

## Careful with that DNEL, Occupational Hygienist!

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At the BOHS conference in Nottingham this year we presented (see Figure 1) a comparison of OELVs and DNELs. This article is an elaboration of that short presentation. In May 2014 a new Excel table with DNEL was published by Gestis and the extended database is incorporated here. The results, therefore, show slight differences from the slides presented in Nottingham.

The DNEL (= Derived No Effect Level) is a new type of limit value introduced in 2008 in Annex I of the European REACH legislation. REACH is the safe use of chemicals, traded in Europe. Companies must guarantee the safe use in the whole life cycle if they manufacture or import over 1 ton of them per year. For volumes over 10 t/a the DNEL or, in case of a carcinogen, the DMEL (Derived Minimal Effect Level) can be used to demonstrate safe use for human, including occupational, exposure.

Industry have derived since 2008 several thousand DNELs/DMELs for the workplace air and even for substances that already have working conditions legislation-based occupational workplace air exposure limit values (OELV) like the WEL in the UK, the MAK in Germany and the European IOLVs etc.



Figure 1 First sheet of the ignite on DNEL versus OELV

The DNEL/DMEL deriving in REACH is a strictly standardised process, dividing the no adverse effect levels, derived from animal, experimental toxicity studies by one or more fixed safety factors. It differs substantially from the more holistic, human health-based OELV setting by organisations like the EU SCOEL, the German DFG, or the Dutch Health Council and the US ACGIH-TLV. Observational epidemiological results in occupational target groups play an important role in the OELV but are ignored at large in the DNEL/DMEL.

The approach differences make that the DNELs/DMEL and OELV numbers can differ

substantially despite that they are based on the same scientific data sets.

How big the differences are; and the question of whether DNELs/DMELs are systemic higher or lower than OELVs has become subject of speculation. Companies and industry interest groups noticed that the DNELs may be much lower than the OELVs due to the rigorous safety factors. On the other hand workers' organisations and NGOs feared that industry may establish DNELs higher than the OELVs. Some non-conclusive or biased comparisons between OELVs and DNELs/DMELs have already been made using small series or using the OELVs from a single country, including OELVs for which technical and/or economic considerations could not be excluded. Therefore, there is a strong need to have an extensive and unbiased comparison of the two types of standards.

DOHSBaseCompare is a database product with a focus on occupational hygiene relevant substance information. It started in the late 80s as an initiative within the Dutch Occupational Hygiene Society (from which it received its name) and has been privatised since 1995. In the last decades it grew to, as far as we know, the largest database for substances with OELVs and measurement methods. If there are multiple OELVs per substance, the OELVs are presented according to a hierarchy (we presented a poster on the hierarchy for OELVs at OH2014).

The DOHSBaseCompare database contains about 3800 OELVs, many of them health-based and established by the European SCOEL, the Dutch Health Council, the German Deutsche Forschungsgemeinschaft and the American ACGIH-TLV.

