EEB: PubCon on REACh restriction: sensitisers in textiles and leather
Comments to the draft opinion of the SEAC
Submission for deadline of 24/08/2020

EEB appreciates the opportunity to provide input into the public consultation concerning the SEAC's draft opinion. EEB submitted comments (ref. #2379) to the PubCon on the initial Annex XV dossier for this restriction proposal.

Specific input to Q3: concentration of Cr

3: The Dossier Submitter and RAC propose a concentration limit of 1mg/kg of Cr(VI) in leather. However, SEAC considers that a 1 mg/kg limit may not be technically feasible as the currently applied standard for sampling and analyses EN ISO 17075 does not support reliable quantification lower than 3 mg/kg. Please provide any relevant information on when a 1 mg/kg limit could be achieved and what would be needed to get there.

The first public consultation for this restriction proposal has revealed that even with ISO 17075, LoD and LoQ of 0.75 and 2.5 mg/kg, respectively can be achieved, as duly acknowledged in the SEAC's draft opinion (p. 28). The draft opinion then states that *a majority of stakeholders [...] from the leather industry [...] stat[ed] that it would not be possible to enforce a level below 3 mg/kg with current analytical methods.*

This statement is surprising for two reasons:

- It appears to be a mere claim, as opposed to the independent scientific data establishing the lower LoD/LoQ and the experimental conditions needed to achieve these.
- Enforcement of a restriction is the task and prerogative of border enforcement agencies – which are less subject to conflicts of commercial interest than the leather industry. If such a statement were made by enforcement agencies, it should be given attention, although even then it should be substantiated by data.

Next to this rather procedural comment, we would like to shed some light on major methodological shortcomings in how the limit of quantification in ISO 17075-1 is defined. (Ironically, Annex B of the standard actually uses the word "defined" instead of "derived" or "determined".)

LoD and LoQ

In our earlier comments (#2379), we pointed out that ISO 17075-1 considers 3 mg/kg as both the LoD (paragraph 8.3, and annex B) and the LoQ (paragraph 1), which contrasts with the more usual approach in standards that bases LoD and LoQ on the standard deviation of blank samples. In view of the claimed poor reproducibility of the extraction process, such a deviation from the usual process may be justified, however it is not explained nor backed up by data.

In view of these findings, we urge the SEAC to rely on the independent, transparent and peer-reviewed data provided to define a limit of 1 mg/kg, rather than on a number that owes more to tradition and agreement than to scientific methods.

The LoD derivation method

The method used in Annex B to "define" (sic) the LoD suffers from a series of weaknesses:

- It is not clearly explained
- It rests on few data points
- The derivation method is logically absurd.

In the following, we shall explain why Annex B is of poor technical quality – and why "standardised" may not be mistaken for "validated", "reliable", "meaningful" or "robust".

The data used

The LoD is purportedly based on two data series:

- The first data series, displayed in Table B.1, is based on results from interlaboratory trials on two types of leathers (containing both ca. 7 mg/kg of Cr(VI)), from which repeatability and reproducibility data are derived. These data do not provide any information on the number of repeats or the number of laboratories in the test series.
- The second data series, displayed in table B.2, originates in measurements for one type of leather (containing ca. 20 mg/kg of Cr(VI)) by sixteen unidentified laboratories who conducted two or three measurements each.

These tests were carried out in 2007 (according to the top of annex B in the revised 2017 version of the standard) or in 2003-2005 (according to the legend of figure B.1 in both the 2007 and the 2017 version). This shows that the method was not scrutinised during the standard's revision in 2017.

