

622 Case studies on notification of substances in articles according to Article 7(2) under REACH

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624

CASE 1: Clothes

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626 Description

627 Clothing was selected to exemplify a situation where exposure could be expected. Furthermore, the
628 example represents a case from a sector with major attention and comprehensive knowledge about
629 chemical substances in their articles. The company NN, which participated in this case, has already
630 established a program setting demand to the content of dangerous substances in products from their
631 suppliers. This has resulted in a phase-out of SVHC in their textiles.

632 Criteria for selecting clothes

- 633 • Users and application: A large group of users and a wide application; The users includes vulner-
634 able groups such as children
- 635 • Type of material: Represents a material used in many other articles than clothing, which could
636 make the case applicable for other producers/importers of articles.
- 637 • Exposure scenarios: An example of possible direct exposure to skin and migration of sub-
638 stances.
- 639 • Supply chain pattern: Represents a supply chain with high degree of imported articles and minor
640 production within the EU.
- 641 • Documentation: A Swedish company, NN provided information on their import of belt buckles.

642 Producer/Importer of articles

643 The selected company imports belt buckles and jewels from a non-EU Member State. Therefore, the
644 role of the company in the supply chain is as EU-importer of articles in relation to the belt buckles.

645 Substance identity

646 The company must consult the candidate list for authorization. It should be done as soon as the list
647 is made available by the Agency. Metallic lead, which was in focus in this case study, is not classi-
648 fied in the Annex I of Directive 67/548/EEC. However, an ongoing voluntary risk assessment is be-
649 ing conducted by the lead industry. It is assumed in the example that metallic lead is a possible can-
650 didate to Annex XIV¹⁴.

651 The company explained that it is often difficult to obtain complete lists of chemical from the suppli-
652 ers. However, this is not necessary when a company has to check whether he has obligations ac-
653 cording to the Articles 7(2) and 33. The suppliers could be asked directly about the content of the
654 specific substances at the candidate list.

¹⁴ Note that substances fulfilling the criteria of article 57 can be included on the candidate list only according to the procedure described in article 59. For more information see the Guidance on Preparing an Annex XV dossier for identifying SVHC and Guidance on Inclusion of Substances to Annex XIV of REACH.

655 **Check for existing registration**

656 To be done when REACH enters into force.

657 **Information on concentration of the substance**

658 There is no obligation to deliver SDS for articles or other information from non-EU Member States.
 659 The different ways to obtain information suggested in Chapter 3 and Section 6.3 of this TGD could
 660 be applied. The starting point should be the simplest way.

661 In this case the company has an upper limit for the content of lead in the belt buckles at 0.3% (w/w)
 662 and in their jewelers at 0.01% (w/w). The use of these maximum concentrations in the assessment
 663 will give a worst case scenario.

664 The alloy use in the buckle was not made known in this case. However, it should be noticed that the
 665 chemical compositions of most alloys are published as national, European or international stan-
 666 dards. If an alloy is not standardized, its chemical composition can usual be obtained by routine
 667 chemical analysis.

668 **Information on amount of substance used**

669 The total yearly amount of lead in the articles of the company was estimated on the basis of the
 670 amount of belt buckles imported the year before. The calculations were based on the total amount of
 671 belt buckles imported and the maximum concentration of lead in a buckle at 0.3%.

672 **Illustration of the decision process on registration**673 **Example: Company A - Metallic lead in belt buckles**674 *Consult Chapter 1:*675 **Are you the first EU producer or importer of the object?**

676 YES

677 **Is your object an article?**

678 YES, belt buckles and jewels are articles

679 *Use Chapter 4 "Checking if requirements under Article 7 or 33 apply":*680 **1. Is there an intended release from the article**

681 NO

682 **Conclusion for registration: No need for registration.**683 **2. Does the article contain SVHC - included in the candidate list?**

684 The list has to be checked when they are available. Metallic lead (7439-92-1) is not classified in the Annex I of Direc-
 685 tive 67/548EEC but it is a substance with properties of very high concern, which might be included in the candidate list.
 686 In this example it is assumed that it is on this list.

687 YES

688 *Go to Chapter 6 "Checking if Article 33 applies and if notification is required":*689 **1. Determine the concentration of the SVHC, which in this example is lead**

690 The company limit for lead in jewels is 0.01% (w/w), which is below the threshold limit at 0.1% (w/w). For lead in a
 691 functional item as a buckle the company limit is 0.3% (w/w). Thus the maximum concentration of lead in the buckles
 692 exceed the threshold limit. It is not possible for the company to analyze large parties of buckles and they assume that
 693 the concentration in all buckles is 0.3% (w/w). The company imports approx. 13 000 000 buckles per year (in total ap-
 694 prox. 650 different orders/styles).

