit on dealing with substances by group: propose strategies for future regulation by group and, where necessary, amendments to relevant EU legal instruments.

A prohibition of a hazardous substance has often led to a similar and equally hazardous substance being used instead, known as false substitution. The basis of EU chemicals legislation is that substances are dealt with one at a time. However, in some cases it must be possible to deal with substances by group. The Inquiry is to:

- analyse the results of the surveys and other relevant sources;
- propose strategies for how substances with similar hazardous qualities can be dealt with by group in the implementation of different EU legal instruments; and
- analyse and, where necessary, propose amendments to relevant EU legal instruments to enable regulation of groups of chemicals.

Remit on combination effects: sum up the state of scientific knowledge and identify opportunities and obstacles in different relevant EU legal instruments and previous measures in the area.

Knowledge about combination effects is currently inadequate. The state of scientific knowledge about combination effects therefore needs to be summarised. Only a few EU legal instruments currently prescribe that account should be taken of combination effects. A survey is needed of the opportunities and obstacles in relevant EU legal instruments when it comes to considering exposure to several different chemical substances simultaneously. Measures that could help achieve the interim target on knowledge about substances' health and environmental qualities are contained in the 7th General Union Environment Action Programme, the Council conclusions adopted during the Swedish Presidency in 2009 and the Government Bill *Towards a toxin-free everyday environment* (Govt Bill 2013/14:39). The Inquiry is to:

- compile research in the area;
- identify opportunities and obstacles in relevant EU legal instruments; and
- survey previous measures.

Remit on combination effects: propose strategies to enable regulation based on, or taking account of, combination effects, propose other strategies to reduce the risks and, where necessary, propose amendments to relevant EU legal instruments.

A clear picture of possible success factors is needed, based on existing opportunities and obstacles and what has previously been done. The Inquiry is to:

- propose strategies to enable account to be taken of combination effects;
- propose, where necessary, other measures that could lead to a reduced risk of undesired combination effects; and

- on the basis of the itemised remits specified above, propose any necessary amendments to relevant EU legal instruments to enable account to be taken of combination effects.

Impact assessments

The Inquiry's proposals and background material must follow the requirements of the Committees Ordinance (1998:1474) concerning impact assessments and cost estimations. The proposals must be followed by economic impact assessments and analyses of their cost-effectiveness. The proposals must contain alternative courses of action. If the Inquiry proposes measures entailing costs, the Inquiry must propose financing for these measures. The Inquiry must also provide an environmental assessment of the proposals.

Consultation and reporting of the remit

The Inquiry is to conduct its work in close dialogue with relevant agencies, researchers, stakeholders, companies, industry organisations and other actors in this area. The Inquiry is to survey and draw on the experiences of similar work in other relevant EU countries.

The report (including an English translation) is to be submitted to the Government Offices (Ministry of the Environment and Energy) by 29 September 2019.

(Ministry of the Environment and Energy)