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WATCH COMMITTEE

Current Regulatory position on Lead

Issue

1. Is there a need to conduct an updated review of the toxicological profile of lead and lead compounds, leading to a reconsideration of appropriate risk management standards in the UK occupational context?

Timing Considerations

2. Routine

Recommendation

3. WATCH is invited to consider the issues noted in this cover paper and to respond to the actions in paragraph 19.

Background

4. Concerns were raised at ACTS in May 2008 about recent evidence that blood levels of lead of the order of 10 µg/dl may be associated with cardiovascular disease. Given that all of the recent published literature relating to this issue had not been presented to and debated within the ACTS/WATCH system, ACTS considered that a systematic literature search was needed and suggested that this could be carried out by HSE. It was envisaged that such a review should be considered by WATCH and would inform on the need to pursue a revision of exposure limits for lead.

5. WATCH initially discussed this issue in June 2008. The Chairman recalled that in recent years SCOEL had developed a position on appropriate EU-wide air and blood lead exposure standards. However, it was also noted that blood lead suspension levels in some EU countries (e.g. France and Germany) are lower than in the UK and this had come about by national regulatory initiatives. It was therefore agreed that a brief paper on the topic, reviewing the current position and regulatory situation, should be prepared by HSE for the October 2008 WATCH meeting. This paper fulfils that commitment.

Argument

6. The Control of Lead at Work Regulation (CLAW) 2002 is the UK instrument which implements the requirements of the Chemical Agents Directive (CAD) relating to lead. Both a binding OEL value and a binding biological limit value have been set under CAD. These are 0.15 mg/m³ 8 hr TWA and 70 µg Pb/100 ml blood respectively. The CAD requires that for any chemical agent for which a binding OEL or biological limit is established, Member States (MSs) shall establish a corresponding national binding limit based on, but not exceeding, the Community limit value. The current UK limit values for lead are:

- 0.15 mg/m³ 8 hr TWA for inhalation;
- Action levels of 25 µg/dl PbB for women of reproductive capacity, 40 µg/dl PbB for young persons (16-17) and 50 µg/dl PbB for any other employee;
- Suspension levels of 30 µg/dl PbB for women of reproductive capacity, 50 µg/dl PbB for young persons (16-17) and 60 µg/dl PbB for any other employee.

The inhalation OEL is a ceiling limit which must not be exceeded when calculated as an 8hr TWA.

7. In 2002 DG Employment's SCOEL (Scientific Committee on Occupational Exposure Limits) committee produced a recommendation on OELs for lead and its inorganic compounds. This is provided as Annexe 2. The recommendations proposed in the relevant SCOEL Summary Document are:

- Biological limit value, lead in blood (PbB): 30 µg/100 ml
 - Atmospheric limit value: 0.1 mg/m³ 8 hr TWA (inorganic lead fumes and dusts of <10µm).
- SCOEL noted that the recommended binding biological limit value was not seen as being entirely protective of the offspring of working women. It was also noted that no threshold for potential central nervous system (CNS) effects in new born and infants could be identified and therefore the exposure of fertile women to lead should be minimised. The airborne level was recommended as being consistent with the biological limit value and using the preferred values approach of SCOEL. It is understood that DG Employment recognises the need to re-visit the issue of biological limit values, including lead. However, no immediate actions are foreseen.

8. Lead has also been considered via a voluntary risk assessment within the EU Existing Substances Regulations (ESR) framework. A risk assessment report (RAR) was recently produced by industry (Lead Development Association International) in accordance with the methodology outlined in the ESR Technical Guidance Document (TGD). The RAR was subsequently reviewed by the Netherlands ESR Competent Authority, discussed several times within the appropriate EU forum (TCNES – Technical Committee on New and Existing Substances) and finalised in the first half of 2008.

9. The RAR provides a thorough and comprehensive account of the available exposure and hazard information on lead up to and including 2006. The human health report is 900-pages long. WATCH Members are therefore provided only with:

- an extract from the ESR RAR ("General Aspects") which gives a general overview of the toxicological profile of lead – Annexe I to this cover paper;
- an extract from the ESR RAR relating to national legislation for lead in individual EU Member States – Annexe 4;
- a summary of the occupational exposure data from the ESR RAR – Annexe 5.

10. The risk assessment identifies three leading health effects, each one applicable to a specific population:

- developmental neurotoxicity for pregnant women (NOAEL = 10 µg/dL blood);
- effects on female fertility for women of child-bearing capacity (NOAEL = 30 µg/dL blood) and;
- repeated dose effects on the nervous system in adults (NOAEL = 40 µg/dL blood).