The derivation method

Figure B.1 claims to derive the LoD graphically based on measurement uncertainties from the first (2 data points) and second series. We have reproduced here figure B.1 and added the elements in blue and red for illustration purposes.
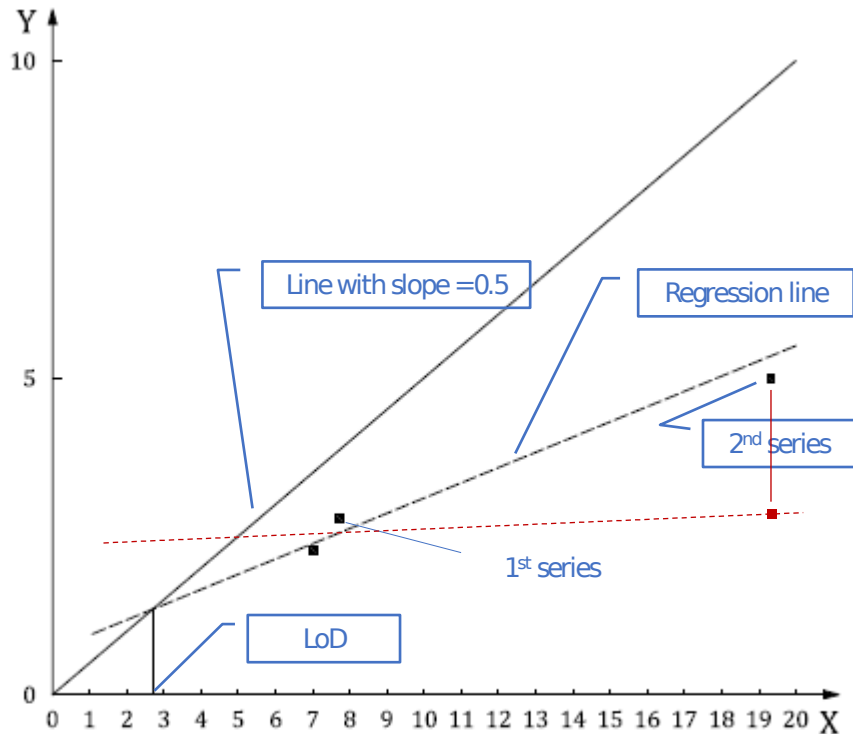
Key

X mean values of the interlaboratory tests (2003 to 2005)

Y measurements uncertainties associated to the mean value

The figure plots measurement uncertainties (vertical axis – it is not mentioned what exactly is meant with "uncertainties") against the mean values of the Cr(VI) content found (horizontal axis). The three types of leather tested correspond to the three data points.

The figure also contains a line with a slope of 0.5. Points above this line would have an uncertainty higher than 50% of the measured values and putatively be considered poor data points, the ones below would have an uncertainty below 50% of the measured mean and be considered good data points. This interpretation is not mentioned in the standard, but it is our attempt at rationalising an obscure derivation method – however, this assumption is corroborated by a news story by *International Leather Maker*, a news outlet of the leather industry.[1]

The LoD is then determined as the intersection of this line with a linear regression function for the three data points, i.e. the point below which any measurement would result in errors >50% of the measured mean.

At first sight, this approach may look scientifically valid.

However, it attracts some fundamental criticism:

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[1] https://internationalleathermaker.com/news/fullstory.php/aid/7561/
An_update_on_chromium__VI__in_leather_methodology.html

- As anyone with a background in data science or physics would acknowledge, drawing a linear regression line through three data points is hardly robust scientific practise. This shortcoming is exacerbated by the close proximity of the two data points from the 1st series, effectively leaving high degrees of uncertainty in the slope (or even shape) of the regression line.
- The experiments were not set up with the purpose of deriving and LoD or LoQ: data points use to determine and LoD are supposed to be in the vicinity of that LoD. Using data points at roughly three- or tenfold higher concentrations for this purpose, and no data from the vicinity of the LoD is poor scientific practise. This contrasts with the approach described by scientists determining substantially lower LoD and LoQ values.
- It is not at all clear why the measurement uncertainty should scale linearly with the measured content of Cr(VI). If the sample preparation method is particularly error-prone (as claimed by industry) and results in formation of Cr(VI), one would expect a different curve. Cr(VI) formation (due to sample preparation), i.e. the source of the variation and uncertainty, should then scale with Cr(III) content (next to pH, moisture, ageing etc.), as Cr(VI) can be produced from Cr(III), which is present in large excess. However, one would certainly not expect Cr(VI) formation to scale with Cr(VI) concentration in the leather sample, as no autocatalytic effect is known. In other words, one should rather expect the uncertainty to be roughly a constant with respect to Cr(VI) concentration in the leather sample.