DNELs/DMELs are disseminated by European Chemicals Agency (ECHA) in the

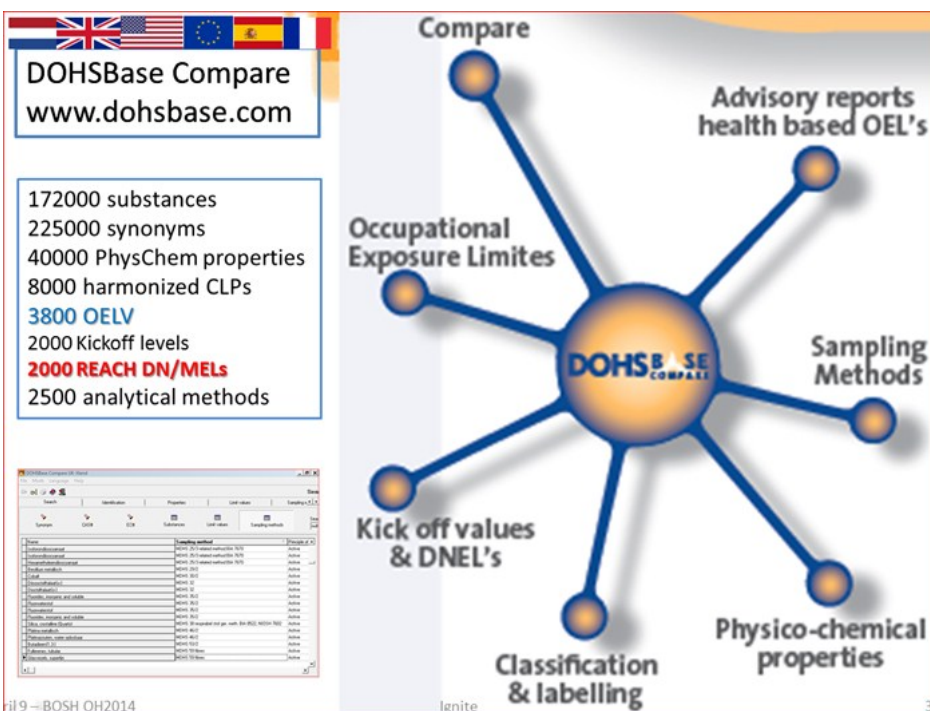


Figure 2 DOHSBaseCompare data structure

individual substance registration database <http://www.echa.europa.eu/web/guest/information-on-chemicals/registered-substances> and also published in the individual SDSs of the manufacturers and/or importers. An Excel-table of DNELs/DMELs (May 2014) is published on the site of IFA (<http://www.dguv.de/medien/ifa/en/gestis/dnel/DNEL-Substance-list.xls>), as part of the GESTIS DNEL database.

We linked the OELVs in the database of DOHSBaseCompare to the GESTIS August 2013 DNEL table. In case of multiple long-term DNELs per substance Chemical Abstract Number (CAS#) the lowest value was chosen. Also if both local and systemic DNELs were presented, the lowest of the two was chosen. This resulted in 411 substances having both a DNEL and an OELV. We compared the values for both the OELV and the DNEL for these 411 substances with each other. The results are displayed in Figure 3. The horizontal x-axis represents the 11 orders of magnitude of the values of existing DNELs in the population of 411 substances. On the vertical axis we put the values of the OELVs (12 orders of magnitude). Both axes have a logarithmic scale. On the intersection of the substance OELV and DNEL value, a symbol is placed. The zeppelin-shaped cloud pictures the relation between DNEL/DMEL and OELV.

The power of 0,83 in the trend function  $y = 1,027x^{0,8316}$  shows a nearly linear relation between DNEL/DMEL and OELV. The intercept of 1,027 shows that on the average the ratio of DNEL/DMEL and OEL is nearly one.

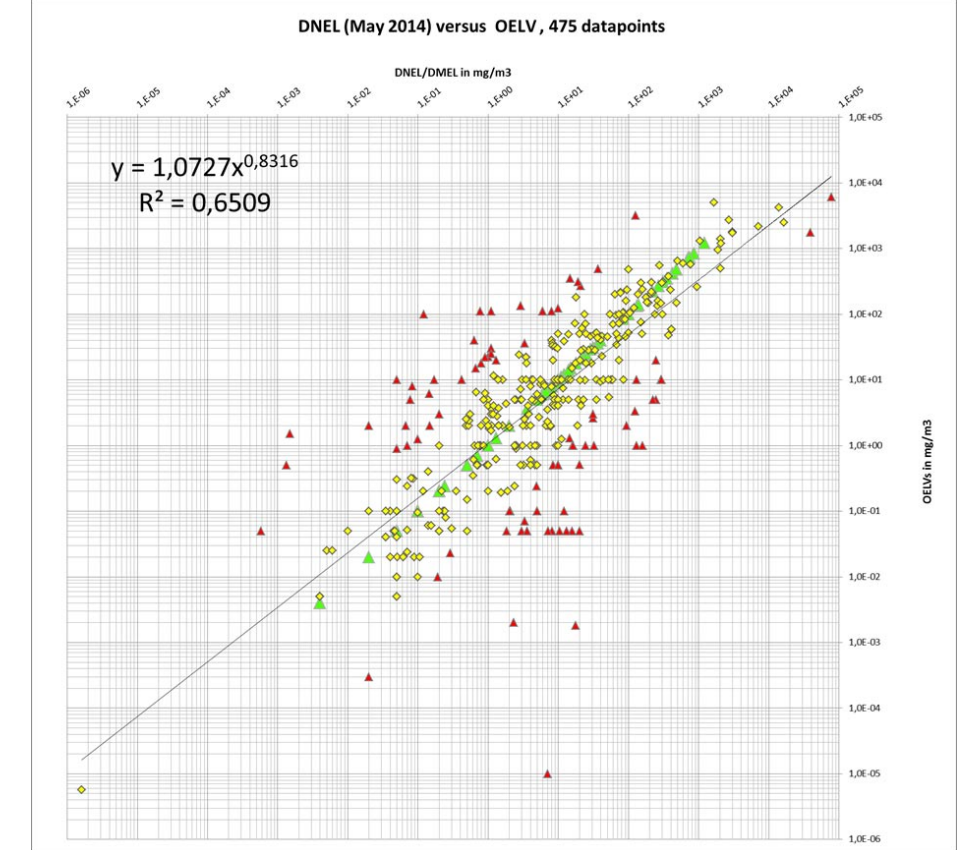
So, at large there is no tendency that DNELs/DMELs are systematically higher or lower than OELVs. Only at the upper right side with the highest values, the DNELs seem to be somewhat higher than the OELVs.