695	Based on experience from tests it is known that most of the buckles contain much less than 0.1% of lead, however, it is
696	not documented by chemical analysis or certificates from the supplier.
697	Concentration above 0.1% (w/w)?
698	YES. Conclusion after this step: communicate information according to Art. 33 and continue to the next step in
699	the assessment.
700	2. Is the SVHC (lead) intended released?
701	NO. Continue
702	3. Has the substance already been registered for that use?
703	To be checked once REACH has entered into force. It is assumed that lead isn't registered for that use: → NO.
704	4. Determine the amount of the SVHC (lead) present in all articles?
705	The buckles are the only articles brought into the EU by the company with a lead concentration above the threshold
706	limit at 0.1%. The total amount of lead brought into the EU per year by all the buckles is:
707	The import of buckles in 2005: 13,000,000 items
708	The weight of one buckle: 100 g
709	The maximum lead concentration in a buckle: 0.3% (w/w)
710	<i>Calculation of the total lead amount in the buckles in 2005:</i>
711	• The total amount of lead: $(0.3 \cdot 0.01) \cdot (100 \cdot 10^{-6}) \cdot 13,000,000 = 3.9 \text{ t per year}$
712	5. Is the total amount of the lead > 1 t/a?
713	YES. The total amount of lead brought into the EU-market is 3.9 t/a. This amount exceeds the threshold limit at 1 t/a.
714	6. Can exposure be excluded during normal or reasonable foreseeable conditions of use?
715	<i>The function of the substance in the articles:</i>
716	Small amount of lead lowers the melting point of the alloy. Lead would almost certainly be present as discrete particles
717	in the matrix of the alloy and as such it would retain its own intrinsic properties.
718	<i>The use(s) of the article:</i>
719	Normal use(s): The importer sells the belt buckles to companies, which are producing belts of e.g. leather for both chil-
720	dren and adults.
721	Reasonable foreseeable use(s): If the producer of the belt treat the buckle in such a way that particles are emitted from
722	the buckle e.g. at grinding or sand papering, appropriate protection has to be used. If soldering or welding is used, lead
723	will be emitted in the form of gas and appropriate protection has to be used. Furthermore, children can suck on the
724	buckle in the end-use situation.
725	<i>Potential for emission during use(s) and disposal – Look at the routes of exposure:</i>
726	The routes of exposure in the case of metallic lead are by inhalation and by ingestion. Inhalation can be discounted in
727	this case. However, it is within the realms of possibility that lead may be transferred from the buckle to the hands of the
728	consumer and subsequently ingested.
729	Furthermore, it can not be excluded that there will be an emission of lead from the metal buckle after disposal.
730	Lead has been used in articles for many years. Therefore, it would be obviously to look for further information for 'that
731	use' of lead in sector organizations, the open literature and databases. Look for emission of lead from buckles and simi-
732	lar materials and exposure of humans and the environment.
733	<i>Can exposure to humans or environment be excluded?</i>
734	NO
735	Conclusion: Notification is required
736	Go to Section 6.11
737	Communicate information to the recipients according to Art. 33

738 Comment on the case

739 The case illustrates the possibility of using the maximum concentration or company upper limit of a
740 specific SVHC in articles as a worst case scenario for assessing whether an importer has an obliga-
741 tion under Articles 7(2) and 33. The use of the maximum concentration leads to the conclusion that
742 both notification and communication of information is required. A next step could include a more
743 precise determination of the lead concentration in the buckle by chemical analysis if applicable. The
744 information to be delivered within the supply chain, according to Article 33 could e.g. include rec-
745 ommendations of protective equipment to be used during production of the finished belt and in-
746 structions on waste handling.

747 The results obtained completing the workflows 1 and 2 in this guidance could be documented in a
748 table e.g. as in the example above either on paper or electronically. Certificates from suppliers of
749 the articles stating the limits of the SVHC, results of possible chemical analyses and data of the im-
750 ported articles volumes could be annexed. Documentation procedures to be followed during the as-
751 sessment of obligation under Article 7 and 33 could be implemented e.g. as a part of a possible ex-
752 isting quality management system.