A further absurdity can be seen in the data in the 2nd series (table B.2). It can immediately be seen that the data contain some serious outliers. Two laboratories (507a and 1008a) measure consistently (if that can be said at all of three measurements) very high values – these laboratories measure reasonably repeatably, but they are not able to reproduce the other laboratories' data. E.g. the storage practise of such laboratories should be investigated, rather than the inherent quality of the measurement system be pulled into question. Likewise, two laboratories (505a and 1010a) measure very low values; no indication is given that the empirical results were dealt with critically in agreeing on this standard.

As a thought experiment, one may wonder what would happen if the outliers had been removed (or, even better, their methods scrutinised and optimised), as would normally be done. In that case (see red elements in the figure above), the y-coordinate of the point corresponding to the 2nd series would be divided by ca. 2. As a result, the regression line would be roughly flat, and the LoD would go up from 3 to 50 mg/kg. This is a mathematically absurd result, proving *ad absurdum* that the regression method cannot be relevant to determine the LoD.

As noted above, a reasonable LoD should be derived from carefully measured and transparently reported data in the vicinity of the real LoD, i.e. between e.g. 0.3 and 3 mg/kg.

Specific input to Q4: dynamic link with CLP

During the consultation on the Annex XV dossier, some stakeholders argued that the dynamic link with CLP would lead to additional costs and that compliance testing costs for the textile sector were underestimated in the Background Document. Little supporting information was provided. [...]

We do not have any direct information on any such costs, however, we would like to highlight that such dynamic links are commonplace in European legislation, e.g. the IED Art. 58, BPR Art. 10, CM Directive Art. 4. Such a dynamic link is exactly what creates simplicity and clarity, as no inconsistencies and loopholes are created, and as fewer enumerative lists have to be generated and updated. Internet searches of studies by lobby organisations regarding such dynamic links have not yielded any informative results.

Specific input to Q5: negative substitution costs

5: SEAC has concerns regarding 'negative' substitution costs reported in the Dossier for the neoprene plasticisers, for phthalates and for rosins (if replaced with acryl-based glue). [...] SEAC requests more information on the availability of safer alternatives for neoprene plasticisers, phthalates and rosins,

EEB raised questions earlier on (comment #2379) on the meaning of the term "neoprene plasticisers". We enquired about the type of substances used and doubted the existence of such substances.

The SEAC opinion contains no further information or rationalisation of this concept. Instead, it contains odd formulations (p. 39 "phthalate and neoprene plasticisers", formally a zeugma; p. 41 "for the plasticiser neoprene"), contrasted by sensible ones (p. 37 "plasticiser for neoprene"). We would like to highlight the semantic difference between "PVC plasticiser" (i.e. a substance that softens PVC) and "phthalate plasticiser" (i.e. a substance that has the chemical structure of a(n) (ortho)phthalate and is often used to soften PVC) and request the SEAC to clarify whether:

- Plasticisers for neoprene (polychloroprene) are meant, and what type of substances they may be. To the best of our knowledge, polychloroprene is not plasticised; OR
- Plasticisers that are called neoprene (and that would be chemically unrelated to polychloroprene), and what they are used for.

Lack of clarity of such terminology will result in lack of clarity of the scope and stipulations of the restriction – some industrial actors will likely take advantage of this uncertainty, others as well as enforcement or consumer protection agencies may be confused.