The 87 green triangles near the trend line represent the substances with the DNELs/DMELs equal to the OELVs. For these (~18%) substances the manufacturers/importers have chosen to use the SCOEL, the German DFG MAK or another existing health-based OELV.

However more than 80% have chosen to derive their own limit. 63% of the DN/MEs differ up to one order of magnitude from the OELVs (the yellow rhomb's) and 18% even more than one order of magnitude (red bullets)!

An in-depth analysis on the cause of the differences for individual substances is not yet performed. We can indicate, however, that in some cases DNELs are not adjusted for sensitising properties. If the DNEL of a sensitizer is derived from oral experiments they may become 100 times higher than the holistic OELV where this property was taken into account.

Also, the settings of DNELs ignores the fact that exposure to dust in concentrations more than 10 mg/m<sup>3</sup> gives problems with the visibility of safety signals at the workplace. OELVs for dusts do not normally exceed 10 mg/



**Figure 3 The comparison of the DNEL/DMEL and the OELV of 411 substances for which both are established**

m<sup>3</sup> as a safety precaution. Several DNELs for dusts are exceeding 100 mg/m<sup>3</sup>. Further DNELs do not distinguish between the inhalable and respirable fraction, which is quite significant with regards to load of the lungs.

Some will argue that the large differences between OELVs and DNELs prove that limits are useless in working conditions control and will plea for the use of Control Banding systems, like COSHH essentials. In the Wednesday afternoon session 6a at OH2014, we discussed a validation of different Control band schemes, which showed quite poor results (see <http://www.bohs.org/events/annual-conference/>).

Others will plea to harmonise the methods of setting DNELs and OELVs and consequently extend this to other aspects of REACH and the EU workplace chemical substance and carcinogens Directives. It is indeed remarkable that the REACH legislation was constructed without integrating it into the existing regulations.

National working condition legislation requires compliance with the legal OELV. If the DNEL is lower than the legal OELV, then Dutch law enforcement now advises use of DNEL, based on the precautionary principle, unless you can demonstrate safe use otherwise. In view of the above it would be wise for Occupational Hygienists to be careful at this moment when applying a DNEL for working conditions control.

Two different types of limit values to protect workers' health with such large mutual differences is of course not what the founders of the EU had in mind. Substance hazards are intrinsic properties and should not differ between countries nor legislations! As the EU reputation may be at stake, OELV and DNEL stakeholders are strongly advised to overcome their individual interests, join forces and bring REACH and Working Conditions Regulations in Europe on one line as quickly as possible

At the BOHS 2014 conference it was suggested the harmonisation of working conditions tools (like e.g. limit values, exposure assessment, dealing with vapour mixtures and control banding) should be an important theme for the IOHA London 2015 conference. Some groups and individual occupational hygienists are considering to propose in that direction. Hopefully the IOHA 2015 organizing committee will make this theme central for the conference.

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