11. By comparing the appropriate NOAEL values with the exposure estimates, the risk assessment identifies a need for risk reduction measures in relation to developmental toxicity (pregnant women) in all of the occupational scenarios considered (see annexe 5). Risks are also identified for effects on female fertility (women of child-bearing capacity) in the majority of the occupational scenarios considered (lead production, lead battery production, oxide and stabiliser production, crystal glass production, abatement, demolition and scrap industries, bronze and brass foundries, stained glass workshops, incineration plants) and for repeated dose effects on the nervous system (adults) in a significant number of the occupational scenarios identified (lead production, lead battery production, oxide and stabiliser production, crystal glass production, abatement, demolition and scrap industries, stained glass workshops, incineration plants).

12. Given the voluntary nature of the risk assessment, no formal risk reduction strategy is currently being developed by any EU regulatory authority. However, within the framework of REACH (EC No 1907/2006), which repealed ESR, the registration dossier for lead will have to address the risks identified in the RAR and identify the risk management measures that will ensure its safe production and use. It is also possible for the regulatory authorities to propose Community-wide restrictions and/or to nominate lead as a Substance of Very High Concern (SVHC) requiring authorisation.

13. Concerns were raised at ACTS in May 2008 about recent evidence that blood levels of lead of the order of 10µg/dl may be associated with cardiovascular disease (Menke et al., 2006 – Annexe 3 to this cover paper). HSE notes that although this publication is not directly referenced in the ESR RAR, a paper by Schober et al (2006), included in the RAR, used the same NHANES III (Third National Health and Nutrition Examination Survey) baseline data and the same mortality follow-up design as Menke et al (2006) to identify similar correlations between blood lead levels of the order of 10 µg/dL and increased cardiovascular mortality.

14. The RAR provides an extensive analysis of the potential relationships between lead, blood pressure and cardiovascular disease under conditions of environmental exposure in the general population, occupational exposure and in studies of experimental animals. The RAR concludes that at relatively low blood lead levels (below 45 µg/dL) there is at best a weak statistical association with increased blood pressure and increased incidence of cardiovascular disease, which is likely to be the product of residual confounding rather than the causal consequence of lead exposure. This conclusion is reached on the basis that the relationship was inconsistent among studies, control for powerful confounders was poor/difficult, the effect size was small (< 1 mm Hg blood pressure with a doubling of blood lead), no clear dose-effect relationship was observed across studies and the highest quality studies failed to identify a correlation. Based on these considerations, the RAR concludes that the effect is not an endpoint of concern to take forward to the risk characterisation.

15. In February 2008 the Joint Research Centre (Ispra) drafted the TCNES opinion on the industry voluntary risk assessment. This concluded that the voluntary risk assessment was in line with the methodology of the ESR TGD but that the risk assessment was mainly based on human epidemiological data for which no guidance is available in the TGD. Justification was given in the risk assessment for the use of these data. They also commented that the conclusions of the risk assessment were plausible and all concerns could be supported by TCNES based on the assumption that the methodology and the information presented were correct. However, some member states (MSs) would have preferred a more conservative approach and did not support all the conclusions. In particular, some MSs disagreed with the NOAEL of 10µg/dL identified for developmental neurotoxicity.

Link to HSC Strategy

16. This is a generic, “business enabling” issue of relevance to HSE’s substance-specific assessments within both Statutory work and the Disease Reduction Programme.

Consultation

17. No wider consultation on the content of this cover paper beyond HSE has been undertaken at this stage.

European Context

18. This topic is being considered independently of any EU programme or initiative. However, there are close links to activities rounding off the EU Existing Substances Regulation, to REACH and to the DG Employment-led EU occupational exposure limit-setting programme.

Action

19. WATCH is asked to consider this paper and to express its view on the following propositions:

- i) The toxicological and occupational exposure profiles available to HSE and WATCH for lead and lead compounds are up-to-date and reasonably clear.
- ii) It is not so much the scientific/technical data and their interpretation that requires revisiting; the key issue is deciding what regulatory action should be taken, based on the available information and understandings.

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Attachments

- Annexe 1 "General Aspects" from the ESR RAR
- Annexe 2 SCOEL/SUM/83 final (January 2002)
- Annexe 3 Menke et al., 2006
- Annexe 4 Extract from the ESR RAR relating to national legislation in the EU for lead
- Annexe 5 Summary of the occupational exposure data from the ESR RAR

References

Schober SE, Mirel LB, Graubard BI, Brody DJ, Flegal KM (2006). Blood lead levels and death from all causes, cardiovascular disease and cancer: results from the NHANES III mortality study. *Environ Health Perspect*, 114 (10), 1538 -1541.

Menke A, Muntner P, Batuman V, Silbergeld E.K and Guallar E (2006). Blood Lead Below 0.48 $\mu\text{mol/L}$ (10 $\mu\text{g/dL}$) and Mortality Among US Adults. *Circulation*, 114;1388-1394; originally published online Sep 18, 2006;